UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
MCALLEN DIVISION

CLARISSA ORNELAS AND ANTHONY BERMUDEZ, INDIVIDUALLY AND AS NEXT FRIENDS OF A.B., A MINOR	§	
Plaintiffs,	§	**CIVIL ACTION NO. 7:22-cv-203**
v.	§	
ABBOTT LABORATORIES, INC.,	§	**JURY TRIAL DEMANDED**
Defendant.	§	

PLAINTIFF'S ORIGINAL COMPLAINT

NOW COME Plaintiffs, Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, complaining of Abbott Laboratories, Inc. ("Abbott"), and would respectfully show as follows:

I. PARTIES

1. Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, are citizens of the United States and residents of Mission, Hidalgo County, Texas. Plaintiffs Clarissa Ornelas and Anthony Bermudez are the biological parents of A.B., a Minor, and bring this lawsuit in their individual capacities and in their capacity as Next Friends of A.B., a minor.

2. Defendant Abbott Laboratories, Inc. (hereinafter "Defendant Abbott") is an Illinois company with its principal place of business located at 100 Abbott Park Road, Abbott Park, Lake County, Illinois. Defendant Abbott may be served through its

registered agent, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

II. JURISDICTION AND VENUE

3. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because: (1) there is complete diversity of the parties; and (2) the amount in controversy exceeds seventy-five thousand ($75,000.00) dollars, exclusive of interests and costs. Venue is proper in this District under 28 U.S.C. § 1391 because a substantial portion of the acts and conduct giving rise to the claims occurred within the District.

4. This Court has specific personal jurisdiction over Defendant Abbott because Defendant Abbott has purposefully availed itself of the privileges and benefits of doing business in Texas.

5. Defendant Abbott subjected itself to jurisdiction in Texas by doing business in Texas and by contracting with Texas businesses and by performing such contracts in part in Texas, and by committing torts where one or more elements of the tort, or one or more of the tortious acts, occurred in Texas.

6. The claims against Defendant Abbott are linked to its conduct, key elements of the episode-in-suit occurred in Texas, and Defendant Abbott participated in placing the infant formula at issue into the stream of commerce in Texas. Defendant Abbott's contacts with Texas relate to the sale of infant formula, and all of the conduct associated with such products at issue in the potential claims is related to and connected with such contacts.

7. Defendant Abbott markets and sells its products across the United States, including the State of Texas. Defendant Abbott manufactured and sold the products involved in the incident made the basis of this lawsuit, and the incident made the basis of this lawsuit occurred in the State of Texas. Defendant Abbott has purposefully availed itself of the privilege of conducting activities in the State of Texas. Defendant Abbott cultivated a market for its products in the State of Texas and the defective product was purchased and consumed in the State of Texas. Defendant Abbott advertised its products in the State of Texas. Defendant Abbott engages in wide-ranging promotional activities, including television, print, online, and direct mail advertisements in the State of Texas. Defendant Abbott has ongoing connections with its products and the products' owners in the State of Texas. Defendant Abbott systematically served a market in the State of Texas for the very products that Plaintiffs allege were contaminated and severely injured them in this State. As such, there is a strong relationship among Defendant Abbott, the State of Texas, and the subject litigation. Defendant Abbott contracts with Texas residents, including Texas entities and individuals, as part of its business operations. Defendant Abbott has recruited and continues to recruit Texas residents for employment inside and outside the State of Texas. Defendant Abbott conducts substantial business in the State of Texas and has continuous, systematic and specific contacts in the State of Texas. At all relevant times, Defendant Abbott was and is regularly doing business in the State of Texas. At all relevant times, said Defendant has been engaged in the business of manufacturing, testing, inspecting, labeling, packaging, marketing, distributing, and selling products, including the products involved in the incident made the basis of this

suit, through a worldwide chain of distribution that has targeted and benefited from the Texas market.

III. NATURE OF THE ACTION

8. Defendant Abbott Laboratories, Inc. manufactures, labels, markets, distributes, and sells infant formulas, among other products, under the Similac, Alimentum, and EleCare brands that have been recalled due to bacterial contamination. Defendant Abbott Laboratories, Inc. manufactures, labels, markets, distributes and sells its products, including infant formula, throughout the globe, including throughout the United States, and specifically in the State of Texas.

9. On February 17, 2022, the U.S. Food and Drug Administration ("FDA"), in conjunction with the Center for Disease Control ("CDC"), announced that it was investigating Defendant Abbott's Similac, Alimentum, and EleCare infant formula products manufactured at Defendant Abbott's facility in Sturgis, Michigan ("Sturgis Facility"), following multiple consumer complaints of *Cronobacter Sakazakii* and *Salmonella* infection in infants who had consumed formula that was manufactured, packaged, and labeled at Defendant Abbott's Sturgis Facility. The FDA's advisory notice told consumers to avoid purchasing or using Defendant Abbott's Similac, Alimentum, and EleCare, and Defendant Abbott initiated a voluntary recall of those products on or about February 17, 2022.

10. Defendant Abbott later announced and admitted that it found evidence of *Cronobacter sakazakii* and *Salmonella* at its Sturgis Facility.

11. On February 28, 2022, Defendant Abbott also recalled several lots of Similac PM 60/40 infant formula "after learning of the death of an infant who tested positive for *Cronobacter Sakazakii*" after having consumed formula from a contaminated lot identified by Defendant Abbott.

12. Defendant Abbott knew, or in the exercise of due diligence should have known, about the ongoing risk and harm of contamination and related noncompliance issues and unsafe practices at its Sturgis Facility in 2019, if not before.

13. Rather than recalling its contaminated and dangerous infant formula in September 2021, Defendant Abbott made a conscious and deliberate decision to wait until February 2022 to recall the products, after the FDA publicly announced it was investigating Defendant Abbott. Countless innocent consumers purchased and were affected by Defendant Abbott's products from the time Defendant knew of the contamination, through the date Abbott finally recalled their contaminated products.

14. Defendant Abbott's conscious decision not to recall its contaminated infant formulas caused severe and life-altering injuries in A.B., a Minor.

15. In or around August 2021, A.B., a Minor, consumed contaminated powdered infant formula produced at Defendant Abbott's Sturgis, Michigan manufacturing facility. As a proximate or producing cause of consuming this recalled powdered infant formula, A.B., a Minor, developed a severe *Salmonella* infection that required hospitalization and extensive medical treatment.

16. In or around early February of 2022, A.B., a Minor, consumed contaminated powdered infant formula produced at Defendant Abbott's Sturgis, Michigan

manufacturing facility. As a proximate or producing cause of consuming this recalled powdered infant formula, A.B., a Minor, developed a severe *Salmonella* infection that required extensive medical treatment.

17. At all times relevant to this suit, Defendant Abbott's powdered infant formula was the sole source of nutrition for A.B., a Minor.

IV. FACTUAL BACKGROUND

A. DEFENDANT ABBOTT'S POWDERED INFANT FORMULA ("PIF")

18. Defendant Abbott is an American multinational medical device and health care company.

19. Defendant Abbott was founded 130 years ago, and its products are currently distributed and sold in over 160 countries.

20. In 2021, Defendant Abbott had gross sales of $43.1 billion.

21. Defendant Abbott's nutrition division ("Abbott Nutrition") was created in 1903 and, since that time, it has been the number one seller of pediatric nutrition products.

22. According to the *Global Infant Formula Market Report 2021-2025*, Defendant Abbott is considered one of the most dominant players in the baby formula market, which is expected to be valued at $93 billion by the year 2025.

23. Defendant Abbott, through Abbott Nutrition, was and is engaged in the manufacture, distribution, marketing, and sale of several powdered infant formula brands, including the Similac, Alimentum, EleCare, and Similac PM 60/40 brands that were recalled.

24. Defendant Abbott's products are marketed, distributed, and sold in a uniform manner throughout the United States, and are available for purchase at thousands of retail locations and online through Abbott's website and those of other major retailers.

25. Defendant Abbott holds itself out as a responsible company that is committed to manufacturing nutrition products that are safe for infants and others to consume.

26. On its website and elsewhere, Defendant Abbott emphasizes its commitment to developing and manufacturing nutrition products that are safe for infants and others to consume.

27. Despite these and other representations about the safety of its products, Abbott marketed, distributed, and sold contaminated infant formulas throughout the United States, including in the State of Texas.

B. FDA INVESTIGATION OF THE STURGIS FACILITY AND SUBSEQUENT RECALLS

28. In September 2021, the Minnesota Department of Health investigated a case involving an infant who fell ill from *Cronobacter Sakazakii.*

29. Minnesota state health officials "knew that the infant had consumed powdered formula produced at an Abbott Nutrition facility in Sturgis, Michigan, and shared this information with the FDA and CDC in September."

30. The FDA received reports of the first illness on September 21, 2021, and the agency, upon information and belief,notified Abbott Laboratories the following day.

31. The FDA completed an inspection of the Sturgis Facility on September 24, 2021, and issued five citations for violations of federal food-safety regulations:

a. Defendant Abbott's "personnel working directly with infant formula, its raw materials, packaging, or equipment or utensil contact surfaces did not wash hands thoroughly in a hand washing facility at a suitable temperature after the hands may have become soiled or contaminated;"

b. Defendant Abbott "did not maintain a building used in the manufacture, processing, packing or condition holding of infant formula in a clean and sanitary condition;"

c. "An instrument [Defendant Abbott] used to measure, regulate, or control a processing parameter was not properly maintained;"

d. Defendant Abbott "did not monitor the temperature in a thermal processing equipment at a frequency as is necessary to maintain temperature control;" and

e. Defendant Abbott "did not install a filter capable of retaining particles 0.5 micrometer or smaller when compressed gas is used at a product filling machine."

32. The FDA also found "several positive Cronobacter results" from environmental samples during another inspection of the Sturgis facility, and an FDA review of Abbott's internal documents indicated that Abbott Laboratories previously destroyed infant formulas in connection with the contamination issue.

33. The FDA continues to investigate complaints.

34. Additional illnesses have now been reported from months prior to Abbott's February 17, 2022 recall, including August, November, December, January and February, and all of these infants consumed powdered infant formula manufactured at Abbott's

Sturgis Facility, as identified in the recalled lot numbers. Dozens of infants were hospitalized, sustained permanent injuries, and numerous infants have died.

35. On October 19, 2021, a former employee of Defendant Abbott who worked in the Quality Systems subunit at Abbott's Sturgis Facility sent a 34-page Report to the FDA detailing Defendant Abbott's longstanding pattern, routine, habit, and practice of food-safety violations at the Sturgis Facility, unsafe and dangerous operation from a food safety standpoint at Defendant Abbott's Sturgis Facility, along with a culture of concealing and destroying evidence, and silencing and retaliating against those who reported violations or questioned Defendant Abbott's unsafe practices.

36. Among other things, this whistleblower reported to the FDA that Defendant Abbott:

a. Knowingly and intentionally falsified records;

b. Withheld material information relating to food safety;

c. Released untested infant formula;

d. Knowingly deceived FDA investigators during a 2019 site audit;

e. Failed to implement and observe clean-in-place procedures necessary to ensure food safety;

f. Failed to take necessary corrective measures as demanded by Current Good Manufacturing Practices; and

g. Failed to implement proper procedures necessary to ensure legally required traceability of infant formula manufactured at the Sturgis Facility

37. On February 17, 2022, approximately five months after Defendant Abbott was issued five citations by the FDA for health and safety violations and unsafe practices,

including violations of federal food-safety regulations, the FDA announced that it was investigating complaints of infant illnesses related to products manufactured at Defendant Abbott's Sturgis Facility, including Defendant Abbott's Similac, Alimentum, and EleCare products following several consumers' complaints of *Cronobacter sakazakii* and *Salmonella* contamination.

38. The FDA's advisory notice alerted consumers to avoid purchasing or using Defendant Abbott's Similac, Alimentum and EleCare products.

39. After the FDA made its public announcement, Defendant Abbott recalled the Similac, Alimentum and EleCare brand products.

40. This first formula recall came almost five months after it learned about potential contamination and serious noncompliance issues at its Sturgis Facility and known reported illness(es) related to powdered infant formula produced at that facility.

41. In conjunction with this first formula recall, Defendant Abbott announced that it had found evidence of *Cronobacter Sakazakii* at the Sturgis Facility, but affirmatively represented it had been found only in non-product-contact areas.

42. This public statement was directly contradicted by the FDA's inspection report issued March 18, 2022, which determined that Abbott had found *Cronobacter* both in the production areas, and in the finished formula itself.

43. Defendant Abbott has yet to explain why it waited approximately five months to make this announcement or warn innocent consumers about the inherent and deadly risk of products manufactured at the Sturgis Facility.

44. On May 16, 2022, the United States of America, on behalf of the United States Food and Drug Administration, filed a Complaint for Permanent Injunction and Proposed Consent Decree against Defendant Abbott relating to its dangerous and unsafe practices and business operations at Defendant Abbott's Sturgis Facility.

45. In its Complaint for Permanent Injunction against Defendant Abbott, the United States of America, on behalf of the FDA, pled the following:

> Ongoing inadequacies in manufacturing conditions and practices at Defendants' facilities demonstrate that Defendants have been unwilling or unable to implement sustainable corrective actions to ensure the safety and qualify of food manufactured for infants, a consumer group particularly vulnerable to foodborne pathogens. Defendants' violations of the Act and the likelihood that violations will recur in the absence of court action demonstrate that injunctive relief is necessary.

46. The United States Government's Proposed Consent Decree sets forth numerous violations of statutes and regulations and lists a litany of unsafe and dangerous practices in the manufacturing process by Defendant Abbott in relation to its operation, supervision, manufacturing, management, oversight, testing, and quality control of the Sturgis Facility, including but not limited to:

> Defendants violated 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce articles of food, namely infant formulas, as defined in 21 U.S.C § 321(z), that are adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have been processed in a manner that does not comply with current good manufacturing practice requirements for infant formulas set forth at 21 U.S.C. § 350a(b)(s) and 21 C.F.R Part 106.

47. The Complaint for Permanent Injunction and Proposed Consent Decree follows the House Appropriations Chair, Representative Rosa DeLauro, making public

the 34-page, detailed report prepared by a former Abbott employee turned whistleblower.

48. The Report, referenced in paragraphs 35 and 36 above, set forth a litany of Abbott's failures and unsafe / dangerous practices with regard to maintaining sanitary conditions, manufacturing product, testing outgoing product, as well as falsifying records and concealing information from regulators.

49. The Whistleblower's account corroborates and confirms many of the deficient food safety practices described in the FDA Form 483s issued in 2019, 2021 and 2022.

C. EFFECTS OF DEFENDANT ABBOTT'S CONTAMINATED FORMULA

50. *Cronobacter* bacteria can cause sepsis, meningitis, bowel damage and deadly infections. Symptoms of sepsis and meningitis include poor feeding, irritability, temperature changes, grunting breaths and abnormal movements. *Cronobacter* infection may spread through the blood to other parts of the body, cause bowel damage, meningitis, brain damage, neurological problems and/or conditions, and death.

51. *Salmonella* bacteria can cause sepsis, meningitis, bowel damage, and deadly infections. Most people with *Salmonella* infections develop diarrhea, fever and abdominal cramps. More severe cases may include high fevers, aches, headaches, lethargy, rash, blood in the urine or stool, and death

52. From July 2021 to February 2022, Plaintiffs Clarissa Ornelas and Anthony Bermudez's minor infant son, A.B., consumed contaminated powdered infant formula

produced at Defendant Abbott's Sturgis, Michigan manufacturing facility, which was later recalled. As a proximate and/or producing cause of consuming this recalled infant formula, A.B., developed a severe *Salmonella* infection on two separate occasions which required extensive medical treatment, including hospitalization. Minor A.B.'s medical treatment and care is on-going.

V. CLAIMS FOR RELIEF

(A) STRICT LIABILITY – FAILURE TO WARN

53. Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor ("Plaintiffs"), incorporate by reference each preceding and succeeding paragraph as if set forth fully herein.

54. Defendant Abbott is liable under a theory of strict products liability as set forth in § 402A of the Restatement (Second) of Torts.

55. At all relevant times, Defendant Abbott was engaged in the business of manufacturing, formulating, designing, marketing, advertising, testing, promoting, selling, distributing, and otherwise introducing contaminated Similac, Alimentum, and EleCare powdered infant formula into the stream of interstate commerce.

56. At all relevant times, Defendant Abbott knew or should have known that consumption of its contaminated Similac, Alimentum, and EleCare powdered infant formula significantly increased the risk of becoming infected with *Cronobacter* or *Salmonella*.

57. Had Plaintiffs received warning or instruction from Defendant Abbott regarding its contaminated Similac, Alimentum, and EleCare powdered infant formula, they would not have fed it to A.B., a Minor.

58. Plaintiffs were unaware that Defendant Abbott's Similac, Alimentum, and EleCare powdered infant formula was contaminated and significantly increased A.B.'s risk of becoming infected with *Cronobacter* and/or *Salmonella* and sustaining personal injuries and damages.

59. As the direct and proximate result of the reasonably foreseeable use of contaminated infant formula manufactured, formulated, marketed, tested, promoted, sold, distributed, and introduced into the stream of commerce by Defendant Abbott, Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, Individually and as Next Friends of A.B., a Minor, suffered irreparable harm, and Plaintiffs will continue to suffer damages for which they are entitled to recovery, including compensatory damages, consequential damages, interest, costs and attorneys' fees.

(B) STRICT LIABILITY – DESIGN AND MANUFACTURING DEFECT

60. Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein.

61. Defendant Abbott is liable under a theory of strict products liability as set forth in §402A of the Restatement (Second) of Torts.

62. At all relevant times, Defendant Abbott was engaged in the business of manufacturing, formulating, creating, designing, testing, labeling, packaging, supplying, marketing, promoting, selling, advertising, and otherwise introducing Similac, Alimentum, and EleCare powdered infant formula into the stream of interstate commerce, which they sold and distributed throughout the United States.

63. At all relevant times, Defendant Abbott's contaminated infant formula was expected to and did reach Plaintiffs without a substantial change in condition.

64. At all relevant times, the contaminated Similac, Alimentum, and EleCare powdered infant formula was defectively and improperly manufactured and designed by Defendant Abbott in that when the powdered infant formula left the hands of Defendant Abbott, its foreseeable risks far outweighed the benefits associated with its design and formulation.

65. At all relevant times, the contaminated Similac, Alimentum, and EleCare powdered infant formula was defectively manufactured and designed by Defendant Abbott in that its manufacture and formulation was more dangerous than an ordinary consumer would expect when used in its intended and reasonably foreseeable manner.

66. At all relevant times, the contaminated Similac, Alimentum, and EleCare powdered infant formula created significant risks of harm to the health and safety of consumers that far outweighed the risks posed by other products on the market used for the same purpose.

67. At all relevant times, a reasonable and safer alternative design existed that could have feasibly been employed by Defendant Abbott to manufacture and sell infant formula with the same purpose as the contaminated Similac, Alimentum, and EleCare powdered infant formula. These safer alternative designs were both economically and technologically feasible at the time the product left Defendant Abbott's control, and, if used, would have prevented or significantly reduced the risk of Plaintiffs' personal injuries without substantially impairing the product's utility. Despite knowledge of this reasonable and safer alternative design, Defendant Abbott failed to alter the infant formulas' designs and formulation. The magnitude of the danger created by the contaminated powdered infant formula far outweighed the costs associated with using an alternative, safer design.

68. At all relevant times, Defendant Abbott's contaminated Similac, Alimentum, and EleCare powdered infant formula deviated in its construction or quality from its specifications or planned output in a manner that rendered it unreasonably dangerous and unfit for its intended or reasonably foreseeable uses.

69. Plaintiffs allege there were no mandatory federal safety standards or regulations applicable to the product, or if there were, they were inadequate to protect the public from unreasonable risks of injury or damage; alternatively, Plaintiffs allege Defendant Abbott, before or after marketing the product, withheld or misrepresented information or material relevant to the federal government's or agency's determination of adequacy of the safety standards or regulations that would be at issue.

70. Food manufacturers must adhere to FDA's current good manufacturing practice regulation, codified at 21 C.F.R. Part 117, Subpart B, which establish basic practices that must be followed and conditions that must be maintained during food manufacturing operations. *See* 21 C.F.R. §§ 117.10 through 117.110. Defendant Abbott violated numerous provisions of the Federal Food, Drug and Cosmetic Act, including but not limited to 21 U.S.C. § 331(a) by:

a. introducing into interstate commerce articles of food, namely infant formulas as defined in 21 U.S.C. § 321(z), that are adulterated within the meaning of 21 U.S.C. § 350a(a)(3) in that they have been processed in a manner that does not comply with current good manufacturing practice requirements for infant formula set forth at 21 U.S.C. § 350a(b)(2) and 21 C.F.R. Part 106; and

b. introducing into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that powdered infant formula was prepared, packed or held under insanitary conditions whereby they may have become contaminated or whereby they may have been rendered injurious to health.

71. The factory environment at Abbott's Sturgis facility was not controlled so as to prevent contamination. Moreover, as it relates to safety standards, Defendant Abbott withheld or misled the government with a well thought out plan to have an environmental monitoring program that was purposefully designed to underreport

contamination, combined with a verification program that was effectively designed to not find contamination using their end product testing. Defendant Abbott therefore knew or should have known that they were manufacturing contaminated products.

72. As a direct and proximate result of the defective design and manufacture of the contaminated Similac, Alimentum, and EleCare powdered infant formula, manufactured, formulated, marketed, tested, promoted, sold, distributed, and introduced into the stream of commerce by Defendant Abbott, Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, suffered and will continue to suffer damages for which they are entitled to recovery, including compensatory damages, consequential damages, interest, costs and attorneys' fees.

(C) NEGLIGENCE

73. Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein.

74. At all relevant times, Defendant Abbott manufactured, designed, formulated, marketed, tested, promoted, supplied, sold, and/or distributed the powdered infant formulas in the regular course of business.

75. At all relevant times, Defendant Abbott had a duty to act with reasonable care in the design, development, marketing, labeling, manufacturing, formulating, testing, monitoring, distribution, and sale of its powdered infant formula.

76. At all relevant times, Defendant Abbott had a duty to act with reasonable care and to warn Plaintiffs and the consuming public of the risk, dangers, and adverse side effects of its contaminated Similac, Alimentum, and EleCare powdered infant formula.

77. At all relevant times, Defendant Abbott knew or should have known that its contaminated Similac, Alimentum, and EleCare powdered infant formula was unreasonably dangerous and defective when used in a reasonably foreseeable manner.

78. Defendant Abbott breached its duty to Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, and was otherwise negligent in the design, development, marketing, labeling, manufacturing, formulating, testing, monitoring, distribution, and sale of the powdered infant formula utilized by Plaintiffs, which was inherently dangerous and defective and unfit and unsafe for its intended and reasonably foreseeable use.

79. As a direct and proximate result of Defendant Abbott's negligence, Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, suffered and will continue to suffer injuries and damages for which they are entitled to recovery, including compensatory damages, consequential damages, interest, costs and attorneys' fees.

(D) FRAUD

80. Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein.

81. At all relevant times, Defendant Abbott intentionally, willfully and/or recklessly, with the intent to deceive, misrepresented or concealed material facts to consumers and users, including Plaintiffs Clarissa Ornelas and Anthony Bermudez.

82. At all relevant times, Defendant Abbott misrepresented or concealed material facts concerning the contaminated Similac, Alimentum, and EleCare powdered infant formula to consumers, including Plaintiff Ornelas, with knowledge of the falsity of their misrepresentations.

83. Defendant Abbott, through its advertisements, knowingly misrepresented to Plaintiff and the public that its contaminated Similac, Alimentum, and EleCare powdered infant formulas were safe to consume.

84. Defendant Abbott intentionally failed to disclose that its Similac, Alimentum, and EleCare powdered infant formula was manufactured in a facility known by Defendant Abbott to be contaminated with bacteria that posed a significant threat to the health and safety of its consumers, and in a manner that posed a significant threat to the health and safety of its consumers.

85. Defendant Abbott knew or, by the exercise of reasonable care, should have known about the issues plaguing its manufacturing facilities with bacteria that affected the safe nature of its Similac, Alimentum and EleCare powdered infant formula, and its likelihood to increase the risk of becoming infected with *Cronobacter* or *Salmonella*. Defendant Abbott falsely marketed, advertised, labeled and sold its product knowing the deficiencies of its manufacturing facility that gave rise to the adulterated Similac, Alimentum and EleCare powdered infant formula as safe for public use and consumption.

86. At all relevant times, Defendant Abbott actively, knowingly, and intentionally concealed and misrepresented these material facts to the consuming public with the intent to deceive the public and Plaintiffs, and with the intent that consumers would purchase and use the powdered infant formula.

87. At all relevant times, the consuming public, including Plaintiffs Clarissa Ornelas and Anthony Bermudez, would not otherwise have purchased or used the contaminated Similac, Alimentum, and EleCare powdered infant formula if they had been informed of the risks associated with its use and consumption.

88. At all relevant times, Plaintiffs Clarissa Ornelas and Anthony Bermudez relied on Defendant Abbott's misrepresentations concerning the safety of its infant formula when purchasing Similac, Alimentum, and EleCare powdered infant formula and feeding it to Minor A.B., and their reliance was reasonable and justified.

89. As a direct and proximate result of Defendant Abbott's fraudulent conduct concerning the contaminated Similac, Alimentum, and EleCare powdered infant formula as described herein, Plaintiffs suffered and will continue to suffer from injuries and damages for which they are entitled to recovery, including compensatory damages, consequential damages, interest, costs and attorneys' fees.

(E) NEGLIGENT MISREPRESENTATION

90. Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein.

91. At all relevant times, the Defendant Abbott was engaged in the business of manufacturing, formulating, marketing, testing, promoting, selling, and distributing powdered infant formula.

92. At all relevant times, Defendant Abbott had a duty to disclose to consumers and the public material facts about its powdered infant formula, including the material facts that its contaminated Similac, Alimentum, and EleCare powdered infant formula was unsafe to consume and that consuming it would substantially increase the risk of becoming infected with *Cronobacter* and/or *Salmonella*.

93. Through its acts and omissions in advertising, promoting, labeling, and otherwise, Defendant Abbott made public misrepresentations of material facts and concealed material facts from consumers like Plaintiffs Clarissa Ornelas and Anthony

Bermudez concerning the character, safety, and effectiveness of its contaminated Similac, Alimentum, and EleCare powdered infant formula.

94. Had Defendant Abbott disclosed true and accurate material facts concerning the risks of harm associated with the use of its contaminated Similac, Alimentum, and EleCare powdered infant formula, in particular, the risk of becoming infected with *Cronobacter* and/or *Salmonella*, Plaintiffs Clarissa Ornelas and Anthony Bermudez would not have purchased, received or used the powdered infant formula.

95. Plaintiffs Clarissa Ornelas and Anthony Bermudez's reliance upon Defendant Abbott's misrepresentations and omissions were justified and reasonable because, among other things, those misrepresentations and omissions were made by individuals and entities who were in a position to know the material facts concerning Defendant Abbott's contaminated Similac, Alimentum, and EleCare powdered infant formula, and the connection between the contaminated infant formula and the risk of becoming infected with *Cronobacter* and/or *Salmonella*, while Plaintiffs were not in a position to know these material facts; and because Defendant Abbott failed to warn or otherwise provide notice to the consuming public as to the risks of harm associated with its contaminated Similac, Alimentum, and EleCare powdered infant formula, thereby inducing Plaintiffs to purchase and use Defendant Abbott's contaminated powdered infant formula in lieu of safer alternative infant formulas, and in ways that created unreasonably dangerous risks to the health of A.B., a Minor.

96. At all relevant times, Defendant Abbott's corporate officers, directors, and managing agents knew of and ratified the acts of Defendant Abbott as alleged herein.

97. As a direct and proximate result of Defendant Abbott's negligent misrepresentations and omissions concerning the risk of harm associated with its contaminated Similac, Alimentum, and EleCare powdered infant formula, Plaintiffs suffered and will continue to suffer from injuries and damages for which they are entitled to recovery, including compensatory damages, consequential damages, interest, costs and attorneys' fees.

(F) BREACH OF EXPRESS WARRANTY

98. Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein.

99. Defendant Abbott, through its advertising and promotional materials, expressly warranted and affirmed that its powdered infant formula was safe for the uses for which they were intended and for uses which were reasonably foreseeable. Defendant Abbott's express warranties extended beyond delivery of the infant formula and expressly warranted the future performance of the powdered infant formula.

100. Defendant Abbott, through its advertisements, made express warranties to Plaintiffs Clarissa Ornelas and Anthony Bermudez, as well as to the public, that its powdered infant formula was safe to use and consume.

101. At all relevant times, Defendant Abbott breached these express warranties in that its powdered infant formula was unsafe for use and consumption because the powders were contaminated and therefore significantly increased the risk of becoming infected with *Cronobacter* and/or *Salmonella*.

102. At all relevant times, Defendant Abbott had knowledge of the hazards and health risks posed by using and consuming its contaminated Similac, Alimentum, and EleCare powdered infant formula.

103. At all relevant times, Defendant Abbott willfully failed to disclose the defects and health risks associated with the consumption of its contaminated Similac, Alimentum, and EleCare powdered infant formula to Plaintiffs Clarissa Ornelas and Anthony Bermudez, and the consuming public.

104. At all relevant times, in reliance upon the express warranties made by Defendant Abbott, Plaintiffs Clarissa Ornelas and Anthony Bermudez purchased, received and fed Defendant Abbott's contaminated powdered infant formula to A.B., a Minor, believing that it was safe.

105. As a direct and proximate result of Defendant Abbott's express warranties concerning its contaminated Similac, Alimentum, and EleCare powdered infant formula as described herein, Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, suffered and will continue to suffer from injuries and damages for which they are entitled to a recovery, including compensatory damages, consequential damages, interest, costs and attorneys' fees.

(G) BREACH OF IMPLIED WARRANTY

106. Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein.

107. At the time Defendant Abbott manufactured, marketed, labeled, promoted, distributed, and sold its contaminated Similac, Alimentum, and EleCare powdered infant formula, Defendant Abbott knew of the uses for which the powdered infant formula was intended, and impliedly warranted the powdered infant formula was merchantable and fit for the ordinary purposes for which it was intended.

108. At the time it left Defendant Abbott's possession, the contaminated Similac, Alimentum, and EleCare powdered infant formula was not merchantable or fit for its ordinary purpose because it had a propensity to lead to the serious injuries described herein.

109. Members of the consuming public, including consumers such as Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, were intended beneficiaries and third-party beneficiaries of this warranty.

110. Plaintiffs Clarissa Ornelas and Anthony Bermudez reasonably relied on representations that the powdered infant formula was safe and free of defects.

111. Defendant Abbott's breach of the implied warranty of merchantability and fitness for a particular purpose was the direct and proximate cause of Plaintiffs' injuries.

112. As a direct and proximate result of Defendant Abbott's breach of implied warranties concerning its contaminated Similac, Alimentum, and EleCare powdered infant formula, as described herein, Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, suffered and will continue to suffer from injuries and damages for which they are entitled to recovery, including compensatory damages, consequential damages, interest, costs and attorneys' fees.

(H) VIOLATION OF THE TEXAS DECEPTIVE TRADE PRACTICES-CONSUMER PROTECTION ACT, TEX. BUS. & COM. CODE § 17.41 ET. SEQ.

113. Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein.

114. Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, are consumers under the Deceptive Trade Practices Act ("DTPA") because Plaintiffs are individuals who acquired goods by purchase. Defendant Abbott is a corporation that can be sued under the DTPA. Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, purchased and used Defendant Abbott's contaminated powdered infant formula for personal use and thereby suffered ascertainable losses, including mental anguish, as a result of Defendant Abbott's acts and omissions in violation of the DTPA.

115. Defendant Abbott violated the DTPA when Defendant engaged in false, misleading or deceptive practices that Plaintiff relied on to Plaintiffs' detriment. Specifically, Defendant engaged in the following acts or practices proscribed by law:

a. Representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;

b. Advertising goods or services with the intent not to sell them as advertised;

c. Failing to disclose information concerning goods or services which was known at the time of the transaction when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed;

d. Engaging in fraudulent or deceptive conduct that created a likelihood of confusion or misunderstanding;

e. Engaging in an unconscionable action or course of action that, to Plaintiff's detriment, took advantage of Plaintiff's lack of knowledge, ability, experience or capacity to a grossly unfair degree; and

f. Breached an implied warranty of merchantability and fitness for a particular purpose as set forth in Paragraph (G), above.

116. Defendant Abbott violated the DTPA's consumer protection laws through their use of false and misleading representations and omissions of material facts relating to the safety of its contaminated Similac, Alimentum, and EleCare powdered infant formula.

117. Defendant Abbott uniformly communicated the purported benefits of its contaminated Similac, Alimentum, and EleCare powdered infant formula while failing to disclose the serious and dangerous risk of using these products and the true state of the infant formula's safety, efficacy, and usefulness. Defendant Abbott made these representations to consumers, including Plaintiffs Clarissa Ornelas and Anthony Bermudez, in the marketing and advertising described herein. Defendant Abbott's

conduct in connection with its contaminated infant formula was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding because Defendant Abbott misleadingly, falsely, and deceptively represented and omitted numerous material facts regarding, among other things, the utility, benefits, safety, efficacy, and advantages of its contaminated Similac, Alimentum, and EleCare powdered infant formula, especially in light of their knowledge that the product they placed in the stream of commerce was contaminated with *Cronobacter* and/or *Salmonella*.

118. Additionally, Defendant Abbott's violation of these DTPA consumer protection laws were committed knowingly and intentionally; therefore, Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, should recover, in addition to the actual damages, treble damages as allowed by law.

119. Defendant Abbott's violation of consumer protection laws concerning its contaminated Similac, Alimentum, and EleCare powdered infant formula, as described herein, was a producing cause of Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor's, injuries and damages for which they are entitled to recover, including compensatory damages, consequential damages, treble damages, interest, costs and attorneys' fees.

(I) FRAUDULENT CONCEALMENT

120. Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein.

121. Prior to Plaintiff Clarissa Ornelas and Anthony Bermudez's purchase and use of the contaminated powdered infant formula, and during the period in which they actually used the contaminated powdered infant formula, Defendant Abbott fraudulently suppressed material information regarding the safety and efficacy of the powdered infant formula, including but not limited to information concerning the powdered infant formula's contamination. The fraudulent misrepresentations and fraudulent concealment described throughout this Complaint were intentional and intended maintain the sales volumes of Defendant Abbott's powdered infant formula.

122. Defendant Abbott intentionally concealed safety issues with its contaminated Similac, Alimentum, and EleCare powdered infant formula in order to induce consumers, including Plaintiffs Clarissa Ornelas and Anthony Bermudez, to purchase and obtain the powdered infant formula.

123. At the time Defendant Abbott concealed the fact that the contaminated Similac, Alimentum, and EleCare powdered infant formula was not safe as manufactured and marketed, it was under a duty to communicate this information to the general public in such a manner that the general public could appreciate the risks associated with using the powdered infant formula.

124. Plaintiffs Clarissa Ornelas and Anthony Bermudez relied upon Defendant Abbott's false and fraudulent misrepresentations and concealments regarding the safety of its powdered infant formula.

125. As a direct and proximate result of Defendant Abbott's malicious and intentional concealment of material and information, Defendant Abbott caused or significantly contributed to Plaintiffs' injuries.

126. Defendant Abbott furthered this fraudulent concealment through a continued and systematic failure to disclose information to Plaintiffs Clarissa Ornelas and Anthony Bermudez, and the public.

127. Defendant Abbott's acts, before, during and after the acts and omissions which caused Plaintiffs' injuries, prevented Plaintiffs from discovering the injury or cause thereof.

128. Defendant Abbott's conduct as described in the preceding paragraphs amounts to conduct purposely committed, which Defendant Abbott must have realized was dangerous, needless, and reckless, without regard to the consequences or the rights and safety of Plaintiffs Clarissa Ornelas, Anthony Bermudez, and their infant son, A.B..

129. As a direct and proximate result of Defendant Abbott's fraudulent concealment concerning the contaminated Similac, Alimentum, and EleCare powdered infant formula as described herein, Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, suffered and will continue to suffer

injuries and damages for which recovery is entitled, including compensatory damages, consequential damages, interest, costs and attorneys' fees.

(J) GROSS NEGLIGENCE

130. Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein.

131. Defendant Abbott risked the lives of the consumers and users of its powdered infant formula, including A.B., a Minor, with knowledge of the infant formula's contamination and safety problems, and suppressed this knowledge from Plaintiffs Clarissa Ornelas, Anthony Bermudez and the general public. Defendant Abbott made conscious decisions not to redesign, relabel, or withdraw its contaminated Similac, Alimentum, and EleCare powdered infant formula, and not to warn or inform Plaintiffs or the unsuspecting consuming public about the risks posed by its contaminated Similac, Alimentum, and EleCare powdered infant formula.

132. Defendant Abbott's conduct, as described herein, was outrageous and involved an extreme risk of harm, serious injury, and death to others.

133. Despite its knowledge of this extreme risk of harm, Defendant Abbott nevertheless persisted and proceeded in performing the acts and omissions described herein with a conscious indifference to, and with reckless disregard of, the rights, safety or welfare of others.

134. Defendant Abbott's extreme and outrageous conduct warrants exemplary damages.

135. Defendant Abbott's gross negligence was a proximate cause of Plaintiffs' injuries and damages. Accordingly, Defendant Abbott was grossly negligent, and Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, are entitled to recover exemplary damages in an amount sufficient to punish Defendant Abbott and deter others from engaging in similar conduct.

(K) UNJUST ENRICHMENT

136. Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein.

137. Defendant Abbott profited unjustly from the sale of contaminated Similac, Alimentum, and EleCare powdered infant formula as a result of concealing its knowledge that the powdered infant formula posed a serious health risk to consumers.

138. As a proximate result of their wrongful acts and omissions described herein, and as a result of their ill-gotten benefits and profits, Defendant Abbott has been unjustly enriched at the expense of Plaintiffs and other purchasers of the contaminated Similac, Alimentum, and EleCare powdered infant formula.

139. The circumstances as described herein are such that it would be inequitable for Defendant Abbott to retain these ill-gotten benefits and profits without paying the

value thereof to Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, and the other purchasers of contaminated Similac, Alimentum, and EleCare powdered infant formula.

140. Plaintiff Ornelas is entitled to restitution of the amount of Defendant Abbott's ill-gotten gains, benefits, and profits, including interest, resulting from the unlawful, unjust, and inequitable conduct described herein.

141. Accordingly, Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, seek an order establishing Defendant Abbott as the constructive trustee of the gains, benefits, and profits that served to unjustly enrich it, together with interest during the period in which Defendant Abbott has retained such benefits and profits, and requiring Defendant Abbott to disgorge those profits to Plaintiffs Clarissa Ornelas and Anthony Bermudez, as well as the other purchasers of the contaminated Similac, Alimentum, and EleCare powdered infant formula in a manner to be determined by the Court.

VI. INJURIES AND DAMAGES

142. The infant formula sold was defective, unreasonably dangerous, and a substantial factor in causing Plaintiffs' injuries.

143. As a direct and proximate result of the occurrence made the basis of this lawsuit, unreasonably dangerous conditions or products, and the negligent and/or grossly negligent acts or omissions of the Defendant set out above, Plaintiffs Clarissa Ornelas and Anthony Bermudez, individually and as Next Friend of A.B., a Minor,

suffered significant and life-altering personal injuries and damages for which they are entitled to monetary compensation, as set out further below, and which the jury deems just and fair, to include the following elements of damages which have occurred in the past and, in all reasonable probability, will be sustained in the future:

a. Medical care and expenses incurred in the past on behalf of A.B., a Minor. These expenses were incurred by Plaintiffs Clarissa Ornelas and Anthony Bermudez as Next Friends of A.B., a Minor, for A.B.'s injuries resulting from Defendant's acts and/or omissions, and such charges are reasonable and are usual and customary for such services;

b. Medical care and expenses that, in reasonable probability, will be incurred on behalf of A.B., a Minor, in the future from the time of trial until A.B., a Minor, reaches the age of eighteen years;

c. Medical care and expenses that, in reasonable probability, A.B., a Minor, will incur after he reaches the age of eighteen years;

d. Physical pain and mental anguish sustained by A.B., a Minor, in the past;

e. Physical pain and mental anguish, which, in reasonable probability, will be sustained by A.B., a Minor, in the future;

f. Physical impairment sustained in the past;

g. Physical impairment that, in reasonable probability, A.B., a Minor, will sustained in the future;

h. Loss of earning capacity sustained in the past;

i. Loss of earning capacity that, in reasonable probability, will be sustained in the future from the time of trial until A.B., a Minor reaches the age of eighteen years;

j. Loss of earning capacity that, in reasonable probability, will be sustained in the future after A.B., a Minor reaches the age of eighteen years.

k. Disfigurement sustained in the past; and

l. Disfigurement that, in reasonable probability, A.B., a Minor will sustain in the future.

144. Additionally, because A.B. was injured as a direct and proximate result of Defendant's gross negligence, Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, are entitled to recover exemplary damages from Defendant Abbott. *See* Tex. Civ. Prac. & Rem. Code Ann. §71.009.

VII. REQUEST FOR RELIEF

145. As a result of the foregoing, Plaintiffs requests that this Court enter a judgment in favor of Plaintiffs Clarissa Ornelas and Anthony Bermudez, Individually and as Next Friends of A.B., a Minor, and against Defendant Abbott for:

a. actual damages in such amount to be determined at trial;

b. exemplary damages sufficient to punish Defendant Abbott and deter it and others from future wrongful conduct;

c. treble damages as allowed by law;

d. attorneys' fees as allowed by law;

e. costs and expenses as allowed by law;

f. pre- and post-judgment interest as allowed by law; and

g. any other relief the Court may deem just and proper.

VIII. JURY TRIAL DEMANDED

146. Plaintiff demands a trial by jury on all claims so triable.

Dated: June 27, 2022.

Respectfully Submitted,

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