

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA**

**IN RE: ZANTAC (RANITIDINE)  
PRODUCTS LIABILITY  
LITIGATION**

**MDL NO 2924  
20-MD-2924**

**JUDGE ROBIN L ROSENBERG  
MAGISTRATE JUDGE BRUCE REINHART**

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**THIS DOCUMENT RELATES TO: ALL CASES**

**SECOND AMENDED MASTER PERSONAL INJURY COMPLAINT**

Pursuant to this Court’s Order [DE 3751], Plaintiffs file this Second Amended Master Personal Injury Complaint (“SAMPIC”) against Defendants identified below.<sup>1</sup> Plaintiffs bring this SAMPIC because Plaintiffs developed cancers from taking medication that Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold.

For decades, Defendants widely promoted and/or sold Zantac (ranitidine) as being safe and effective for use to combat heartburn symptoms, making it the first pharmaceutical drug to reach \$1 billion in sales. But Defendants concealed from the public a devastating secret. The secret: Zantac transform over time and under certain conditions into a well-known cancer-causing compound, N-Nitrosodimethylamine (“NDMA”). When that secret was revealed in 2019,

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<sup>1</sup> Plaintiffs file this SAMPIC to comply with the Court’s previous Orders—most recently its order requiring Plaintiffs to file “a second amended master personal injury complaint” that does not “include any counts that the Court dismissed with prejudice or without leave to amend” and which “fully conform[s] to the Court’s orders of dismissal.” [DE 3751 at 1]. In doing so, Plaintiffs fully reserve all appellate rights: Although “[a]n amended complaint supersedes and replaces the original complaint,” a plaintiff does not waive his right to appeal the dismissal of a claim in the original complaint by amending the complaint and omitting the dismissed claim.” *Reynolds v. Behrman Cap. IV L.P.*, 988 F.3d 1314, 1319–20 (11th Cir. 2021) (holding that a plaintiff “did not waive his right to appeal the district court’s dismissal of [a defendant] by failing to name [that defendant] in the amended complaint because amendment would have been futile”).

manufacturers quickly withdrew their product from the market and, in 2020, the U.S. Food and Drug Administration (“FDA”) ultimately directed removal of all ranitidine-containing products from shelves nationwide. Now, Plaintiffs across the country seek to hold Defendants accountable for causing hundreds of thousands of people to develop cancer.

This SAMPIC sets forth allegations of fact and law common to the personal-injury claims within this multidistrict litigation (“MDL”). Each Plaintiff individually seeks compensatory and punitive damages (where available), restitution, and all other available remedies as a result of injuries caused by Defendants’ defective pharmaceutical products. The SAMPIC is intended to plead all causes of action in the broadest sense and pursuant to all applicable laws and choice-of-law principles, including the statutory and common law of each Plaintiff’s state.

This SAMPIC does not necessarily include all claims asserted in all of the transferred actions to this Court, and it is not intended to consolidate for any purpose the separate claims of the individual Plaintiffs in this MDL. Each Plaintiff in this MDL will adopt this SAMPIC and specific causes of action alleged herein against specific Defendants through a separate Short Form Complaint – Version 3 (“SFC”), attached hereto as Exhibit A. Any individual facts, jurisdictional allegations, additional legal claims, and/or requests for relief of an individual Plaintiff may be set forth as necessary in the SFC filed by the respective Plaintiff. This SAMPIC does not constitute a waiver or dismissal of any actions or claims asserted in those individual actions, and no Plaintiff relinquishes the right to amend his or her individual claims to include additional claims as discovery proceeds and facts and other circumstances may warrant pursuant to PTO No. 31 or the appropriate Federal Rules of Civil Procedure.

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## **INTRODUCTION**

1. Zantac is the branded name for ranitidine, a “blockbuster” drug that was sold as a safe and effective antacid. But ranitidine transforms over time and under particular conditions into high levels of NDMA, a carcinogen that is as potent as it is dangerous. After almost four decades and billions of dollars of sales, ranitidine consumption has caused scores of consumers to develop cancer. Plaintiffs bring these actions for personal injuries and/or death as a result of Defendants’ design, testing, marketing, labeling, packaging, handling, distribution, storage and sale of ranitidine-containing products.

2. Until its recent recall by the FDA, ranitidine was a popular heartburn drug consumed by millions of people every day. Recent scientific studies, however, confirm what drug companies knew or should have known decades earlier: ingesting ranitidine exposes the consumer to unsafe and excessive amounts of NDMA.

3. NDMA is a well-known potent carcinogen. It was first discovered in the early 1900s as a byproduct of manufacturing rocket fuel. Today, its only use is to induce cancerous tumors in animals as part of laboratory experiments. Its only function is to cause cancer. It has no medicinal purpose whatsoever.

4. NDMA is not akin to other compounds that have a salutary effect at low levels and a negative effect with greater exposure. There is no recommended daily dose of NDMA. The ideal level of exposure is zero. Nonetheless, the FDA previously set an allowable daily limit of NDMA of 96 nanograms (ng) to minimize the risks posed by this dangerous molecule. Yet a single pill of ranitidine can contain quantities of NDMA that are hundreds, if not thousands, of times higher than the allowable limit.

5. Those recent revelations by the scientific community have caused widespread

recalls of ranitidine both domestically and internationally. In fact, after numerous voluntary recalls, on April 1, 2020, the FDA ordered the immediate withdrawal of all ranitidine-containing products sold in the United States, citing unacceptable levels of NDMA accumulation.

6. The high levels of NDMA observed in ranitidine-containing products are a function of various factors. The ranitidine molecule internally degrades to form NDMA. The degradation of ranitidine into NDMA can increase over time under normal storage conditions, but more so with exposure to heat and/or humidity. Once in the body, ranitidine continues to degrade and can yield increasing levels of NDMA in the human digestive system.

7. In the aggregate, ranitidine-containing products were akin to billions of Trojan horses that smuggled dangerously high levels of NDMA into the bodies of millions of consumers where it then produced more NDMA once in the body.

8. Zantac wreaked such widespread harm in large part because Glaxo—the inventor of ranitidine—succumbed to a temptation that is all too familiar to pharmaceutical innovators: maximizing the profits of an incredibly lucrative, government-conferred monopoly.

9. To encourage pharmaceutical companies to invest in research and development (“R&D”), the U.S. legal and regulatory system offers drug companies who invent “new chemical entities” two powerful inducements. First, innovators obtain patent protection for their pharmaceutical compounds. Second, approved new drugs enjoy FDA exclusivity, irrespective of whether the molecule is protected by one or more issued patents. Taken together, these policies assure that a pharmaceutical innovator will receive the exclusive right, for a limited period of time, to sell its drug to the American public.

10. The argument for monopoly pharmaceutical franchises rests on the profit-motive. R&D is time consuming and expensive, and not all drug-development efforts will

succeed. Once a drug is approved, some period of monopoly profits is necessary to allow innovators to recoup their sunk R&D costs in both successful and unsuccessful pursuits. A costly pursuit of a new potential blockbuster that ultimately fails can be financially devastating for smaller pharmaceutical companies.

11. In some ways, the system works as intended. Pharmaceutical companies do invent new and useful medicines that—absent high profit potential—might not otherwise come to market. But once an innovator possesses a blockbuster monopoly franchise, it has a virtual license to mint money. Most pharmaceutical ingredients are cheap commodities, which brand-name manufacturers then resell at a monopoly markup. During the exclusivity period, brand-name drugs routinely enjoy gross profit margins of 70, 80, or even 90+ percent. No other industry comes close to matching this profit-generating potential.

12. As a result of these economic realities, branded drug manufacturers have a strong—and too often perverse—incentive to sell as much product as they can during their exclusivity window. That is why brand-name manufacturers spend billions of dollars per year in sales and marketing efforts to push incremental sales of a brand-name drug. Where every \$1 in new sales can produce upwards of \$.90 in gross profit, staggering sales and marketing budgets are a very profitable investment. But while it makes sense for brand-name manufacturers to spend vast sums of money to develop and promote FDA approved drugs, they have no equivalent economic or regulatory incentive to uncover and investigate developing risks posed by their products.

13. That problem is especially acute for bestselling, blockbuster drugs. And Zantac is the brand that gave meaning to a blockbuster pharmaceutical product, becoming the first drug ever to generate over \$1 billion in annual sales. Zantac's success catapulted Glaxo ahead of its previously larger rivals, fueling the market capitalization and corporate combinations that gave the

company its current name: GlaxoSmithKline. It is little wonder Glaxo spared no expense to both get Zantac to market and to aggressively promote it to millions of consumers. Yet Glaxo did not part with a comparative pittance to investigate the obvious cancer risk posed by ranitidine. Turning a blind eye was far more profitable.

14. Ultimately, the law holds Zantac's manufacturers responsible for the personal injuries and death caused by such an unsafe product. And the civil justice system is the first, last, and only line of defense against the unchecked avarice that is a byproduct of a regulatory regime with the well-intentioned aim of bringing safe and effective medicines to market. Plaintiffs seek redress both to compensate them for the horrific losses they have suffered in the past and to strongly deter future misconduct.

## **PARTIES**

### **PLAINTIFFS**

15. Pursuant to PTO # 31 and the Court's Orders on Defendants' Motions to Dismiss, this SAMPIC is filed on behalf of all individually injured Plaintiffs and, if applicable, Plaintiffs' spouses, children, parents, decedents, heirs, estates, wards, guardians or other legally appointed representatives who file a Short Form Complaint.

16. Plaintiffs in these individual actions are citizens and/or residents of the United States who have suffered personal injuries and/or death as a result of using Defendants' dangerously defective ranitidine-containing products.

17. Plaintiffs were diagnosed with various cancers and their sequelae, which were directly and proximately caused by their use of ranitidine-containing products. These injuries include, but are not limited to, the following types of cancer: bladder, breast, colorectal/intestinal, esophageal, gastric, intestinal, kidney, liver, lung, pancreatic, and prostate.



**DEFENDANTS**

18. Defendants are entities that designed, manufactured, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine.

**Boehringer Ingelheim (BI)<sup>2</sup>**

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

Defendant Boehringer Ingelheim Pharmaceuticals, Inc., is a citizen of Delaware and Connecticut.

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

Defendant Boehringer Ingelheim Corporation is a citizen of Nevada and Connecticut.

21. Defendant Boehringer Ingelheim USA Corporation is a Delaware corporation with its principal place of business located at 900 Ridgebury Rd., Ridgebury, Connecticut 06877.

Defendant Boehringer Ingelheim USA Corporation is a citizen of Delaware and Connecticut.

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

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

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<sup>2</sup> Defendant Boehringer Ingelheim also manufactured generic ranitidine under ANDA 074662, as well as through its former subsidiary Ben Venue Laboratories Inc. d/b/a Bedford Laboratories (ANDA 074764). Ben Venue Laboratories Inc. is no longer in operation.

24. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. is a direct or indirect subsidiary of Defendants Boehringer Ingelheim Corporation and Boehringer Ingelheim USA Corporation, which are themselves wholly owned, directly or indirectly, by Defendant Boehringer Ingelheim International GmbH.<sup>3</sup> Collectively, these entities and Defendant Boehringer Ingelheim Promeco, S.A. de C.V. shall be referred to as “Boehringer Ingelheim” or “BI.”

**GlaxoSmithKline (GSK)**

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

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

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

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<sup>3</sup> Pursuant to the Joint Stipulation Relating to Boehringer Ingelheim Defendants [DE 1478], Defendants Boehringer Ingelheim International GmbH and Boehringer Ingelheim Promeco, S.A. de C.V. stipulated that Defendants Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation are the proper parties for purposes of all relief sought in this litigation.

28. Defendants GlaxoSmithKline LLC and GlaxoSmithKline (America) Inc. are subsidiaries of Defendant GlaxoSmithKline plc.<sup>4</sup> Collectively, these entities shall be referred to as “GSK.”

**Pfizer**

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

**Sanofi**

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

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

32. Non-party Sanofi SA is a corporation formed and existing under the laws of France, having a principal place of business at 54 Rue La Boetie, 8th Arrondissement, Paris, France 75008. Sanofi SA is a citizen of France.

33. Defendant Patheon Manufacturing Services LLC is a Delaware limited liability company with its principal place of business located at 5900 Martin Luther King Jr. Hwy,

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<sup>4</sup> Pursuant to the Joint Stipulation Relating to GlaxoSmithKline PLC [DE 1470], Defendant GlaxoSmithKline plc stipulated that Defendants GlaxoSmithKline LLC and GlaxoSmithKline (America) Inc. are the proper parties for purposes of all relief sought in this litigation.

Greenville, North Carolina 27834. Thermo Fisher Scientific, Inc. is the sole member of Defendant Patheon Manufacturing Services LLC. Thermo Fisher Scientific, Inc. is a Delaware corporation with its principal place of business in Massachusetts. Defendant Patheon Manufacturing Services LLC is a citizen of Delaware and Massachusetts.

34. Defendant Chattem, Inc. (“Chattem”) is a Tennessee corporation with its principal place of business located at 1715 West 38th Street Chattanooga, Tennessee 37409. Defendant Chattem is a citizen of Tennessee. Defendant Chattem is a wholly owned subsidiary of Sanofi SA.

35. Defendant Chattem purchased ranitidine and repackaged and/or relabeled it under its own brand.

36. Defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. are subsidiaries of Defendant Sanofi SA.<sup>5</sup> Defendants Patheon Manufacturing Services LLC and Boehringer Ingelheim Promeco, S.A. de C.V. packaged and manufactured the finished Zantac product for Sanofi. Collectively, these entities shall be referred to as “Sanofi.”

\* \* \*

37. BI, GSK, Pfizer, and Sanofi, shall be referred to collectively as the “Defendants.” At all relevant times, the Defendants have conducted business and derived substantial revenue from their design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of Zantac within each of the States and Territories of the United States, Puerto Rico, and the District of Columbia.<sup>6</sup>

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<sup>5</sup> Pursuant to the Joint Stipulation Relating to Sanofi Defendants [DE 1450], Sanofi SA stipulated that Defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. are the proper parties for purposes of all relief sought in this litigation.

<sup>6</sup> All references to “States” include Puerto Rico and the District of Columbia.

### **JURISDICTION & VENUE**

38. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a). In each of the actions there is complete diversity among Plaintiffs and Defendants and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.

39. A substantial part of the events, actions, or omissions giving rise to Plaintiffs' causes of action occurred in the federal judicial district identified in each SFC.

40. Venue is proper in each of those districts under 28 U.S.C. § 1391(a).

41. Pursuant to the Transfer Orders of the Judicial Panel on Multidistrict Litigation, venue in actions sharing common questions with the initially transferred actions is proper in this Court for coordinated pretrial proceedings pursuant to 28 U.S.C. § 1407.

42. Defendants have significant contacts with the federal judicial district identified in each Plaintiff's SFC such that they are subject to the personal jurisdiction of the courts in each of those districts.

43. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products within the judicial district listed in the SFCs and targeted the consumer market within those districts.

44. At all times alleged herein, Defendants were authorized to conduct or engage in business within each of the States and Territories of the United States and supplied ranitidine-containing products within each of the States and Territories of the United States. Defendants received financial benefit and profits as a result of designing, manufacturing, testing, marketing, labeling, packaging, handling, distributing, storing, and/or selling ranitidine-containing products within each of the States and Territories of the United States.

45. Defendants each have significant contacts in each of the States and Territories of

the United States, such that personal jurisdiction would be proper in any of them. Defendants have derived revenue from the sale of their ranitidine-containing products in each of the States and Territories of the United States.

46. Venue is proper for pretrial purposes in the Southern District of Florida, pursuant to this Court's PTO No. 11 Setting Forth Procedures for Direct Filed Personal Injury Cases. Prior to trial, Plaintiffs may seek remand and/or transfer of their actions to the federal district of their choice, provided venue would have been proper if filed in the first instance, as specified in the SFC and PTO No. 11.

### **FACTUAL ALLEGATIONS**

#### **I. THE CREATION OF RANITIDINE-CONTAINING PRODUCTS AND THEIR INTRODUCTION TO THE MARKET**

47. Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine under the brand name Zantac by either prescription or over the counter ("OTC"). Defendants sold or otherwise made available ranitidine in the following forms: injection, syrup, granules, tablets and/or capsules.

##### **A. GSK Develops Zantac Through a Flurry of Aggressive Marketing Maneuvers**

48. Ranitidine belongs to a class of medications called histamine H<sub>2</sub>-receptor antagonists (or H<sub>2</sub> blockers), which decrease the amount of acid produced by cells in the lining of the stomach. Other drugs within this class include cimetidine (branded Tagamet), famotidine (Pepcid), and nizatidine (Axid).

49. GSK-predecessor Smith, Kline & French discovered and developed Tagamet, the first H<sub>2</sub> blocker and the prototypical histamine H<sub>2</sub> receptor antagonist from which the later members of the class were developed.

50. GSK<sup>7</sup> developed Zantac specifically in response to the success of cimetidine. Recognizing the extraordinary potential of having its own H<sub>2</sub> blocker in the burgeoning anti-ulcer market, GSK was all too willing to ensure its drug succeeded at all costs.

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

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

53. In 1983, the FDA granted approval to Glaxo to sell Zantac, pursuant to the New Drug Application (“NDA”) No. 18-703, and it quickly became GSK’s most successful product—a “blockbuster.” Indeed, Zantac became the first prescription drug in history to reach \$1 billion in sales.

54. To accomplish this feat, GSK entered into a joint promotion agreement with Hoffmann-LaRoche, Inc., [REDACTED]

[REDACTED]<sup>8</sup> More salespersons drove more sales and blockbuster profits for GSK.

55. In June of 1986, the FDA approved Zantac for maintenance therapy of duodenal ulcers and for treatment of patients with gastroesophageal reflux disease (GERD).

56. In December 1993, GSK (through Glaxo Wellcome plc) entered into a partnership agreement with Pfizer-predecessor company Warner-Lambert Co. to develop and market an OTC

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<sup>7</sup> GSK, as it’s known today, was created through a series of mergers and acquisitions: In 1989, Smith, Kline & French merged with the Beecham Group to form SmithKline Beecham plc. In 1995, Glaxo merged with the Wellcome Foundation to become Glaxo Wellcome plc. In 2000, Glaxo Wellcome plc merged with SmithKline Beecham plc to form GlaxoSmithKline plc and GlaxoSmithKline LLC.

<sup>8</sup> GSKZAN0000348881; GSKZAN0000348871

version of Zantac.<sup>9</sup> In 1995, the FDA approved OTC Zantac 75 mg tablets through NDA 20-520. In 1998, the FDA approved OTC Zantac 75 mg effervescent tablets through NDA 20-745.

57. In 1998, GSK (Glaxo Wellcome plc) and Warner-Lambert Co. ended their partnership. As part of the separation, Warner-Lambert Co. retained control over the OTC NDA for Zantac and the Zantac trademark in the United States and Canada but was required to obtain approval from GSK prior to making any product or trademark improvements or changes. GSK retained rights to sell OTC Zantac outside of the United States and Canada,<sup>10</sup> and retained control over the Zantac trademark internationally.<sup>11</sup>

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

59. In October 2000, GSK sold to Pfizer the full rights to OTC Zantac in the United States and Canada pursuant to a divestiture and transfer agreement. As part of that agreement, GSK divested all domestic Zantac OTC assets to Pfizer, including all trademark rights. The agreement removed the restrictions on Pfizer's ability to seek product line extensions or the approval for higher doses of OTC Zantac. GSK retained the right to exclusive use of the Zantac name for any prescription ranitidine-containing product in the United States.

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

61. During the time that Pfizer owned the rights to OTC Zantac, GSK continued to manufacture the product.

62. In 2006, pursuant to a Stock and Asset Purchase Agreement, Pfizer sold and

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<sup>9</sup> GSKZAN0000022775

<sup>10</sup> GSK also still held the right to sell prescription Zantac in the United States.

<sup>11</sup> PFI00245109.



divested its entire consumer health division (including employees and documents) to Johnson & Johnson (“J&J”).<sup>12</sup> Because of antitrust issues, however, Zantac was transferred to Boehringer Ingelheim.

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

64. GSK continued marketing prescription Zantac in the United States until 2017 and still holds the NDAs for several prescription formulations of Zantac. GSK continued to maintain manufacturing and supply agreements relating to various formulations of both prescription and OTC Zantac. According to its recent annual report, GSK claims to have “discontinued making and selling prescription Zantac tablets in 2017 . . . in the U.S.”<sup>13</sup>

65. Boehringer Ingelheim owned and controlled the NDA for OTC Zantac between December 2006 and January 2017, and manufactured, marketed, and distributed the drug in the United States during that period.<sup>14</sup>

66. In 2017, Boehringer Ingelheim sold the rights of OTC Zantac to Sanofi pursuant to an asset swap agreement. As part of that deal, Sanofi obtained control and responsibility over Boehringer Ingelheim’s entire consumer healthcare business, including the OTC Zantac NDAs. As part of this agreement, Boehringer Ingelheim and Sanofi entered into a manufacturing

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<sup>12</sup> PFI00191352.

<sup>13</sup> GlaxoSmithKline, plc, *Annual Report* 37 (2019), <https://www.gsk.com/media/5894/annual-report.pdf>.

<sup>14</sup> Boehringer Ingelheim also owned and controlled ANDA 074662.

agreement wherein Boehringer continued to manufacture OTC Zantac for Sanofi.

67. Sanofi has controlled the OTC Zantac NDAs and marketed, sold, and distributed Zantac in the United States from January 2017 until 2019 when it issued a global recall and ceased marketing, selling, and distributing OTC Zantac. In addition, Sanofi has marketed, sold, and distributed ranitidine globally since 1983.<sup>15</sup>

68. Throughout the time that Sanofi controlled the OTC Zantac NDAs, Boehringer Ingelheim Promeco, S.A. de C.V. and Patheon Manufacturing Services LLC manufactured the finished drug product.

69. Sanofi voluntarily recalled all brand-name OTC Zantac and ranitidine on October 18, 2019.

70. Pfizer and Boehringer Ingelheim have made demands for indemnification per the Stock and Asset Purchase Agreement against J&J for legal claims related to OTC Zantac products.

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

72. The times during which each Defendant manufactured and sold branded Zantac are alleged below:

Manufacturer/ Repackager	Product	Prescription or Over the Counter	Sale Start Date Year	Sale End Date Year
GlaxoSmithKline	Pills, Syrup, and Injection	Prescription	1983	2019
Pfizer	Pills	OTC	1998	2006
Boehringer Ingelheim	Pills	OTC	2007	2016
Sanofi	Pills	OTC	2017	2019

## II. NDMA IS A CARCINOGEN WHOSE DANGEROUS PROPERTIES ARE WELL ESTABLISHED

<sup>15</sup> SANOFI\_ZAN\_MDL\_0000208478

73. According to the Environmental Protection Agency (“EPA”), “NDMA is a semivolatile organic chemical that forms in both industrial and natural processes.”<sup>16</sup> It is one of the simplest members of a class of N-nitrosamines, a family of potent carcinogens. Scientists have long recognized the dangers that NDMA poses to human health. A 1979 news article noted that “NDMA has caused cancer in nearly every laboratory animal tested so far.”<sup>17</sup> NDMA is no longer produced or commercially used in the United States except for research. Its only use today is to cause cancer in laboratory animals.

74. Both the EPA and the International Agency for Research on Cancer (“IARC”) classify NDMA as a probable human carcinogen.<sup>18</sup>

75. The IARC classification is based upon data that demonstrates NDMA “is carcinogenic in all animal species tested: mice, rats, Syrian gold, Chinese and European hamsters, guinea-pigs, rabbits, ducks, mastomys, various fish, newts and frogs. It induces benign and malignant tumors following its administration by various routes, including ingestion and inhalation, in various organs in various species.” Further, in 1978, IARC stated that NDMA

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<sup>16</sup> U.S. Environmental Protection Agency, *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA)* (Nov. 2017), [https://www.epa.gov/sites/production/files/2017-10/documents/ndma\\_fact\\_sheet\\_update\\_9-15-17\\_508.pdf](https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf).

<sup>17</sup> Jane Brody, *Bottoms Up: Alcohol in Moderation Can Extend Life*, The Globe & Mail (CANADA) (Oct. 11, 1979); see Rudy Platiel, *Anger Grows as Officials Unable to Trace Poison in Reserve’s Water*, The Globe & Mail (CANADA) (Jan. 6, 1990) (reporting that residents of Six Nations Indian Reserve “have been advised not to drink, cook or wash in the water because testing has found high levels of N-nitrosodimethylamine (NDMA), an industrial byproduct chemical that has been linked to cancer”); Kyrtopoulos et al, *DNA Adducts in Humans After Exposure to Methylating Agents*, 405 Mut. Res. 135 (1998) (noting that “chronic exposure of rats to very low doses of NDMA gives rise predominantly to liver tumors, including tumors of the liver cells (hepatocellular carcinomas), bile ducts, blood vessels and Kupffer cells”).

<sup>18</sup> See EPA Technical Fact Sheet, *supra* note 43; Int’l Agency for Research on Cancer (IARC), *Summaries & Evaluations, N-NITROSODIMETHYLAMINE* (1978), <http://www.inchem.org/documents/iarc/vol17/n-nitrosodimethylamine.html>.

“should be regarded for practical purposes as if it were carcinogenic to humans.”<sup>19</sup>

76. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.<sup>20</sup>

77. The Department of Health and Human Services (“DHHS”) states that NDMA is reasonably anticipated to be a human carcinogen.<sup>21</sup> This classification is based upon DHHS’s findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.<sup>22</sup>

78. The FDA considers NDMA a carcinogenic impurity<sup>23</sup> and chemical that “could cause cancer” in humans.<sup>24</sup> The FDA recognizes that NDMA is “known to be toxic.”<sup>25</sup>

79. The World Health Organization states that there is “conclusive evidence that NDMA is a potent carcinogen” and that there is “clear evidence of carcinogenicity.”<sup>26</sup> NDMA belongs to the so-called “cohort of concern” which is a group of highly potent mutagenic carcinogens that have been classified as probable human carcinogens.<sup>27</sup>

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<sup>19</sup> 17 Int’l Agency for Research on Cancer, *IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Some N-Nitroso Compounds* 151–52 (May 1978).

<sup>20</sup> See EPA Technical Fact Sheet, *supra* note 43.

<sup>21</sup> *Id.* at 3.

<sup>22</sup> *Id.*

<sup>23</sup> ApotexCorp\_0000000786

<sup>24</sup> FDA Statement, Janet Woodcock, Director – Ctr. for Drug Evaluation & Research, *Statement Alerting Patients and Health Care Professionals of NDMA Found in Samples of Ranitidine* (Sept. 13, 2019), <https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine>.

<sup>25</sup> Amneal\_prod 1\_0000002938.

<sup>26</sup> World Health Org., *Guidelines for Drinking Water Quality, N-Nitrosodimethylamine (NDMA)* (3d ed. 2008), [https://www.who.int/water\\_sanitation\\_health/dwq/chemicals/ndmasummary\\_2ndadd.pdf](https://www.who.int/water_sanitation_health/dwq/chemicals/ndmasummary_2ndadd.pdf).

<sup>27</sup> International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), *Assessment and Control of DNA Reactive (Mutagenic) Impurities in*

80. NDMA is among the chemicals known to the state of California to cause cancer (Title 27, California Code of Regulations, Section 27001), pursuant to California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65).

81. The EMA has referred to NDMA as "highly carcinogenic." It recommended that "primary attention with respect to risk for patients should be on these highly carcinogenic N-nitrosamines" (including NDMA), and categorized NDMA as "of highest concern with respect to mutagenic and carcinogenic potential."<sup>28</sup>

82. In 1989, the Agency for Toxic Substances and Disease Registry (ATSDR) stated that it is "reasonable to expect that exposure to NDMA by eating, drinking or breathing could cause cancer in humans" and that the "carcinogenicity of orally-administered NDMA has been demonstrated unequivocally in acute, intermediate and chronic durations studies" in animals and "it is important to recognize that this evidence also indicates that oral exposures of acute and intermediate duration are sufficient to induce cancer." Moreover, "hepatotoxicity has been demonstrated in all animal species that have been tested and has been observed in humans who were exposed to NDMA by ingestion or inhalation."<sup>29</sup>

83. The International Register of Potentially Toxic Chemicals (IRPTC 1988) lists regulations imposed by 13 countries for NDMA for occupational exposure, packing, storing and transport, disposal, and warns of its probable human carcinogenicity and its high level of toxicity by ingestion or inhalation.

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Pharmaceuticals to Limit Potential Carcinogenic Risk, M7(R1), March 2017; [https://database.ich.org/sites/default/files/M7\\_R1\\_Guideline.pdf](https://database.ich.org/sites/default/files/M7_R1_Guideline.pdf).

<sup>28</sup> Nitrosamines EMEA-H-A5(3)-1490 - Assessment Report (europa.eu) (June 25, 2020), [https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-assessment-report\\_en.pdf](https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-assessment-report_en.pdf).

<sup>29</sup> ATSDR Toxicological Profile For N-Nitrosodimethylamine (December 1989), <http://www.atsdr.cdc.gov/toxprofiles/tp141.pdf>.

84. OSHA classifies NDMA as “a carcinogen” that requires special and significant precautions along with specific hazard warnings.<sup>30</sup>

85. A review of Defendants’ own internal documents reveals that there is simply no question of material fact that it has been widely known within the medical and scientific community for over 40 years that NDMA is toxic and a known carcinogen.

86. In September 2019, Defendant GSK [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]<sup>31</sup> In addition, GSK noted that [REDACTED]  
[REDACTED]  
[REDACTED] *Id.* GSK  
concluded that [REDACTED]  
[REDACTED] *Id.*

87. [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

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<sup>30</sup> 29 C.F.R § 1910.1003 (2012).

<sup>31</sup> GSKZAN0000236640.

<sup>32</sup> GSKZAN0000369506.

<sup>33</sup> GSKZAN0000257640.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

88.

[REDACTED]

[REDACTED]

[REDACTED] Subsequently, GSK sent a “Dear Healthcare Provider” letter to the medical community echoing the above statement.<sup>36</sup>

Another internal GSK communication [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

38

89. Likewise, Defendant Sanofi [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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<sup>34</sup> *Id.*

<sup>35</sup> GSKZAN0000163882.

<sup>36</sup> See GSK Dear HCP Letter, (October 3, 2019), publicly available (for example, <https://www.hpra.ie/docs/default-source/Safety-Notices/gsk-hcp-letter-03oct2019.pdf>).

<sup>37</sup> GSKZAN0000178581.

<sup>38</sup> GSKZAN0000172037.

<sup>39</sup> SANOFI\_ZAN\_MDL\_0000169790.

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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<sup>40</sup> SANOFI ZAN MDL 0000206858.

<sup>41</sup> DRLMDL0000077291.

<sup>42</sup> DRLMDL0000070414.

<sup>43</sup> *Id.*

<sup>44</sup> DRLMDL0000069991



[REDACTED]

[REDACTED]

[REDACTED]

93. Glenmark admitted in its recall notification letter that “a carcinogenic impurity, NDMA, has been found in ranitidine medications at levels exceeding the FDA allowable limit.”<sup>46</sup>

94. Lannett admitted in its press release regarding its recall of ranitidine syrup that “NDMA is classified as a probable human carcinogen or substance that can cause cancer.”<sup>47</sup>

95. Wockhardt admitted [REDACTED]

[REDACTED]<sup>48</sup>

96. Aurobindo admitted in its recall notice that NDMA is “classified as a probable human carcinogen.”<sup>49</sup> In addition, [REDACTED]

[REDACTED]<sup>50</sup> [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]<sup>51</sup>

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

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<sup>45</sup> ApotexCorp 0000030734.

<sup>46</sup> GiantEagle\_MDL2924\_00000303.

<sup>47</sup> LANNETT0006894.

<sup>48</sup> WOCKHARDT00014477.

<sup>49</sup> Aurobindo prod2 0000000668.

<sup>50</sup> Aurobindo\_prod2\_\_0000000465.

<sup>51</sup> *Id.*

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

99. This continued in 2020 when the FDA required recalls of numerous generic manufacturers’ metformin, including metformin made by Apotex, Amneal, Granules, Sun Pharmaceuticals, Nostrum, and Teva.<sup>52</sup>

100. NDMA is a genotoxin which interacts with DNA and may subsequently induce mutations. Genotoxins are not considered to have a safe threshold or dose due to their ability to alter DNA.

101. The FDA has set an acceptable daily intake (“ADI”) level for NDMA at 96 ng. That means that consumption of 96 ng of NDMA a day would increase the risk of developing cancer by 0.001% over the course of a lifetime. That risk increases as the level of NDMA exposure increases. However, any level above 96 ng is considered unacceptable.<sup>53</sup>

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

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<sup>52</sup> <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin>.

<sup>53</sup> U.S. Food & Drug Admin., *FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)* (Feb. 28, 2019), <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan>.

and lung.

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

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

105. NDMA is a very small molecule. That allows it to pass through the blood-brain and placental barrier. This is particularly concerning as ranitidine has been marketed for pregnant women and young children for years.

106. Exposure to high levels of NDMA has been linked to liver damage in humans.<sup>54</sup>

107. Numerous *in vitro* studies confirm that NDMA is a mutagen—causing genetic mutations in human and animal cells.

108. Overall, the animal data demonstrates that NDMA is carcinogenic in all animal species tested: mice; rats; Syrian golden, Chinese and European hamsters; guinea pigs; rabbits; ducks; mastomys; fish; newts; and frogs.

109. The EPA classified NDMA as a probable human carcinogen “based on the induction of tumors at multiple sites in different mammal species exposed to NDMA by various routes.”<sup>55</sup>

110. Pursuant to EPA cancer guidelines, “tumors observed in animals are generally

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<sup>54</sup> See EPA Technical Fact Sheet, *supra* note 43.

<sup>55</sup> *Id.*

assumed to indicate that an agent may produce tumors in humans.”<sup>56</sup>

111. In addition to the overwhelming animal data linking NDMA to cancer, there are numerous human epidemiological studies exploring the effects of dietary exposure to various cancers. These studies consistently show increased risks of various cancers.

112. 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 micrograms/day.<sup>57</sup>

113. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 746 cases, researchers observed statistically significant elevated rates of gastric cancer in persons exposed to more than 0.191 micrograms/day.<sup>58</sup>

114. In another 1995 epidemiological case-control study looking at, in part, the effects of dietary consumption on cancer, researchers observed a statistically significant elevated risk of developing aerodigestive cancer after being exposed to NDMA at 0.179 micrograms/day.<sup>59</sup>

115. In a 1999 epidemiological cohort study looking at NDMA dietary exposure with 189 cases and a follow up of 24 years, researchers noted that “N-nitroso compounds are potent carcinogens” and that dietary exposure to NDMA more than doubled the risk of developing colorectal cancer.<sup>60</sup>

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<sup>56</sup> See U.S. Env'tl. Protection Agency, Risk Assessment Forum, *Guidelines for Carcinogen Risk Assessment* (Mar. 2005), [https://www3.epa.gov/airtoxics/cancer\\_guidelines\\_final\\_3-25-05.pdf](https://www3.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf).

<sup>57</sup> Pobel et al., *Nitrosamine, Nitrate and Nitrite in Relation to Gastric Cancer: A Case-control Study in Marseille, France*, 11 Eur. J. Epidemiol. 67–73 (1995).

<sup>58</sup> La Vecchia, et al., *Nitrosamine Intake & Gastric Cancer Risk*, 4 Eur. J. Cancer Prev. 469–74 (1995).

<sup>59</sup> Rogers et al., *Consumption of Nitrate, Nitrite, and Nitrosodimethylamine and the Risk of Upper Aerodigestive Tract Cancer*, 5 Cancer Epidemiol. Biomarkers Prev. 29–36 (1995).

<sup>60</sup> 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 852–56 (1999).

116. In a 2000 epidemiological cohort study looking at occupational exposure of workers in the rubber industry, researchers observed significant increased risks for NDMA exposure for esophagus, oral cavity, and pharynx cancer.<sup>61</sup>

117. In a 2011 epidemiological cohort study looking at NDMA dietary exposure with 3,268 cases and a follow up of 11.4 years, researchers concluded that “[d]ietary NDMA intake was significantly associated with increased cancer risk in men and women” for all cancers, and that “NDMA was associated with increased risk of gastrointestinal cancers” including rectal cancers.<sup>62</sup>

118. In a 2014 epidemiological case-control study looking at NDMA dietary exposure with 1,760 cases, researchers found a statistically significant elevated association between NDMA exposure and rectal cancer.<sup>63</sup>

119. NDMA is also known to be genotoxic—meaning, it can cause DNA damage in human cells. Indeed, multiple studies demonstrate that NDMA is genotoxic both *in vivo* and *in vitro*. However, recent studies have shown that the ability of NDMA to cause mutations in cells is affected by the presence of enzymes typically found in living humans, suggesting that “humans may be especially sensitive to the carcinogenicity of NDMA.”<sup>64</sup>

120. In addition to studies demonstrating that NDMA directly causes cancer, research shows that exposure to NDMA (1) can exacerbate existing but dormant (*i.e.* not malignant) tumor cells; (2) promote otherwise “initiated cancer cells” to develop into cancerous tumors; and (3)

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<sup>61</sup> Straif et al., *Exposure to High Concentrations of Nitrosamines and Cancer Mortality Among a Cohort of Rubber Workers*, 57 *Occup. Envtl. Med* 180–87 (2000).

<sup>62</sup> Loh et al., *N-nitroso Compounds and Cancer Incidence: The European Prospective Investigation into Cancer and Nutrition (EPIC)–Norfolk Study*, 93 *Am. J. Clinical Nutrition* 1053–61 (2011).

<sup>63</sup> Zhu et al., *Dietary N-nitroso Compounds and Risk of Colorectal Cancer: A Case-control Study in Newfoundland and Labrador and Ontario, Canada*, 111 *Brit. J. Nutrition* 6, 1109–17 (2014).

<sup>64</sup> World Health Org., *supra* note 53.

reduce the ability of the body to combat cancer as NDMA is immunosuppressive. Thus, in addition to NDMA being a direct cause of cancer itself, NDMA can also be a contributing factor to a cancer injury caused by some other source.

### **III. NDMA IS DISCOVERED IN RANITIDINE-CONTAINING PRODUCTS, LEADING TO MARKET WITHDRAWAL**

121. On September 9, 2019, pharmacy and testing laboratory Valisure LLC and ValisureRX LLC (collectively, “Valisure”) filed a Citizen Petition calling for the recall of all ranitidine-containing products due to detecting exceedingly high levels of NDMA when testing ranitidine pills using gas chromatography-mass spectrometry. FDA and European regulators started reviewing the safety of ranitidine with specific focus on the presence of NDMA.<sup>65</sup> This set off a cascade of recalls by the Defendants.

122. On September 13, 2019, the FDA’s Director for Drug Evaluation and Research, Dr. Janet Woodcock, issued a statement warning that some ranitidine medicines may contain NDMA.<sup>66</sup>

123. On September 24, 2019, Sandoz voluntarily recalled all of its ranitidine-containing products due to concerns of a “nitrosamine impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled medicine.”<sup>67</sup>

124. On September 26, 2019, generic manufacturer Apotex Corp. and Walgreens,

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<sup>65</sup> FDA Statement, Woodcock, *supra* note 51; Press Release, European Medicines Agency, *EMA to Review Ranitidine Medicines Following Detection of NDMA* (Sept. 13, 2019), <https://www.ema.europa.eu/en/news/ema-review-ranitidine-medicines-following-detection-ndma>.

<sup>66</sup> FDA Statement, Woodcock, *supra* note 51.

<sup>67</sup> FDA News Release, U.S. Food & Drug Admin., *FDA Announces Voluntary Recall of Sandoz Ranitidine Capsules Following Detection of an Impurity* (Sept. 24, 2019), <https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-sandoz-ranitidine-capsules-following-detection-impurity>.

Walmart, and Rite Aid voluntarily recalled all ranitidine products and removed them from shelves.<sup>68</sup> Apotex issued a statement, noting that “Apotex has learned from the U.S. Food and Drug Administration and other Global regulators that some ranitidine medicines including brand and generic formulations of ranitidine regardless of the manufacturer, contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA).”<sup>69</sup>

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

126. On October 2, 2019, the FDA ordered manufacturers of ranitidine to test their products and recommended using a liquid chromatography with high resolution mass spectrometer (“LC-HRMS”) testing protocol, which “does not use elevated temperatures.”<sup>70</sup>

127. On October 8, 2019, GSK voluntarily recalled all ranitidine-containing products internationally.<sup>71</sup> As part of the recall, GSK publicly acknowledged that unacceptable levels of NDMA were discovered in Zantac and noted that “GSK is continuing with investigations into the

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<sup>68</sup> U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Sept. 26, 2019), <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine>.

<sup>69</sup> Company Announcement, U.S. Food & Drug Admin., *Apotex Corp. Issues Voluntary Nationwide Recall of Ranitidine Tablets 75mg and 150mg (All Pack Sizes and Formats) Due to the Potential for Detection of an Amount of Unexpected Impurity, N-nitrosodimethylamine (NDMA) Impurity in the Product* (Sept. 25, 2019), <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/apotex-corp-issues-voluntary-nationwide-recall-ranitidine-tablets-75mg-and-150mg-all-pack-sizes-and->

<sup>70</sup> U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Oct. 2, 2019), <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine>.

<sup>71</sup> Press Release, Gov. UK, *Zantac – MHRA Drug Alert Issued as GlaxoSmithKline Recalls All Unexpired Stock* (Oct. 8, 2019), <https://www.gov.uk/government/news/zantac-mhra-drug-alert-issued-as-glaxosmithkline-recalls-all-unexpired-stock>.

potential source of the NDMA.”<sup>72</sup>

128. On October 18 and 23, 2019, Defendant Sanofi and Dr. Reddy’s voluntarily recalled all of their ranitidine-containing products.<sup>73</sup>

129. On October 28, 2019, Generic Manufacturers Perrigo, Novitium, and Lannett voluntarily recalled all their ranitidine-containing products.<sup>74</sup>

130. In its recall notice, Generic Manufacturer Perrigo stated, “[a]fter regulatory bodies announced that ranitidine may potentially contain NDMA, Perrigo promptly began testing of its externally sourced ranitidine API (active pharmaceutical ingredient) and ranitidine-based products. On October 8, 2019, Perrigo halted shipments of the product based upon preliminary results. Based on the totality of data gathered to date, Perrigo has made the decision to conduct this voluntary recall.”<sup>75</sup>

131. Generic Manufacturer Lannett also acknowledged the presence of NDMA in the drug product in its recall notice: “Lannett was notified by FDA of the potential presence of NDMA on September 17, 2019 and immediately commenced testing of the Active Pharmaceutical Ingredient (API) and drug product. The analysis confirmed the presence of NDMA.”<sup>76</sup>

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<sup>72</sup> Justin George Varghese, *GSK Recalls Popular Heartburn Drug Zantac Globally After Cancer Scare*, Reuters (Oct. 8, 2019), <https://www.reuters.com/article/us-gsk-heartburn-zantac/gsk-recalls-popular-heartburn-drug-zantac-globally-after-cancer-scare-idUSKBN1WN1SL>.

<sup>73</sup> U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Oct. 23, 2019), <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine>.

<sup>74</sup> *Id.*

<sup>75</sup> Company Announcement, U.S. Food & Drug Admin., *Perrigo Company plc Issues Voluntary Worldwide Recall of Ranitidine Due to Possible Presence of Impurity, N-nitrosodimethylamine (NDMA) Impurity in the Product* (Oct. 23, 2019), <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/perrigo-company-plc-issues-voluntary-worldwide-recall-ranitidine-due-possible-presence-impurity-n>.

<sup>76</sup> Company Announcement, U.S. Food & Drug Admin., *Lannett Issues Voluntary Nationwide Recall of Ranitidine Syrup (Ranitidine Oral Solution, USP), 15mg/ml Due to an Elevated Level*



132. On November 1, 2019, the FDA announced the results of recent testing, finding unacceptable levels of NDMA in ranitidine-containing products, and requested that drug makers begin to voluntarily recall their ranitidine-containing products if the FDA or manufacturers discovered NDMA levels above the acceptable limits.<sup>77</sup>

133. On December 4, 2019, the FDA issued a statement notifying consumers who wished to continue taking ranitidine to consider limiting their intake of nitrite-containing foods, *e.g.*, processed meats and preservatives like sodium nitrite.<sup>78</sup> This advice *mirrored* an admonition issued by Italian scientists in 1981 after finding that ranitidine reacted with nitrites *in vitro* to form toxic and mutagenic effects in bacteria. The prudent advice of Dr. de Flora published in October 1981 in *The Lancet* was to “avoid nitrosation as far as possible by, for example, suggesting a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals or by giving inhibitors of nitrosation such as ascorbic acid.”<sup>79</sup> If GSK had only heeded Dr. de Flora’s advice in 1981, millions of people might have avoided exposure to NDMA formed as a result of ranitidine’s interaction with the human digestive system.

134. Between November 1, 2019 and February 27, 2020, the following Generic Manufacturers recalled their products from the market, citing NDMA concerns: Aurobindo,

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*of the Unexpected Impurity, N-nitrosodimethylamine (NDMA)* (Oct. 25, 2019), <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lannett-issues-voluntary-nationwide-recall-ranitidine-syrup-ranitidine-oral-solution-usp-15mgml-due>.

<sup>77</sup> U.S. Food & Drug Admin., Laboratory Tests | Ranitidine, <https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-tests-ranitidine> (content current as of Nov. 1, 2019).

<sup>78</sup> U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Dec. 4, 2019), <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine>.

<sup>79</sup> Silvio de Flora, *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, *The Lancet*, Oct. 31, 1981, at 993–94.

Amneal, American Health Packaging, GSMS, and Glenmark.<sup>80</sup>

135. On January 2, 2020, research laboratory, Emery Pharma, submitted a Citizen Petition to the FDA, showing that the ranitidine molecule is heat-labile and under certain temperatures progressively accumulates NDMA.

136. Emery's Citizen Petition outlined its substantial concern that ranitidine is a time- and temperature-sensitive pharmaceutical product that develops NDMA when exposed to heat, a common occurrence during shipping, handling, and storage. Emery requested that the FDA issue a directive to manufacturers to clearly label ranitidine with a warning that "by-products that are probable carcinogens can be generated if exposed to heat." In addition to warning about this condition, Emery requested agency directives to manufacturers and distributors to ship ranitidine products in temperature-controlled vehicles.<sup>81</sup>

137. In response,<sup>82</sup> on April 1, 2020, the FDA recounted that a recall is an "effective methods [sic.] of removing or correcting defective FDA-regulated products . . . particularly when those products present a danger to health."<sup>83</sup> The FDA sought the voluntary consent of manufacturers to accept the recall "to protect the public health from products that present a risk of injury."<sup>84</sup> The FDA found that the recall of all ranitidine-containing products and a public warning of the recall was necessary because the "product being recalled presents a serious health risk."<sup>85</sup>

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<sup>80</sup> See generally U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine> (content current as of Apr. 16, 2020).

<sup>81</sup> Emery Pharma FDA Citizen Petition (Jan. 2, 2020) <https://emerypharma.com/news/emery-pharma-ranitidine-fda-citizen-petition/>.

<sup>82</sup> Letter of Janet Woodcock, U.S. Food & Drug Admin., Docket No. FDA-2020-P-0042 (Apr. 1, 2020), available at <https://emerypharma.com/wp-content/uploads/2020/04/FDA-2020-P-0042-CP-Response-4-1-2020.pdf>.

<sup>83</sup> *Id.* at 5 (citing 21 CFR 7.40(a)).

<sup>84</sup> *Id.*

<sup>85</sup> *Id.* at 7.

The FDA therefore sent Information Requests to all applicants and pending applicants of ranitidine-containing products “requesting a market withdrawal.”<sup>86</sup>

138. The FDA found its stability testing raised concerns that NDMA levels in some ranitidine-containing products stored at room temperature can increase with time to unacceptable levels. In the same vein, FDA testing revealed that higher NDMA levels were found as the products approached their expiration dates. The FDA’s testing eroded the agency’s confidence that any ranitidine-containing product would remain stable through its labeled expiration date. Consequently, the FDA requested a market withdrawal of all ranitidine products. The FDA also announced to the public that the Agency’s laboratory tests indicate that temperature and time contribute to an increase in NDMA levels in some ranitidine products. The FDA’s decision to withdraw the drug rendered moot Emery’s request for temperature-controlled shipping conditions.

139. The FDA’s reaction was consistent with comparable regulatory action throughout the world. Before the FDA acted, over 43 different countries and jurisdictions restricted or banned ranitidine-containing products.<sup>87</sup>

140. The European Medicines Agency (“EMA”), the European Union’s equivalent to the FDA, through an Article 31 Referral, determined the sale of all ranitidine-containing products should be suspended on September 19, 2019. On April 30, 2020, the Human Medicines Committee of the EMA “has recommended the suspension of all ranitidine medicines in the EU due to the presence of low levels of an impurity called N-nitrosodimethylamine (NDMA).” The EMA recognizes NDMA as a probable human carcinogen and issued a “precautionary suspension of

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<sup>86</sup> *Id.* at 10 n.43.

<sup>87</sup> Margaret Newkirk & Susan Berfield, *FDA Recalls Are Always Voluntary and Sometimes Haphazard—and The Agency Doesn’t Want More Authority to Protect Consumers*, Bloomberg Businessweek (Dec. 3, 2019), <https://www.bloomberg.com/graphics/2019-voluntary-drug-recalls-zantac/>.

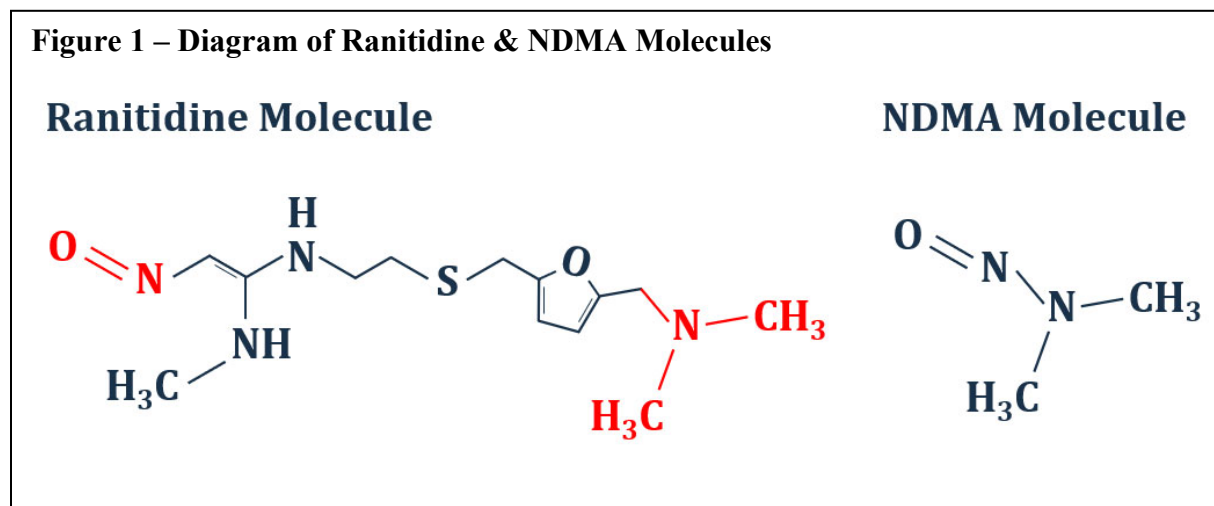
these medicines in the EU” because “NDMA has been found in several ranitidine medicines above levels considered acceptable, and there are unresolved questions about the source of the impurities.”<sup>88</sup>

141. On September 17, 2020, after a ranitidine manufacturer requested that the EMA re-examine its decision and permit ranitidine to be marketed again in the EU, the EMA confirmed its prior recommendation to suspend all ranitidine medicines in the EU due to the presence of NDMA noting that it is a probable human carcinogen and that there is evidence that NDMA forms from the degradation of ranitidine itself with increasing levels seen over shelf life.<sup>89</sup>

#### IV. HOW RANITIDINE TRANSFORMS INTO NDMA

142. The ranitidine molecule itself contains the constituent molecules to form NDMA.

See Figure 1.



143. The degradation occurs independently in two parts of the ranitidine molecule, with the products of the degradation combining to produce NDMA.

<sup>88</sup> Eur. Med. Agency, *Suspension of Ranitidine Medicines in the EU* (Apr. 30, 2020), [https://www.ema.europa.eu/en/documents/referral/ranitidine-article-31-referral-suspension-ranitidine-medicines-eu\\_en.pdf](https://www.ema.europa.eu/en/documents/referral/ranitidine-article-31-referral-suspension-ranitidine-medicines-eu_en.pdf).

<sup>89</sup> Eur. Med. Agency, *EMA Confirms Recommendation to Suspend All Ranitidine Medicines in the EU* (Nov. 24, 2020), [https://www.ema.europa.eu/en/documents/referral/ranitidine-article-31-referral-ema-confirms-recommendation-suspend-all-ranitidine-medicines-eu\\_en.pdf](https://www.ema.europa.eu/en/documents/referral/ranitidine-article-31-referral-ema-confirms-recommendation-suspend-all-ranitidine-medicines-eu_en.pdf).

144. 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 U.S. water supply.<sup>90</sup> Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater-treatment plants were specifically linked to the presence of ranitidine.<sup>91</sup>

145. The high levels of NDMA observed in ranitidine-containing products are a function of various factors. The ranitidine molecule internally degrades to form NDMA. The degradation of ranitidine can increase over time under normal storage conditions, but more so with exposure to heat and/or humidity. Once in the body, ranitidine continues to degrade and can yield increasing levels of NDMA in the human digestive system, and when it interacts with nitrogenous products.

#### **A. Formation of NDMA in the Environment of the Human Stomach**

146. When the ranitidine molecule is exposed to the acidic environment of the stomach, particularly when accompanied by nitrites (a chemical commonly found in heartburn-inducing foods), the Nitroso molecule ( $O=N$ ) and the DMA molecule ( $H_3C-N-CH_3$ ) break off and reform as NDMA.

147. In 1981, Dr. Silvio de Flora, an Italian researcher from the University of Genoa, published the results of experiments he conducted on ranitidine in the well-known journal, *The Lancet*. When ranitidine was exposed to human gastric fluid in combination with nitrites, his experiment showed “toxic and mutagenic effects.”<sup>92</sup> Dr. de Flora hypothesized that these mutagenic effects could have been caused by the “formation of more than one nitroso derivative

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<sup>90</sup> Ogawa et al., *Purification and Properties of a New Enzyme, NG, NG-dimethylarginine Dimethylaminohydrolase, from Rat Kidney*, 264 J. Bio. Chem. 17, 10205–209 (1989).

<sup>91</sup> Mitch et al., *N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review*, 20 Env. Eng. Sci. 5, 389–404 (2003).

<sup>92</sup> De Flora, *supra* note 106.

[which includes NDMA] under our experimental conditions.” *Id.* Dr. de Flora cautioned that, in the context of ranitidine ingestion, “it would seem prudent to ... suggest[] a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals.”<sup>93</sup> *Id.*

148. GSK knew of Dr. de Flora’s publication because, two weeks later, GSK responded in *The Lancet*, claiming that the levels of nitrite needed to induce the production of nitroso derivatives (*i.e.*, NDMA) were not likely to be experienced by people in the real world.<sup>94</sup>

149. This response reflects GSK’s reputation for “adopting the most combative, scorched-earth positions in defense of its brands.”<sup>95</sup> The company has no compunctions against distorting objective science to maintain its lucrative monopoly franchises, and its egregious conduct surrounding Zantac is not some isolated incident.

150. GSK endangered patient health while reaping billions of dollars in profits from Paxil, Wellbutrin, and Avandia. As we now know, the company was involved in covering up scientific data, offering illegal kickbacks to prescribing physicians, intimidating witnesses, and defrauding Medicare to profit from these medicines. In the wake of Congressional hearings into the company’s outrageous misbehavior,<sup>96</sup> GSK’s actions resulted in a criminal investigation and the then-largest guilty plea by a pharmaceutical company for fraud and failure to report safety data

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<sup>93</sup> This admonition came two years before the FDA approved Zantac in 1983. Notwithstanding, in 1998 GSK applied for and obtained an indication for OTC Zantac “[f]or the prevention of meal-induced heartburn at a dose of 75 mg taken 30 to 60 minutes prior to a meal.” See Ctr. for Drug Eval. & Research, *Approval Package* (June 8, 1998), available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/98/20520s1\\_Zantac.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/20520s1_Zantac.pdf). So GSK specifically invited patients to take Zantac shortly before eating heartburn-inducing food.

<sup>94</sup> R. T., Brittain et al., *Safety of Ranitidine*, *The Lancet* 1119 (Nov. 14, 1981).

<sup>95</sup> Jim Edwards, *GSK’s Alleged Coverup of Bad Avandia Data: A Snapshot of Its Poisonous Corporate Culture*, Moneywatch (July 13, 2010) <https://www.cbsnews.com/news/gsk-alleged-coverup-of-bad-avandia-data-a-snapshot-of-its-poisonous-corporate-culture/>.

<sup>96</sup> *Staff Report on GlaxoSmithKline and the Diabetes Drug Avandia*, Senate Comm. on Finance, 111th Cong. 2d Sess. 1 (Comm. Print Jan. 2010).

in the country's history.<sup>97</sup> There is currently an open investigation of GSK and Sanofi being conducted by the Department of Justice relating to the failure to disclose to the federal government information about the potential presence of NDMA in Zantac.<sup>98</sup>

151. GSK attended an FDA Advisory Committee in May 1982 where its representative testified and presented evidence relating to the safety of Zantac, including the potential for ranitidine to form nitrosamines. However, GSK failed to disclose its new evidence relating to ranitidine and the formation of a nitrosamine, specifically the formation of NDMA.<sup>99</sup>

152. One month later, in June 1982, GSK submitted its draft Summary Basis of Approval and labeling for Zantac. Again, GSK failed to submit or otherwise disclose its new evidence relating to ranitidine and the formation of NMDA.<sup>100</sup>

153. In its submission to the FDA, GSK discussed its findings from internal studies performed in 1980 that ranitidine formed a different nitrosamine, n-nitroso-nitrolic acid, a potent mutagen, but explained that these results had no "practical clinical significance"<sup>101</sup>:

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<sup>97</sup> U.S. Dep't of Justice, *GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012), <https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report>.

<sup>98</sup> [https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/investors/docs/2020\\_07\\_29\\_HY\\_financial\\_report\\_EN.pdf](https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/investors/docs/2020_07_29_HY_financial_report_EN.pdf);

<sup>99</sup> GSKZAN0000050413.

<sup>100</sup> GSKZNDAA0000071900.

<sup>101</sup> Excerpted from the Summary Basis of Approval submitted to the FDA to obtain approval of Zantac in the early 1980s. This document was obtained through a Freedom of Information Act request to the FDA.



Although N-nitroso-nitrolic acid was a potent mutagen, it is not likely to be formed in the stomach of a patient ingesting ranitidine, as an unrealistically large amount of nitrite needs to be present to form and maintain the nitrosamine. For this reason, and also because ranitidine was not carcinogenic in life-span studies in rodents, the in vitro nitrosation of ranitidine to a mutagenic nitrosamine does not seem to have practical clinical significance.

154. In 1980—before Zantac was approved by the FDA—GSK conducted another study to examine, among other things, how long-term use of ranitidine could affect the levels of nitrite in the human stomach.<sup>102</sup> Remarkably, GSK admitted that ranitidine use caused the proliferation of bacteria in the human stomach that are known to convert nitrates to nitrites, which leads to elevated levels of nitrite in the stomach environment. GSK acknowledged this could increase the risk of forming nitrosamines and, in turn, cancer, but then dismissed this risk because people were allegedly only expected to use ranitidine-containing products for a short-term period:

**The importance of this finding is not clear. High levels of nitrite could react with certain organic compounds to form nitrosamines, which are known carcinogens. To date, however, neither ranitidine nor cimetidine have been carcinogenic in rodents, so the level of human risk cannot be estimated from animal studies. Ranitidine is recommended only for short-term use and carcinogenic risk, if any, should thus be minimized.**

155. GSK knew—and indeed specifically admitted—that ranitidine could react with nitrite in the human stomach to form nitrosamines and, at the same time, that long-term use of ranitidine could lead to elevated levels of nitrite in the human stomach. GSK also knew but did not disclose that it had new evidence showing that NDMA was generated by ranitidine under certain conditions.

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<sup>102</sup> The results of this study are discussed in the Summary Basis of Approval, obtained from the FDA.



156. In response to Dr. de Flora's findings, in 1982, GSK conducted a clinical study specifically investigating gastric contents in human patients.<sup>103</sup> The study, in part, specifically measured the levels of N-Nitroso compounds in human gastric fluid. GSK indicated that there were no elevated levels, and even published the results of this study five years later, in 1987. The study, however, was flawed. It did not use gold-standard mass spectrometry to test for NDMA, but instead, used a process that could not measure N-nitrosamines efficiently. And worse, in the testing it did do, GSK refused to test gastric samples that contained ranitidine in them out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded."<sup>104</sup> In other words, GSK intentionally engineered the study to exclude the very samples most likely to contain a dangerous carcinogen.

157. Given the above information that was disclosed relating to the nitrosation potential and formation of nitrosamines, it is shocking that GSK conducted an internal study to assess the formation of NDMA and found that ranitidine, when exposed to sodium nitrite, formed hundreds of thousands of nanograms of NDMA. The GSK study was never published or disclosed to the public.

158. In 1983, the same year GSK started marketing Zantac in the United States, seven researchers from the University of Genoa published a study discussing ranitidine and its genotoxic effects (ability to harm DNA).<sup>105</sup> The researchers concluded "it appears that reaction of ranitidine with excess sodium nitrite under acid conditions gives rise to a nitroso-derivative (or derivatives) [like NDMA] capable of inducing DNA damage in mammalian cells." *Id.*

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<sup>103</sup> Thomas et al., *Effects of One Year's Treatment with Ranitidine and of Truncal Vagotomy on Gastric Contents*, 6 Gut. Vol. 28, 726–38 (1987).

<sup>104</sup> *Id.*

<sup>105</sup> Maura et al., *DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells*, 18 Tox. Ltrrs. 97–102 (1983).

159. Then, again in 1983, Dr. de Flora, along with four other researchers, published their complete findings.<sup>106</sup> The results “confirm our preliminary findings on the formation of genotoxic derivatives from nitrite and ranitidine.” Again, the authors noted that, “the widespread clinical use [of ranitidine] and the possibility of a long-term maintenance therapy suggest the prudent adoption of some simple measures, such as a diet low in nitrates and nitrites or the prescription of these anti-ulcer drugs at a suitable interval from meals.” This admonition carries weight considering GSK’s studies indicate that long-term ranitidine consumption, itself, leads to elevated levels of nitrites in the human gut.

160. In addition, as multiple Defendants have noted in internal documents and recent submissions to regulatory authorities, a mechanism for ranitidine to form NDMA [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]<sup>107</sup> Therefore, this potential mechanism was disregarded.

161. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]<sup>108</sup>

162. However, in 1985 GSK [REDACTED]

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<sup>106</sup> De Flora et al., *Genotoxicity of Nitrosated Ranitidine*, 4 Carcinogenesis 3, 255–60 (1983).

<sup>107</sup> SANOFI\_ZAN\_MDL-0000033849-SANOFI\_ZAN\_MDL\_0000033891, at SANOFI\_ZAN\_MDL\_0000033873.

<sup>108</sup> GSKZNDAA0000072103-GSKZNDAA0000072128.

[REDACTED]

[REDACTED] 109 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] 110

[REDACTED]

163. The high instability of the ranitidine molecule was elucidated in scientific studies investigating ranitidine as a source of NDMA in drinking water and specific mechanisms for the breakdown of ranitidine were proposed.<sup>111</sup> These studies underscore the instability of the NDMA group on the ranitidine molecule and its ability to form NDMA in the environment of water-treatment plants that supply many U.S. cities with water.

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<sup>109</sup> GSKZAN0000369313, ([REDACTED])

<sup>110</sup> GSKZNDAA0000636549

<sup>111</sup> Le Roux et al., *NDMA Formation by Chloramination of Ranitidine: Kinetics and Mechanism*, 46 *Envtl. Sci. Tech.* 20, 11095–103 (2012).

164. In 2002, researchers conducted a controlled study to evaluate the concentration of nitrosamines, including NDMA, in the gastric fluid and urine in children with gastritis before and after four to six weeks of treatment with ranitidine.<sup>112</sup> The study reported statistically significant increases in the nitrosamine concentration, including NDMA, in the gastric juice and urine in 93.3% of children after taking ranitidine for only four weeks. The researchers noted that nitrosamines belong to the most potent known carcinogens and no organisms have been found that would be resistant to the harmful effects, that neoplastic lesions induced by nitroso compounds may develop in any organ, and that nitrosamines induced a wide spectrum of tumors in studies using animal models. *Id.* In addition, the authors noted specifically that NDMA induced similar symptoms of acute poisoning in humans and animals. *Id.* They advised that prophylactic measures to avoid nitrosamine formation include a diet high in fruits and inclusion of ascorbic acid as well as limiting intake of processed meat. The conclusion was that ranitidine should only be recommended in children after careful consideration. *Id.*

165. Despite the direct evidence that children taking ranitidine were being exposed to dangerously high levels of carcinogenic nitrosamines including NDMA, Defendants recklessly continued to market and promote Zantac and/or ranitidine as safe and effective for children.

166. Similarly, in 2016, researchers at Stanford University conducted an experiment on healthy adult volunteers.<sup>113</sup> They measured the NDMA in urine of healthy individuals over the course of 24 hours, administered one dose of ranitidine, and then measured the NDMA in the urine of the same individuals for another 24 hours. The study reported that on average, the level of

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<sup>112</sup> Krawczynski, et al. *Nitrosamines in Children with Chronic Gastritis*, Journal of the Polish Pediatric Society (GSKZAN0000235261).

<sup>113</sup> Zeng et al., *Oral intake of Ranitidine Increases Urinary Excretion of N-nitrosodimethylamine*, 37 Carcinogenesis 625–34 (2016).

NDMA increased by 400 times, to approximately 47,000 ng. The only change during that 24-hour period was the consumption of ranitidine. In the study, the scientists further explained that previous studies have indicated a high metabolic conversion rate of NDMA, meaning it will be processed by the human body. This study showed that ranitidine generates NDMA in the human body.

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

168. In its September 9, 2019 Citizen’s Petition to the FDA,<sup>114</sup> Valisure disclosed as part of its testing of ranitidine-containing products that in every lot tested there were exceedingly high levels of NDMA. Valisure’s ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method FY19-005-DPA for the determination of NDMA levels. As per the FDA protocol, this method was validated to a lower limit of detection of 25 ng.<sup>115</sup> The results of Valisure’s testing show levels of NDMA well above 2 million ng per 150 mg Zantac tablet, shown below in Table 1.

<p><b>Table 1 – Ranitidine Samples Tested by Valisure Laboratory Using GC/MS Protocol</b></p>
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<sup>114</sup> Valisure, *Citizen Petition on Ranitidine* (Sept. 9, 2019), available at <https://www.valisure.com/wp-content/uploads/Valisure-Ranitidine-FDA-Citizen-Petition-v4.12.pdf>

<sup>115</sup> U.S. Food & Drug Admin., *Combined N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay, FY19-005-DPA-S* (Jan. 28, 2019).

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

169. This testing by GC-MS demonstrates the instability of the ranitidine molecule and its propensity to break down under higher temperatures.

170. Valisure was concerned that the extremely high levels of NDMA observed in its testing were a product of the modest oven heating parameter of 130 °C in the FDA recommended GC/MS protocol. So Valisure developed a low temperature GC/MS method that could still detect NDMA but would only subject samples to 37 °C, the average temperature of the human body. This method was validated to a lower limit of detection of 100 ng.

171. Valisure tested ranitidine tablets 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. The inclusion of nitrite in gastric fluid testing is

commonplace and helps simulate the environment of a human stomach.

172. Indeed, ranitidine-containing products were specifically advertised to be used when consuming foods containing high levels of nitrates, such as tacos or pizza.<sup>116</sup>

173. The results of Valisure's tests on ranitidine tablets in biologically relevant conditions demonstrate significant NDMA formation under simulated gastric conditions with nitrite present (*see* Table 2).

<b>Table 2 – Valisure Biologically Relevant Tests for NDMA Formation</b>		
<b>Ranitidine Tablet Studies</b>	<b>NDMA (ng/mL)</b>	<b>NDMA per tablet (ng)</b>
Tablet without Solvent	Not Detected	Not Detected
Tablet	Not Detected	Not Detected
Simulated Gastric Fluid ("SGF")	Not Detected	Not Detected
Simulated Intestinal Fluid ("SIF")	Not Detected	Not Detected
SGF with 10 mM Sodium Nitrite	Not Detected	Not Detected
SGF with 25 mM Sodium Nitrite	236	23,600
SGF with 50 mM Sodium Nitrite	3,045	304,500

174. Under biologically relevant conditions, when nitrites are present, high levels of NDMA are found in one dose of 150 mg ranitidine, ranging between 245 and 3,100 times above the FDA-allowable limit. One would need to smoke over 500 cigarettes to achieve the same levels of NDMA found in one dose of 150 mg ranitidine at the 25 nanogram level (over 7,000 for the 50 nanogram level).

175. Following the release of Valisure Citizen's Petition, the FDA conducted additional laboratory tests, which showed NDMA levels in all ranitidine samples it tested, including API and

<sup>116</sup> See, e.g., Zantac television commercial, *Family Taco Night*, <https://www.ispot.tv/ad/dY7n/zantac-family-taco-night>; Zantac television commercial, *Spicy*, [https://youtu.be/jzS2kuB5\\_wg](https://youtu.be/jzS2kuB5_wg); Zantac television commercial, *Heartburn*, <https://youtu.be/Z3QMwkSUIEg>; Zantac television commercial, *Zantac Heartburn Challenge*, <https://youtu.be/qvh9gyWqQns>.

the finished drug, both tablets and syrup. The FDA developed simulated gastric fluid (“SGF”) and simulated intestinal fluid (“SIF”) models to use with the LC-MS testing method to estimate the biological significance of *in vitro* findings. These models are intended to detect the formation of NDMA in systems that approximate the stomach and intestine.

176. When the scientific data is assessed overall, the literature demonstrates that the ingestion of ranitidine already containing NDMA combined with the presence of human-relevant levels of nitrite in the stomach—a substance that is commonly found in foods that induce heartburn and that is known to be elevated in people taking ranitidine for longer than a month—the ranitidine molecule transforms into more NDMA which would dramatically increase a person’s risk of developing cancer.

#### **B. Formation of NDMA in Other Organs of the Human Body**

177. 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.

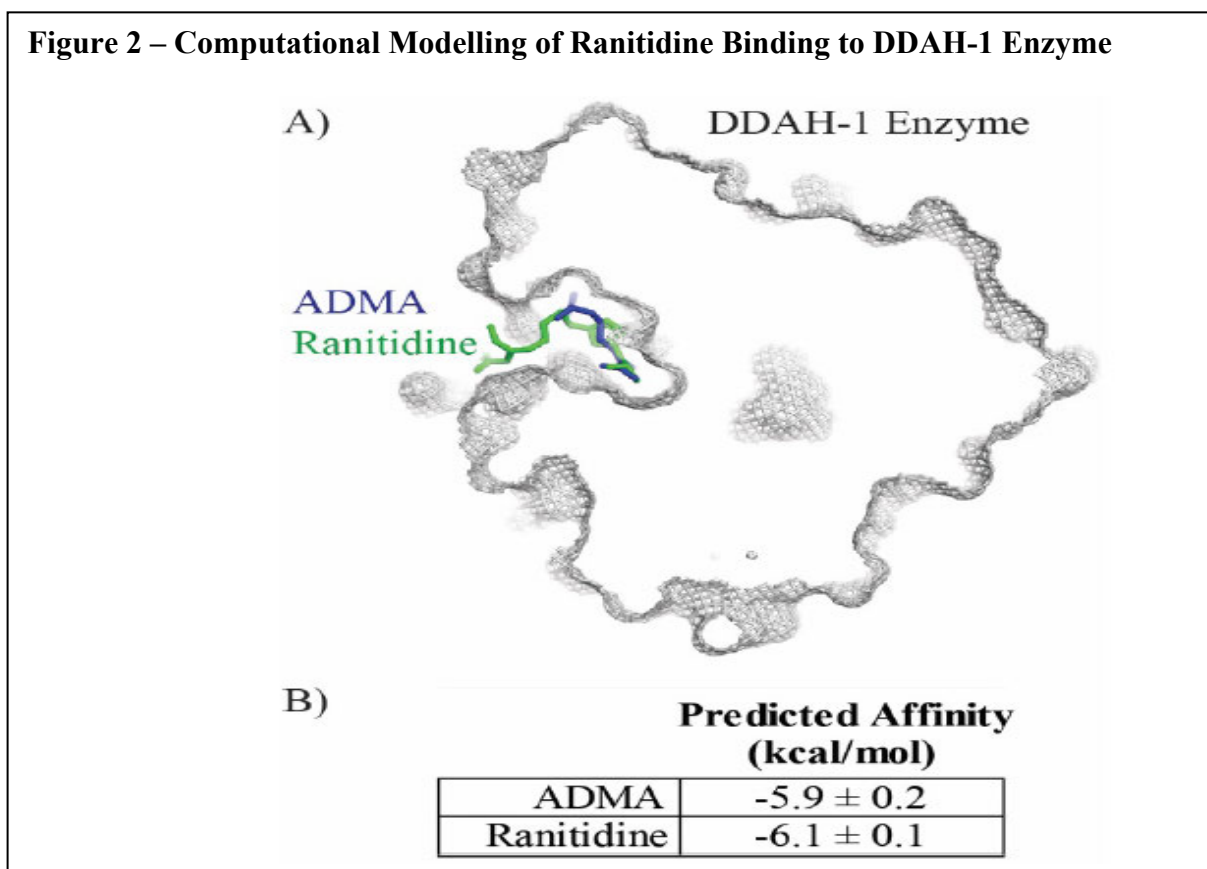
178. Valisure explained that liberated DMA can lead to the formation of NDMA when exposed to nitrite present on the ranitidine molecule, nitrite freely circulating in the body, or other potential pathways, particularly in weak acidic conditions such as that in the kidney or bladder. The original scientific 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].”<sup>117</sup>

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<sup>117</sup> Ogawa, *et al.*, *supra* note 117.

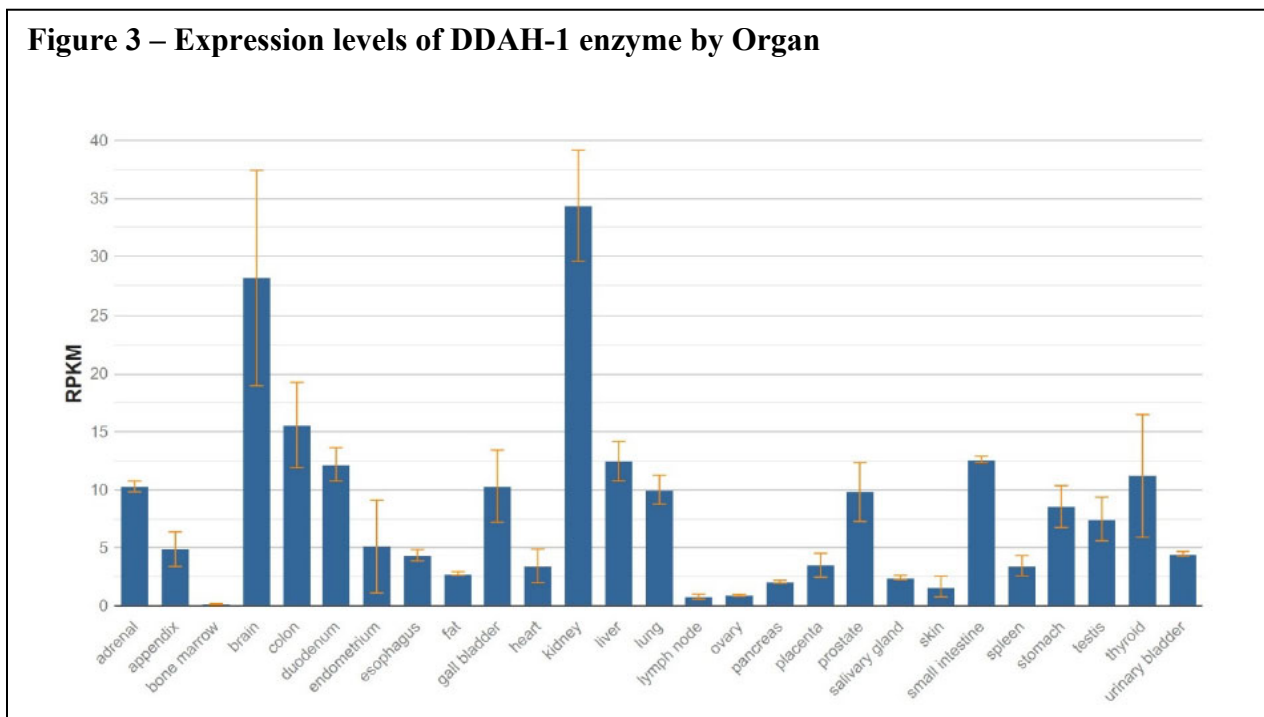


179. Valisure reported as illustrated in Figure 2, below, computational modelling demonstrates that ranitidine (shown in green) can readily bind to the DDAH-1 enzyme (shown as a cross-section in grey) in a manner similar to the natural substrate of DDAH-1 known as asymmetric dimethylarginine (“ADMA,” shown in blue).



180. Valisure reported that these results suggest 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.

181. Figure 3 below, derived from the National Center for Biotechnology Information, illustrates the expression of the DDAH-1 gene in various tissues in the human body.



182. DDAH-1 is most strongly expressed in the kidneys but also broadly distributed throughout the body, such as in the brain, colon, liver, small intestine, stomach, bladder, and prostate. Valisure noted that 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.

183. The possible enzymatic reaction of ranitidine to DDAH-1, or other enzymes, suggests that high levels of NDMA can form throughout the human body. Indeed, ranitidine metabolizes and circulates throughout the human body, crossing the placental and blood-brain barrier, within 1-2 hours. When ranitidine interacts with the DDAH-1 enzyme in various organs throughout the body, it breaks down into NDMA. This observation is validated by the Stanford study, discussed above.

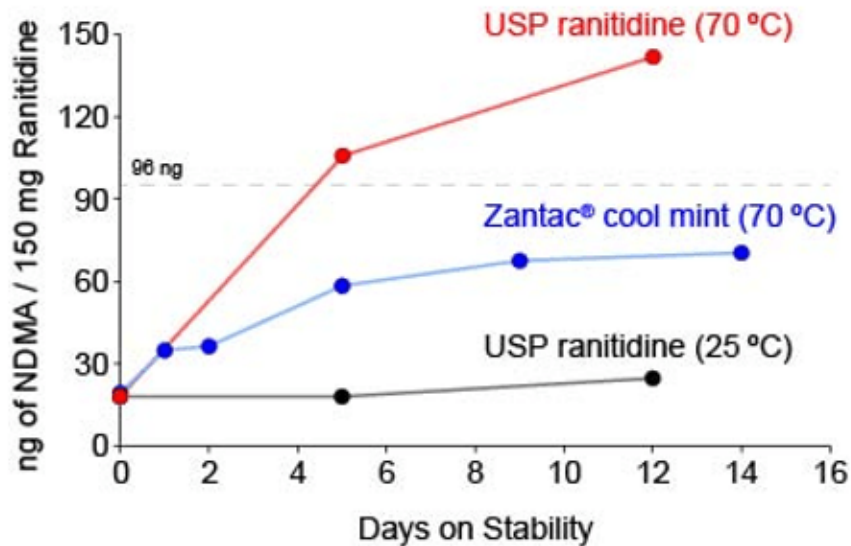
### **C. Formation of NDMA by Exposure to Heat, Moisture, and/or Time**

184. The risk of creating NDMA by exposing ranitidine to heat has been well-known and documented. Early studies, including the one conducted by GSK in the early 1980s, demonstrated that nitrosamines were formed when ranitidine was exposed to heat. This point was underscored in the Valisure petition, which initially used a high-heat testing method.

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

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

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



187. The researchers cautioned:

NDMA accumulates in ranitidine-containing drug products on exposure to elevated temperatures, which would be routinely reached during shipment and during storage. More importantly, these conditions occur post-lot release by the manufacturer. Hence, while NDMA levels in ranitidine may be acceptable at the source, they may not be so when the drug is purchased and subsequently at the time of consumption by the consumer.<sup>118</sup>

188. The results of this data demonstrate that in normal transport and storage, and especially when exposed to heat or humidity, the ranitidine molecule systematically breaks down into NDMA, accumulating over time in the finished product. Considering ranitidine-containing products have an approved shelf life of 36 months, the possibility of the drug accumulating dangerously high levels of NDMA prior to consumption is very real—a point underscored by the FDA’s swift removal of the product from the market.

189. In fact, the FDA acknowledged that testing revealed that NDMA levels in ranitidine

<sup>118</sup> Emery Pharma, *Emery Pharma Ranitidine: FDA Citizen Petition* (Jan. 2, 2020), available at <https://emerypharma.com/news/emery-pharma-ranitidine-fda-citizen-petition/>.

products stored at room temperature can increase with time to unacceptable levels.<sup>119</sup>

190. In 2019, the findings by Valisure unleashed an avalanche of regulatory authorities throughout the world demanding that the manufacturers of Zantac and/or ranitidine conduct testing of their products for the presence of NDMA as well as investigate the root cause as to how NDMA was being generated. In April 2020, the FDA requested that manufacturers immediately remove all ranitidine-containing products from the market.

191. In the interim between the Valisure findings being released to the public and the FDA announcement requesting recall of all ranitidine products in April 2020, the manufacturers were investigating the root cause of NDMA in their products.

192. After undertaking an investigation, GSK concluded that “the presence of NDMA in ranitidine drug substance is due to a slow degradation reaction occurring primarily in the solid state. The two constituent parts of NDMA, the nitroso group and the dimethylamino group, are both derived from internal degradation reactions which occur at slow rates with the ranitidine molecule.”<sup>120</sup> Unsurprisingly, GSK [REDACTED]

[REDACTED]

[REDACTED]<sup>121</sup> In addition, GSK’s testing revealed [REDACTED]

[REDACTED]

[REDACTED]<sup>122</sup>

193. Similarly, Sanofi [REDACTED]

[REDACTED]

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<sup>119</sup> Woodcock Letter, *supra* note 109.

<sup>120</sup> GSKZAN0000052019-GSKZAN0000052127

<sup>121</sup> *Id.* p. 2.

<sup>122</sup> *Id.* p. 12.

[REDACTED]

[REDACTED]<sup>123</sup>

194. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]<sup>124</sup>

195. Defendants could dictate the conditions under which API was transported to them. The labeling requirements do not apply to transporting API, in part because the finished product and API are packaged differently and may degrade under different conditions.

196. Based upon the documents produced by Defendants and based upon further information and belief, both the Defendants failed to ensure that their Ranitidine-Containing Products (in both API and finished dose form) were kept safely from excessive heat and humidity.<sup>125</sup>

#### **V. EVIDENCE DIRECTLY LINKS RANITIDINE EXPOSURE TO CANCER**

197. In addition to numerous epidemiology studies examining how NDMA causes cancer in humans, researchers have also specifically looked at ranitidine and found an association with cancer.

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<sup>123</sup> SANOFI\_ZAN\_MDL\_0000151458

<sup>124</sup> SANOFI\_ZAN\_MDL\_0000166517-527, at p. 11.

<sup>125</sup> See, e.g., BOE ZAN MDL 0000203482 (“[REDACTED]”); GSKZAN0000178835 ([REDACTED])

[REDACTED]

DRLMDL0000087754

DRLMDL0000077957

198. One epidemiology study, published in 2004, showed that men taking either ranitidine or cimetidine (Tagamet) had increased risks of bladder cancer.<sup>126</sup>

199. In one epidemiology study specifically designed to look at breast cancer, ranitidine was shown to more than double the risk, an effect that was even more pronounced in those with specific gene mutations.<sup>127</sup>

200. In another epidemiological study looking at various cancer risks and histamine H<sub>2</sub>-receptor antagonists (or H<sub>2</sub> blockers), including ranitidine, the data showed that ranitidine consumption increased the risk of prostate, lung, esophageal, pancreatic, and kidney cancer.<sup>128</sup> Of particular note, the study indicated that people under the age of 60 who took ranitidine were five times more likely to develop prostate cancer. In addition, there was more than a doubling of the risk of pancreatic cancer with ranitidine use.

201. A study published in 2018, demonstrated an increased risk of liver cancer associated with use of ranitidine in comparison with other H<sub>2</sub> blockers in the class. The purpose of the study was to determine whether there was an increased risk of liver cancer associated with proton pump inhibitors, a different class of medications indicated for the treatment of GERD. This finding is particularly notable as the authors adjusted for variables.<sup>129</sup>

202. In 2018, a study found an increased risk in hepatocellular carcinoma associated

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<sup>126</sup> D. Michaud et al., *Peptic Ulcer Disease and the Risk of Bladder Cancer in a Prospective Study of Male Health Professionals*, 13 *Cancer Epi. Biomarkers & Prevention* 250–54 (Feb. 2004).

<sup>127</sup> Robert W. Mathes et al., *Relationship Between Histamine2-receptor Antagonist Medications and Risk of Invasive Breast Cancer*, 17 *Cancer Epi. Biomarkers & Prevention* 1, 67–72 (2008).

<sup>128</sup> Laurel A Habel et al., *Cimetidine Use and Risk of Breast, Prostate, and Other Cancers*, 9 *Pharmacoepidemiology & Drug Safety* 149–55 (2000).

<sup>129</sup> Kim Tu Tran et al., *Proton Pump Inhibitor and Histamine-2 receptor Antagonist Use and Risk of Liver Cancer in Two Population-based Studies*, 48 *Alimentary Pharmacology & Therapeutics* 1, 55–64 (2018).

with use of H<sub>2</sub> blockers.<sup>130</sup> The authors were evaluating the risk of cancer in association with proton pump inhibitors and looked at H<sub>2</sub> blockers as a confounder. The study only considered use of H<sub>2</sub> blockers within one year of cancer diagnosis and still found an increased odds ratio associated with use of H<sub>2</sub> blockers and hepatocellular carcinoma, a type of liver cancer.

203. A number of other studies have been published over the years showing an increased risk of various cancers associated with use of ranitidine and/or H<sub>2</sub> blockers.<sup>131</sup> These cancers include breast, gastric, pancreatic, and stomach cancer. Additional research reports that ranitidine use was associated with a significant increase in the risk of bladder, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, and prostate cancer.<sup>132</sup>

#### **VI. DEFENDANTS KNEW OR SHOULD HAVE KNOWN OF THE NDMA RISK**

204. As early as 1981, two years before Zantac entered the market, research showed elevated rates of NDMA, when properly tested.<sup>133</sup> This was known or should have been known by the Defendants as the information was available in medical literature.

205. In 1981, GSK, the originator of the ranitidine molecule, published a study focusing on the metabolites of ranitidine in urine using liquid chromatography.<sup>134</sup> Many metabolites were

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<sup>130</sup> Y-H J Shao et al., *Association Between Proton Pump Inhibitors and the Risk of Hepatocellular Carcinoma*, 48 *Alimentary Pharmacology & Therapeutics* 4, 460–68 (2018).

<sup>131</sup> Mathes et al., *supra* note 154; *see also* Jeong Soo Ahn et al., *Acid Suppressive Drugs and Gastric Cancer: A Meta-analysis of Observational Studies*, 19 *World J. Gastroenterology* 16, 2560 (2013); Shih-Wei Lai et al., *Use of Proton Pump Inhibitors Correlates with Increased Risk of Pancreatic Cancer: A Case-control Study in Taiwan*, 46 *Kuwait Med J.* 1, 44–48 (2014); Poulsen et al., *Proton Pump Inhibitors and Risk of Gastric Cancer – A Population Based Cohort Study*, 100 *Brit. J. Cancer* 1503–07 (2009); E Wennerström, *Acid-suppressing Therapies and Subsite-specific Risk of Stomach Cancer*, 116 *Brit. J. Cancer* 9, 1234–38 (2017).

<sup>132</sup> Richard H. Adamson & Bruce A. Chabne, *The Finding of N-Nitrosodimethylamine in Common Medicines*, *The Oncologist*, June 2020; 25(6): 460–62, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7288647/>.

<sup>133</sup> *See supra* ¶ 348 (discussing de Flora research).

<sup>134</sup> 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, 161–68 (1981).



listed, though there is no indication that the study looked for NDMA.

206. Indeed, in that same year, Dr. de Flora published a note discussing the results of his experiments showing that ranitidine was turning into mutagenic N-nitroso compounds, of which NDMA is one, in human gastric fluid when accompanied by nitrites—a substance commonly found in food and in the body.<sup>135</sup> GSK was aware of this study because GSK specifically responded to the note and attempted to discredit it. Defendants knew or should have known about this scientific exchange as it was published in a popular scientific journal. Defendants were obligated to investigate this issue properly. None did.

207. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso compounds, GSK published a clinical study specifically investigating gastric contents in human patients and N-nitroso compounds.<sup>136</sup> That study specifically indicated that there were no elevated levels of N-nitroso compounds (of which NDMA is one). But the study was flawed. 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. Not only is that approach not accurate, but GSK also removed all gastric samples that contained ranitidine out of concern that samples with ranitidine would contain “high concentrations of N-nitroso compounds being recorded.” Without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed. The inadequacy of that test was knowable in light of its scientific publication in 1987. All Defendants either knew or should have known about the inadequacy of that study and should have investigated the issue properly and/or took action to protect consumers from the NDMA risks

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<sup>135</sup> De Flora, *supra* note 106.

<sup>136</sup> Thomas et al., *supra* note 130.

in their products. None did.

### **THE FEDERAL REGULATORY LANDSCAPE**

208. Plaintiffs reference federal law herein not in any attempt to enforce it, but only to demonstrate that their state-law tort claims do not impose any additional obligations on Defendants, beyond what is already required of them under federal law.

#### **I. DEFENDANTS MADE FALSE STATEMENTS IN THE LABELING OF RANITIDINE-CONTAINING PRODUCTS**

209. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a “layman can use a drug safely and for the purposes for which it is intended,”<sup>137</sup> and conform to requirements governing the appearance of the label.<sup>138</sup>

210. “Labeling” encompasses all written, printed or graphic material accompanying the drug or device,<sup>139</sup> and therefore broadly encompasses nearly every form of promotional activity, including not only “package inserts” but also advertising.

211. “Most, if not all, labeling is advertising. The term ‘labeling’ is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising.”<sup>140</sup>

212. All drug manufacturers are also responsible for conducting stability testing, which must be “designed to assess the stability characteristics of drug products.”<sup>141</sup> Manufacturers must adopt a written testing program that includes: “(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability; (2) Storage conditions for

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<sup>137</sup> 21 C.F.R. § 201.5.

<sup>138</sup> *Id.* § 201.15.

<sup>139</sup> *Id.*; 65 Fed. Reg. 14286 (Mar. 16, 2000).

<sup>140</sup> *United States v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).

<sup>141</sup> 21 C.F.R. § 211.166(a).

samples retained for testing; (3) Reliable, meaningful, and specific test methods; (4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed; (5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted.”<sup>142</sup>

213. The purpose of stability testing is, in part, to determine the “appropriate storage conditions and expiration dates.”<sup>143</sup> And expiration dates, in turn, must be set to “assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use.”<sup>144</sup> An expiration date is “related to any storage conditions stated on the labeling, as determined by stability studies listed in § 211.166.”<sup>145</sup>

214. Each manufacturer must therefore conduct its own tests to determine and set accurate retest or expiration dates.

215. The FDA made clear when it first adopted the expiration-date provision that the regulation means what it says. The purpose of the expiration date is not merely to consider the “stability of a specific active ingredient.” Instead, a compliant expiration date must account for multiple factors, including “the stability of the inactive ingredients, the interaction of active and inactive ingredients, the manufacturing process, the dosage form, the container closure system, the conditions under which the drug product is shipped, stored, and handled by wholesalers and retailers, and the length of time between initial manufacture and final use.”<sup>146</sup>

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

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<sup>142</sup> *Id.*

<sup>143</sup> *Id.*

<sup>144</sup> *Id.* § 211.137(a).

<sup>145</sup> *Id.* § 211.137(b).

<sup>146</sup> 43 Fed. Reg. 45059 (Sept. 29, 1978).

date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted . . . until the tentative expiration date is verified or the appropriate expiration date determined.”<sup>147</sup>

217. After a drug is approved, a manufacturer can make changes to its drug application. To do so, manufacturers must comply with the requirements of §§ 314.70 and 314.71.<sup>148</sup>

218. Some of the requirements in those regulations require a manufacturer of an approved drug to obtain FDA approval before implementing a label change.<sup>149</sup>

219. But the FDA has long recognized a “changes being effected” (“CBE”) supplement that permits a manufacturer to make immediate changes, subject to FDA’s post-change review.<sup>150</sup>

220. A manufacturer of an approved drug can use the CBE supplement to immediately make an “[a]ddition to a specification or changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength, quality, purity, or potency that it purports or is represented to possess.”<sup>151</sup> “A specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the tests described.”<sup>152</sup>

221. A manufacturer, therefore, need not seek FDA pre-approval to make changes to its stability studies to identify the appropriate expiration date—which must “assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use”<sup>153</sup>—or to

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<sup>147</sup> 21 C.F.R. § 211.166(b).

<sup>148</sup> *See id.* § 314.97(a) (requiring generics to comply with §§ 314.70, 314.71).

<sup>149</sup> *Id.* § 314.70(b).

<sup>150</sup> *Id.* § 314.70(c)(3), (c)(6).

<sup>151</sup> *Id.* § 314.70(c)(6)(i).

<sup>152</sup> 65 Fed. Reg. 83042 (Dec. 29, 2000).

<sup>153</sup> 21 C.F.R. § 211.137(a).

ensure that the drug is shipped and stored under appropriate conditions.

222. A manufacturer of an approved drug can also use the CBE supplement to make changes “in the labeling to reflect newly acquired information” in order to “add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter”; “add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product”; and “delete false, misleading, or unsupported indications for use or claims for effectiveness.”<sup>154</sup>

223. A manufacturer of an approved drug may make minor changes to a label with no approval or notice, so long as that change is described in an annual report. The illustrative but non-exhaustive list of minor changes includes “[a] change in the labeling concerning the description of the drug product or in the information about how the drug product is supplied, that does not involve a change in the dosage strength or dosage form.”<sup>155</sup>

224. A “minor change” further includes “[a]n extension of an expiration dating period based upon full shelf life data on production batches obtained from a protocol approved in the NDA.”<sup>156</sup>

225. At no time did any Defendant attempt to include a warning on the labels for ranitidine-containing products that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; (iv) consumed daily for a period of greater than a few months. The FDA never rejected such cancer warnings.

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<sup>154</sup> *Id.* § 314.70(c)(6)(iii)(A), (C), (D).

<sup>155</sup> *Id.* § 314.70 (d)(2)(ix).

<sup>156</sup> *Id.* § 314.70 (d)(2)(vi); *see also id.* § 314.70(d)(2)(vii), (x).

226. At no time did any Defendant attempt to change its label to delete a false or misleading expiration date, or to add a proper expiration date to ensure that ranitidine-containing products would not break down into NDMA prior to human consumption.

227. Based on the public scientific information, the Defendants knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

228. At no time did any Defendant change its label to shorten the expiration date. Defendants had the ability to unilaterally make such label changes (for both prescription and OTC) without prior FDA approval pursuant to the CBE regulation. Had any Defendant attempted such label changes, the FDA would not have rejected them.

229. Because they failed to include appropriate expiration dates on their products, Defendants made false statements in the labeling of their products.

## **II. FEDERAL LAW REQUIRED THE DEFENDANTS TO NOTIFY THE FDA ABOUT THE PRESENCE OF NDMA IN RANITIDINE-CONTAINING PRODUCTS**

230. During the time that Defendants manufactured and sold ranitidine-containing products in the United States, the weight of scientific evidence showed that ranitidine exposed users to unsafe levels of NDMA. Defendants failed to report these risks to the FDA.

231. Defendants concealed the ranitidine–NDMA link from ordinary 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 ranitidine to the agency’s attention.

232. 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.

233. 21 C.F.R. § 314.81(b)(2)(v) provides that the manufacturer's annual report must also 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.

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

235. Knowledge regarding the risk of NDMA in ranitidine was sufficiently available in the publicly available scientific literature such that any Defendant, consistent with its heightened obligations to ensure the safety of its products, also should have known about the potential NDMA risks associated with ranitidine consumption.

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

237. When the FDA eventually learned about the NDMA risks posed by ranitidine-

containing products, it ordered manufacturers to voluntarily remove the products from the market. Thus, had any Defendant alerted the FDA to the risks of NDMA, the FDA would have required the manufacturers to remove ranitidine-containing products from the market.

### **III. GOOD MANUFACTURING PRACTICES**

238. Under federal law, a manufacturer must manufacture, store, warehouse, and distribute pharmaceutical drugs in accordance with “Current Good Manufacturing Practices” (“CGMPs”) to ensure they meet safety, quality, purity, identity, and strength standards.<sup>157</sup>

239. 21 C.F.R. § 210.1(a) states that the CGMPs establish “minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.” Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

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

241. Testing conducted by the FDA confirms that under accelerated conditions the elevated temperatures can lead to the presence of NDMA in the drug product.<sup>158</sup> FDA has also concluded that NDMA can increase in ranitidine under storage conditions allowed by the labels,

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<sup>157</sup> 21 U.S.C. § 351(a)(2)(B).

<sup>158</sup> Woodcock Letter, *supra* note 109.



and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during normal distribution and handling. FDA's testing also showed that the level of NDMA in ranitidine-containing products increases with time. And while Emery's Citizen Petition sought to obtain a directive regarding temperature-controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the drug, that request was deemed moot by the FDA because the agency sought to withdraw ranitidine-containing products altogether.

242. Nothing prevented any Defendant from, on their own, taking actions to prevent accumulation of NDMA in ranitidine-containing products by ensuring that ranitidine was not exposed to heat or moisture over long periods.

#### **PLAINTIFFS' USE OF RANITIDINE-CONTAINING PRODUCTS**

243. Plaintiffs were prescribed and/or ingested ranitidine at various times as part of their treatment for gastric ulcers, heartburn, acid indigestion, sour stomach, and other gastrointestinal conditions.

244. Plaintiffs used ranitidine-containing products designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by Defendants. Those products, unbeknownst to Plaintiffs, transformed into dangerous levels of NDMA.

245. Plaintiffs developed cancer, serious and/or permanent injuries, adverse effects, and/or death as set forth in the individual SFCs.

246. Plaintiffs suffered significant bodily injuries, pain and suffering, mental anguish, disfigurement, embarrassment, inconvenience, loss of earnings and earning capacity and have and will incur past and future medical expenses as set forth in the individual SFCs or any other responsive discovery adduced in the respective constituent actions.

247. Based on prevailing scientific evidence, exposure to NDMA caused by consuming Defendants' ranitidine-containing products causes cancer in humans.

248. At all relevant times, Defendants knew or should have known that there was a significant increased risk of cancer associated with the transformation of ranitidine into NDMA, and death related to those diseases. Defendants continued to design, manufacture, test, market, label, package, handle, distribute, store, and/or sell and profit from sales of ranitidine until it was withdrawn from the market.

249. Defendants knowingly, purposely, and deliberately failed to warn Plaintiffs, patients, consumers, medical providers, the FDA, and the public of the increased risk of serious injury associated with using ranitidine, and death related to those events.

250. Plaintiffs' prescribing physicians would not have prescribed ranitidine to Plaintiffs, would have changed the way in which they treated Plaintiffs' relevant conditions, changed the way they warned Plaintiffs about the signs and symptoms of serious adverse effects of ranitidine, and discussed with Plaintiffs the true risks of cancer, had Defendants provided said physicians with an appropriate and adequate warning regarding the risks associated with the use of ranitidine-containing products.

251. Upon information and belief, Plaintiffs' physicians were unaware of the increased risk of multiple types of cancer associated with the use of ranitidine due to its transformation into NDMA and, if they had been informed, would have used and prescribed alternative therapies to Plaintiffs.

252. Plaintiffs would not have taken ranitidine had Plaintiffs known of or been fully and adequately informed by Defendants of the true increased risks and serious dangers of taking the drugs.

253. As a direct and proximate result of Defendants' conduct, Plaintiffs suffered serious and/or permanent injuries, adverse effects, and/or death as set forth in the individual SFCs or any other responsive discovery adduced in the respective constituent actions, which resulted in damages to Plaintiffs in sums in excess of \$75,000.

254. Defendants' conduct was committed with knowing, reckless, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish and deter similar conduct in the future.

#### **TOLLING / FRAUDULENT CONCEALMENT**

255. Plaintiffs assert all applicable 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.

256. The discovery rule applies to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts that Plaintiffs had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

257. The nature of Plaintiffs' injuries, damages, or their causal relationship to Defendants' conduct was not discovered, and through reasonable care and due diligence could not have been discovered until a date within the applicable statute of limitations for filing Plaintiffs' claims.

258. Plaintiffs bring this SAMPIC within the applicable statute of limitations. Specifically, Plaintiffs bring this action within the prescribed time limits following Plaintiffs' injuries and/or death and Plaintiffs' knowledge of the wrongful cause. Prior to such time, Plaintiffs

did not know and had no reason to know of their injuries and/or the wrongful cause of those injuries.

259. The running of the statute of limitations is tolled due to equitable tolling. Defendants are estopped from relying on any statutes of limitation or repose by virtue of their acts of fraudulent concealment, through affirmative misrepresentations and omissions to Plaintiffs and defects associated with ranitidine-containing products as they transform into NDMA. Defendants affirmatively withheld and/or misrepresented facts concerning the safety of ranitidine. As a result of Defendants' misrepresentations and concealment, Plaintiffs and Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence, of facts related to Defendants' misrepresentations or omissions, that Plaintiffs had been exposed to the risks alleged herein, or that those risks were the direct and proximate result of the wrongful acts and/or omissions of Defendants.

260. Given Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defects—information over which Defendants had exclusive control—and because Plaintiffs could not reasonably have known that Defendants' ranitidine-containing products were and are defective, Defendants are estopped from relying on any statutes of limitations or repose that might otherwise be applicable to the claims asserted herein.

#### **EXEMPLARY / PUNITIVE DAMAGES ALLEGATIONS**

261. Defendants' conduct as alleged herein was done with reckless disregard for human life, oppression, and malice. Defendants were fully aware of the safety risks of ranitidine, particularly the carcinogenic potential of ranitidine as it transforms into NDMA within the chemical environment of the human body and/or during transport and/or storage. Nonetheless,

Defendants deliberately crafted their label and marketing to mislead consumers.

262. This was not done by accident or through some justifiable negligence. Rather, Defendants knew they could profit by convincing consumers that ranitidine was harmless to humans, and that full disclosure of the true risks of ranitidine would limit the amount of money Defendants would make selling the drugs. Defendants' object was accomplished not only through a misleading label, but through a comprehensive scheme of selective misleading research and testing, false advertising, and deceptive omissions as more fully alleged throughout this pleading. Plaintiffs were denied the right to make an informed decision about whether to purchase and use ranitidine-containing products, knowing the full risks attendant to that use. Such conduct was done with conscious disregard of Plaintiffs' rights.

263. Accordingly, Plaintiffs request punitive damages (where available) against Defendants for the harms caused to Plaintiffs.

### **CAUSES OF ACTION**

#### **COUNT I: STRICT PRODUCTS LIABILITY—FAILURE TO WARN THROUGH WARNINGS AND PRECAUTIONS**

264. Plaintiffs incorporate by reference each allegation set forth in paragraphs 18-37 (describing Defendants), 121-141 (describing the recall of ranitidine), 146-183 (describing the breakdown of ranitidine after ingestion), 184-196 (describing the breakdown of ranitidine before ingestion), 204-207 (describing Defendant's knowledge), and 243-254 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

265. The allegations in this Count apply to each Defendant during the time periods in which each was manufacturing ranitidine-containing products. The relevant time periods are alleged in paragraph 72, which is incorporated by reference.

266. Ranitidine leads to NDMA exposure in the following ways: (1) the NDMA levels

in ranitidine increase as the drug breaks down in the human digestive system and interacts with various enzymes in the human body; (2) the ranitidine molecule internally degrades to form NDMA, and the NDMA levels in the drug substance and the drug product increase over time under normal storage conditions, but more so with exposure to heat or humidity.

267. NDMA is a potent carcinogen in humans. Higher exposures to NDMA over longer time periods lead to even higher risks of cancer.

268. To mitigate degradation of ranitidine into NDMA in the stomach, consumers should have been warned not to take ranitidine with and after meals or in combination with a high-nitrite diet. No ranitidine-containing product contained this warning.

269. To mitigate degradation of ranitidine into NDMA over time, and in the presence of heat or humidity, consumers should have been warned to consume ranitidine shortly after manufacturing and to store it in a cool, dry place (e.g. not in a bathroom). No ranitidine-containing product contained this warning.

270. To mitigate the risk of NDMA causing cancer, consumers should have been warned to consume ranitidine for only short periods of time. No ranitidine-containing product warned that cancer could result from long-term ingestion of ranitidine.

271. Defendants knew or should have known about each of these risks in time to warn consumers.

272. As was alleged in more detail above, in 1981 Dr. Silvio de Flora published the results of experiments in *The Lancet* showing that ranitidine produced NDMA in combination with gastric fluid and nitrites. This study put all future manufacturers of ranitidine on notice of the risks of consuming ranitidine in combination with high-nitrite foods.

273. GSK responded in *The Lancet* in November, 1981. This response shows that GSK

was in fact aware of Dr. de Flora's research.

274. GSK told the FDA that Dr. de Flora's research has no "practical clinical significance."

275. GSK conducted another study around 1981 that found that ranitidine could cause nitrates to convert into nitrites in the human stomach, which, in combination with Dr. de Flora's research, would mean a heightened risk of NDMA formation. This should have sparked reconsideration of the claim that nitrites levels would not be high enough in the stomach for Dr. de Flora's research to have practical significance.

276. In April 1982, GSK performed a study [REDACTED]

[REDACTED] Though other manufacturers may not have been aware of this study, any of them could have performed similar studies, and had the same reasons as GSK to be concerned.

277. After Zantac had been approved for marketing by the FDA, GSK conducted a study on how ranitidine breaks down in the human stomach and concluded that the amount of nitrosamines formed was low. It was published in 1987. However, GSK used a less reliable test (a nitrogen oxide assay) designed for use in food and discarded two-thirds of the samples because they contained ranitidine (which the study claimed might produce a false positive).

278. In 1983, after GSK's flawed study, but before it was published, a University of Genoa study determined that ranitidine could react with nitrite and produce NDMA, which could induce DNA damage.

279. Also in 1983, Dr. de Flora published his complete findings, confirming his initial results about the risks of NDMA breakdown in the human stomach in combination with nitrites.

GSK did not modify its position.

280. In 2002, a study indicated that NDMA was found in the urine and gastric fluid of children after taking ranitidine for four weeks.

281. In 2012, a study indicated that ranitidine may be a source of NDMA in drinking water.

282. In 2016, a Stanford University study suggested that NDMA amounts in humans increased after consuming ranitidine.

283. In 2019, Valisure tested ranitidine tablets to determine if they contained NDMA. Valisure's ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method FY19-005-DPA8 for the determination of NDMA levels. As per the FDA protocol developed for Valsartan, this method was validated to a lower limit of detection of 25 ng.<sup>159</sup> Valisure found when using the GC/MS headspace analysis method that ranitidine would transform into high levels of NDMA.

284. This testing by GC-MS demonstrates the instability of the ranitidine molecule and its propensity to break down under high temperatures.

285. Any Defendant could have studied ranitidine using the tests Valisure performed, and would have discovered that ranitidine transforms into NDMA when subjected to heat.

286. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of ranitidine

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<sup>159</sup> U.S. Food & Drug Admin., *Combined N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay, FY19-005-DPA-S* (Jan. 28, 2019).



and NDMA. These actions were under the ultimate control and supervision of Defendants.

287. Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, sold, and/or otherwise released into the stream of commerce their ranitidine-containing products, and in the course of the same, directly marketed the products to consumers and end users, including Plaintiffs, and therefore had a duty to warn of the risks associated with the use of ranitidine.

288. At all relevant times, Defendants had a duty to properly manufacture, test, market, label, package, handle, distribute, store, sell, provide proper warnings, and/or take such steps as necessary to ensure their ranitidine-containing products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs of dangers associated with ranitidine. Defendants, as manufacturers and sellers of pharmaceutical medication, are held to the knowledge of an expert in the field.

289. Defendants had a continuing duty to provide appropriate and accurate warnings and precautions.

290. At the time of manufacture, Defendants could have provided warnings or instructions regarding the full and complete risks of ranitidine because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

291. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their products and to those who would foreseeably use or be harmed by Defendants' ranitidine-containing products.

292. Even though Defendants knew or should have known that ranitidine posed a grave

risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to ranitidine-containing products. The dangerous propensities of ranitidine-containing products and the carcinogenic characteristics of NDMA, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, but were not known to end users and consumers, such as Plaintiffs.

293. Defendants knew or should have known that ranitidine-containing products created significant risks of serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn or instruct consumers, i.e., the reasonably foreseeable users and their physicians of the risks of exposure to ranitidine-containing products. Defendants failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in ranitidine-containing products, and further, have made false and/or misleading statements concerning the safety of ranitidine.

294. Defendants possessed new information or new analyses of existing information that empowered them unilaterally to change the warnings and precautions section of their ranitidine-containing products' label.

295. Despite this ability, Defendants failed to warn of the risks of NDMA and their ranitidine-containing products in the warnings and precautions section of their ranitidine-containing products' label.

296. At all relevant times, the Ranitidine-Containing Products were defective at the time they left the Defendants' control. No extrinsic changes were made to alter the products Defendants manufactured. The warnings Plaintiffs and their doctors observed were not changed from when they left Defendants' control.

297. Plaintiffs were exposed to Defendants' ranitidine-containing products without knowledge of their dangerous characteristics.

298. At all relevant times, Plaintiffs used and/or were exposed to the use of Defendants' ranitidine-containing products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

299. Plaintiffs could not have reasonably discovered the defects and risks associated with ranitidine-containing products prior to or at the time Plaintiffs consumed the drugs. Plaintiffs and their physicians relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Defendants' products.

300. Defendants knew or should have known that the minimal warnings disseminated with their ranitidine-containing products were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.

301. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs to avoid using the drug. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to ranitidine; continued to aggressively promote the efficacy of ranitidine-containing products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting ranitidine.

302. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their ranitidine-containing products on the warnings and precautions section of their products' labels, Plaintiffs could have avoided the risk of developing injuries and could have obtained or used alternative medication. However, as a result of Defendants' concealment of the dangers posed by their ranitidine-containing products, Plaintiffs were not alerted, and so could not avert their injuries.

303. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems associated with ranitidine-containing products, and suppressed this knowledge from the general public. Defendants made conscious decisions not to warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

304. Defendants' lack of adequate warnings and instructions in the warnings and precautions section of their ranitidine-containing products' labels were a substantial factor in causing Plaintiffs' injuries.

305. As a direct and proximate result of Defendants' failure to provide an adequate warning of the risks of ranitidine-containing products, Plaintiffs have been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

**SUB-COUNT I-1 ALABAMA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

306. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

307. Under Alabama law, a manufacturer has the duty to provide an adequate warning to consumers of a product's danger when used in its intended manner.

308. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

309. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-2 ALASKA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

310. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

311. Under Alaska law, a product is defective if, as marketed, it poses a risk of injury to someone who uses the product in a reasonably foreseeable manner and the product is marketed without adequate warnings of the risk. Manufacturers have a duty to provide adequate warnings.

312. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under

humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

313. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-3 ARIZONA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

314. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

315. Under Arizona manufacturers have a duty to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

316. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

317. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-4 ARKANSAS: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

318. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

319. Under Arkansas law, manufacturers have a duty to provide adequate warnings. A product is defective if it poses a risk of injury to someone who uses the product in a reasonably foreseeable manner and the product is marketed without adequate warnings of the risks.

320. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

321. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-5 CALIFORNIA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

322. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305

as if fully stated herein.

323. Under California law, manufacturers have a duty to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

324. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

325. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

WHEREFORE, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-6 COLORADO: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

326. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

327. Under Colorado law, a manufacturer has the duty to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use. A product is defective and unreasonably dangerous if it lacks an adequate warning.

328. Each Defendant breached this duty for the ranitidine containing-products it



manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

329. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-7 CONNECTICUT: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

330. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

331. Under Connecticut law, a manufacturer “may be subject to liability for harm caused to a claimant who proves by a fair preponderance of the evidence that the product was defective in that adequate warnings or instructions were not provided. (b) In determining whether instructions or warnings were required and, if required, whether they were adequate, the trier of fact may consider: (1) The likelihood that the product would cause the harm suffered by the claimant; (2) the ability of the product seller to anticipate at the time of manufacture that the expected product user would be aware of the product risk, and the nature of the potential harm; and (3) the technological feasibility and cost of warnings and instructions.” Conn. Gen. Stat. § 52-572q.

332. Each Defendant breached this duty for the ranitidine containing-products it

manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

333. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-8 DISTRICT OF COLUMBIA: STRICT PRODUCTS  
LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND  
PRECAUTIONS**

334. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

335. Under District of Columbia law, a manufacturer has the duty to warn expected users of risks that result from foreseeable uses of the product when the manufacturer knows or has reason to know that the product is dangerous.

336. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

337. Plaintiffs or their doctors would have read and heeded these warnings. As a result,

Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-9 FLORIDA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

338. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

339. Under Florida law, a manufacturer has the duty to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

340. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

341. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-10 GEORGIA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

342. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

343. Under Georgia law, a manufacturer has the duty to provide an adequate warning where it knows or has reason to believe that a use of the product may cause harm.

344. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

345. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-11 HAWAII: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

346. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

347. Under Hawaii law, a manufacturer has the duty to provide adequate instructions for safe use and an adequate warning of dangers inherent in improper use.

348. Each Defendant breached this duty for the ranitidine containing-products it

manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

349. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-12 IDAHO: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

350. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

351. Under Idaho law, a manufacturer has the duty to provide an adequate warning about risks of danger which arise during the known or foreseeable use of the product.

352. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

353. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-13 ILLINOIS: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

354. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

355. Under Illinois law, a manufacturer has a duty to adequately warn of the potential risks or hazards associated with a product where there is unequal knowledge, actual or constructive of a dangerous condition, and the defendant, possessed of such knowledge, knows or should know that harm might or could occur if no warning is given.

356. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

357. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-14 INDIANA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

358. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

359. Under Indiana law, a manufacturer has the duty to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

360. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

361. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-15 KANSAS: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

362. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

363. Under Kansas law, a manufacturer has a duty to provide adequate instructions for safe use and adequate warnings of dangers inherent in use.

364. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate

because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

365. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-16 KENTUCKY: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

366. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

367. Under Kentucky law, a manufacturer has the duty to provide both adequate directions for use and an adequate warning of potential danger from foreseeable uses or misuses. The ultimate question is whether the totality of directions or cautionary language constituted an adequate warning in the light of the foreseeable use and user of the product.

368. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

369. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have



been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-17 LOUISIANA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

370. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

371. Under Louisiana law, a manufacturer has the duty to provide an adequate warning, which is “a warning or instruction that would lead an ordinary reasonable user or handler of a product to contemplate the danger in using or handling the product and either to decline to use or handle the product or, if possible, to use or handle the product in such a manner as to avoid the damage for which the claim is made.” La. Rev. Stat. § 9:2800.53(9).

372. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

373. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT I-18 MAINE: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

374. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

375. Under Maine law, a manufacturer has the duty to provide an adequate warning of the risks of a product that it knew or should have known about.

376. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

377. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-19 MARYLAND: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

378. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

379. Under Maryland law, a manufacturer has the duty to provide an adequate warning of a danger it knew or should have had known about.

380. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

381. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-20 MICHIGAN: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

382. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

383. Under Michigan law, a manufacturer has the duty to provide an adequate warning of dangers that it knew or should have known about.

384. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

385. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT I-21 MINNESOTA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

386. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

387. Under Minnesota law, a manufacturer has the duty to provide adequate instructions for safe use and an adequate warning of dangers inherent in improper usage.

388. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

389. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-22 MISSISSIPPI: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

390. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

391. Under Mississippi law, a manufacturer has the duty to provide an adequate warning sufficient to render the product not unreasonably dangerous to the user if it knew or in light of reasonably available knowledge should have known about the danger that caused the damage.

392. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

393. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-23 MISSOURI: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

394. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

395. Under Missouri law, a manufacturer has the duty to provide an adequate warning of the risks of its products.

396. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

397. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-24 MONTANA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

398. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

399. Under Montana law, a manufacturer has the duty to provide an adequate warning of the risks of its products.

400. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

401. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have

been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-25 NEBRASKA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

402. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

403. Under Nebraska law, a manufacturer has the duty to adequately warn about a risk or hazard inherent in the way a product is designed that is related to the intended or reasonably foreseeable uses that may be made of the products it sells.

404. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

405. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT I-26 NEVADA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

406. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

407. Under Nevada law, a manufacturer has the duty to provide an adequate warning of the risks of its products.

408. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

409. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-27 NEW HAMPSHIRE: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

410. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

411. Under New Hampshire law, a manufacturer has the duty to provide an adequate warning of the risks of its products sufficient to make foreseeable uses not unreasonably dangerous.

412. Each Defendant breached this duty for the ranitidine containing-products it



manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

413. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT I-28 NEW JERSEY: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

414. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

415. Under New Jersey law, a manufacturer has the duty to provide adequate instructions for safe use and an adequate warning of dangers inherent in improper usage.

416. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

417. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-29 NEW MEXICO: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

418. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

419. Under New Mexico law, a manufacturer has the duty to provide an adequate warning. Five criteria guide adequacy: 1. the warning must adequately indicate the scope of the danger; 2. the warning must reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it; and 5. the means to convey the warning must be adequate. *See Serna v. Roche Labs., Div. of Hoffman-LaRoche, Inc.*, 101 N.M. 522, 524 (N.M. Ct. App. 1984).

420. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

421. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-30 NEW YORK: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

422. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

423. Under New York law, a manufacturer has a duty to warn against latent dangers resulting from foreseeable uses of its product of which it knew or should have known.

424. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

425. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-31 NORTH DAKOTA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

426. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

427. Under North Dakota law, a manufacturer has the duty to provide an adequate warning of dangers inherent in its intended or reasonably anticipated use.

428. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

429. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

WHEREFORE, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-32 OHIO: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

430. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

431. Under Ohio law, a manufacturer has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

432. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and

when consumed long after manufacture.

433. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-33 OKLAHOMA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

434. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

435. Under Oklahoma law, a manufacturer has the duty to provide an adequate warning that would inform an ordinary consumer of the risk of harm.

436. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

437. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-34 OREGON: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

438. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

439. Under Oregon law, a manufacturer has the duty to provide an adequate warning of the risks of its products.

440. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

441. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-35 PUERTO RICO: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

442. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

443. Under Puerto Rico law, a manufacturer has the duty to provide an adequate warnings of risks in its products that it knows or should have known about.

444. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

445. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT I-36 RHODE ISLAND: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

446. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

447. Under Rhode Island law, a manufacturer has the duty to provide an adequate warning of dangerous propensities of its products that it knew or should have known about.

448. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

449. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-37 SOUTH CAROLINA: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

450. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

451. Under South Carolina law, a manufacturer has the duty to provide an adequate warning of the risks of its products and adequate instructions for use.

452. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

453. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.



**SUB-COUNT I-38 SOUTH DAKOTA: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

454. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

455. Under South Dakota law, a manufacturer has the duty to provide an adequate warning of the risks of its products that it knew or should have known about at the time the drug is ingested.

456. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

457. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-39 TENNESSEE: STRICT PRODUCTS LIABILITY—FAILURE  
TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

458. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

459. Under Tennessee law, a manufacturer has the duty to provide an adequate warning of the risks of its products. A warning is inadequate if it does not contain a full and complete

disclosure of potential adverse reactions.

460. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

461. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-40 TEXAS: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

462. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

463. Under Texas law, a manufacturer has the duty to provide an adequate warning of potential harms to users from its products that it knew or had reason to know at the time the product left its control.

464. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

465. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-41 UTAH: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

466. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

467. Under Utah law, a manufacturer has the duty to provide an adequate warning of the dangers from a foreseeable use of its product that it knows or should have known about.

468. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

469. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-42 VERMONT: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

470. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

471. Under Vermont law, a manufacturer has the duty to provide an adequate warning of the risks of its products.

472. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

473. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-43 WASHINGTON: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

474. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

475. Under Washington law a “product is not reasonably safe because adequate warnings or instructions were not provided with the product, if, at the time of manufacture, the likelihood that the product would cause the claimant’s harm or similar harms, and the seriousness

of those harms, rendered the warnings or instructions of the manufacturer inadequate and the manufacturer could have provided the warnings or instructions which the claimant alleges would have been adequate.” RCW 7.72.030(1)(b).

476. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

477. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs’ favor for compensatory damages, together with interest, costs herein incurred, attorneys’ fees and all such other and further relief as this Court deems just and proper.

**SUB-COUNT I-44 WEST VIRGINIA: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

478. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

479. Under West Virginia law, a manufacturer has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

480. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate

because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

481. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-45 WISCONSIN: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

482. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

483. Under Wisconsin law, a “product is defective because of inadequate instructions or warnings only if the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the manufacturer and the omission of the instructions or warnings renders the product not reasonably safe.” Wis. Stat. § 895.047(1)(a).

484. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

485. Plaintiffs or their doctors would have read and heeded these warnings. As a result,

Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT I-46 WYOMING: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

486. Plaintiffs incorporate by reference each allegation set forth in paragraphs 264-305 as if fully stated herein.

487. Under Wyoming law, a manufacturer has the duty to provide an adequate warning of the risks of its products that it knew or should have known about. To be adequate, a warning must indicate the scope of danger and the extent or seriousness of harm that could result if the product is misused or the warning is not followed, and must be physically adequate and conveyed by adequate means to alert a reasonable person of the danger.

488. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

489. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**COUNT II: NEGLIGENCE—FAILURE TO WARN THROUGH WARNINGS  
AND PRECAUTIONS**

490. Plaintiffs incorporate by reference each allegation set forth in paragraphs 18-37 (describing Defendants), 121-141 (describing the recall of ranitidine), 146-183 (describing the breakdown of ranitidine after ingestion), 184-196 (describing the breakdown of ranitidine before ingestion), 204-207 (describing Defendant's knowledge), and 243-254 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein. The allegations in this Count apply to each Defendant during the time periods in which each was manufacturing ranitidine-containing products. The relevant time periods are alleged in paragraph 72, which is incorporated by reference.

491. Ranitidine leads to NDMA exposure in the following ways: (1) the NDMA levels in ranitidine increase as the drug breaks down in the human digestive system and interacts with various enzymes in the human body; (2) the ranitidine molecule internally degrades to form NDMA, and the NDMA levels in the drug substance and the drug product increase over time under normal storage conditions, but more so with exposure to heat or humidity.

492. NDMA is a potent carcinogen in humans. Higher exposures to NDMA over longer time periods lead to even higher risks of cancer.

493. To mitigate degradation of ranitidine into NDMA in the stomach, consumers should have been warned not to take ranitidine with or after meals or in combination with a high-nitrite diet. No ranitidine-containing product contained this warning.



494. To mitigate degradation of ranitidine into NDMA over time, and in the presence of heat or humidity, consumers could be warned to consume ranitidine shortly after manufacturing and to store it in a cool, dry place (e.g. not in a bathroom). No ranitidine-containing product contained this warning.

495. To mitigate the risk of NDMA causing cancer, consumers should have been warned to consume ranitidine for only short periods of time. No ranitidine-containing product warned that cancer could result from long-term ingestion of ranitidine.

496. Defendants knew or should have known about each of these risks in time to warn consumers.

497. As was alleged in more detail above, in 1981 Dr. Silvio de Flora published the results of experiments in The Lancet showing that ranitidine produced NDMA in combination with gastric fluid and nitrites. This study put all future manufacturers of ranitidine on notice of the risks of consuming ranitidine in combination with high-nitrite foods.

498. GSK responded in The Lancet in November, 1981. This response shows that GSK was in fact aware of Dr. de Flora's research.

499. GSK told the FDA that Dr. de Flora's research has no "practical clinical significance."

500. GSK conducted another study around 1981 that found that ranitidine could cause nitrates to convert into nitrites in the human stomach, which, in combination with Dr. de Flora's research, would mean a heightened risk of NDMA formation. This should have sparked reconsideration of the claim that nitrites would not be high enough in the stomach for Dr. de Flora's research to have practical significance.

501. In April 1982, GSK performed a study [REDACTED]

[REDACTED]

[REDACTED] Though other Defendants may not have been aware of this study, any of them could have performed similar studies, and had the same reasons as GSK to be concerned.

502. After Zantac had been approved for marketing by the FDA, GSK conducted a study on how ranitidine breaks down in the human stomach, and concluded that the amount of nitrosamines formed was low. That study was published in 1987. However, GSK used a less reliable test (a nitrogen oxide assay) designed for use in food and discarded two-thirds of the samples because they contained ranitidine (which the study claimed might produce a false positive).

503. In 1983, after GSK's flawed study, but before it was published, a University of Genoa study determined that ranitidine could react with nitrite and produce NDMA, which could induce DNA damage.

504. Also in 1983, Dr. de Flora published his complete findings, confirming his initial results about the risks of NDMA breakdown in the human stomach in combination with nitrites. GSK did not modify its position.

505. In 2002, a study indicated that NDMA was found in the urine and gastric fluid of children after taking ranitidine for four weeks.

506. In 2012, a study indicated that ranitidine may be a source of NDMA in drinking water.

507. In 2016, a Stanford University study suggested that NDMA amounts in humans increased after consuming ranitidine.

508. In 2019, Valisure tested ranitidine tablets to determine if they contained NDMA.

Valisure's ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method FY19-005-DPA8 for the determination of NDMA levels. Valisure found when using the GC/MS headspace analysis method that ranitidine would transform into high levels of NDMA.

509. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of ranitidine and NDMA. These actions were under the ultimate control and supervision of Defendants.

510. At all relevant times, Defendants had a duty to properly manufacture, test, market, label, package, handle, distribute, store, sell, provide proper warnings, and/or take such steps as necessary to ensure their ranitidine-containing products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs of dangers associated with ranitidine. Defendants, as manufacturers and sellers of pharmaceutical medication, are held to the knowledge of an expert in the field.

511. Defendants had a continuing duty to provide appropriate and accurate warnings and precautions.

512. At the time of manufacture, Defendants could have provided warnings or instructions regarding the full and complete risks of ranitidine because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

513. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their products and to those who would foreseeably use or be harmed by Defendants' ranitidine-

containing products.

514. Even though Defendants knew or should have known that ranitidine posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to ranitidine-containing products. The dangerous propensities of ranitidine-containing products and the carcinogenic characteristics of NDMA, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, but were not known to end users and consumers, such as Plaintiffs.

515. Defendants knew or should have known that ranitidine-containing products created significant risks of serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn or instruct consumers, i.e., the reasonably foreseeable users, and physicians of the risks of exposure to ranitidine-containing products. Defendants failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in ranitidine-containing products, and further, have made false and/or misleading statements concerning the safety of ranitidine.

516. Defendants possessed new information or new analyses of existing information that empowered them unilaterally to change the warnings and precautions section of their ranitidine-containing products' label.

517. Despite this ability, Defendants failed to warn of the risks of NDMA and their ranitidine-containing products in the warnings and precautions section of their ranitidine-containing products' label.

518. At all relevant times, the Ranitidine-Containing Products were defective at the time they left the Defendants' control. No extrinsic changes were made to alter the products Defendants

manufactured. The warnings Plaintiffs and their doctors observed were not changed from when they left Defendants' control.

519. Plaintiffs were exposed to Defendants' ranitidine-containing products without knowledge of their dangerous characteristics.

520. At all relevant times, Plaintiffs used and/or were exposed to the use of Defendants' ranitidine-containing products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

521. Plaintiffs could not have reasonably discovered the defects and risks associated with ranitidine-containing products prior to or at the time Plaintiffs consumed the drugs. Plaintiffs and their physicians relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Defendants' products.

522. Defendants knew or should have known that the minimal warnings disseminated with their ranitidine-containing products were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.

523. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs to avoid using the drug. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to ranitidine; continued to aggressively promote the efficacy of ranitidine-containing products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed,

downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting ranitidine.

524. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their ranitidine-containing products on the warnings and precautions section of their products' labels, Plaintiffs could have avoided the risk of developing injuries and could have obtained or used alternative medication. However, as a result of Defendants' concealment of the dangers posed by their ranitidine-containing products, Plaintiffs were not alerted, and so could not avert their injuries.

525. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems associated with ranitidine-containing products, and suppressed this knowledge from the general public. Defendants made conscious decisions not to warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

526. Defendants' lack of adequate warnings and instructions in the warnings and precautions section of their ranitidine-containing products' labels were a substantial factor in causing Plaintiffs' injuries.

527. As a direct and proximate result of Defendants' failure to provide an adequate warning of the risks of ranitidine-containing products, Plaintiffs have been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

**SUB-COUNT II-1 ALABAMA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

528. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527

as if fully stated herein.

529. Under Alabama law, a manufacturer has a duty of reasonable care to provide an adequate warning to consumers of a product's danger when used in its intended manner.

530. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

531. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-2 ALASKA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

532. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

533. Under Alaska law, a manufacturer has a duty of reasonable care to provide an adequate warning of a risk of injury to someone who uses the product in a reasonably foreseeable manner.

534. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably

inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

535. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-3 ARIZONA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

536. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

537. Under Arizona manufacturers have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

538. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

539. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.



**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-4 ARKANSAS: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

540. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

541. Under Arkansas law, manufacturers have a duty of reasonable care to provide adequate warnings of risks of injury to someone who uses the product in a reasonably foreseeable manner.

542. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

543. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-5 CALIFORNIA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

544. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527

as if fully stated herein.

545. Under California law, manufacturers have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

546. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

547. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-6 COLORADO: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

548. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

549. Under Colorado law, a manufacturer has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

550. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably

inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

551. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-7 CONNECTICUT: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

552. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

553. Under Connecticut law, a manufacturer “may be subject to liability for harm caused to a claimant who proves by a fair preponderance of the evidence that the product was defective in that adequate warnings or instructions were not provided. (b) In determining whether instructions or warnings were required and, if required, whether they were adequate, the trier of fact may consider: (1) The likelihood that the product would cause the harm suffered by the claimant; (2) the ability of the product seller to anticipate at the time of manufacture that the expected product user would be aware of the product risk, and the nature of the potential harm; and (3) the technological feasibility and cost of warnings and instructions.” Conn. Gen. Stat. § 52-572q.

554. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably

inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

555. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-8 DELAWARE: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

556. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

557. Under Delaware law, a manufacturer has a duty of reasonable care to provide adequate warnings that inform the user of risks of harm it knew or should have known may be involved a reasonably expected use.

558. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

559. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-9 DISTRICT OF COLUMBIA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

560. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

561. Under District of Columbia law, a manufacturer has the duty of reasonable care to warn expected users of risks that result from foreseeable uses of the product when the manufacturer knows or has reason to know that the product is dangerous.

562. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

563. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-10 FLORIDA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

564. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527

as if fully stated herein.

565. Under Florida law, a manufacturer has the duty of reasonable care to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

566. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

567. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-11 GEORGIA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

568. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

569. Under Georgia law, a manufacturer has the duty of reasonable care to provide an adequate warning where it knows or has reason to believe that a use of the product may cause harm.

570. Each Defendant breached this duty for the ranitidine containing-products it

manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

571. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-12 HAWAII: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

572. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

573. Under Hawaii law, a manufacturer has the duty of reasonable care to provide adequate instructions for safe use and an adequate warning of dangers inherent in improper use.

574. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

575. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-13 IDAHO: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

576. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

577. Under Idaho law, a manufacturer has a duty of reasonable care to provide an adequate warning about risks of danger which arise during the known or foreseeable use of the product.

578. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

579. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-14 ILLINOIS: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

580. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527



as if fully stated herein.

581. Under Illinois law, a manufacturer has a duty of reasonable care to adequately warn of the potential risks or hazards associated with a product where there is unequal knowledge, actual or constructive of a dangerous condition, and the defendant, possessed of such knowledge, knows or should know that harm might or could occur if no warning is given.

582. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

583. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-15 INDIANA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

584. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

585. Under Indiana law, a manufacturer has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

586. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably

inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

587. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-16 IOWA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

588. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

589. Under Iowa law, a manufacturer has a duty of reasonable care to provide adequate instructions and warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of those reasonable instructions or warnings, and the omission of the instructions or warnings renders the product not reasonably safe.

590. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

591. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have

been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-17 KANSAS: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

592. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

593. Under Kansas law, a manufacturer has a duty of reasonable care to provide adequate instructions for safe use and adequate warnings of dangers inherent in use.

594. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

595. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-18 KENTUCKY: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

596. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527

as if fully stated herein.

597. Under Kentucky law, a manufacturer has a duty of reasonable care to provide both adequate directions for use and an adequate warning of potential danger from foreseeable uses or misuses. The ultimate question is whether the totality of directions or cautionary language constituted an adequate warning in the light of the foreseeable use and user of the product.

598. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

599. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-19 MAINE: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

600. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

601. Under Maine law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of a product that it knew or should have known about.

602. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably

inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

603. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-20 MARYLAND: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

604. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

605. Under Maryland law, a manufacturer has a duty of reasonable care to provide an adequate warning of a danger it knew or should have had known about.

606. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

607. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-21 MASSACHUSETTS: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

608. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

609. Under Massachusetts law, a manufacturer has a duty of reasonable care to provide an adequate warning of those dangers to persons who it is foreseeable will come in contact with, and consequently be endangered by, that product. This includes a duty to warn or provide instructions about risks that were reasonably foreseeable or could have been discovered by way of reasonable testing.

610. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

611. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-22 MICHIGAN: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

612. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

613. Under Michigan law, a manufacturer has a duty of reasonable care to provide an adequate warning of dangers that it knew or should have known about.

614. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

615. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT II-23 MINNESOTA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

616. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

617. Under Minnesota law, a manufacturer has a duty of reasonable care to provide adequate instructions for safe use and an adequate warning of dangers inherent in improper usage.

618. Each Defendant breached this duty for the ranitidine containing-products it

manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

619. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-24 MISSISSIPPI: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

620. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

621. Under Mississippi law, a manufacturer has a duty of reasonable care to provide an adequate warning sufficient to render the product not unreasonably dangerous to the user if it knew or in light of reasonably available knowledge should have known about the danger that caused the damage.

622. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

623. Plaintiffs or their doctors would have read and heeded these warnings. As a result,



Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-25 MISSOURI: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

624. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

625. Under Missouri law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products.

626. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

627. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-26 MONTANA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

628. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

629. Under Montana law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products.

630. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

631. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-27 NEBRASKA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

632. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

633. Under Nebraska law, a manufacturer has a duty of reasonable care to adequately warn about a risk or hazard inherent in the way a product is designed that is related to the intended or reasonably foreseeable uses that may be made of the products it sells.

634. Each Defendant breached this duty for the ranitidine containing-products it

manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

635. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT II-28 NEVADA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

636. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

637. Under Nevada law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products.

638. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

639. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-29 NEW HAMPSHIRE: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

640. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

641. Under New Hampshire law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products sufficient to make foreseeable uses not unreasonably dangerous.

642. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

643. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT II-30 NEW MEXICO: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

644. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527

as if fully stated herein.

645. Under New Mexico law, a manufacturer has a duty of reasonable care to provide an adequate warning. Five criteria guide adequacy: 1. the warning must adequately indicate the scope of the danger; 2. the warning must reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it; and 5. the means to convey the warning must be adequate. See Roche Labs., Div. of Hoffman-LaRoche, Inc., 101 N.M. 522, 524 (N.M. Ct. App. 1984).

646. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

647. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-31 NEW YORK: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

648. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

649. Under New York law, a manufacturer has a duty to warn against latent dangers resulting from foreseeable uses of its product of which it knew or should have known.

650. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

651. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-32 NORTH CAROLINA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

652. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

653. Under North Carolina law, a manufacturer has a duty of reasonable care to provide an adequate warning

654. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

655. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-33 NORTH DAKOTA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

656. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

657. Under North Dakota law, a manufacturer has a duty of reasonable care to provide an adequate warning of dangers inherent in its intended or reasonably anticipated use.

658. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

659. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-34 OKLAHOMA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

660. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

661. Under Oklahoma law, a manufacturer has a duty of reasonable care to provide an adequate warning that would inform an ordinary consumer of the risk of harm.

662. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

663. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-35 OREGON: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

664. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

665. Under Oregon law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products.

666. Each Defendant breached this duty for the ranitidine containing-products it



manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

667. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-36 PENNSYLVANIA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

668. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

669. Under Pennsylvania law, a manufacturer has a duty of reasonable care to provide an adequate warning.

670. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

671. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-37 PUERTO RICO: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

672. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

673. Under Puerto Rico law, a manufacturer has a duty of reasonable care to provide an adequate warning of risks in its products that it knows or should have known about.

674. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

675. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT II-38 RHODE ISLAND: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

676. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

677. Under Rhode Island law, a manufacturer has a duty of reasonable care to provide an adequate warning of dangerous propensities of its products that it knew or should have known about.

678. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

679. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-39 SOUTH CAROLINA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

680. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

681. Under South Carolina law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products and adequate instructions for use.

682. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-

nitrite diet, and when consumed long after manufacture.

683. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-40 SOUTH DAKOTA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

684. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

685. Under South Dakota law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products that it knew or should have known about at the time the drug is ingested.

686. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

687. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-41 TENNESSEE: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

688. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

689. Under Tennessee law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products. A warning is inadequate if it does not contain a full and complete disclosure of potential adverse reactions.

690. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

691. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-42 TEXAS: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

692. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527

as if fully stated herein.

693. Under Texas law, a manufacturer has a duty of reasonable care to provide an adequate warning of potential harms to users from its products that it knew or had reason to know at the time the product left its control.

694. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

695. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-43 UTAH: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

696. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

697. Under Utah law, a manufacturer has a duty of reasonable care to provide an adequate warning of the dangers from a foreseeable use of its product that it knows or should have known about.

698. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably

inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

699. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-44 VERMONT: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

700. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

701. Under Vermont law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products.

702. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

703. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-45 VIRGINIA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

704. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

705. Under Virginia law, a manufacturer has a duty of reasonable care to provide an adequate warning

706. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

707. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-46 WEST VIRGINIA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

708. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.



709. Under West Virginia law, a manufacturer has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

710. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

711. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-47 WISCONSIN: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

712. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

713. Under Wisconsin law, a “product is defective because of inadequate instructions or warnings only if the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the manufacturer and the omission of the instructions or warnings renders the product not reasonably safe.” Wis. Stat. § 895.047(1)(a).

714. Each Defendant breached this duty for the ranitidine containing-products it

manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

715. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT II-48 WYOMING: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH WARNINGS AND PRECAUTIONS**

716. Plaintiffs incorporate by reference each allegation set forth in paragraphs 490-527 as if fully stated herein.

717. Under Wyoming law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products that it knew or should have known about. To be adequate, a warning must indicate the scope of danger and the extent or seriousness of harm that could result if the product is misused or the warning is not followed, and must be physically adequate and conveyed by adequate means to alert a reasonable person of the danger.

718. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

719. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**COUNT III: STRICT PRODUCTS LIABILITY—FAILURE TO WARN  
THROUGH PROPER EXPIRATION DATES**

720. Plaintiffs incorporate by reference each allegation set forth in paragraphs 18-37 (describing Defendants).

721. The allegations in this Count apply to each Defendant during the time periods in which each was manufacturing ranitidine-containing products. The relevant time periods are alleged in paragraph 72, which is incorporated by reference.

722. Plaintiffs incorporate by reference each allegation set forth in paragraphs 121-141 (describing the recall of ranitidine), 184-196 (describing the breakdown of ranitidine before ingestion), 204-207 (describing Defendant's knowledge), 243-254 (describing Plaintiffs' use of ranitidine and injury), and 208-229 (describing the regulatory framework for drug manufacturers) as if fully stated herein.

723. Ranitidine leads to NDMA exposure in the following ways: (1) the NDMA levels in ranitidine increase as the drug breaks down in the human digestive system and interacts with various enzymes in the human body; (2) the ranitidine molecule internally degrades to form NDMA, and the NDMA levels in the drug substance and the drug product increase over time under normal storage conditions, but more so with exposure to heat or humidity.

724. NDMA is a potent carcinogen in humans. Higher exposures to NDMA over longer

time periods lead to even higher risks of cancer.

725. To mitigate degradation of ranitidine into NDMA over time, and in the presence of heat or humidity, consumers could be warned to consume ranitidine shortly after manufacturing. No ranitidine-containing product contained this warning.

726. In fact, ranitidine-containing products had expiration dating periods of one or two years, allowing accumulation of more and more unsafe levels of NDMA. A much shorter period of a matter of months would have ensured that ranitidine contained far lower levels of NDMA when consumed.

727. Defendants knew or should have known about each of these risks. Simple, widely available and cost-effective tests reveal these risks.

728. In setting expiration and/or retest dates for their ranitidine-containing drugs, Defendants were required to take into consideration the real-world conditions the drugs would be exposed to, including the conditions under which the drugs would be stored and shipped. *See* 21 C.F.R. § 211.137.

729. In setting the expiration and/or retest dates for their ranitidine-containing drugs, Defendants were also required to base those dates on stability testing, which in turn must account for storage conditions. 21 C.F.R. § 211.166.

730. Storage conditions must account for conditions, including the storage container, heat, light, and humidity, among other things.

731. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of ranitidine

and NDMA. These actions were under the ultimate control and supervision of Defendants.

732. Defendants, as a manufacturer of pharmaceutical medication, are held to the knowledge of an expert in the field.

733. Defendants knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to ranitidine after months or years of degradation into NDMA.

734. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their products and to those who would foreseeably use or be harmed by Defendants' ranitidine-containing products.

735. Even though Defendants knew or should have known that ranitidine posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to ranitidine-containing products. The dangerous propensities of ranitidine-containing products and the carcinogenic characteristics of NDMA, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, but were not known to end users and consumers, such as Plaintiffs.

736. Defendants knew or should have known that ranitidine-containing products created significant risks of serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn or instruct consumers, i.e., the reasonably foreseeable users, and/or physicians of the risks of exposure to ranitidine-containing products. Defendants failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in ranitidine-containing products, and further, have made false and/or misleading statements concerning the

safety of ranitidine.

737. At all relevant times, the Ranitidine-Containing Products were defective at the time they left the Defendants' control. No extrinsic changes were made to alter the products Defendants manufactured. The expiration date Plaintiffs observed were not changed from when they left Defendants' control.

738. Plaintiffs were exposed to Defendants' ranitidine-containing products without knowledge of their dangerous characteristics.

739. At all relevant times, Plaintiffs used and/or were exposed to the use of Defendants' ranitidine-containing products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

740. Plaintiffs could not have reasonably discovered the defects and risks associated with ranitidine-containing products prior to or at the time Plaintiffs consumed the drugs. Plaintiffs and their physicians relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Defendants' products.

741. Defendants knew or should have known that the expiration dating periods disseminated with their ranitidine-containing products were inadequate because they were long enough for dangerous levels of NDMA to build up in ranitidine.

742. This alleged failure to warn is not limited to the information contained on the section of the ranitidine-containing products' label devoted to health warnings. Defendants were able, in accord with federal law, to comply with relevant state law by providing a short expiration dating period that would accurately warn consumers not to consume ranitidine after significant portions of it had progressively deteriorated into NDMA. But Defendants did not disclose these known risks through any medium.

743. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their ranitidine-containing products, Plaintiffs could have avoided the risk of developing injuries and could have obtained or used alternative medication. However, as a result of Defendants' concealment of the dangers posed by their ranitidine-containing products, Plaintiffs were not alerted, and so could not avert their injuries.

744. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems associated with ranitidine-containing products, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

745. Defendants' lack of adequate warnings and instructions accompanying their ranitidine-containing products were a substantial factor in causing Plaintiffs' injuries.

746. As a direct and proximate result of Defendants' failure to provide an adequate warning of the risks of ranitidine-containing products, Plaintiffs have been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

**SUB-COUNT III-1 ALABAMA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

747. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

748. Under Alabama law, a manufacturer has the duty to provide an adequate warning to consumers of a product's danger when used in its intended manner.

749. Each Defendant breached this duty for the ranitidine containing-products it

manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

750. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-2 ALASKA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

751. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

752. Under Alaska law, a product is defective if, as marketed, it poses a risk of injury to someone who uses the product in a reasonably foreseeable manner and the product is marketed without adequate warnings of the risk. Manufacturers have a duty to provide adequate warnings.

753. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

754. Plaintiffs or their doctors would have read and heeded these warnings. As a result,



Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-3 ARIZONA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

755. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

756. Under Arizona manufacturers have a duty to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

757. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

758. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-4 ARKANSAS: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

759. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

760. Under Arkansas law, manufacturers have a duty to provide adequate warnings. A product is defective if it poses a risk of injury to someone who uses the product in a reasonably foreseeable manner and the product is marketed without adequate warnings of the risks.

761. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

762. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-5 CALIFORNIA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

763. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

764. Under California law, manufacturers have a duty to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical

knowledge available at the time of manufacture and distribution.

765. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

766. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-6 COLORADO: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

767. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

768. Under Colorado law, a manufacturer has the duty to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use. A product is defective and unreasonably dangerous if it lacks an adequate warning.

769. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA

over time.

770. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-7 CONNECTICUT: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

771. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

772. Under Connecticut law, a manufacturer “may be subject to liability for harm caused to a claimant who proves by a fair preponderance of the evidence that the product was defective in that adequate warnings or instructions were not provided. (b) In determining whether instructions or warnings were required and, if required, whether they were adequate, the trier of fact may consider: (1) The likelihood that the product would cause the harm suffered by the claimant; (2) the ability of the product seller to anticipate at the time of manufacture that the expected product user would be aware of the product risk, and the nature of the potential harm; and (3) the technological feasibility and cost of warnings and instructions.” Conn. Gen. Stat. § 52-572q.

773. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA

over time.

774. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-8 DISTRICT OF COLUMBIA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

775. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

776. Under District of Columbia law, a manufacturer has the duty to warn expected users of risks that result from foreseeable uses of the product when the manufacturer knows or has reason to know that the product is dangerous.

777. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

778. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-9 FLORIDA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

779. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

780. Under Florida law, a manufacturer has the duty to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

781. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

782. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-10 GEORGIA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

783. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746

as if fully stated herein.

784. Under Georgia law, a manufacturer has the duty to provide an adequate warning where it knows or has reason to believe that a use of the product may cause harm.

785. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

786. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-11 HAWAII: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

787. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

788. Under Hawaii law, a manufacturer has the duty to provide adequate instructions for safe use and an adequate warning of dangers inherent in improper use.

789. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA

over time.

790. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-12 IDAHO: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

791. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

792. Under Idaho law, a manufacturer has the duty to provide an adequate warning about risks of danger which arise during the known or foreseeable use of the product.

793. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

794. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.



**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-13 ILLINOIS: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

795. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

796. Under Illinois law, a manufacturer has a duty to adequately warn of the potential risks or hazards associated with a product where there is unequal knowledge, actual or constructive of a dangerous condition, and the defendant, possessed of such knowledge, knows or should know that harm might or could occur if no warning is given.

797. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

798. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-14 INDIANA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

799. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

800. Under Indiana law, a manufacturer has the duty to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

801. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

802. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-15 KANSAS: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

803. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

804. Under Kansas law, a manufacturer has a duty to provide adequate instructions for safe use and adequate warnings of dangers inherent in use.

805. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate

because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

806. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-16 KENTUCKY: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

807. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

808. Under Kentucky law, a manufacturer has the duty to provide both adequate directions for use and an adequate warning of potential danger from foreseeable uses or misuses. The ultimate question is whether the totality of directions or cautionary language constituted an adequate warning in the light of the foreseeable use and user of the product.

809. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

810. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have

been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-17 LOUISIANA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

811. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

812. Under Louisiana law, a manufacturer has the duty to provide an adequate warning, which is “a warning or instruction that would lead an ordinary reasonable user or handler of a product to contemplate the danger in using or handling the product and either to decline to use or handle the product or, if possible, to use or handle the product in such a manner as to avoid the damage for which the claim is made.” La. Rev. Stat. § 9:2800.53(9).

813. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

814. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT III-18 MAINE: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

815. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

816. Under Maine law, a manufacturer has the duty to provide an adequate warning of the risks of a product that it knew or should have known about.

817. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

818. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-19 MARYLAND: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

819. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

820. Under Maryland law, a manufacturer has the duty to provide an adequate warning of a danger it knew or should have had known about.

821. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

822. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-20 MICHIGAN: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

823. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

824. Under Michigan law, a manufacturer has the duty to provide an adequate warning of dangers that it knew or should have known about.

825. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

826. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT III-21 MINNESOTA: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

827. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

828. Under Minnesota law, a manufacturer has the duty to provide adequate instructions for safe use and an adequate warning of dangers inherent in improper usage.

829. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

830. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-22 MISSISSIPPI: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

831. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

832. Under Mississippi law, a manufacturer has the duty to provide an adequate warning sufficient to render the product not unreasonably dangerous to the user if it knew or in light of reasonably available knowledge should have known about the danger that caused the damage.

833. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

834. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-23 MISSOURI: STRICT PRODUCTS LIABILITY—FAILURE  
TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

835. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

836. Under Missouri law, a manufacturer has the duty to provide an adequate warning of the risks of its products.



837. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

838. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-24 MONTANA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

839. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

840. Under Montana law, a manufacturer has the duty to provide an adequate warning of the risks of its products.

841. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

842. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have

been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-25 NEBRASKA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

843. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

844. Under Nebraska law, a manufacturer has the duty to adequately warn about a risk or hazard inherent in the way a product is designed that is related to the intended or reasonably foreseeable uses that may be made of the products it sells.

845. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

846. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT III-26 NEVADA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

847. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

848. Under Nevada law, a manufacturer has the duty to provide an adequate warning of the risks of its products.

849. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

850. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-27 NEW HAMPSHIRE: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

851. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

852. Under New Hampshire law, a manufacturer has the duty to provide an adequate warning of the risks of its products sufficient to make foreseeable uses not unreasonably dangerous.

853. Each Defendant breached this duty for the ranitidine containing-products it

manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

854. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT III-28 NEW JERSEY: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

855. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

856. Under New Jersey law, a manufacturer has the duty to provide adequate instructions for safe use and an adequate warning of dangers inherent in improper usage.

857. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

858. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-29 NEW MEXICO: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

859. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

860. Under New Mexico law, a manufacturer has the duty to provide an adequate warning. Five criteria guide adequacy: 1. the warning must adequately indicate the scope of the danger; 2. the warning must reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it; and 5. the means to convey the warning must be adequate. See Roche Labs., Div. of Hoffman-LaRoche, Inc., 101 N.M. 522, 524 (N.M. Ct. App. 1984).

861. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

862. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-30 NEW YORK: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

863. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

864. Under New York law, a manufacturer has a duty to warn against latent dangers resulting from foreseeable uses of its product of which it knew or should have known.

865. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

866. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-31 NORTH DAKOTA: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

867. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

868. Under North Dakota law, a manufacturer has the duty to provide an adequate warning of dangers inherent in its intended or reasonably anticipated use.

869. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

870. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-32 OHIO: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

871. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

872. Under Ohio law, a manufacturer has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

873. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA

over time.

874. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-33 OKLAHOMA: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

875. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

876. Under Oklahoma law, a manufacturer has the duty to provide an adequate warning that would inform an ordinary consumer of the risk of harm.

877. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

878. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.



**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-34 OREGON: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

879. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

880. Under Oregon law, a manufacturer has the duty to provide an adequate warning of the risks of its products.

881. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

882. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-35 PUERTO RICO: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

883. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

884. Under Puerto Rico law, a manufacturer has the duty to provide an adequate warnings of risks in its products that it knows or should have known about.

885. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

886. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT III-36 RHODE ISLAND: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

887. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

888. Under Rhode Island law, a manufacturer has the duty to provide an adequate warning of dangerous propensities of its products that it knew or should have known about.

889. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

890. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-37 SOUTH CAROLINA: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

891. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

892. Under South Carolina law, a manufacturer has the duty to provide an adequate warning of the risks of its products and adequate instructions for use.

893. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

894. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-38 SOUTH DAKOTA: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

895. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

896. Under South Dakota law, a manufacturer has the duty to provide an adequate warning of the risks of its products that it knew or should have known about at the time the drug is ingested.

897. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

898. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-39 TENNESSEE: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

899. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

900. Under Tennessee law, a manufacturer has the duty to provide an adequate warning of the risks of its products. A warning is inadequate if it does not contain a full and complete

disclosure of potential adverse reactions.

901. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

902. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-40 TEXAS: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

903. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

904. Under Texas law, a manufacturer has the duty to provide an adequate warning of potential harms to users from its products that it knew or had reason to know at the time the product left its control.

905. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

906. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-41 UTAH: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

907. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

908. Under Utah law, a manufacturer has the duty to provide an adequate warning of the dangers from a foreseeable use of its product that it knows or should have known about.

909. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

910. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-42 VERMONT: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

911. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

912. Under Vermont law, a manufacturer has the duty to provide an adequate warning of the risks of its products.

913. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

914. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-43 WASHINGTON: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

915. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

916. Under Washington law a “product is not reasonably safe because adequate warnings or instructions were not provided with the product, if, at the time of manufacture, the likelihood that the product would cause the claimant’s harm or similar harms, and the seriousness

of those harms, rendered the warnings or instructions of the manufacturer inadequate and the manufacturer could have provided the warnings or instructions which the claimant alleges would have been adequate.” RCW 7.72.030(1)(b).

917. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

918. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs’ favor for compensatory damages, together with interest, costs herein incurred, attorneys’ fees and all such other and further relief as this Court deems just and proper.

**SUB-COUNT III-44 WEST VIRGINIA: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

919. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

920. Under West Virginia law, a manufacturer has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

921. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate



because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

922. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-45 WISCONSIN: STRICT PRODUCTS LIABILITY—  
FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

923. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

924. Under Wisconsin law, a “product is defective because of inadequate instructions or warnings only if the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the manufacturer and the omission of the instructions or warnings renders the product not reasonably safe.” Wis. Stat. § 895.047(a)(1).

925. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

926. Plaintiffs or their doctors would have read and heeded these warnings. As a result,

Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT III-46 WYOMING: STRICT PRODUCTS LIABILITY—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

927. Plaintiffs incorporate by reference each allegation set forth in paragraphs 720-746 as if fully stated herein.

928. Under Wyoming law, a manufacturer has the duty to provide an adequate warning of the risks of its products that it knew or should have known about. To be adequate, a warning must indicate the scope of danger and the extent or seriousness of harm that could result if the product is misused or the warning is not followed, and must be physically adequate and conveyed by adequate means to alert a reasonable person of the danger.

929. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

930. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**COUNT IV: NEGLIGENCE—FAILURE TO WARN THROUGH PROPER EXPIRATION DATES**

931. Plaintiffs incorporate by reference each allegation set forth in paragraphs 18-37 (describing Defendants).

932. The allegations in this Count apply to each Defendant during the time periods in which each was manufacturing ranitidine-containing products. The relevant time periods are alleged in paragraph 72, which is incorporated by reference.

933. Plaintiffs incorporate by reference each allegation set forth in paragraphs 121-141 (describing the recall of ranitidine), 184-196 (describing the breakdown of ranitidine before ingestion), 204-207 (describing Defendant's knowledge), 208-229 (describing the regulatory framework for drug manufacturers), and 243-254 (describing Plaintiffs' use of ranitidine and injury) as if fully stated herein.

934. Ranitidine leads to NDMA exposure in the following ways: (1) the NDMA levels in ranitidine increase as the drug breaks down in the human digestive system and interacts with various enzymes in the human body; (2) the ranitidine molecule internally degrades to form NDMA, and the NDMA levels in the drug substance and the drug product increase over time under normal storage conditions, but more so with exposure to heat or humidity.

935. NDMA is a potent carcinogen in humans. Higher exposures to NDMA over longer time periods lead to even higher risks of cancer.

936. To mitigate degradation of ranitidine into NDMA over time, and in the presence of heat or humidity, consumers could be warned to consume ranitidine shortly after manufacturing.

No ranitidine-containing product contained this warning.

937. In fact, ranitidine-containing products had expiration dating periods of one or two years, allowing gradual accumulation of more and more NDMA. A much shorter period of a matter of months would have ensured that ranitidine contained far lower levels of NDMA when consumed.

938. Defendants knew or should have known about each of these risks in time to warn consumers. Simple, widely available and cost-effective tests reveal these risks.

939. In setting expiration and/or retest dates for their ranitidine-containing drugs, Defendants were required to take into consideration the real-world conditions the drugs would be exposed to, including the conditions under which the drugs would be stored and shipped. See 21 C.F.R. § 211.137.

940. In setting the expiration and/or retest dates for their ranitidine-containing drugs, Defendants were also required to base those dates on stability testing, which in turn must account for storage conditions. 21 C.F.R. § 211.166.

941. Storage conditions must account for conditions, including the storage container, heat, light, and humidity, among other things.

942. At all relevant times, each Defendant failed to adhere to their duties to set accurate expiration dates based upon stability testing that complied with the manufacturers' duties to account for these real-world conditions. These actions were under the ultimate control and supervision of Defendants.

943. Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, because they do not contain adequate

warnings or instructions concerning the dangerous characteristics of ranitidine and NDMA.

944. Defendants, as a manufacturer of pharmaceutical medication, are held to the knowledge of an expert in the field.

945. Defendants knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to ranitidine after months or years of degradation into NDMA.

946. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their products and to those who would foreseeably use or be harmed by Defendants' ranitidine-containing products.

947. Even though Defendants knew or should have known that ranitidine posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to ranitidine-containing products. The dangerous propensities of ranitidine-containing products and the carcinogenic characteristics of NDMA, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, but were not known to end users and consumers, such as Plaintiffs.

948. Defendants knew or should have known that ranitidine-containing products created significant risks of serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn or instruct consumers, i.e., the reasonably foreseeable users, and/or physicians of the risks of exposure to ranitidine-containing products. Defendants failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in ranitidine-containing products, and further, have made false and/or misleading statements concerning the

safety of ranitidine.

949. At all relevant times, the Ranitidine-Containing Products were defective at the time they left the Defendants' control. No extrinsic changes were made to alter the products Defendants manufactured. The expiration dates Plaintiffs and their doctors observed were not changed from when they left Defendants' control.

950. Plaintiffs were exposed to Defendants' ranitidine-containing products without knowledge of their dangerous characteristics.

951. At all relevant times, Plaintiffs used and/or were exposed to the use of Defendants' ranitidine-containing products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

952. Plaintiffs could not have reasonably discovered the defects and risks associated with ranitidine-containing products prior to or at the time Plaintiffs consumed the drugs. Plaintiffs and their physicians relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Defendants' products.

953. Defendants knew or should have known that the expiration dating periods disseminated with their ranitidine-containing products were inadequate because they were long enough for dangerous levels of NDMA to build up in ranitidine.

954. This alleged failure to warn is not limited to the information contained on the section of the ranitidine-containing products' label devoted to health warnings. Defendants were able, in accord with federal law, to comply with relevant state law by providing a short expiration dating period that would accurately warn consumers not to consume ranitidine after significant portions of it had progressively deteriorated into NDMA. But Defendants did not disclose these known risks through any medium.

955. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their ranitidine-containing products, Plaintiffs could have avoided the risk of developing injuries and could have obtained or used alternative medication. However, as a result of Defendants' concealment of the dangers posed by their ranitidine-containing products, Plaintiffs were not alerted, and so could not avert their injuries.

956. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems associated with ranitidine-containing products, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

957. Defendants' lack of adequate warnings and instructions accompanying their ranitidine-containing products were a substantial factor in causing Plaintiffs' injuries.

958. As a direct and proximate result of Defendants' failure to provide an adequate warning of the risks of ranitidine-containing products, Plaintiffs have been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

**SUB-COUNT IV-1 ALABAMA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

959. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

960. Under Alabama law, a manufacturer has a duty of reasonable care to provide an adequate warning to consumers of a product's danger when used in its intended manner.

961. Each Defendant breached this duty for the ranitidine containing-products it

manufactured. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

962. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-2 ALASKA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

963. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

964. Under Alaska law, a manufacturer has a duty of reasonable care to provide an adequate warning of a risk of injury to someone who uses the product in a reasonably foreseeable manner.

965. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

966. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have



been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-3 ARIZONA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

967. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

968. Under Arizona manufacturers have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

969. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

970. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-4 ARKANSAS: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

971. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958

as if fully stated herein.

972. Under Arkansas law, manufacturers have a duty of reasonable care to provide adequate warnings of risks of injury to someone who uses the product in a reasonably foreseeable manner.

973. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

974. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-5 CALIFORNIA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

975. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

976. Under California law, manufacturers have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

977. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded

into NDMA over time.

978. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-6 COLORADO: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

979. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

980. Under Colorado law, a manufacturer has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

981. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

982. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-7 CONNECTICUT: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

983. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

984. Under Connecticut law, a manufacturer “may be subject to liability for harm caused to a claimant who proves by a fair preponderance of the evidence that the product was defective in that adequate warnings or instructions were not provided. (b) In determining whether instructions or warnings were required and, if required, whether they were adequate, the trier of fact may consider: (1) The likelihood that the product would cause the harm suffered by the claimant; (2) the ability of the product seller to anticipate at the time of manufacture that the expected product user would be aware of the product risk, and the nature of the potential harm; and (3) the technological feasibility and cost of warnings and instructions.” Conn. Gen. Stat. § 52-572q.

985. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

986. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-8 DELAWARE: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

987. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

988. Under Delaware law, a manufacturer has a duty of reasonable care to provide adequate warnings that inform the user of risks of harm it knew or should have known may be involved a reasonably expected use.

989. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

990. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-9 DISTRICT OF COLUMBIA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

991. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

992. Under District of Columbia law, a manufacturer has the duty of reasonable care to warn expected users of risks that result from foreseeable uses of the product when the manufacturer knows or has reason to know that the product is dangerous.

993. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

994. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-10 FLORIDA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

995. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

996. Under Florida law, a manufacturer has the duty of reasonable care to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

997. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded

into NDMA over time.

998. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-11 GEORGIA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

999. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1000. Under Georgia law, a manufacturer has the duty of reasonable care to provide an adequate warning where it knows or has reason to believe that a use of the product may cause harm.

1001. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1002. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-12 HAWAII: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1003. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1004. Under Hawaii law, a manufacturer has the duty of reasonable care to provide adequate instructions for safe use and an adequate warning of dangers inherent in improper use.

1005. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1006. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-13 IDAHO: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1007. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1008. Under Idaho law, a manufacturer has a duty of reasonable care to provide an



adequate warning about risks of danger which arise during the known or foreseeable use of the product.

1009. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1010. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-14 ILLINOIS: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1011. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1012. Under Illinois law, a manufacturer has a duty of reasonable care to adequately warn of the potential risks or hazards associated with a product where there is unequal knowledge, actual or constructive of a dangerous condition, and the defendant, possessed of such knowledge, knows or should know that harm might or could occur if no warning is given.

1013. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1014. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-15 INDIANA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1015. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1016. Under Indiana law, a manufacturer has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

1017. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1018. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-16 IOWA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1019. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1020. Under Iowa law, a manufacturer has a duty of reasonable care to provide adequate instructions and warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of those reasonable instructions or warnings, and the omission of the instructions or warnings renders the product not reasonably safe.

1021. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1022. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-17 KANSAS: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1023. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1024. Under Kansas law, a manufacturer has a duty of reasonable care to provide adequate instructions for safe use and adequate warnings of dangers inherent in use.

1025. Each Defendant breached this duty for the ranitidine containing-products it

manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1026. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-18 KENTUCKY: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1027. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1028. Under Kentucky law, a manufacturer has a duty of reasonable care to provide both adequate directions for use and an adequate warning of potential danger from foreseeable uses or misuses. The ultimate question is whether the totality of directions or cautionary language constituted an adequate warning in the light of the foreseeable use and user of the product.

1029. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1030. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-19 MAINE: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1031. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1032. Under Maine law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of a product that it knew or should have known about.

1033. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1034. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-20 MARYLAND: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1035. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1036. Under Maryland law, a manufacturer has a duty of reasonable care to provide an

adequate warning of a danger it knew or should have had known about.

1037. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1038. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-21 MASSACHUSETTS: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1039. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1040. Under Massachusetts law, a manufacturer has a duty of reasonable care to provide an adequate warning of those dangers to persons who it is foreseeable will come in contact with, and consequently be endangered by, that product. This includes a duty to warn or provide instructions about risks that were reasonably foreseeable or could have been discovered by way of reasonable testing.

1041. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1042. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-22 MICHIGAN: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

1043. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1044. Under Michigan law, a manufacturer has a duty of reasonable care to provide an adequate warning of dangers that it knew or should have known about.

1045. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1046. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT IV-23 MINNESOTA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

1047. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1048. Under Minnesota law, a manufacturer has a duty of reasonable care to provide adequate instructions for safe use and an adequate warning of dangers inherent in improper usage.

1049. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1050. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-24 MISSISSIPPI: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1051. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1052. Under Mississippi law, a manufacturer has a duty of reasonable care to provide an adequate warning sufficient to render the product not unreasonably dangerous to the user if it knew or in light of reasonably available knowledge should have known about the danger that caused the damage.

1053. Each Defendant breached this duty for the ranitidine containing-products it



manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1054. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-25 MISSOURI: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1055. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1056. Under Missouri law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products.

1057. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1058. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-26 MONTANA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

1059. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1060. Under Montana law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products.

1061. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1062. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-27 NEBRASKA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

1063. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1064. Under Nebraska law, a manufacturer has a duty of reasonable care to adequately

warn about a risk or hazard inherent in the way a product is designed that is related to the intended or reasonably foreseeable uses that may be made of the products it sells.

1065. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1066. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT IV-28 NEVADA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1067. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1068. Under Nevada law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products.

1069. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1070. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have

been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-29 NEW HAMPSHIRE: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

1071. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1072. Under New Hampshire law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products sufficient to make foreseeable uses not unreasonably dangerous.

1073. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1074. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT IV-30 NEW MEXICO: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

1075. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958

as if fully stated herein.

1076. Under New Mexico law, a manufacturer has a duty of reasonable care to provide an adequate warning. Five criteria guide adequacy: 1. the warning must adequately indicate the scope of the danger; 2. the warning must reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it; and 5. the means to convey the warning must be adequate. See Roche Labs., Div. of Hoffman-LaRoche, Inc., 101 N.M. 522, 524 (N.M. Ct. App. 1984).

1077. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1078. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-31 NEW YORK: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1079. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1080. Under New York law, a manufacturer has a duty to warn against latent dangers

resulting from foreseeable uses of its product of which it knew or should have known.

1081. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1082. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-32 NORTH CAROLINA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

1083. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1084. Under North Carolina law, a manufacturer has a duty of reasonable care to provide an adequate warning

1085. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1086. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-33 NORTH DAKOTA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

1087. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1088. Under North Dakota law, a manufacturer has a duty of reasonable care to provide an adequate warning of dangers inherent in its intended or reasonably anticipated use.

1089. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1090. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-34 OKLAHOMA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

1091. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1092. Under Oklahoma law, a manufacturer has a duty of reasonable care to provide an

adequate warning that would inform an ordinary consumer of the risk of harm.

1093. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1094. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-35 OREGON: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1095. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1096. Under Oregon law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products.

1097. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1098. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.



**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-36 PENNSYLVANIA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

1099. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1100. Under Pennsylvania law, a manufacturer has a duty of reasonable care to provide an adequate warning.

1101. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1102. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-37 PUERTO RICO: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

1103. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1104. Under Puerto Rico law, a manufacturer has a duty of reasonable care to provide an

adequate warning of risks in its products that it knows or should have known about.

1105. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1106. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT IV-38 RHODE ISLAND: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1107. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1108. Under Rhode Island law, a manufacturer has a duty of reasonable care to provide an adequate warning of dangerous propensities of its products that it knew or should have known about.

1109. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1110. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have

been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-39 SOUTH CAROLINA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

1111. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1112. Under South Carolina law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products and adequate instructions for use.

1113. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1114. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-40 SOUTH DAKOTA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

1115. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1116. Under South Dakota law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products that it knew or should have known about at the time the drug is ingested.

1117. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1118. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-41 TENNESSEE: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1119. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1120. Under Tennessee law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products. A warning is inadequate if it does not contain a full and complete disclosure of potential adverse reactions.

1121. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1122. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-42 TEXAS: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1123. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1124. Under Texas law, a manufacturer has a duty of reasonable care to provide an adequate warning of potential harms to users from its products that it knew or had reason to know at the time the product left its control.

1125. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1126. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-43 UTAH: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1127. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1128. Under Utah law, a manufacturer has a duty of reasonable care to provide an adequate warning of the dangers from a foreseeable use of its product that it knows or should have known about.

1129. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1130. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-44 VERMONT: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1131. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1132. Under Vermont law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products.

1133. Each Defendant breached this duty for the ranitidine containing-products it

manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1134. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-45 VIRGINIA: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1135. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1136. Under Virginia law, a manufacturer has a duty of reasonable care to provide an adequate warning

1137. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1138. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-46 WEST VIRGINIA: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

1139. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1140. Under West Virginia law, a manufacturer has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

1141. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1142. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IV-47 WISCONSIN: NEGLIGENCE—FAILURE TO WARN CONSUMERS THROUGH PROPER EXPIRATION DATES**

1143. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.



1144. Under Wisconsin law, a “product is defective because of inadequate instructions or warnings only if the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the manufacturer and the omission of the instructions or warnings renders the product not reasonably safe.” Wis. Stat. § 895.047(a)(1).

1145. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1146. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs’ 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.

**SUB-COUNT IV-48 WYOMING: NEGLIGENCE—FAILURE TO WARN  
CONSUMERS THROUGH PROPER EXPIRATION DATES**

1147. Plaintiffs incorporate by reference each allegation set forth in paragraphs 931-958 as if fully stated herein.

1148. Under Wyoming law, a manufacturer has a duty of reasonable care to provide an adequate warning of the risks of its products that it knew or should have known about. To be adequate, a warning must indicate the scope of danger and the extent or seriousness of harm that could result if the product is misused or the warning is not followed, and must be physically adequate and conveyed by adequate means to alert a reasonable person of the danger.

1149. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1150. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**COUNT V: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO  
WARNINGS AND PRECAUTIONS**

1151. Plaintiffs incorporate by reference each allegation set forth in paragraphs 18-37 (describing Defendants), 121-141 (describing the recall of ranitidine), 146-183 (describing the breakdown of ranitidine after ingestion), 184-196 (describing the breakdown of ranitidine before ingestion), 204-207 (describing Defendant's knowledge), and 243-254 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1152. The allegations in this Count apply to each Defendant during the time periods in which each was manufacturing ranitidine-containing products. The relevant time periods are alleged in paragraph 72, which is incorporated by reference.

1153. Ranitidine leads to NDMA exposure in the following ways: (1) the NDMA levels in ranitidine increase as the drug breaks down in the human digestive system and interacts with various enzymes in the human body; (2) the ranitidine molecule internally degrades to form NDMA, and the NDMA levels in the drug substance and the drug product increase over time under

normal storage conditions, but more so with exposure to heat or humidity.

1154. NDMA is a potent carcinogen in humans. Higher exposures to NDMA over longer time periods lead to even higher risks of cancer.

1155. To mitigate degradation of ranitidine into NDMA in the stomach, consumers could be warned not to take ranitidine after meals or in combination with a high-nitrite diet. No ranitidine-containing product contained this warning.

1156. To mitigate degradation of ranitidine into NDMA over time, and in the presence of heat or humidity, consumers could be warned to consume ranitidine shortly after manufacturing and to store it in a cool, dry place (not in a bathroom). No ranitidine-containing product contained this warning.

1157. To mitigate the risk of NDMA causing cancer, consumers could be warned to consume ranitidine for only short periods of time. No ranitidine-containing product warned that cancer could result from long-term ingestion of high amounts of ranitidine.

1158. Defendants knew or should have known about each of these risks in time to warn consumers.

1159. As was alleged in more detail above, in 1981 Dr. Silvio de Flora published the results of experiments in The Lancet showing that ranitidine produced NDMA in combination with gastric fluid and nitrites. This study put all future manufacturers of ranitidine on notice of the risks of consuming ranitidine in combination with high-nitrite foods.

1160. GSK responded in The Lancet in November, 1981. This response shows that GSK was in fact aware of Dr. de Flora's research.

1161. GSK told the FDA that Dr. de Flora's research has no "practical clinical significance."

1162. GSK conducted another study around 1981 that found that ranitidine could cause nitrates to convert into nitrites in the human stomach, which, in combination with Dr. de Flora's research, would mean a heightened risk of NDMA formation. This should have sparked reconsideration of the claim that nitrites would not be high enough in the stomach for Dr. de Flora's research to have practical significance.

1163. In April 1982, GSK [REDACTED]  
This study was never published. [REDACTED]  
[REDACTED]

[REDACTED] Though other manufacturers may not have been aware of this study, any of them could have performed similar studies, and had the same reasons as GSK to be concerned.

1164. After Zantac had been approved for marketing by the FDA, GSK conducted a study on how ranitidine breaks down in the human stomach, and concluded that the amount of NDMA formed was low. It published that study in 1987. However, GSK used a less reliable test (a nitrogen oxide assay) designed for use in food and discarded two-thirds of the samples because they contained ranitidine (which the study claimed might produce a false positive).

1165. In 1983, after GSK's flawed study, but before it was published, a University of Genoa study determined that ranitidine could react with nitrite and produce NDMA, which could induce DNA damage.

1166. Also in 1983, Dr. de Flora published his complete findings, confirming his initial results about the risks of NDMA breakdown in the human stomach in combination with nitrites. GSK did not modify its position.

1167. In 2012, a study indicated that ranitidine may be a source of NDMA in drinking water.

1168. In 2016, a Stanford University study suggested that NDMA amounts in humans increased after consuming ranitidine.

1169. In 2019, Valisure tested ranitidine tablets to determine if they contained NDMA. Valisure's ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method FY19-005-DPA8 for the determination of NDMA levels. Valisure found when using the GC/MS headspace analysis method that ranitidine would transform into high levels of NDMA.

1170. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of ranitidine and NDMA. These actions were under the ultimate control and supervision of Defendants.

1171. Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, sold, and/or otherwise released into the stream of commerce their ranitidine-containing products, and in the course of the same, directly marketed the products to consumers and end users, including Plaintiffs, and therefore had a duty to warn of the risks associated with the use of ranitidine.

1172. At all relevant times, Defendants had a duty to properly manufacture, test, market, label, package, handle, distribute, store, sell, provide proper warnings, and/or take such steps as necessary to ensure their ranitidine-containing products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs of dangers associated with ranitidine. Defendants, as manufacturers and sellers of pharmaceutical medication, are held to the knowledge of an expert in the field.

1173. Defendants had a continuing duty to provide appropriate and accurate warnings and

precautions.

1174. At the time of manufacture, Defendants could have provided warnings or instructions regarding the full and complete risks of ranitidine because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

1175. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their products and to those who would foreseeably use or be harmed by Defendants' ranitidine-containing products.

1176. Even though Defendants knew or should have known that ranitidine posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to ranitidine-containing products. The dangerous propensities of ranitidine-containing products and the carcinogenic characteristics of NDMA, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, but were not known to end users and consumers, such as Plaintiffs.

1177. Defendants knew or should have known that ranitidine-containing products created significant risks of serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn or instruct consumers, i.e., the reasonably foreseeable users, and physicians of the risks of exposure to ranitidine-containing products. Defendants failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in ranitidine-containing products, and further, have made false and/or misleading statements concerning the safety of ranitidine.

1178. Defendants possessed new information or new analyses of existing information that empowered them unilaterally to change the warnings and precautions section of their ranitidine-containing products' label.

1179. Despite this ability, Defendants failed to warn of the risks of NDMA and their ranitidine-containing products in the warnings and precautions section of their ranitidine-containing products' label.

1180. At all relevant times, the Ranitidine-Containing Products were defective at the time they left the Defendants' control. No extrinsic changes were made to alter the products Defendants manufactured. The warnings Plaintiffs and their doctors observed were not changed from when they left Defendants' control.

1181. Plaintiffs were exposed to Defendants' ranitidine-containing products without knowledge of their dangerous characteristics.

1182. At all relevant times, Plaintiffs used and/or were exposed to the use of Defendants' ranitidine-containing products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

1183. Plaintiffs could not have reasonably discovered the defects and risks associated with ranitidine-containing products prior to or at the time Plaintiffs consumed the drugs. Plaintiffs and their physicians relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Defendants' products.

1184. Defendants knew or should have known that the minimal warnings disseminated with their ranitidine-containing products were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary,

intended and reasonably foreseeable uses.

1185. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs to avoid using the drug. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to ranitidine; continued to aggressively promote the efficacy of ranitidine-containing products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting ranitidine.

1186. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their ranitidine-containing products on the warnings and precautions section of their products' labels, Plaintiffs could have avoided the risk of developing injuries and could have obtained or used alternative medication. However, as a result of Defendants' concealment of the dangers posed by their ranitidine-containing products, Plaintiffs could not have averted their injuries.

1187. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems associated with ranitidine-containing products, and suppressed this knowledge from the general public. Defendants made conscious decisions not to warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

1188. Defendants' lack of adequate warnings and instructions in the warnings and precautions section of their ranitidine-containing products' labels were a substantial factor in



causing Plaintiffs' injuries.

1189. As a direct and proximate result of Defendants' failure to provide an adequate warning of the risks of ranitidine-containing products, Plaintiffs have been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

**SUB-COUNT V-1 ALABAMA: STRICT PRODUCTS LIABILITY—DESIGN  
DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1190. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1191. Under Alabama law, a manufacturer has the duty to provide an adequate warning to consumers of a product's danger when used in its intended manner.

1192. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1193. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-2 ALASKA: STRICT PRODUCTS LIABILITY—DESIGN  
DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1194. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1195. Under Alaska law, a product is defective if, as marketed, it poses a risk of injury to someone who uses the product in a reasonably foreseeable manner and the product is marketed without adequate warnings of the risk. Manufacturers have a duty to provide adequate warnings.

1196. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1197. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-3 ARIZONA: STRICT PRODUCTS LIABILITY—DESIGN  
DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1198. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1199. Under Arizona manufacturers have a duty to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and

medical knowledge available at the time of manufacture and distribution.

1200. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1201. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-4 ARKANSAS: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1202. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1203. Under Arkansas law, manufacturers have a duty to provide adequate warnings. A product is defective if it poses a risk of injury to someone who uses the product in a reasonably foreseeable manner and the product is marketed without adequate warnings of the risks.

1204. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1205. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-5 CALIFORNIA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1206. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1207. Under California law, manufacturers have a duty to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

1208. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1209. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-6 COLORADO: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1210. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1211. Under Colorado law, a manufacturer has the duty to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use. A product is defective and unreasonably dangerous if it lacks an adequate warning.

1212. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1213. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-7 CONNECTICUT: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1214. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1215. Under Connecticut law, a manufacturer “may be subject to liability for harm caused to a claimant who proves by a fair preponderance of the evidence that the product was defective in that adequate warnings or instructions were not provided. (b) In determining whether instructions or warnings were required and, if required, whether they were adequate, the trier of fact may consider: (1) The likelihood that the product would cause the harm suffered by the claimant; (2) the ability of the product seller to anticipate at the time of manufacture that the expected product user would be aware of the product risk, and the nature of the potential harm; and (3) the technological feasibility and cost of warnings and instructions.” Conn. Gen. Stat. § 52-572q.

1216. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1217. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs’ 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.

**SUB-COUNT V-8 DISTRICT OF COLUMBIA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1218. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1219. Under District of Columbia law, a manufacturer has the duty to warn expected users of risks that result from foreseeable uses of the product when the manufacturer knows or has reason to know that the product is dangerous.

1220. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1221. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-9 FLORIDA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1222. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1223. Under Florida law, a manufacturer has the duty to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing

best scientific and medical knowledge available at the time of manufacture and distribution.

1224. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1225. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-10 GEORGIA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1226. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1227. Under Georgia law, a manufacturer has the duty to provide an adequate warning where it knows or has reason to believe that a use of the product may cause harm.

1228. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1229. Plaintiffs or their doctors would have read and heeded these warnings. As a result,



Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-11 HAWAII: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1230. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1231. Under Hawaii law, a manufacturer has the duty to provide adequate instructions for safe use and an adequate warning of dangers inherent in improper use.

1232. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1233. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-12 IDAHO: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1234. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1235. Under Idaho law, a manufacturer has the duty to provide an adequate warning about risks of danger which arise during the known or foreseeable use of the product.

1236. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1237. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-13 ILLINOIS: STRICT PRODUCTS LIABILITY—DESIGN  
DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1238. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1239. Under Illinois law, a manufacturer has a duty to adequately warn of the potential risks or hazards associated with a product where there is unequal knowledge, actual or constructive of a dangerous condition, and the defendant, possessed of such knowledge, knows or should know that harm might or could occur if no warning is given.

1240. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1241. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-14 INDIANA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1242. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1243. Under Indiana law, a manufacturer has the duty to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

1244. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1245. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have

been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-15 KANSAS: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1246. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1247. Under Kansas law, a manufacturer has a duty to provide adequate instructions for safe use and adequate warnings of dangers inherent in use.

1248. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1249. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-16 KENTUCKY: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1250. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-

1189 as if fully stated herein.

1251. Under Kentucky law, a manufacturer has the duty to provide both adequate directions for use and an adequate warning of potential danger from foreseeable uses or misuses. The ultimate question is whether the totality of directions or cautionary language constituted an adequate warning in the light of the foreseeable use and user of the product.

1252. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1253. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-17 LOUISIANA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1254. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1255. Under Louisiana law, a manufacturer has the duty to provide an adequate warning, which is “a warning or instruction that would lead an ordinary reasonable user or handler of a product to contemplate the danger in using or handling the product and either to decline to use or handle the product or, if possible, to use or handle the product in such a manner as to avoid the

damage for which the claim is made.” La. Rev. Stat. § 9:2800.53(9).

1256. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1257. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs’ favor for compensatory damages, together with interest, costs herein incurred, attorneys’ fees and all such other and further relief as this Court deems just and proper.

**SUB-COUNT V-18 MAINE: STRICT PRODUCTS LIABILITY—DESIGN  
DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1258. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1259. Under Maine law, a manufacturer has the duty to provide an adequate warning of the risks of a product that it knew or should have known about.

1260. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1261. Plaintiffs or their doctors would have read and heeded these warnings. As a result,

Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-19 MARYLAND: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1262. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1263. Under Maryland law, a manufacturer has the duty to provide an adequate warning of a danger it knew or should have had known about.

1264. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1265. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-20 MICHIGAN: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1266. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1267. Under Michigan law, a manufacturer has the duty to provide an adequate warning of dangers that it knew or should have known about.

1268. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1269. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT V-21 MINNESOTA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1270. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1271. Under Minnesota law, a manufacturer has the duty to provide adequate instructions for safe use and an adequate warning of dangers inherent in improper usage.

1272. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate



because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1273. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-22 MISSISSIPPI: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1274. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1275. Under Mississippi law, a manufacturer has the duty to provide an adequate warning sufficient to render the product not unreasonably dangerous to the user if it knew or in light of reasonably available knowledge should have known about the danger that caused the damage.

1276. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1277. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-23 MISSOURI: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1278. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1279. Under Missouri law, a manufacturer has the duty to provide an adequate warning of the risks of its products.

1280. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1281. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-24 MONTANA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1282. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1283. Under Montana law, a manufacturer has the duty to provide an adequate warning of the risks of its products.

1284. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1285. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-25 NEBRASKA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1286. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1287. Under Nebraska law, a manufacturer has the duty to adequately warn about a risk or hazard inherent in the way a product is designed that is related to the intended or reasonably foreseeable uses that may be made of the products it sells.

1288. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and

when consumed long after manufacture.

1289. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT V-26 NEVADA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1290. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1291. Under Nevada law, a manufacturer has the duty to provide an adequate warning of the risks of its products.

1292. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1293. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-27 NEW HAMPSHIRE: STRICT PRODUCTS LIABILITY—  
DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1294. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1295. Under New Hampshire law, a manufacturer has the duty to provide an adequate warning of the risks of its products sufficient to make foreseeable uses not unreasonably dangerous.

1296. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1297. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT V-28 NEW JERSEY: STRICT PRODUCTS LIABILITY—DESIGN  
DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1298. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-

1189 as if fully stated herein.

1299. Under New Jersey law, a manufacturer has the duty to provide adequate instructions for safe use and an adequate warning of dangers inherent in improper usage.

1300. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1301. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-29 NEW MEXICO: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1302. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1303. Under New Mexico law, a manufacturer has the duty to provide an adequate warning. Five criteria guide adequacy: 1. the warning must adequately indicate the scope of the danger; 2. the warning must reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it; and 5. the

means to convey the warning must be adequate. *See Roche Labs., Div. of Hoffman-LaRoche, Inc.*, 101 N.M. 522, 524 (N.M. Ct. App. 1984).

1304. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1305. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-30 NEW YORK: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1306. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1307. Under New York law, a manufacturer has a duty to warn against latent dangers resulting from foreseeable uses of its product of which it knew or should have known.

1308. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1309. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-31 NORTH DAKOTA: STRICT PRODUCTS LIABILITY—  
DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1310. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1311. Under North Dakota law, a manufacturer has the duty to provide an adequate warning of dangers inherent in its intended or reasonably anticipated use.

1312. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1313. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.



**SUB-COUNT V-32 OHIO: STRICT PRODUCTS LIABILITY—DESIGN  
DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1314. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1315. Under Ohio law, a manufacturer has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

1316. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1317. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-33 OKLAHOMA: STRICT PRODUCTS LIABILITY—DESIGN  
DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1318. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1319. Under Oklahoma law, a manufacturer has the duty to provide an adequate warning that would inform an ordinary consumer of the risk of harm.

1320. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1321. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-34 OREGON: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1322. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1323. Under Oregon law, a manufacturer has the duty to provide an adequate warning of the risks of its products.

1324. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1325. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have

been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-35 PUERTO RICO: STRICT PRODUCTS LIABILITY—  
DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1326. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1327. Under Puerto Rico law, a manufacturer has the duty to provide an adequate warning of risks in its products that it knows or should have known about.

1328. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1329. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT V-36 RHODE ISLAND: STRICT PRODUCTS LIABILITY—  
DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1330. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-

1189 as if fully stated herein.

1331. Under Rhode Island law, a manufacturer has the duty to provide an adequate warning of dangerous propensities of its products that it knew or should have known about.

1332. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1333. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-37 SOUTH CAROLINA: STRICT PRODUCTS LIABILITY—  
DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1334. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1335. Under South Carolina law, a manufacturer has the duty to provide an adequate warning of the risks of its products and adequate instructions for use.

1336. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and

when consumed long after manufacture.

1337. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-38 SOUTH DAKOTA: STRICT PRODUCTS LIABILITY—  
DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1338. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1339. Under South Dakota law, a manufacturer has the duty to provide an adequate warning of the risks of its products that it knew or should have known about at the time the drug is ingested.

1340. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1341. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-39 TENNESSEE: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1342. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1343. Under Tennessee law, a manufacturer has the duty to provide an adequate warning of the risks of its products. A warning is inadequate if it does not contain a full and complete disclosure of potential adverse reactions.

1344. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1345. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-40 TEXAS: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1346. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-

1189 as if fully stated herein.

1347. Under Texas law, a manufacturer has the duty to provide an adequate warning of potential harms to users from its products that it knew or had reason to know at the time the product left its control.

1348. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1349. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-41 UTAH: STRICT PRODUCTS LIABILITY—DESIGN  
DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1350. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1351. Under Utah law, a manufacturer has the duty to provide an adequate warning of the dangers from a foreseeable use of its product that it knows or should have known about.

1352. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under

humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1353. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-42 VERMONT: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1354. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1355. Under Vermont law, a manufacturer has the duty to provide an adequate warning of the risks of its products.

1356. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1357. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.



**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-43 WASHINGTON: STRICT PRODUCTS LIABILITY—  
DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1358. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1359. Under Washington law a "product is not reasonably safe because adequate warnings or instructions were not provided with the product, if, at the time of manufacture, the likelihood that the product would cause the claimant's harm or similar harms, and the seriousness of those harms, rendered the warnings or instructions of the manufacturer inadequate and the manufacturer could have provided the warnings or instructions which the claimant alleges would have been adequate." RCW 7.72.030(1)(b).

1360. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1361. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT V-44 WEST VIRGINIA: STRICT PRODUCTS LIABILITY—  
DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1362. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1363. Under West Virginia law, a manufacturer has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

1364. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1365. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT V-45 WISCONSIN: STRICT PRODUCTS LIABILITY—DESIGN  
DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1366. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1367. Under Wisconsin law, a “product is defective because of inadequate instructions or warnings only if the foreseeable risks of harm posed by the product could have been reduced or

avoided by the provision of reasonable instructions or warnings by the manufacturer and the omission of the instructions or warnings renders the product not reasonably safe.” Wis. Stat. § 895.047(a)(1).

1368. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1369. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs’ 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.

**SUB-COUNT V-46 WYOMING: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO WARNINGS AND PRECAUTIONS**

1370. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1151-1189 as if fully stated herein.

1371. Under Wyoming law, a manufacturer has the duty to provide an adequate warning of the risks of its products that it knew or should have known about. To be adequate, a warning must indicate the scope of danger and the extent or seriousness of harm that could result if the product is misused or the warning is not followed, and must be physically adequate and conveyed by adequate means to alert a reasonable person of the danger.

1372. Each Defendant breached this duty for the ranitidine containing-products it

manufactured. The warnings included on each ranitidine-containing product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1373. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**COUNT VI: STRICT PRODUCTS LIABILITY – DESIGN DEFECT DUE TO  
IMPROPER EXPIRATION DATES**

1374. Plaintiffs incorporate by reference each allegation set forth in paragraphs 18-37 (describing Defendants).

1375. The allegations in this Count apply to each Defendant during the time periods in which each was manufacturing ranitidine-containing products. The relevant time periods are alleged in paragraph 72, which is incorporated by reference.

1376. Plaintiffs incorporate by reference each allegation set forth in paragraphs 121-141 (describing the recall of ranitidine), 184-196 (describing the breakdown of ranitidine before ingestion), 204-207 (describing Defendant's knowledge), 208-229 (describing the regulatory framework for drug manufacturers), and 243-254 (describing Plaintiffs' use of ranitidine and injury) as if fully stated herein.

1377. Ranitidine leads to NDMA exposure in the following ways: (1) the NDMA levels in ranitidine increase as the drug breaks down in the human digestive system and interacts with

various enzymes in the human body; (2) the ranitidine molecule internally degrades to form NDMA, and the NDMA levels in the drug substance and the drug product increase over time under normal storage conditions, but more so with exposure to heat or humidity.

1378. NDMA is a potent carcinogen in humans. Higher exposures to NDMA over longer time periods lead to even higher risks of cancer.

1379. To mitigate degradation of ranitidine into NDMA over time, and in the presence of heat or humidity, consumers could be warned to consume ranitidine shortly after manufacturing. No ranitidine-containing product contained this warning.

1380. In fact, ranitidine-containing products had expiration dating periods of one or two years, allowing gradual accumulation of more and more NDMA. A much shorter period of a matter of months would have ensured that ranitidine contained far lower levels of NDMA when consumed.

1381. Defendants knew or should have known about each of these risks in time to warn consumers. Simple, widely available and cost-effective tests reveal these risks.

1382. In setting expiration and/or retest dates for their ranitidine-containing drugs, Defendants were required to take into consideration the real-world conditions the drugs would be exposed to, including the conditions under which the drugs would be stored and shipped. *See* 21 C.F.R. § 211.137.

1383. In setting the expiration and/or retest dates for their ranitidine-containing drugs, Defendants were also required to base those dates on stability testing, which in turn must account for storage conditions. 21 C.F.R. § 211.166.

1384. Storage conditions must account for conditions, including the storage container, heat, light, and humidity, among other things.

1385. At all relevant times, the Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of ranitidine and NDMA. These actions were under the ultimate control and supervision of Defendants.

1386. Defendants, as a manufacturer of pharmaceutical medication, are held to the knowledge of an expert in the field.

1387. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates.

1388. Defendants knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to ranitidine after months or years of degradation into NDMA.

1389. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their products and to those who would foreseeably use or be harmed by Defendants' ranitidine-containing products.

1390. Even though Defendants knew or should have known that ranitidine posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to ranitidine-containing products. The dangerous propensities of ranitidine-containing products and the carcinogenic characteristics of NDMA, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, but were not known to end users and consumers, such as Plaintiffs.

1391. Defendants knew or should have known that ranitidine-containing products created significant risks of serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn or instruct consumers, i.e., the reasonably foreseeable users, and/or physicians of the risks of exposure to ranitidine-containing products. Defendants failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in ranitidine-containing products, and further, have made false and/or misleading statements concerning the safety of ranitidine.

1392. At all relevant times, the Ranitidine-Containing Products were defective at the time they left the Defendants' control. No extrinsic changes were made to alter the products Defendants manufactured. The expiration dates Plaintiffs and their doctors observed were not changed from when they left Defendants' control.

1393. Plaintiffs were exposed to Defendants' ranitidine-containing products without knowledge of their dangerous characteristics.

1394. At all relevant times, Plaintiffs used and/or were exposed to the use of Defendants' ranitidine-containing products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

1395. Plaintiffs could not have reasonably discovered the defects and risks associated with ranitidine-containing products prior to or at the time Plaintiffs consumed the drugs. Plaintiffs and their physicians relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Defendants' products.

1396. Defendants knew or should have known that the expiration dating periods disseminated with their ranitidine-containing products were inadequate because they were long enough for dangerous levels of NDMA to build up in ranitidine.

1397. This alleged failure to warn is not limited to the information contained on the section of the ranitidine-containing products' label devoted to health warnings. Defendants were able, in accord with federal law, to comply with relevant state law by providing a short expiration dating period that would accurately warn consumers not to consume ranitidine after significant portions of it had progressively deteriorated into NDMA. But Defendants did not disclose these known risks through any medium.

1398. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their ranitidine-containing products, Plaintiffs could have avoided the risk of developing injuries and could have obtained or used alternative medication. However, as a result of Defendants' concealment of the dangers posed by their ranitidine-containing products, Plaintiffs were not alerted, and so could not avert their injuries.

1399. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems associated with ranitidine-containing products, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

1400. Defendants' lack of adequate warnings and instructions accompanying their ranitidine-containing products were a substantial factor in causing Plaintiffs' injuries.

1401. As a direct and proximate result of Defendants' failure to provide an adequate warning of the risks of ranitidine-containing products, Plaintiffs have been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.



**SUB-COUNT VI-1 ALABAMA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1402. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1403. Under Alabama law, a manufacturer has the duty to provide an adequate warning to consumers of a product's danger when used in its intended manner.

1404. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1405. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-2 ALASKA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1406. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1407. Under Alaska law, a product is defective if, as marketed, it poses a risk of injury to someone who uses the product in a reasonably foreseeable manner and the product is marketed without adequate warnings of the risk. Manufacturers have a duty to provide adequate warnings.

1408. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1409. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-3 ARIZONA: STRICT PRODUCTS LIABILITY—DESIGN  
DEFECT DUE TO IMPROPER EXPIRATION DATES**

1410. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1411. Under Arizona manufacturers have a duty to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

1412. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1413. Plaintiffs or their doctors would have read and heeded these warnings. As a result,

Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-4 ARKANSAS: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1414. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1415. Under Arkansas law, manufacturers have a duty to provide adequate warnings. A product is defective if it poses a risk of injury to someone who uses the product in a reasonably foreseeable manner and the product is marketed without adequate warnings of the risks.

1416. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1417. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-5 CALIFORNIA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1418. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1419. Under California law, manufacturers have a duty to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

1420. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1421. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-6 COLORADO: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1422. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1423. Under Colorado law, a manufacturer has the duty to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be

involved in any intended or reasonably expected use. A product is defective and unreasonably dangerous if it lacks an adequate warning.

1424. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1425. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-7 CONNECTICUT: STRICT PRODUCTS LIABILITY—  
DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1426. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1427. Under Connecticut law, a manufacturer “may be subject to liability for harm caused to a claimant who proves by a fair preponderance of the evidence that the product was defective in that adequate warnings or instructions were not provided. (b) In determining whether instructions or warnings were required and, if required, whether they were adequate, the trier of fact may consider: (1) The likelihood that the product would cause the harm suffered by the claimant; (2) the ability of the product seller to anticipate at the time of manufacture that the expected product user would be aware of the product risk, and the nature of the potential harm;

and (3) the technological feasibility and cost of warnings and instructions.” Conn. Gen. Stat. § 52-572q.

1428. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1429. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs’ 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.

**SUB-COUNT VI-8 DISTRICT OF COLUMBIA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1430. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1431. Under District of Columbia law, a manufacturer has the duty to warn expected users of risks that result from foreseeable uses of the product when the manufacturer knows or has reason to know that the product is dangerous.

1432. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA

over time.

1433. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-9 FLORIDA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1434. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1435. Under Florida law, a manufacturer has the duty to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

1436. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1437. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-10 GEORGIA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1438. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1439. Under Georgia law, a manufacturer has the duty to provide an adequate warning where it knows or has reason to believe that a use of the product may cause harm.

1440. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1441. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-11 HAWAII: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1442. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.



1443. Under Hawaii law, a manufacturer has the duty to provide adequate instructions for safe use and an adequate warning of dangers inherent in improper use.

1444. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1445. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-12 IDAHO: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1446. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1447. Under Idaho law, a manufacturer has the duty to provide an adequate warning about risks of danger which arise during the known or foreseeable use of the product.

1448. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1449. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-13 ILLINOIS: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1450. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1451. Under Illinois law, a manufacturer has a duty to adequately warn of the potential risks or hazards associated with a product where there is unequal knowledge, actual or constructive of a dangerous condition, and the defendant, possessed of such knowledge, knows or should know that harm might or could occur if no warning is given.

1452. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1453. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-14 INDIANA: STRICT PRODUCTS LIABILITY—DESIGN  
DEFECT DUE TO IMPROPER EXPIRATION DATES**

1454. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1455. Under Indiana law, a manufacturer has the duty to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

1456. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1457. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-15 KANSAS: STRICT PRODUCTS LIABILITY—DESIGN  
DEFECT DUE TO IMPROPER EXPIRATION DATES**

1458. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1459. Under Kansas law, a manufacturer has a duty to provide adequate instructions for safe use and adequate warnings of dangers inherent in use.

1460. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1461. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-16 KENTUCKY: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1462. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1463. Under Kentucky law, a manufacturer has the duty to provide both adequate directions for use and an adequate warning of potential danger from foreseeable uses or misuses. The ultimate question is whether the totality of directions or cautionary language constituted an adequate warning in the light of the foreseeable use and user of the product.

1464. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products

were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1465. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-17 LOUISIANA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1466. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1467. Under Louisiana law, a manufacturer has the duty to provide an adequate warning, which is "a warning or instruction that would lead an ordinary reasonable user or handler of a product to contemplate the danger in using or handling the product and either to decline to use or handle the product or, if possible, to use or handle the product in such a manner as to avoid the damage for which the claim is made." La. Rev. Stat. § 9:2800.53(9).

1468. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1469. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have

been harmed by NDMA.

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

**SUB-COUNT VI-18 MAINE: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1470. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1471. Under Maine law, a manufacturer has the duty to provide an adequate warning of the risks of a product that it knew or should have known about.

1472. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1473. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-19 MARYLAND: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1474. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-

1401 as if fully stated herein.

1475. Under Maryland law, a manufacturer has the duty to provide an adequate warning of a danger it knew or should have had known about.

1476. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1477. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-20 MICHIGAN: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1478. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1479. Under Michigan law, a manufacturer has the duty to provide an adequate warning of dangers that it knew or should have known about.

1480. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA

over time.

1481. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT VI-21 MINNESOTA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1482. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1483. Under Minnesota law, a manufacturer has the duty to provide adequate instructions for safe use and an adequate warning of dangers inherent in improper usage.

1484. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1485. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.



**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-22 MISSISSIPPI: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1486. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1487. Under Mississippi law, a manufacturer has the duty to provide an adequate warning sufficient to render the product not unreasonably dangerous to the user if it knew or in light of reasonably available knowledge should have known about the danger that caused the damage.

1488. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1489. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-23 MISSOURI: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1490. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-

1401 as if fully stated herein.

1491. Under Missouri law, a manufacturer has the duty to provide an adequate warning of the risks of its products.

1492. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1493. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-24 MONTANA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1494. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1495. Under Montana law, a manufacturer has the duty to provide an adequate warning of the risks of its products.

1496. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA

over time.

1497. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-25 NEBRASKA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1498. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1499. Under Nebraska law, a manufacturer has the duty to adequately warn about a risk or hazard inherent in the way a product is designed that is related to the intended or reasonably foreseeable uses that may be made of the products it sells.

1500. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1501. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT VI-26 NEVADA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1502. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1503. Under Nevada law, a manufacturer has the duty to provide an adequate warning of the risks of its products.

1504. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1505. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-27 NEW HAMPSHIRE: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1506. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1507. Under New Hampshire law, a manufacturer has the duty to provide an adequate warning of the risks of its products sufficient to make foreseeable uses not unreasonably dangerous.

1508. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1509. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT VI-28 NEW JERSEY: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1510. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1511. Under New Jersey law, a manufacturer has the duty to provide adequate instructions for safe use and an adequate warning of dangers inherent in improper usage.

1512. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA

over time.

1513. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-29 NEW MEXICO: STRICT PRODUCTS LIABILITY—  
DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1514. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1515. Under New Mexico law, a manufacturer has the duty to provide an adequate warning. Five criteria guide adequacy: 1. the warning must adequately indicate the scope of the danger; 2. the warning must reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it; and 5. the means to convey the warning must be adequate. See *Roche Labs., Div. of Hoffman-LaRoche, Inc.*, 101 N.M. 522, 524 (N.M. Ct. App. 1984).

1516. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1517. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-30 NEW YORK: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1518. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1519. Under New York law, a manufacturer has a duty to warn against latent dangers resulting from foreseeable uses of its product of which it knew or should have known.

1520. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1521. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-31 NORTH DAKOTA: STRICT PRODUCTS LIABILITY—  
DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1522. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1523. Under North Dakota law, a manufacturer has the duty to provide an adequate warning of dangers inherent in its intended or reasonably anticipated use.

1524. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1525. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-32 OHIO: STRICT PRODUCTS LIABILITY—DESIGN  
DEFECT DUE TO IMPROPER EXPIRATION DATES**

1526. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1527. Under Ohio law, a manufacturer has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.



1528. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1529. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-33 OKLAHOMA: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1530. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1531. Under Oklahoma law, a manufacturer has the duty to provide an adequate warning that would inform an ordinary consumer of the risk of harm.

1532. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1533. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have

been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-34 OREGON: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1534. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1535. Under Oregon law, a manufacturer has the duty to provide an adequate warning of the risks of its products.

1536. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1537. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-35 PUERTO RICO: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1538. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-

1401 as if fully stated herein.

1539. Under Puerto Rico law, a manufacturer has the duty to provide an adequate warnings of risks in its products that it knows or should have known about.

1540. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1541. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

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

**SUB-COUNT VI-36 RHODE ISLAND: STRICT PRODUCTS LIABILITY—  
DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1542. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1543. Under Rhode Island law, a manufacturer has the duty to provide an adequate warning of dangerous propensities of its products that it knew or should have known about.

1544. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA

over time.

1545. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-37 SOUTH CAROLINA: STRICT PRODUCTS LIABILITY—  
DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1546. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1547. Under South Carolina law, a manufacturer has the duty to provide an adequate warning of the risks of its products and adequate instructions for use.

1548. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1549. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-38 SOUTH DAKOTA: STRICT PRODUCTS LIABILITY—  
DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1550. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1551. Under South Dakota law, a manufacturer has the duty to provide an adequate warning of the risks of its products that it knew or should have known about at the time the drug is ingested.

1552. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1553. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-39 TENNESSEE: STRICT PRODUCTS LIABILITY—DESIGN  
DEFECT DUE TO IMPROPER EXPIRATION DATES**

1554. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-

1401 as if fully stated herein.

1555. Under Tennessee law, a manufacturer has the duty to provide an adequate warning of the risks of its products. A warning is inadequate if it does not contain a full and complete disclosure of potential adverse reactions.

1556. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1557. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-40 TEXAS: STRICT PRODUCTS LIABILITY—DESIGN  
DEFECT DUE TO IMPROPER EXPIRATION DATES**

1558. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1559. Under Texas law, a manufacturer has the duty to provide an adequate warning of potential harms to users from its products that it knew or had reason to know at the time the product left its control.

1560. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate

because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1561. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-41 UTAH: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1562. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1563. Under Utah law, a manufacturer has the duty to provide an adequate warning of the dangers from a foreseeable use of its product that it knows or should have known about.

1564. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1565. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-42 VERMONT: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1566. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1567. Under Vermont law, a manufacturer has the duty to provide an adequate warning of the risks of its products.

1568. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1569. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-43 WASHINGTON: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1570. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.



1571. Under Washington law a “product is not reasonably safe because adequate warnings or instructions were not provided with the product, if, at the time of manufacture, the likelihood that the product would cause the claimant’s harm or similar harms, and the seriousness of those harms, rendered the warnings or instructions of the manufacturer inadequate and the manufacturer could have provided the warnings or instructions which the claimant alleges would have been adequate.” RCW 7.72.030(1)(b).

1572. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1573. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs’ favor for compensatory damages, together with interest, costs herein incurred, attorneys’ fees and all such other and further relief as this Court deems just and proper.

**SUB-COUNT VI-44 WEST VIRGINIA: STRICT PRODUCTS LIABILITY—  
DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1574. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1575. Under West Virginia law, a manufacturer has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be

unreasonably dangerous if distributed without a particular warning.

1576. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1577. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-45 WISCONSIN: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1578. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1579. Under Wisconsin law, a “product is defective because of inadequate instructions or warnings only if the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the manufacturer and the omission of the instructions or warnings renders the product not reasonably safe.” Wis. Stat. § 895.047(a)(1).

1580. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products

were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1581. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VI-46 WYOMING: STRICT PRODUCTS LIABILITY—DESIGN DEFECT DUE TO IMPROPER EXPIRATION DATES**

1582. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1374-1401 as if fully stated herein.

1583. Under Wyoming law, a manufacturer has the duty to provide an adequate warning of the risks of its products that it knew or should have known about. To be adequate, a warning must indicate the scope of danger and the extent or seriousness of harm that could result if the product is misused or the warning is not followed, and must be physically adequate and conveyed by adequate means to alert a reasonable person of the danger.

1584. Each Defendant breached this duty for the ranitidine containing-products it manufactured. The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1585. Plaintiffs or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have consumed the volume of NDMA they ultimately did, and would not have

been harmed by NDMA.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**COUNT VII: NEGLIGENT FAILURE TO TEST**

1586. Plaintiffs incorporate by reference each allegation set forth in paragraphs 18-37 (describing Defendants) and 146-183 (describing the breakdown of NDMA after ingestion).

1587. The allegations in this Count apply to each Defendant during the time periods in which each was manufacturing ranitidine-containing products. The relevant time periods are alleged in paragraph 72, which is incorporated by reference.

1588. Plaintiffs incorporate by reference each allegation set forth in paragraphs 121-141 (describing the recall of ranitidine), 184-196 (describing the breakdown of ranitidine before ingestion), 204-207 (describing Defendant's knowledge), 208-229 (describing the regulatory framework for drug manufacturers), and 243-254 (describing Plaintiffs' use of ranitidine and injury) as if fully stated herein.

1589. Readily available testing methods revealed the dangers of Defendants' ranitidine-containing products. For example, gas chromatography-mass spectrometry, the technique Valisure employed in 2019 to identify NDMA forming in ranitidine, was a widely available, cost-effective, industry-standard testing method. If this testing method had been used by Defendants to test ranitidine, they could have determined that ranitidine transforms into NDMA when subjected to heat.

1590. Upon information and belief, no Defendant tested the effects of temperature, time, humidity, light, or other relevant storage or transportation conditions on the quantity of NDMA in ranitidine-containing products.

1591. Testing of the ranitidine molecule at any time would have revealed that hotter temperatures, longer time periods, and higher humidity each increases the amount of NDMA.

1592. Testing of the ranitidine molecule at any time also would have revealed that the typical temperature, time period, and humidity that ranitidine-containing products were exposed to before being consumed resulted in dangerously high levels of NDMA.

1593. Defendants knew or should have known that ranitidine-containing products posed a grave risk of harm. The dangerous propensities of their products and the carcinogenic characteristics of NDMA as produced within the human body as a result of ingesting ranitidine, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold the product, but were not known to end users and consumers, such as Plaintiffs.

1594. For example, Defendants knew that ranitidine had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA.

1595. Defendants also were on notice of the need to test and fully evaluate the carcinogenicity of ranitidine based on the research by Dr. de Flora and Dr. R.J.N. Tanner performed in the 1980s, which would have alerted the reasonable manufacturer of ranitidine to beware of the potential for NDMA to form in the drug and/or in the human body.

1596. Any of a variety of tests for NDMA would have sparked quick action. The FDA initiated a voluntary recall only seven months after Valisure first publicized its NDMA testing results in September 2019. If any Defendant had performed and publicized a similar test at an earlier time, the FDA and broader market would have acted as quickly and decisively as happened

in 2019, since the dangerous properties of NDMA were widely understood at all relevant times.

1597. Defendants, directly or indirectly, manufactured, tested, and/or sold ranitidine-containing products that were used by Plaintiffs.

1598. At all relevant times, Defendants had reason to know of the need for testing to reveal the hazards and dangers of ranitidine and, specifically, the carcinogenic properties of NDMA when ranitidine-containing products are ingested and/or the elevated levels of NDMA that occurs when ranitidine-containing products are transported and stored based on studies conducted in the 1980s.

1599. Defendants ignored this risk. They did not use widely available tests to detect NDMA.

1600. Ignoring the risks of NDMA was unreasonable and reckless. Indeed, Defendants deliberately refused to test ranitidine-containing products for NDMA levels because they knew that the chemical posed serious health risks to humans.

1601. The Defendants' failure to test their ranitidine-containing products properly directly and proximately caused Plaintiffs' harm. That is because if Defendants had tested their ranitidine-containing products properly, the high levels of NDMA would have become public, which would have eliminated or reduced Plaintiffs' exposure through several alternative routes:

- The FDA, as it did in 2019, would have performed its own testing and had ranitidine voluntarily recalled in less than a year.
- Other manufacturers and laboratories would have reproduced the tests and conducted novel tests to pinpoint the amount of NDMA in ranitidine.
- The medical community would have learned of the risks and stopped prescribing prescription ranitidine to Plaintiffs and/or Plaintiffs would have refused to take the drug if properly advised of the risks posed by the presence of NDMA.
- Even if the FDA did not recall the drug, Defendants would have added additional warnings in time for Plaintiffs to avoid the use that caused Plaintiffs' cancers (for example, requiring only short-term use; recommending a low-nitrite diet, or other changes); or would have made

other changes to the label (such as requiring cold storage in low-humidity conditions).

1602. Defendants also knew or, in the exercise of reasonable care, should have known that users and consumers of ranitidine-containing products were unaware of the risks and the magnitude of the risks associated with use of ranitidine-containing products.

1603. Defendants—who designed, manufactured, tested (in other ways), marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine—were in a superior position to understand the risk of NDMA being present in and/or forming in ranitidine-containing products and had a duty to test for these dangers.

1604. Despite their ability and means to investigate, study, and test the products and to provide adequate warnings, Defendants failed to do so. Indeed, Defendants wrongfully concealed information and further made false and/or misleading statements concerning the safety and use of ranitidine-containing products.

1605. Defendants knew or should have known that it was foreseeable that consumers such as Plaintiffs would suffer injuries as a result of Defendants' failure to exercise ordinary care in the design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of ranitidine-containing products.

1606. Plaintiffs did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to ranitidine-containing products.

1607. Defendants' negligence was a substantial factor in causing Plaintiffs' injuries.

1608. Defendants' conduct, as described above, was reckless. Defendants regularly risked the lives of consumers and users of their products, including Plaintiffs, with full knowledge of the dangers of their products. Defendants have made conscious decisions not to test their ranitidine-containing products. Defendants' reckless conduct therefore warrants an award of

punitive damages.

**SUB-COUNT VII-1 KANSAS: NEGLIGENT FAILURE TO TEST**

1609. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1586-1608 as if fully stated herein.

1610. At all relevant times, Defendants had a duty to exercise reasonable care in the testing of ranitidine-containing products to ensure the products were not unreasonably dangerous to consumers and users.

1611. This duty encompassed testing ranitidine for NDMA, both from degradation over time in ordinary storage and transport, and from chemical reactions in humans.

1612. Defendants had reason to know of the need for testing to reveal the carcinogenic dangers of ranitidine degrading into NDMA when ranitidine-containing products are ingested and/or the elevated levels of NDMA that occurs when ranitidine-containing products are transported and stored.

1613. Defendants ignored this risk. They did not use widely available tests to detect NDMA.

1614. As a direct and proximate result of Defendants' failure to undertake to provide an adequate warning of the risks of ranitidine-containing products, Plaintiffs have been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.



**SUB-COUNT VII-2 TEXAS: NEGLIGENT FAILURE TO TEST**

1615. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1586-1608 as if fully stated herein.

1616. At all relevant times, Defendants had a duty to exercise reasonable care in the testing of ranitidine-containing products to ensure the products were not unreasonably dangerous to consumers and users.

1617. This duty encompassed testing ranitidine for NDMA, both from degradation over time in ordinary storage and transport, and from chemical reactions in humans.

1618. Defendants had reason to know of the need for testing to reveal the carcinogenic dangers of ranitidine degrading into NDMA when ranitidine-containing products are ingested and/or the elevated levels of NDMA that occurs when ranitidine-containing products are transported and stored.

1619. Defendants ignored this risk. They did not use widely available tests to detect NDMA.

1620. As a direct and proximate result of Defendants' failure to undertake to provide an adequate warning of the risks of ranitidine-containing products, Plaintiffs have been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

WHEREFORE, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**COUNT VIII: NEGLIGENT PRODUCT CONTAINERS**

1621. Plaintiffs incorporate by reference each allegation set forth in paragraphs 18-37 (describing Defendants).

1622. The allegations in this Count apply to each Defendant during the time periods in which each was manufacturing ranitidine-containing products. The relevant time periods are alleged in paragraph 72, which is incorporated by reference.

1623. Plaintiffs incorporate by reference each allegation set forth in paragraphs 121-141 (describing the recall of ranitidine), 184-196 (describing the breakdown of ranitidine before ingestion), 204-207 (describing Defendant's knowledge), 208-229 (describing the regulatory framework for drug manufacturers), and 243-254 (describing Plaintiffs' use of ranitidine and injury) as if fully stated herein.

1624. As alleged above, each Defendant was required to conduct stability testing, which was required to take the container into account.

1625. As previously alleged, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

1626. Defendants knew that ranitidine had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA.

1627. The ranitidine-containing products Plaintiffs consumed had excessive levels of NDMA in part because they were subjected to high levels of humidity and were stored for a long period of time (often in humid locations such as bathrooms).

1628. A substantial factor in NDMA formation was the container system manufacturers chose. Pill bottles with large numbers of units of ranitidine are likely to be stored for long periods by consumers after the seal is broken. This exposes the remaining units to humidity over time,

which produces NDMA.

1629. A different container would have reduced the amount of NDMA Plaintiffs consumed in several ways:

- a. Placing each unit of ranitidine in a blister pack or similar individually packaged container would ensure humidity control until the consumer used each unit.
- b. Reducing the number of units of ranitidine in each bottle to a low number would ensure the unused units were subject to humidity for only a shorter time period, since consumers would purchase new bottles more frequently.

1630. Each Defendant could have unilaterally changed the container system it sold. FDA guidance specifically allows changing the number of units in a non-sterile drug under its Changes-Being Effected regulation. *See* FDA, *Guidance for Industry, Changes to an Approved NDA or ANDA, Revision 1*, at 21 (Apr. 2004), <https://www.fda.gov/media/71846/download> (“A change in the number of units (e.g., tablets, capsules) or labeled amount (e.g., grams, milliliters) of a nonsterile drug product in a unit-of-use container.”). FDA guidance also would treat changing to a unit-dose container such as a blister-pack to be a moderate change that could be implemented through the Changes-Being Effected regulation. *See id.* at 20–21 (only requiring pre-approval for *sterile* drug products, when moving *from* unit dose containers to multiple dose containers, rather than non-sterile drug products moving to unit dose containers).

1631. A reasonably prudent manufacturer would have changed the containers for ranitidine-containing products to protect the products from humidity and reduce the time between manufacture and consumption, both of which would reduce the amount of NDMA produced.

1632. Defendants’ negligence was a substantial factor in causing Plaintiffs’ injuries.

1633. Defendants’ conduct, as described above, was reckless. Defendants regularly risked the lives of consumers and users of their products, including Plaintiffs, with full knowledge of the dangers of their products. Defendants have made conscious decisions not to change the containers for their ranitidine-containing products. Defendants’ reckless conduct therefore

warrants an award of punitive damages.

1634. As a direct and proximate result of Defendants' failure to utilize containers that minimize NDMA, Plaintiffs have been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

**SUB-COUNT VIII-1 ALABAMA: NEGLIGENT PRODUCT CONTAINERS**

1635. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1636. Under Alabama law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1637. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1638. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-2 ALASKA: NEGLIGENT PRODUCT CONTAINERS**

1639. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1640. Under Alaska law, a pharmaceutical manufacturer has a duty to exercise reasonable

care in choosing and making the containers for its products.

1641. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1642. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-3 ARIZONA: NEGLIGENT PRODUCT CONTAINERS**

1643. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1644. Under Arizona law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1645. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1646. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-4 ARKANSAS: NEGLIGENT PRODUCT CONTAINERS**

1647. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1648. Under Arkansas law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1649. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1650. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-5 CALIFORNIA: NEGLIGENT PRODUCT CONTAINERS**

1651. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1652. Under California law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1653. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1654. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-6 COLORADO: NEGLIGENT PRODUCT CONTAINERS**

1655. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1656. Under Colorado law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1657. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1658. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-7 CONNECTICUT: NEGLIGENT PRODUCT CONTAINERS**

1659. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1660. Under Connecticut law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1661. Each Defendant breached this duty by failing to utilize containers that would

minimize the NDMA produced in its ranitidine-containing products.

1662. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-8 DELAWARE: NEGLIGENT PRODUCT CONTAINERS**

1663. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1664. Under Delaware law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1665. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1666. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-9 DISTRICT OF COLUMBIA: NEGLIGENT PRODUCT CONTAINERS**

1667. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-



1634 as if fully stated herein.

1668. Under District of Columbia law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1669. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1670. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-10 FLORIDA: NEGLIGENT PRODUCT CONTAINERS**

1671. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1672. Under Florida law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1673. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1674. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-11 GEORGIA: NEGLIGENT PRODUCT CONTAINERS**

1675. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1676. Under Georgia law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1677. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1678. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-12 HAWAII: NEGLIGENT PRODUCT CONTAINERS**

1679. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1680. Under Hawaii law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1681. Each Defendant breached this duty by failing to utilize containers that would

minimize the NDMA produced in its ranitidine-containing products.

1682. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-13 IDAHO: NEGLIGENT PRODUCT CONTAINERS**

1683. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1684. Under Idaho law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1685. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1686. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-14 ILLINOIS: NEGLIGENT PRODUCT CONTAINERS**

1687. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-

1634 as if fully stated herein.

1688. Under Illinois law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1689. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1690. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-15 INDIANA: NEGLIGENT PRODUCT CONTAINERS**

1691. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1692. Under Indiana law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1693. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1694. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-16 IOWA: NEGLIGENT PRODUCT CONTAINERS**

1695. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1696. Under Iowa law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1697. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1698. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-17 KANSAS: NEGLIGENT PRODUCT CONTAINERS**

1699. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1700. Under Kansas law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1701. Each Defendant breached this duty by failing to utilize containers that would

minimize the NDMA produced in its ranitidine-containing products.

1702. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-18 KENTUCKY: NEGLIGENT PRODUCT CONTAINERS**

1703. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1704. Under Kentucky law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1705. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1706. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-19 LOUISIANA: NEGLIGENT PRODUCT CONTAINERS**

1707. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-

1634 as if fully stated herein.

1708. Under Louisiana law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1709. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1710. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

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

**SUB-COUNT VIII-20 MAINE: NEGLIGENT PRODUCT CONTAINERS**

1711. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1712. Under Maine law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1713. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1714. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-21 MARYLAND: NEGLIGENT PRODUCT CONTAINERS**

1715. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1716. Under Maryland law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1717. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1718. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-22 MASSACHUSETTS: NEGLIGENT PRODUCT CONTAINERS**

1719. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1720. Under Massachusetts law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1721. Each Defendant breached this duty by failing to utilize containers that would



minimize the NDMA produced in its ranitidine-containing products.

1722. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-23 MICHIGAN: NEGLIGENT PRODUCT CONTAINERS**

1723. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1724. Under Michigan law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1725. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1726. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

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

**SUB-COUNT VIII-24 MINNESOTA: NEGLIGENT PRODUCT CONTAINERS**

1727. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-

1634 as if fully stated herein.

1728. Under Minnesota law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1729. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1730. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-25 MISSISSIPPI: NEGLIGENT PRODUCT CONTAINERS**

1731. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1732. Under Mississippi law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1733. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1734. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-26 MISSOURI: NEGLIGENT PRODUCT CONTAINERS**

1735. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1736. Under Missouri law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1737. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1738. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-27 MONTANA: NEGLIGENT PRODUCT CONTAINERS**

1739. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1740. Under Montana law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1741. Each Defendant breached this duty by failing to utilize containers that would

minimize the NDMA produced in its ranitidine-containing products.

1742. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-28 NEBRASKA: NEGLIGENT PRODUCT CONTAINERS**

1743. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1744. Under Nebraska law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1745. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1746. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

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

**SUB-COUNT VIII-29 NEVADA: NEGLIGENT PRODUCT CONTAINERS**

1747. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-

1634 as if fully stated herein.

1748. Under Nevada law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1749. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1750. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-30 NEW HAMPSHIRE: NEGLIGENT PRODUCT  
CONTAINERS**

1751. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1752. Under New Hampshire law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1753. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1754. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

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

**SUB-COUNT VIII-31 NEW JERSEY: NEGLIGENT PRODUCT CONTAINERS**

1755. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1756. Under New Jersey law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1757. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1758. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-32 NEW MEXICO: NEGLIGENT PRODUCT CONTAINERS**

1759. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1760. Under New Mexico law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1761. Each Defendant breached this duty by failing to utilize containers that would

minimize the NDMA produced in its ranitidine-containing products.

1762. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-33 NEW YORK: NEGLIGENT PRODUCT CONTAINERS**

1763. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1764. Under New York law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1765. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1766. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-34 NORTH CAROLINA: NEGLIGENT PRODUCT CONTAINERS**

1767. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-

1634 as if fully stated herein.

1768. Under New Jersey law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1769. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1770. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-35 NORTH DAKOTA: NEGLIGENT PRODUCT  
CONTAINERS**

1771. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1772. Under North Dakota law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1773. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1774. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.



**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-36 OHIO: NEGLIGENT PRODUCT CONTAINERS**

1775. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1776. Under Ohio law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1777. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1778. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-37 OKLAHOMA: NEGLIGENT PRODUCT CONTAINERS**

1779. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1780. Under Oklahoma law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1781. Each Defendant breached this duty by failing to utilize containers that would

minimize the NDMA produced in its ranitidine-containing products.

1782. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-38 OREGON: NEGLIGENT PRODUCT CONTAINERS**

1783. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1784. Under Oregon law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1785. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1786. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-39 PENNSYLVANIA: NEGLIGENT PRODUCT CONTAINERS**

1787. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-

1634 as if fully stated herein.

1788. Under Pennsylvania law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1789. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1790. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-40 PUERTO RICO: NEGLIGENT PRODUCT CONTAINERS**

1791. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1792. Under Puerto Rico law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1793. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1794. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

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

**SUB-COUNT VIII-41 RHODE ISLAND: NEGLIGENT PRODUCT CONTAINERS**

1795. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1796. Under Rhode Island law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1797. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1798. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-42 SOUTH CAROLINA: NEGLIGENT PRODUCT CONTAINERS**

1799. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1800. Under South Carolina law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1801. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1802. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-43 SOUTH DAKOTA: NEGLIGENT PRODUCT CONTAINERS**

1803. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1804. Under South Dakota law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1805. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1806. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-44 TENNESSEE: NEGLIGENT PRODUCT CONTAINERS**

1807. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1808. Under Tennessee law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1809. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1810. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-45 TEXAS: NEGLIGENT PRODUCT CONTAINERS**

1811. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1812. Under Texas law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1813. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1814. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-46 UTAH: NEGLIGENT PRODUCT CONTAINERS**

1815. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1816. Under Utah law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1817. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1818. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-47 VERMONT: NEGLIGENT PRODUCT CONTAINERS**

1819. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1820. Under Vermont law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1821. Each Defendant breached this duty by failing to utilize containers that would

minimize the NDMA produced in its ranitidine-containing products.

1822. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-48 VIRGINIA: NEGLIGENT PRODUCT CONTAINERS**

1823. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1824. Under Virginia law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1825. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1826. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-49 WASHINGTON: NEGLIGENT PRODUCT CONTAINERS**

1827. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-



1634 as if fully stated herein.

1828. Under Washington law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1829. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1830. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

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

**SUB-COUNT VIII-50 WEST VIRGINIA: NEGLIGENT PRODUCT  
CONTAINERS**

1831. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1832. Under West Virginia law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1833. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1834. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-51 WISCONSIN: NEGLIGENT PRODUCT CONTAINERS**

1835. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1836. Under Wisconsin law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1837. Each Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its ranitidine-containing products.

1838. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT VIII-52 WYOMING: NEGLIGENT PRODUCT CONTAINERS**

1839. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1621-1634 as if fully stated herein.

1840. Under Wyoming law, a pharmaceutical manufacturer has a duty to exercise reasonable care in choosing and making the containers for its products.

1841. Each Defendant breached this duty by failing to utilize containers that would

minimize the NDMA produced in its ranitidine-containing products.

1842. As a direct and proximate result of this failure, excessive levels of NDMA built up in the ranitidine-containing products each Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

#### **COUNT IX: NEGLIGENT STORAGE AND TRANSPORTATION**

1843. Plaintiffs incorporate by reference each allegation set forth in paragraphs 18-37 (describing Defendants).

1844. The allegations in this Count apply to each Defendant during the time periods in which each was manufacturing ranitidine-containing products. The relevant time periods are alleged in paragraph 72, which is incorporated by reference.

1845. Plaintiffs incorporate by reference each allegation set forth in paragraphs 121-141 (describing the recall of ranitidine), 184-196 (describing the breakdown of ranitidine before ingestion), 204-207 (describing Defendant's knowledge), 208-229 (describing the regulatory framework for drug manufacturers), and 243-254 (describing Plaintiffs' use of ranitidine and injury) as if fully stated herein.

1846. As alleged above, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

1847. Defendants are well aware of the need to maintain sensitive pharmaceutical drugs under proper shipping and storage conditions. Defendants are and were well aware of the importance of precise temperature control down to the degree as well as the importance of precise humidity control. More precise, colder transportation is, of course, more expensive than less precise, warmer transportation.

1848. The temperature and humidity specifications placed on Ranitidine-Containing Products also affect the stability of Ranitidine-Containing Products.

1849. Defendants were aware that Ranitidine is highly sensitive to humidity and moisture. Ranitidine that is subjected to humidity and/or moisture, degrades quickly and forms excessive amount of NDMA.

1850. Manufacturers of a pharmaceutical product must account for these heat and humidity conditions and specifications in order to set proper shipping, storage and handling policies as well as accurate retest and expiration dates.

1851. Testing of the quantity of NDMA in ranitidine performed to date has shown substantial variation among different batches. Some ranitidine has much more NDMA when tested, and some has less.

1852. Defendants admit that substantial variation exists in NDMA levels in their ranitidine containing products, and that levels increase over time but more so when subjected to heat and humidity.

1853. Different ranitidine-containing products listed slightly different storage and transportation requirements, but a common label requirement was “store at 20°C to 25°C (68°F to 77°F)” and “avoid excessive heat or humidity.”

1854. Defendants transport finished drug product from their facilities to distributor

warehouses, as well as storing finished drug products in their facilities.

1855. Some Defendants also purchase API, which they store at their facilities. Their agreements with API manufacturers govern how API is transported to them. The storage and transportation conditions of API is not dictated by the label for finished ranitidine-containing products, and may differ.

1856. Upon information and belief, Defendants systematically caused Ranitidine-Containing Products to be exposed to excessive levels of heat and/or humidity during manufacture, storage, shipping and handling that violated the instructions on the finished products' labels and caused ranitidine to degrade more quickly thereby increasing the levels of NDMA in the product.

1857. Based upon the documents produced by Defendants and based upon further information and belief, both the Defendants failed to ensure that their finished Ranitidine-Containing Products were stored and transported safely and were not exposed to excessive heat and humidity.

1858. Based upon the documents produced by Defendants and based upon further information and belief, both the Defendants failed to ensure that API they stored, transported, or over which they could control storage or transportation, were not exposed to excessive heat and humidity.

1859. Upon information and belief, Defendants failed to implement rigorous policies to ensure substantial compliance with the heat and/or humidity requirements on product labels. This failure led to widespread noncompliance.

1860. For example, Defendants shipped ranitidine-containing products through the mail. This method of transportation—whether through the United States Postal Service or large common carriers such as FedEx and UPS—does not guarantee controlled temperature or humidity. Because

of Defendants' choice to allow this method of transportation, ranitidine-containing products shipped through the mail were systematically subject to excessive heat or humidity on days when the weather was hot or humid. In addition, Defendants failed to properly monitor temperature and/or humidity levels during storage and transport.

1861. Based upon the documents produced by Defendants and based upon further information and belief, both the Defendants failed to ensure that their Ranitidine-Containing Products (in both API and finished dose form) were stored and transported safely and were not exposed to excessive heat and humidity.

1862. Defendants, directly or indirectly, transported, stored, handled, and/or sold ranitidine-containing products that were used by Plaintiffs.

1863. At all relevant times, Defendants had a duty to exercise reasonable care in the storage and transportation of ranitidine API and ranitidine-containing products to ensure the products were not unreasonably dangerous to consumers and users.

1864. At all relevant times, Defendants knew or should have known of the need for storing and transporting finished Ranitidine-Containing Products within the labeled temperature range and at low humidity, and for storing and transporting ranitidine API at a reasonable, low temperature that would prevent degradation, and at low humidity.

1865. Defendants ignored this risk. They did not ensure ranitidine API and Ranitidine-Containing Products were stored at low humidity or within the temperature range on the label. Instead, ranitidine API and Ranitidine-Containing Products were subjected to excessive humidity and/or heat during transportation and shipping which caused the drug to degrade leading to the formation of excessive levels of NDMA.

1866. Ignoring the risks of degradation and NDMA forming was unreasonable and

reckless.

1867. Plaintiffs did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to ranitidine-containing products.

1868. Defendants' negligence was a substantial factor in causing Plaintiffs' injuries.

1869. As a direct and proximate result of Defendants' failure to store and transport ranitidine-containing products properly, Plaintiffs have been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

**SUB-COUNT IX-1 ALABAMA: NEGLIGENT STORAGE AND  
TRANSPORTATION**

1870. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1871. Under Alabama law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1872. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1873. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-2 ALASKA: NEGLIGENT STORAGE AND  
TRANSPORTATION**

1874. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1875. Under Alaska law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1876. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1877. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-3 ARIZONA: NEGLIGENT STORAGE AND  
TRANSPORTATION**

1878. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1879. Under Arizona law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1880. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1881. As a direct and proximate result of these systematic failures, excessive levels of



NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-4 ARKANSAS: NEGLIGENT STORAGE AND TRANSPORTATION**

1882. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1883. Under Arkansas law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1884. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1885. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-5 CALIFORNIA: NEGLIGENT STORAGE AND TRANSPORTATION**

1886. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1887. Under California law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1888. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1889. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-6 COLORADO: NEGLIGENT STORAGE AND  
TRANSPORTATION**

1890. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1891. Under Colorado law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1892. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1893. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-7 CONNECTICUT: NEGLIGENT STORAGE AND  
TRANSPORTATION**

**(Against All Defendants)**

1894. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1895. Under Connecticut law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1896. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1897. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-8 DELAWARE: NEGLIGENT STORAGE AND  
TRANSPORTATION**

1898. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1899. Under Delaware law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1900. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1901. As a direct and proximate result of these systematic failures, excessive levels of

NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-9 DISTRICT OF COLUMBIA: NEGLIGENT STORAGE AND TRANSPORTATION**

1902. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1903. Under District of Columbia law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1904. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1905. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-10 FLORIDA: NEGLIGENT STORAGE AND TRANSPORTATION**

1906. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1907. Under Florida law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1908. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1909. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-11 GEORGIA: NEGLIGENT STORAGE AND TRANSPORTATION**

1910. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1911. Under Georgia law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1912. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1913. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-12 HAWAII: NEGLIGENT STORAGE AND  
TRANSPORTATION**

1914. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1915. Under Hawaii law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1916. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1917. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-13 IDAHO: NEGLIGENT STORAGE AND  
TRANSPORTATION**

1918. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1919. Under Idaho law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1920. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1921. As a direct and proximate result of these systematic failures, excessive levels of

NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-14 ILLINOIS: NEGLIGENT STORAGE AND TRANSPORTATION**

1922. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1923. Under Illinois law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1924. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1925. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-15 INDIANA: NEGLIGENT STORAGE AND TRANSPORTATION**

1926. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1927. Under Indiana law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1928. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1929. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-16 IOWA: NEGLIGENT STORAGE AND  
TRANSPORTATION**

1930. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1931. Under Iowa law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1932. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1933. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.



**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-17 KANSAS: NEGLIGENT STORAGE AND TRANSPORTATION**

1934. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1935. Under Kansas law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1936. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1937. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-18 KENTUCKY: NEGLIGENT STORAGE AND TRANSPORTATION**

1938. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1939. Under Kentucky law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1940. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and

humidity.

1941. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-19 LOUISIANA: NEGLIGENT STORAGE AND TRANSPORTATION**

1942. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1943. Under Louisiana law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1944. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1945. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

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

**SUB-COUNT IX-20 MAINE: NEGLIGENT STORAGE AND TRANSPORTATION**

1946. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-

1869 as if fully stated herein.

1947. Under Maine law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1948. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1949. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-21 MARYLAND: NEGLIGENT STORAGE AND  
TRANSPORTATION**

1950. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1951. Under Maryland law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1952. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1953. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-22 MASSACHUSETTS: NEGLIGENT STORAGE AND TRANSPORTATION**

1954. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1955. Under Massachusetts law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1956. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1957. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-23 MICHIGAN: NEGLIGENT STORAGE AND TRANSPORTATION**

1958. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1959. Under Michigan law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1960. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and

humidity.

1961. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

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

**SUB-COUNT IX-24 MINNESOTA: NEGLIGENT STORAGE AND  
TRANSPORTATION**

1962. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1963. Under Minnesota law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1964. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1965. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-25 MISSISSIPPI: NEGLIGENT STORAGE AND  
TRANSPORTATION**

1966. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1967. Under Mississippi law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1968. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1969. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-26 MISSOURI: NEGLIGENT STORAGE AND  
TRANSPORTATION**

1970. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1971. Under Missouri law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1972. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1973. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and

transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-27 MONTANA: NEGLIGENT STORAGE AND TRANSPORTATION**

1974. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1975. Under Montana law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1976. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1977. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-28 NEBRASKA: NEGLIGENT STORAGE AND TRANSPORTATION**

1978. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1979. Under Nebraska law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1980. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1981. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

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

**SUB-COUNT IX-29 NEVADA: NEGLIGENT STORAGE AND  
TRANSPORTATION**

1982. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1983. Under Nevada law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1984. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1985. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.



**SUB-COUNT IX-30 NEW HAMPSHIRE: NEGLIGENT STORAGE AND TRANSPORTATION**

1986. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1987. Under New Hampshire law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1988. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1989. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

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

**SUB-COUNT IX-31 NEW JERSEY: NEGLIGENT STORAGE AND TRANSPORTATION**

1990. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1991. Under New Jersey law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1992. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1993. As a direct and proximate result of these systematic failures, excessive levels of

NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-32 NEW MEXICO: NEGLIGENT STORAGE AND TRANSPORTATION**

1994. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1995. Under New Mexico law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

1996. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

1997. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-33 NEW YORK: NEGLIGENT STORAGE AND TRANSPORTATION**

1998. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

1999. Under New York law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2000. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

2001. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-34 NORTH CAROLINA: NEGLIGENT STORAGE AND TRANSPORTATION**

2002. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

2003. Under North Carolina law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2004. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

2005. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-35 NORTH DAKOTA: NEGLIGENT STORAGE AND TRANSPORTATION**

2006. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

2007. Under North Dakota law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2008. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

2009. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-36 OHIO: NEGLIGENT STORAGE AND  
TRANSPORTATION**

2010. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

2011. Under Ohio law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2012. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

2013. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and

transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-37 OKLAHOMA: NEGLIGENT STORAGE AND TRANSPORTATION**

2014. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

2015. Under Oklahoma law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2016. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

2017. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-38 OREGON: NEGLIGENT STORAGE AND TRANSPORTATION**

2018. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

2019. Under Oregon law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2020. Each Defendant breached this duty by failing to implement or enforce policies to

ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

2021. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-39 PENNSYLVANIA: NEGLIGENT STORAGE AND TRANSPORTATION**

2022. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

2023. Under Pennsylvania law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2024. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

2025. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-40 PUERTO RICO: NEGLIGENT STORAGE AND TRANSPORTATION**

2026. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-

1869 as if fully stated herein.

2027. Under Puerto Rico law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2028. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

2029. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

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

**SUB-COUNT IX-41 RHODE ISLAND: NEGLIGENT STORAGE AND TRANSPORTATION**

2030. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

2031. Under Rhode Island law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2032. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

2033. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-42 SOUTH CAROLINA: NEGLIGENT STORAGE AND TRANSPORTATION**

2034. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

2035. Under South Carolina law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2036. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

2037. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-43 SOUTH DAKOTA: NEGLIGENT STORAGE AND TRANSPORTATION**

2038. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

2039. Under South Dakota law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2040. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and



humidity.

2041. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-44 TENNESSEE: NEGLIGENT STORAGE AND TRANSPORTATION**

2042. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

2043. Under Tennessee law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2044. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

2045. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-45 TEXAS: NEGLIGENT STORAGE AND TRANSPORTATION**

2046. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-

1869 as if fully stated herein.

2047. Under Texas law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2048. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

2049. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-46 UTAH: NEGLIGENT STORAGE AND  
TRANSPORTATION**

2050. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

2051. Under Utah law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2052. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

2053. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-47 VERMONT: NEGLIGENT STORAGE AND TRANSPORTATION**

2054. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

2055. Under Vermont law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2056. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

2057. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-48 VIRGINIA: NEGLIGENT STORAGE AND TRANSPORTATION**

2058. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

2059. Under Virginia law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2060. Each Defendant breached this duty by failing to implement or enforce policies to

ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

2061. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-49 WASHINGTON: NEGLIGENT STORAGE AND TRANSPORTATION**

2062. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

2063. Under Washington law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2064. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

2065. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

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

**SUB-COUNT IX-50 WEST VIRGINIA: NEGLIGENT STORAGE AND TRANSPORTATION**

2066. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

2067. Under West Virginia law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2068. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

2069. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-51 WISCONSIN: NEGLIGENT STORAGE AND  
TRANSPORTATION**

2070. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

2071. Under Wisconsin law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2072. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

2073. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and

transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT IX-52 WYOMING: NEGLIGENT STORAGE AND  
TRANSPORTATION**

2074. Plaintiffs incorporate by reference each allegation set forth in paragraphs 1843-1869 as if fully stated herein.

2075. Under Wyoming law, a pharmaceutical manufacturer has a duty to exercise reasonable care in transporting and storing products.

2076. Each Defendant breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity.

2077. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the ranitidine-containing products each Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**COUNT X: UNJUST ENRICHMENT**

2078. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1–263 as if fully stated herein.

2079. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold, or otherwise released ranitidine-containing products into the stream of commerce, and therefore owed a duty of reasonable care to

avoid causing harm to those that consumed it, including Plaintiffs.

2080. Defendants knew that ranitidine-containing products posed a grave risk of harm but failed to warn of the dangerous risks associated with use and exposure to the products. The dangerous propensities of their products and the carcinogenic characteristics of NDMA were well known to Defendants.

2081. Defendants were unjustly enriched as a result of their wrongful conduct, including through the false and misleading marketing, promotions, and advertisements that omitted disclosure that the products presented an unreasonable risk of substantial bodily injury resulting from their use.

2082. Defendants requested and received a measurable benefit at the expense of Plaintiffs in the form of payment for their ranitidine-containing products.

2083. Defendants appreciated, recognized, and chose to accept the monetary benefits Plaintiffs conferred onto Defendants at Plaintiffs' detriment. These benefits were the expected result of Defendants acting in their pecuniary interests at the expense of Plaintiffs.

2084. There is no justification for Defendants' enrichment. It would be inequitable, unconscionable, and unjust for Defendants to be permitted to retain these benefits because the benefits were procured as a result of their wrongful conduct.

2085. Defendants wrongfully obfuscated the harm caused by their ranitidine-containing products. Thus, Plaintiffs, who mistakenly enriched Defendants by relying on Defendants' misrepresentations of product safety, could not and did not know the effect that using ranitidine-containing products would have on Plaintiffs' health.

2086. Plaintiffs are entitled to restitution of the benefits Defendants unjustly retained and/or any amounts necessary to return Plaintiffs to the position they occupied prior to dealing

with Defendants. Due to their wrongful conduct and the FDA action recalling ranitidine-containing products in the form of a market withdrawal, Defendants are reasonably notified that Plaintiffs would expect compensation from Defendants' unjust enrichment stemming from their wrongful actions.

#### **SUB-COUNT X-1 ALABAMA: UNJUST ENRICHMENT**

2087. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2088. Under Alabama law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2089. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2090. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

#### **SUB-COUNT X-2 ALASKA: UNJUST ENRICHMENT**

2091. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2092. Under Alaska law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2093. As alleged above, each Defendant was unjustly enriched by selling ranitidine-



containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2094. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-3 ARIZONA: UNJUST ENRICHMENT**

2095. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2096. Under Arizona law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2097. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2098. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-4 ARKANSAS: UNJUST ENRICHMENT**

2099. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2100. Under Arkansas law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2101. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2102. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-5 CALIFORNIA: UNJUST ENRICHMENT**

2103. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2104. Under California law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2105. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2106. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-6 COLORADO: UNJUST ENRICHMENT**

2107. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2108. Under Colorado law, plaintiffs may recover amounts by which defendants have

been unjustly enriched.

2109. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2110. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-7 CONNECTICUT: UNJUST ENRICHMENT**

2111. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2112. Under Connecticut law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2113. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2114. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-8 DELAWARE: UNJUST ENRICHMENT**

2115. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2116. Under Delaware law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2117. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2118. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-9 DISTRICT OF COLUMBIA: UNJUST ENRICHMENT**

2119. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2120. Under District of Columbia law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2121. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2122. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-10 FLORIDA: UNJUST ENRICHMENT**

2123. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-

2086 as if fully stated herein.

2124. Under Florida law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2125. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2126. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

#### **SUB-COUNT X-11 GEORGIA: UNJUST ENRICHMENT**

2127. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2128. Under Georgia law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2129. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2130. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

#### **SUB-COUNT X-12 HAWAII: UNJUST ENRICHMENT**

2131. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2132. Under Hawaii law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2133. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2134. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-13 IDAHO: UNJUST ENRICHMENT**

2135. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2136. Under Idaho law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2137. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2138. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-14 ILLINOIS: UNJUST ENRICHMENT**

2139. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2140. Under Illinois law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2141. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2142. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-15 INDIANA: UNJUST ENRICHMENT**

2143. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2144. Under Indiana law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2145. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2146. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-16 IOWA: UNJUST ENRICHMENT**

2147. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2148. Under Iowa law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2149. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2150. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-17 KANSAS: UNJUST ENRICHMENT**

2151. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2152. Under Kansas law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2153. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a



dangerous carcinogen.

2154. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-18 KENTUCKY: UNJUST ENRICHMENT**

2155. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2156. Under Kentucky law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2157. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2158. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-19 LOUISIANA: UNJUST ENRICHMENT**

2159. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2160. Under Louisiana law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2161. As alleged above, each Defendant was unjustly enriched by selling ranitidine-

containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2162. Justice demands the repayment of Defendants' gain.

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

**SUB-COUNT X-20 MAINE: UNJUST ENRICHMENT**

2163. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2164. Under Maine law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2165. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2166. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-21 MARYLAND: UNJUST ENRICHMENT**

2167. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2168. Under Maryland law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2169. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2170. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-22 MASSACHUSETTS: UNJUST ENRICHMENT**

2171. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2172. Under Massachusetts law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2173. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2174. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-23 MICHIGAN: UNJUST ENRICHMENT**

2175. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2176. Under Michigan law, plaintiffs may recover amounts by which defendants have

been unjustly enriched.

2177. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2178. Justice demands the repayment of Defendants' gain.

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

**SUB-COUNT X-24 MINNESOTA: UNJUST ENRICHMENT**

2179. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2180. Under Minnesota law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2181. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2182. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-25 MISSISSIPPI: UNJUST ENRICHMENT**

2183. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2184. Under Mississippi law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2185. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2186. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-26 MISSOURI: UNJUST ENRICHMENT**

2187. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2188. Under Missouri law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2189. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2190. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-27 MONTANA: UNJUST ENRICHMENT**

2191. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-

2086 as if fully stated herein.

2192. Under Montana law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2193. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2194. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-28 NEBRASKA: UNJUST ENRICHMENT**

2195. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2196. Under Nebraska law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2197. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2198. Justice demands the repayment of Defendants' gain.

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

**SUB-COUNT X-29 NEVADA: UNJUST ENRICHMENT**

2199. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2200. Under Nevada law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2201. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2202. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-30 NEW HAMPSHIRE: UNJUST ENRICHMENT**

2203. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2204. Under New Hampshire law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2205. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2206. Justice demands the repayment of Defendants' gain.

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

**SUB-COUNT X-31 NEW JERSEY: UNJUST ENRICHMENT**

2207. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2208. Under New Jersey law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2209. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2210. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-32 NEW MEXICO: UNJUST ENRICHMENT**

2211. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2212. Under New Mexico law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2213. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.



2214. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-33 NEW YORK: UNJUST ENRICHMENT**

2215. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2216. Under New York law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2217. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2218. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-34 NORTH CAROLINA: UNJUST ENRICHMENT**

2219. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2220. Under North Carolina law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2221. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a

dangerous carcinogen.

2222. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-35 NORTH DAKOTA: UNJUST ENRICHMENT**

2223. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2224. Under North Dakota law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2225. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2226. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-36 OHIO: UNJUST ENRICHMENT**

2227. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2228. Under Ohio law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2229. As alleged above, each Defendant was unjustly enriched by selling ranitidine-

containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2230. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-37 OKLAHOMA: UNJUST ENRICHMENT**

2231. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2232. Under Oklahoma law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2233. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2234. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-38 OREGON: UNJUST ENRICHMENT**

2235. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2236. Under Oregon law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2237. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2238. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-39 PENNSYLVANIA: UNJUST ENRICHMENT**

2239. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2240. Under Pennsylvania law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2241. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2242. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-40 PUERTO RICO: UNJUST ENRICHMENT**

2243. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2244. Under Puerto Rico law, plaintiffs may recover amounts by which defendants have

been unjustly enriched.

2245. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2246. Justice demands the repayment of Defendants' gain.

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

**SUB-COUNT X-41 RHODE ISLAND: UNJUST ENRICHMENT**

2247. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2248. Under Rhode Island law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2249. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2250. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-42 SOUTH CAROLINA: UNJUST ENRICHMENT**

2251. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2252. Under South Carolina law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2253. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2254. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-43 SOUTH DAKOTA: UNJUST ENRICHMENT**

2255. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2256. Under South Dakota law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2257. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2258. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-44 TENNESSEE: UNJUST ENRICHMENT**

2259. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-

2086 as if fully stated herein.

2260. Under Tennessee law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2261. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2262. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-45 TEXAS: UNJUST ENRICHMENT**

2263. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2264. Under Texas law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2265. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2266. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-46 UTAH: UNJUST ENRICHMENT**

2267. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2268. Under Utah law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2269. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2270. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-47 VERMONT: UNJUST ENRICHMENT**

2271. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2272. Under Vermont law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2273. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2274. Justice demands the repayment of Defendants' gain.



**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-48 VIRGINIA: UNJUST ENRICHMENT**

2275. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2276. Under Virginia law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2277. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2278. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-49 WASHINGTON: UNJUST ENRICHMENT**

2279. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2280. Under Washington law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2281. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2282. Justice demands the repayment of Defendants' gain.

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

**SUB-COUNT X-50 WEST VIRGINIA: UNJUST ENRICHMENT**

2283. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2284. Under West Virginia law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2285. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2286. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-51 WISCONSIN: UNJUST ENRICHMENT**

2287. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2288. Under Wisconsin law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2289. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a

dangerous carcinogen.

2290. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT X-52 WYOMING: UNJUST ENRICHMENT**

2291. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2078-2086 as if fully stated herein.

2292. Under Wyoming law, plaintiffs may recover amounts by which defendants have been unjustly enriched.

2293. As alleged above, each Defendant was unjustly enriched by selling ranitidine-containing products to Plaintiffs, who did not know the products degraded into NDMA, a dangerous carcinogen.

2294. Justice demands the repayment of Defendants' gain.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**COUNT XI: LOSS OF CONSORTIUM**

2295. As a direct and proximate result of Defendants' conduct as detailed above, Plaintiffs' spouses and/or family members, as specified in the SFC, have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love, and affection.

2296. Plaintiffs' spouses and/or family member have necessarily paid and have become liable to pay for medical aid, treatment and for medications, and will necessarily incur further

expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

2297. Plaintiffs' spouses allege that their marital relationship has been impaired and depreciated, and the marital association has been altered.

2298. Plaintiffs' spouses and/or family members have suffered great emotional pain and mental anguish.

2299. Plaintiffs' spouses and/or family members have sustained and will continue to sustain several physical injuries, severe emotional distress, economic losses, and other damages for which they are entitled to compensatory damages.

2300. Defendants' actions and omissions as identified in this SAMPIC show that Defendants acted maliciously and/or intentionally disregarded Plaintiffs' rights so as to warrant the imposition of punitive damages.

#### **SUB-COUNT XI-1 ALABAMA: LOSS OF CONSORTIUM**

2301. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2302. Under Alabama law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

#### **SUB-COUNT XI-2 ALASKA: LOSS OF CONSORTIUM**

2303. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2304. Under Alaska law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-3 ARIZONA: LOSS OF CONSORTIUM**

2305. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2306. Under Arizona law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-4 ARKANSAS: LOSS OF CONSORTIUM**

2307. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2308. Under Arkansas law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-5 CALIFORNIA: LOSS OF CONSORTIUM**

2309. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2310. Under California law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-6 COLORADO: LOSS OF CONSORTIUM**

2311. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2312. Under Colorado law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-7 CONNECTICUT: LOSS OF CONSORTIUM**

2313. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2314. Under Connecticut law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-8 DELAWARE: LOSS OF CONSORTIUM**

2315. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2316. Under Delaware law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-9 DISTRICT OF COLUMBIA: LOSS OF CONSORTIUM**

2317. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2318. Under District of Columbia law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-10 FLORIDA: LOSS OF CONSORTIUM**

2319. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-

2300 as if fully stated herein.

2320. Under Florida law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-11 GEORGIA: LOSS OF CONSORTIUM**

2321. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2322. Under Georgia law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-12 HAWAII: LOSS OF CONSORTIUM**

2323. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2324. Under Hawaii law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-13 IDAHO: LOSS OF CONSORTIUM**



2325. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2326. Under Idaho law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-14 ILLINOIS: LOSS OF CONSORTIUM**

2327. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2328. Under Illinois law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-15 INDIANA: LOSS OF CONSORTIUM**

2329. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2330. Under Indiana law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-16 IOWA: LOSS OF CONSORTIUM**

2331. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2332. Under Iowa law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-17 KANSAS: LOSS OF CONSORTIUM**

2333. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2334. Under Kansas law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-18 KENTUCKY: LOSS OF CONSORTIUM**

2335. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2336. Under Kentucky law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-19 LOUISIANA: LOSS OF CONSORTIUM**

2337. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2338. Under Louisiana law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

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

**SUB-COUNT XI-20 MAINE: LOSS OF CONSORTIUM**

2339. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2340. Under Maine law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-21 MARYLAND: LOSS OF CONSORTIUM**

2341. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2342. Under Maryland law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-22 MASSACHUSETTS: LOSS OF CONSORTIUM**

2343. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2344. Under Massachusetts law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-23 MICHIGAN: LOSS OF CONSORTIUM**

2345. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2346. Under Michigan law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

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

**SUB-COUNT XI-24 MINNESOTA: LOSS OF CONSORTIUM**

2347. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2348. Under Minnesota law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-25 MISSISSIPPI: LOSS OF CONSORTIUM**

2349. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2350. Under Mississippi law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-26 MISSOURI: LOSS OF CONSORTIUM**

2351. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2352. Under Missouri law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-27 MONTANA: LOSS OF CONSORTIUM**

2353. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2354. Under Montana law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-28 NEBRASKA: LOSS OF CONSORTIUM**

2355. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2356. Under Nebraska law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

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

**SUB-COUNT XI-29 NEVADA: LOSS OF CONSORTIUM**

2357. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2358. Under Nevada law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-30 NEW HAMPSHIRE: LOSS OF CONSORTIUM**

2359. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2360. Under New Hampshire law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

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

**SUB-COUNT XI-31 NEW JERSEY: LOSS OF CONSORTIUM**

2361. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2362. Under New Jersey law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each

SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-32 NEW MEXICO: LOSS OF CONSORTIUM**

2363. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2364. Under New Mexico law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-33 NEW YORK: LOSS OF CONSORTIUM**

2365. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2366. Under New York law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-34 NORTH CAROLINA: LOSS OF CONSORTIUM**



2367. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2368. Under North Carolina law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-35 NORTH DAKOTA: LOSS OF CONSORTIUM**

2369. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2370. Under North Dakota law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-36 OHIO: LOSS OF CONSORTIUM**

2371. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2372. Under Ohio law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-37 OKLAHOMA: LOSS OF CONSORTIUM**

2373. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2374. Under Oklahoma law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-38 OREGON: LOSS OF CONSORTIUM**

2375. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2376. Under Oregon law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-39 PENNSYLVANIA: LOSS OF CONSORTIUM**

2377. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-

2300 as if fully stated herein.

2378. Under Pennsylvania law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-40 PUERTO RICO: LOSS OF CONSORTIUM**

2379. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2380. Under Puerto Rico law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

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

**SUB-COUNT XI-41 RHODE ISLAND: LOSS OF CONSORTIUM**

2381. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2382. Under Rhode Island law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-42 SOUTH CAROLINA: LOSS OF CONSORTIUM**

2383. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2384. Under South Carolina law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-43 SOUTH DAKOTA: LOSS OF CONSORTIUM**

2385. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2386. Under South Dakota law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-44 TENNESSEE: LOSS OF CONSORTIUM**

2387. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2388. Under Tennessee law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-45 TEXAS: LOSS OF CONSORTIUM**

2389. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2390. Under Texas law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-46 UTAH: LOSS OF CONSORTIUM**

2391. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2392. Under Utah law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-47 VERMONT: LOSS OF CONSORTIUM**

2393. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2394. Under Vermont law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-48 VIRGINIA: LOSS OF CONSORTIUM**

2395. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2396. Under Virginia law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-49 WASHINGTON: LOSS OF CONSORTIUM**

2397. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2398. Under Washington law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

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

**SUB-COUNT XI-50 WEST VIRGINIA: LOSS OF CONSORTIUM**

2399. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2400. Under West Virginia law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-51 WISCONSIN: LOSS OF CONSORTIUM**

2401. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2402. Under Wisconsin law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XI-52 WYOMING: LOSS OF CONSORTIUM**

2403. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2295-2300 as if fully stated herein.

2404. Under Wyoming law, Plaintiffs are entitled to damages for loss of consortium under the facts herein alleged based on their injuries, expenditures, and suffering as alleged in each SFC.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**COUNT XII: SURVIVAL ACTIONS**

2405. As a direct and proximate result of the conduct of Defendants, Decedents, prior to their deaths, were obligated to spend various sums of money to treat their injuries, which debts have been assumed by their estates. As a direct and proximate cause of the aforesaid, Decedents were caused pain and suffering, mental anguish and impairment of the enjoyment of life, until the date of their deaths and, as a direct and proximate result of the aforesaid, Decedents suffered a loss of earnings and earning capacity. Plaintiffs' spouses, as Administrators of the Estates of Decedents, beneficiaries and/or lawful representatives bring this claim on behalf of the estates for damages under any and all applicable statute or common law.

2406. As a direct and proximate result of the conduct of Defendants, Decedents, and their spouses, until the time of Decedents' deaths, suffered a disintegration and deterioration of the family unit and the relationships existing therein, resulting in enhanced anguish, depression and



other symptoms of psychological stress and disorder.

2407. As a direct and proximate result of the conduct of Defendants and including the observances of the suffering of the Decedents, until the date of their deaths, Plaintiffs suffered permanent and ongoing psychological damage.

2408. As a direct and proximate result of the aforesaid and including the observance of the suffering and physical deterioration of Decedents until the date of their deaths, Plaintiffs have and will continue to suffer permanent and ongoing psychological damage which may require future psychological and medical treatment. Plaintiffs' spouses, as Administrators of the Estates of the Decedents, beneficiaries and/or lawful representatives bring the claims on behalf of the Estates for damages any and all applicable statutes or common law and in their own right.

2409. Defendants' actions, as described above, were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiffs and the public.

2410. As a result of Defendants' conduct, Plaintiffs suffered the injuries and damages specified herein.

2411. Defendants' actions and omissions as identified in this SAMPIC show that Defendants acted maliciously and/or intentionally disregarded Plaintiffs' rights so as to warrant the imposition of punitive damages.

#### **SUB-COUNT XII-1 ALABAMA: SURVIVAL ACTION**

2412. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2413. Under Alabama law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-2 ALASKA: SURVIVAL ACTIONS**

2414. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2415. Under Alaska law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-3 ARIZONA: SURVIVAL ACTIONS**

2416. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2417. Under Arizona law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-4 ARKANSAS: SURVIVAL ACTIONS**

2418. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2419. Under Arkansas law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-5 CALIFORNIA: SURVIVAL ACTIONS**

2420. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2421. Under California law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-6 COLORADO: SURVIVAL ACTIONS**

2422. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2423. Under Colorado law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-7 CONNECTICUT: SURVIVAL ACTIONS**

2424. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2425. Under Connecticut law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-8 DELAWARE: SURVIVAL ACTIONS**

2426. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2427. Under Delaware law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-9 DISTRICT OF COLUMBIA: SURVIVAL ACTIONS**

2428. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2429. Under District of Columbia law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-10 FLORIDA: SURVIVAL ACTIONS**

2430. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2431. Under Florida law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-11 GEORGIA: SURVIVAL ACTIONS**

2432. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2433. Under Georgia law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-12 HAWAII: SURVIVAL ACTIONS**

2434. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2435. Under Hawaii law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-13 IDAHO: SURVIVAL ACTIONS**

2436. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2437. Under Idaho law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-14 ILLINOIS: SURVIVAL ACTIONS**

2438. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2439. Under Illinois law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-15 INDIANA: SURVIVAL ACTIONS**

2440. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2441. Under Indiana law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-16 IOWA: SURVIVAL ACTIONS**

2442. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2443. Under Iowa law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-17 KANSAS: SURVIVAL ACTIONS**

2444. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2445. Under Kansas law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-18 KENTUCKY: SURVIVAL ACTIONS**

2446. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2447. Under Kentucky law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-19 LOUISIANA: SURVIVAL ACTIONS**

2448. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2449. Under Louisiana law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

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

**SUB-COUNT XII-20 MAINE: SURVIVAL ACTIONS**

2450. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2451. Under Maine law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.



**SUB-COUNT XII-21 MARYLAND: SURVIVAL ACTIONS**

2452. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2453. Under Maryland law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-22 MASSACHUSETTS: SURVIVAL ACTIONS**

2454. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2455. Under Massachusetts law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-23 MICHIGAN: SURVIVAL ACTIONS**

2456. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2457. Under Michigan law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

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

**SUB-COUNT XII-24 MINNESOTA: SURVIVAL ACTIONS**

2458. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2459. Under Minnesota law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-25 MISSISSIPPI: SURVIVAL ACTIONS**

2460. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2461. Under Mississippi law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-26 MISSOURI: SURVIVAL ACTIONS**

2462. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2463. Under Missouri law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-27 MONTANA: SURVIVAL ACTIONS**

2464. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2465. Under Montana law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-28 NEBRASKA: SURVIVAL ACTIONS**

2466. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2467. Under Nebraska law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

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

**SUB-COUNT XII-29 NEVADA: SURVIVAL ACTIONS**

2468. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2469. Under Nevada law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-30 NEW HAMPSHIRE: SURVIVAL ACTIONS**

2470. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2471. Under New Hampshire law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

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

**SUB-COUNT XII-31 NEW JERSEY: SURVIVAL ACTIONS**

2472. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2473. Under New Jersey law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-32 NEW MEXICO: SURVIVAL ACTIONS**

2474. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2475. Under New Mexico law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-33 NEW YORK: SURVIVAL ACTIONS**

2476. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2477. Under New York law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-34 NORTH CAROLINA: SURVIVAL ACTIONS**

2478. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2479. Under North Carolina law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-35 NORTH DAKOTA: SURVIVAL ACTIONS**

2480. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2481. Under North Dakota law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-36 OHIO: SURVIVAL ACTIONS**

2482. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2483. Under Ohio law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-37 OKLAHOMA: SURVIVAL ACTIONS**

2484. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2485. Under Oklahoma law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-38 OREGON: SURVIVAL ACTIONS**

2486. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2487. Under Oregon law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-39 PENNSYLVANIA: SURVIVAL ACTIONS**

2488. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2489. Under Pennsylvania law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-40 PUERTO RICO: SURVIVAL ACTIONS**

2490. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2491. Under Puerto Rico law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

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

**SUB-COUNT XII-41 RHODE ISLAND: SURVIVAL ACTIONS**

2492. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2493. Under Rhode Island law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-42 SOUTH CAROLINA: SURVIVAL ACTIONS**

2494. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2495. Under South Carolina law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.



**SUB-COUNT XII-43 SOUTH DAKOTA: SURVIVAL ACTIONS**

2496. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2497. Under South Dakota law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-44 TENNESSEE: SURVIVAL ACTIONS**

2498. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2499. Under Tennessee law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-45 TEXAS: SURVIVAL ACTIONS**

2500. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2501. Under Texas law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-46 UTAH: SURVIVAL ACTIONS**

2502. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2503. Under Utah law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-47 VERMONT: SURVIVAL ACTIONS**

2504. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2505. Under Vermont law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-48 VIRGINIA: SURVIVAL ACTIONS**

2506. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2507. Under Virginia law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-49 WASHINGTON: SURVIVAL ACTIONS**

2508. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2509. Under Washington law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

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

**SUB-COUNT XII-50 WEST VIRGINIA: SURVIVAL ACTIONS**

2510. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2511. Under West Virginia law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XII-51 WISCONSIN: SURVIVAL ACTIONS**

2512. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2513. Under Wisconsin law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

#### **SUB-COUNT XII-52 WYOMING: SURVIVAL ACTIONS**

2514. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2405-2411 as if fully stated herein.

2515. Under Wyoming law, the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

#### **COUNT XIII: WRONGFUL DEATH**

2516. Plaintiffs Decedents' spouses, beneficiaries, and/or lawful representatives of Decedents' Estates bring this claim on behalf of themselves and as the Decedents' lawful beneficiaries.

2517. As a direct and proximate result of the conduct of Defendants and the defective nature of ranitidine-containing products as outlined above, Decedents suffered bodily injury resulting in pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses for hospitalization, medical and nursing

treatment, loss of earnings, loss of ability to earn, funeral expenses and death.

2518. As a direct and proximate cause of the conduct of Defendants, Decedents' beneficiaries have incurred hospital, nursing and medical expenses, and estate administration expenses as a result of Decedents' deaths.

2519. Defendants' actions and omissions as identified in this SAMPIC show that Defendants acted maliciously and/or intentionally disregarded Plaintiffs' rights so as to warrant the imposition of punitive damages.

#### **SUB-COUNT XIII-1 ALABAMA: WRONGFUL DEATH**

2520. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2521. Under Alabama law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

#### **SUB-COUNT XIII-2 ALASKA: WRONGFUL DEATH**

2522. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2523. Under Alaska law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-3 ARIZONA: WRONGFUL DEATH**

2524. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2525. Under Arizona law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-4 ARKANSAS: WRONGFUL DEATH**

2526. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2527. Under Arkansas law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-5 CALIFORNIA: WRONGFUL DEATH**

2528. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2529. Under California law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-6 COLORADO: WRONGFUL DEATH**

2530. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2531. Under Colorado law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-7 CONNECTICUT: WRONGFUL DEATH**

2532. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2533. Under Connecticut law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-8 DELAWARE: WRONGFUL DEATH**

2534. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2535. Under Delaware law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-9 DISTRICT OF COLUMBIA: WRONGFUL DEATH**

2536. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2537. Under District of Columbia law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-10 FLORIDA: WRONGFUL DEATH**

2538. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2539. Under Florida law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.



**SUB-COUNT XIII-11 GEORGIA: WRONGFUL DEATH**

2540. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2541. Under Georgia law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-12 HAWAII: WRONGFUL DEATH**

2542. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2543. Under Hawaii law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-13 IDAHO: WRONGFUL DEATH**

2544. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2545. Under Idaho law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-14 ILLINOIS: WRONGFUL DEATH**

2546. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2547. Under Illinois law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-15 INDIANA: WRONGFUL DEATH**

2548. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2549. Under Indiana law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-16 IOWA: WRONGFUL DEATH**

2550. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2551. Under Iowa law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-17 KANSAS: WRONGFUL DEATH**

2552. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2553. Under Kansas law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-18 KENTUCKY: WRONGFUL DEATH**

2554. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2555. Under Kentucky law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-19 LOUISIANA: WRONGFUL DEATH**

2556. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2557. Under Louisiana law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

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

**SUB-COUNT XIII-20 MAINE: WRONGFUL DEATH**

2558. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2559. Under Maine law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-21 MARYLAND: WRONGFUL DEATH**

2560. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2561. Under Maryland law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-22 MASSACHUSETTS: WRONGFUL DEATH**

2562. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2563. Under Massachusetts law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-23 MICHIGAN: WRONGFUL DEATH**

2564. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2565. Under Michigan law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

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

**SUB-COUNT XIII-24 MINNESOTA: WRONGFUL DEATH**

2566. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2567. Under Minnesota law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-25 MISSISSIPPI: WRONGFUL DEATH**

2568. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2569. Under Mississippi law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-26 MISSOURI: WRONGFUL DEATH**

2570. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2571. Under Missouri law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-27 MONTANA: WRONGFUL DEATH**

2572. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2573. Under Montana law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-28 NEBRASKA: WRONGFUL DEATH**

2574. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2575. Under Nebraska law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

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

**SUB-COUNT XIII-29 NEVADA: WRONGFUL DEATH**

2576. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2577. Under Nevada law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-30 NEW HAMPSHIRE: WRONGFUL DEATH**

2578. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2579. Under New Hampshire law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

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

**SUB-COUNT XIII-31 NEW JERSEY: WRONGFUL DEATH**

2580. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2581. Under New Jersey law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-32 NEW MEXICO: WRONGFUL DEATH**

2582. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2583. Under New Mexico law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.



**SUB-COUNT XIII-33 NEW YORK: WRONGFUL DEATH**

2584. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2585. Under New York law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-34 NORTH CAROLINA: WRONGFUL DEATH**

2586. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2587. Under North Carolina law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-35 NORTH DAKOTA: WRONGFUL DEATH**

2588. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2589. Under North Dakota law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-36 OHIO: WRONGFUL DEATH**

2590. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2591. Under Ohio law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-37 OKLAHOMA: WRONGFUL DEATH**

2592. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2593. Under Oklahoma law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-38 OREGON: WRONGFUL DEATH**

2594. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2595. Under Oregon law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-39 PENNSYLVANIA: WRONGFUL DEATH**

2596. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2597. Under Pennsylvania law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-40 PUERTO RICO: WRONGFUL DEATH**

2598. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2599. Under Puerto Rico law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

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

**SUB-COUNT XIII-41 RHODE ISLAND: WRONGFUL DEATH**

2600. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2601. Under Rhode Island law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-42 SOUTH CAROLINA: WRONGFUL DEATH**

2602. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2603. Under South Carolina law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-43 SOUTH DAKOTA: WRONGFUL DEATH**

2604. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2605. Under South Dakota law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-44 TENNESSEE: WRONGFUL DEATH**

2606. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2607. Under Tennessee law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-45 TEXAS: WRONGFUL DEATH**

2608. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2609. Under Texas law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-46 UTAH: WRONGFUL DEATH**

2610. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2611. Under Utah law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-47 VERMONT: WRONGFUL DEATH**

2612. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2613. Under Vermont law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-48 VIRGINIA: WRONGFUL DEATH**

2614. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2615. Under Virginia law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-49 WASHINGTON: WRONGFUL DEATH**

2616. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2617. Under Washington law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

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

**SUB-COUNT XIII-50 WEST VIRGINIA: WRONGFUL DEATH**

2618. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2619. Under West Virginia law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-51 WISCONSIN: WRONGFUL DEATH**

2620. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2621. Under Wisconsin law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**SUB-COUNT XIII-52 WYOMING: WRONGFUL DEATH**

2622. Plaintiffs incorporate by reference each allegation set forth in paragraphs 2516-2519 as if fully stated herein.

2623. Under Wyoming law, Plaintiffs or the Estates of the Decedents alleged in each SFC are entitled to damages for the harms inflicted upon the decedent.

**WHEREFORE**, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' 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.

**JURY TRIAL DEMAND**

2624. Pursuant to Federal Rule of Civil Procedure 38(b) Plaintiffs hereby demand a trial by jury on all the triable issues within this pleading.

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs request the Court to enter judgment in Plaintiffs' favor and against Defendants for:

- a. actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;
- b. exemplary and punitive damages sufficient to punish and deter Defendants and others from future wrongful practices;
- c. pre-judgment and post-judgment interest;
- d. reasonable attorneys' fees as provided by law;
- e. costs and expenses of these actions;
- f. statutory damages, treble damages and other relief permitted by the laws of the states that will govern these actions; and
- g. any other relief the Court may deem just and proper.



DATED: August 2, 2021

Respectfully submitted,

/s/ Tracy A. Finken

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*Plaintiffs' Leadership Development Committee*

**CERTIFICATE OF SERVICE**

I hereby certify that on August 2, 2021, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF and that the foregoing document is being served on all counsel of record or parties registered to receive CM/ECF Electronic Filings.

/s/ Robert C. Gilbert  
Robert C. Gilbert