UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI

DANYELLE JACKSON, INDIVIDUALLY AND AS MOTHER AND GENERAL GUARDIAN OF C.J., A MINOR,	)	**Civil Action No.:** 4:22-cv-1193
	)	**JULY TRIAL DEMANDED**
Plaintiffs,	)	
v.	)	
WAL-MART, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiff Danyelle Jackson and Plaintiff C.J., pursuant to Fed. R. Civ. P. 17(c)(1)(A), by and through their undersigned counsel, bring this Complaint for damages against Defendant Wal-Mart, Inc. (hereinafter, "Wal-Mart" or "Defendant") and in support state the following:

1. This is an action brought on behalf of Plaintiffs, Danyelle Jackson (hereinafter, "Plaintiff Mother"), the natural and general guardian and mother of C.J. (hereinafter, "Plaintiff Child"), a minor, arising out of the failure of Defendant to warn about the dangers of prenatal exposure to Paracetamol, also known as Acetaminophen (hereinafter "APAP") and its propensity to cause autism spectrum disorder (hereinafter "ASD") in children. As a result, Plaintiffs have suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

2. Defendant entirely failed its duty to adequately warn of the hazards of prenatal exposure to APAP, which was a direct and proximate cause of Plaintiffs' injuries and associated damages.

STATEMENT OF PARTIES

3. At all material times Plaintiffs have been citizens and residents of Saint Charles County, Missouri, and the United States.

4. Wal-Mart is incorporated in Delaware, with its principal place of business in Arkansas.

5. Wal-Mart is a multinational company involved in the research, development, testing, manufacture, labeling, production, marketing, promotion, and/or sale of APAP through its over-the-counter store brand, "Equate" (hereinafter, the "Equate APAP").

6. Wal-Mart is individually, and jointly and severally liable to Plaintiffs for damages they suffered, arising from Defendant's design, manufacture, marketing, labeling, distribution, sale, and placement of the defective Equate APAP into the market, effectuated directly and indirectly through its agents, servants, employees, and/or owners, all acting within the course and scope of its agencies, services, employments, and/or ownership.

7. Wal-Mart is vicariously liable for the acts and/or omissions of its employees and/or agents, who were at all material times acting on behalf of Wal-Mart and within the scope of its employment or agency.

VENUE AND JURISDICTION

8. This Court has subject-matter jurisdiction under 28 U.S.C. § 1332(a), based on complete diversity of citizenship between Plaintiffs and Defendant. *See supra* ¶¶ 3–5.

9. The amount in controversy exceeds $75,000.

10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because the events or omissions giving rise to Plaintiffs' claims occurred in this judicial district.

11. Defendant has and continues to conduct substantial business in the State of Missouri and in this District, distributes the Equate APAP in this District, receives substantial compensation and profits from sales of the Equate APAP in this District, and has made material omissions and misrepresentations and breaches of warranties in this District, so as to subject Defendant to in personam jurisdiction in this District.

12. Defendant is registered to transact business in Missouri.

FACTS COMMON TO ALL COUNTS

APAP Is Marketed as the Safe Pain Reliever for Pregnant Women, but APAP Can Cause ASD in Children

13. APAP is widely used by pregnant women to relieve pain during the term of their pregnancy.

14. APAP was initially discovered in the late 1800's.

15. APAP was introduced to the US market in 1955 as the first aspirin-free pain reliever. APAP was originally marketed and sold as a product to reduce fever in children, packaged like a red fire truck with the slogan, "for little hotheads."

16. APAP is sold in billions of units annually in North America alone.

17. APAP has long been marketed as the safest, and the *only* appropriate, over-the-counter pain relief drug on the market for pregnant women.

18. More than 65% of women in the United States use APAP during pregnancy.

19. Based upon information and belief, a majority of women who use APAP during pregnancy do so electively for the treatment of headaches, muscle pain, back pain, and infection.

20. These pregnant women electively choose to take APAP because Defendant has marketed APAP as a safe pain reliever for pregnant women.

21. However, increasing experimental and epidemiological research shows that prenatal exposure to APAP alters fetal development, which significantly increases the risks of neurodevelopmental disorders, including but not limited to, autism spectrum disorder ("ASD") and attention-deficit/hyperactivity disorder ("ADHD").

22. The human brain is vulnerable and extremely sensitive in utero. Undisturbed development of the human brain in utero is vital to the health and wellness of a child's development.

23. During this sensitive time-period in utero, certain chemicals have been found to cause permanent brain injury at low exposure levels.

24. Once ingested by the mother, APAP is known to readily cross the placenta and blood-brain barrier.

25. ASD is a serious neurological and developmental disorder that affects how people interact with others, communicate, learn, and behave.

26. There are three functional levels of ASD, with Level 1 requiring support with activities of daily living, Level 2 requiring substantial support with activities of daily living, and Level 3 requiring very substantial support with activities of daily living.

27. Treatments for ASD include behavioral management therapy, cognitive behavior therapy, joint attention therapies, medications, occupational therapy, physical therapy, social skill training, and speech-language therapy. Treatment for ASD lasts a lifetime, as there is no cure.

28. ADHD is a chronic neurodevelopmental disorder resulting in attention difficulty, hyperactivity, and impulsiveness.

29. In or around 2018, the Center for Disease Control and Prevention ("CDC") found that 1 in 44 (2.3%) 8-year-old children have been diagnosed with ASD.

30. This represents an increase from a prior CDC finding that 1 in 68 U.S. children born in 2002 have ASD, which already represented a more than a 100% increase compared with children born a decade prior.

31. Parental awareness and changes in diagnoses do not account for the rapid rise in these diagnoses.

32. Rather, neurotic exposures, such as prenatal APAP exposure, explain a trending increase in diagnosis.

33. For years, the scientific community has published studies showing that prenatal ingestion of APAP can cause neurodevelopmental disorders, like ASD.

34. For instance, since 2013, there have been six European birth cohort studies, examining over 70,000 mother-child pairs, showing the association between prenatal use of APAP and the neurodevelopmental disorders of ASD and ADHD.

35. At this time, the overall body of scientific evidence shows that prenatal use of APAP can cause neurodevelopmental disorders, like ASD, in the child.

36. During all relevant times herein, Defendant was engaged in the business of manufacturing and selling the Equate APAP in the United States, and the weight of the scientific evidence available showed prenatal exposure to APAP significantly increases the risk of neurodevelopmental disorders in children exposed to APAP prenatally, including but not limited to ASD.

37. The scientific evidence regarding the risks of in utero exposure of APAP was available to Defendant, and Defendant knew or should have known that prenatal use of APAP can cause ASD or ADHD.

38. Based on information and belief, Defendant has concealed the prenatal APAP exposure-neurodevelopmental link from consumers, like Plaintiff Mother, in part by not reporting the link to the FDA, which relies on drug manufacturers to bring new information about a drug to the agency's attention.

39. Moreover, despite knowing that prenatal use of APAP can cause ASD, Defendant continues to market the Equate APAP as the safe pain reliever for pregnant women, making mothers believe they are choosing a safe drug for even minor aches, pains, and headaches.

Plaintiff Mother Took Equate APAP while Pregnant, and It Caused ASD in Plaintiff Child

40. Plaintiff Mother began using the Equate APAP in or around January 2014 when she was pregnant with her Plaintiff Child.

41. Over the course of her pregnancy, and during each trimester, Plaintiff Mother electively took the Equate APAP approximately once a week to treat headaches.

42. Plaintiff Mother believed it was safe for her to take the Equate APAP during her pregnancy.

43. There is no warning on the Equate APAP labels specifically addressing the risks of ASD if a mother ingests APAP while pregnant.

44. Had Plaintiff Mother known of the risk of taking APAP while pregnant, specifically that it could cause ASD in her child, she would not have taken the Equate APAP.

45. Plaintiff Child was born on September 4, 2014.

46. Plaintiff Mother started to have concerns about Plaintiff Child's development when he was around twenty-four months old and was still nonverbal.

47. Plaintiff Child was ultimately diagnosed with ASD in 2017.

48. Plaintiff Child's ASD puts an incredible strain on Plaintiff Mother.

49. For instance, Plaintiff Child requires significant accommodations at home and at school in order to be successful and communicate with others.

50. Plaintiff Mother has grave concerns for Plaintiff Child's future.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

51. Due to Defendant's acts of fraudulent concealment, Defendant is estopped from relying on any statutes of limitations or repose. Such acts include Defendant's intentional concealment from Plaintiff Mother and the general public that APAP is defective when there is prenatal exposure, while continuing to market the Equate APAP with the adverse effects described in this Complaint.

52. Given Defendant's affirmative actions of concealment by failing to disclose information about the defects known to them but not the public—information over which Defendant had exclusive control—and because Plaintiff Mother could not reasonably have known that the Equate APAP was defective, Defendant is estopped from relying on any statutes of limitations that might overwise be applicable to the claims asserted in this Complaint.

COUNT I: STRICT LIABILITY – FAILURE TO WARN

53. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

54. At the time of Plaintiffs' injuries, the Equate APAP was defective and unreasonably dangerous to foreseeable consumers, including Plaintiff Mother, because it lacked an adequate warning.

55. At all relevant times, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, labeling, selling, distributing, and promoting the Equate APAP, which was defective and unreasonably dangerous to consumers, including Plaintiff Mother, because it did not contain adequate warnings or instructions concerning the dangerous characteristics of ingesting APAP during pregnancy. These actions were under the ultimate control and supervision of Defendant. At all relevant times, Defendant registered, researched, manufactured, distributed, marketed, labeled, promoted, and sold the Equate APAP within this District and aimed the marketing at the ultimate consumer. Defendant was at all relevant times involved in the retail and promotion of the Equate APAP marketed and sold in this District.

56. Defendant had a duty to warn of the risks associated with the use of the Equate APAP.

57. The Equate APAP ingested by Plaintiff Mother during pregnancy was in the same or substantially similar condition as it was when it left possession of the Defendant.

58. Defendant expected and intended the Equate APAP to reach users such as Plaintiff Mother in the condition in which the Equate APAP was sold.

59. Plaintiff Mother did not materially alter the Equate APAP prior to ingestion.

60. Plaintiff Mother ingested the Equate APAP as indicated on the Equate APAP label.

61. Plaintiff Mother was unaware of the defects and dangers of the Equate APAP and was unaware that prenatal exposure increases the risk of brain and behavioral development of children in utero.

62. The labels on the Equate APAP to consumers lack any warning specific to pregnant women. The information that Defendant did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff Mother

to utilize the products safely and with adequate protection or decide to not ingest the Equate APAP at all.

63. This alleged failure to warn is not limited to the information contained on the Equate APAP's labeling. Defendant was able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with APAP through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But Defendant did not disclose these known risks through any medium.

64. At all relevant times, Defendant had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, and supply the Equate APAP; provide proper warnings for the Equate APAP; and take such steps as necessary to ensure the Equate APAP did not cause users and consumers, and their children, to suffer from unreasonable and dangerous risks. Defendant had a continuing duty to warn Plaintiff Mother of dangers associated with APAP. Defendant, as manufacturer, seller, and/or distributor of pharmaceutical medication, is held to the knowledge of an expert in the field.

65. At the time of manufacture, Defendant could have provided the warnings or instructions regarding the full and complete risks of the Equate APAP because Defendant knew or should have known of the unreasonable risks of ASD caused by prenatal exposure to and/or the use of such products.

66. At all relevant times, Defendant failed and deliberately refused to investigate, study, test, or promote the safety of the Equate APAP, or to minimize the dangers to consumers of the Equate APAP and to those who would foreseeably use or be harmed by the Equate APAP, including Plaintiffs.

67. Defendant failed to adequately warn consumers, like Plaintiff Mother, about the significant increased risk of neurodevelopmental disorders in children exposed to APAP prenatally, including but not limited to ASD.

68. Defendant failed to adequately inform reasonably foreseeable consumers, like Plaintiff Mother, of the proper usage of the Equate APAP.

69. Even though Defendant knew or should have known that APAP posed a grave risk of harm to Plaintiff Child, Defendant failed to exercise reasonable care to warn of the dangerous risks associated with use and prenatal exposure.

70. Plaintiff Mother was exposed to the Equate APAP without knowledge of its dangerous characteristics.

71. At all relevant times, Plaintiff Mother used and/or was exposed to the use of the Equate APAP while using it for its intended or reasonably foreseeable purposes, without knowledge of its dangerous characteristics.

72. Plaintiff Mother could not have reasonably discovered the defects and risks associated with the Equate APAP prior to or at the time of Plaintiff consuming APAP. Plaintiff Mother relied upon the skill, superior knowledge, and judgment of Defendant to know about and disclose serious health risks associated with using the Equate APAP.

73. If Plaintiff Mother had been properly warned of the defects, dangers, and risks associated with prenatal exposure to APAP, Plaintiff Mother would have utilized the Equate APAP safely and with adequate protection or would have decided to not ingest the Equate APAP at all.

74. Defendant is liable to Plaintiffs for injuries caused by Defendant's negligent or willful failure, as described above, to provide adequate warnings or other relevant information and

data regarding the appropriate use of the Equate APAP and the risks associated with the use of APAP.

75. As a direct and proximate result of Defendant placing defective Equate APAP into the stream of commerce, and Plaintiff Mother's ingestion of the Equate APAP during pregnancy, Plaintiff Child was exposed to APAP prenatally, causing him to develop ASD.

76. As a direct and proximate result of Defendant placing defective Equate APAP into the stream of commerce, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT II: NEGLIGENCE

77. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

78. Although Defendant had a duty to use reasonable care in testing, developing, designing, manufacturing, marketing, labeling, selling, distributing, promoting, and preparing written instructions and warnings for the Equate APAP, Defendant failed to do so.

79. Defendant, directly or indirectly, caused the Equate APAP to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff Mother. At all relevant times, Defendant registered, researched, manufactured, distributed, marketed, promoted, and sold the Equate APAP within this district and aimed at a consumer market within this district.

80. Defendant knew, or in the exercise of reasonable care should have known, that the Equate APAP was defectively and unreasonably designed and/or manufactured, and/or marketed, and was unreasonably dangerous and likely to injure persons that were prenatally exposed to them. Defendant knew or should have known that Plaintiff Mother was unaware of the dangers and

defects inherent in the Equate APAP when she was ingesting it during her pregnancy with Plaintiff Child.

81. At all relevant times, Defendant had a duty to exercise reasonable care in the marketing, advertisement, promotion, and sale of the Equate APAP. Defendant's duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the risks of using APAP during pregnancy and appropriate, complete, and accurate warnings concerning the potential adverse effects of APAP and, in particular, the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP.

82. At all relevant times, Defendant knew or, in the exercise of reasonable care, should have known of the hazards and dangers of APAP ingestion while pregnant and, specifically, the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP.

83. Defendant failed to provide any kind of warning to pregnant consumers, like Plaintiff Mother, about the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP.

84. Accordingly, at all relevant times, Defendant knew or, in the exercise of reasonable care, should have known that use of the Equate APAP could cause Plaintiffs' injuries, and thus, create a dangerous and unreasonable risk of injury to the users of these products, including Plaintiffs.

85. As such, Defendant breached its duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, testing, marketing, labeling, supply, promotion, advertisement, packaging, sale, and distribution of the Equate APAP, in that

Defendant manufactured and produced defective Equate APAP, which carries the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP; knew or had reason to know of the defects inherent in the Equate APAP; knew or had reason to know that a user's or consumer's use of the Equate APAP created a significant risk of harm and unreasonably dangerous side effects; and failed to prevent or adequately warn of these risks and injuries.

86. Defendant had a duty to disclose the truth about the risks associated with APAP in its promotional efforts outside of the context of labeling. Defendant was negligent in its promotion of APAP outside of the labeling context by failing to disclose material risk information as part of their promotion and marketing of the Equate APAP, including through the internet, television, and print advertisements.

87. Despite Defendant's ability and means to investigate, study, and test the Equate APAP and to provide adequate warnings, Defendant failed to do so. Indeed, Defendant wrongfully concealed information and further made false and/or misleading statements concerning the safety and use of APAP.

88. Defendant's negligence included:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing the Equate APAP while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of APAP and the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP, and, consequently, the risk of serious harm associated with human use of APAP during pregnancy;

b. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not the Equate APAP was safe for its intended consumer use and unborn children;

c. Failing to provide adequate instructions, guidelines, and safety precautions to those persons Defendant could reasonably foresee would use the Equate APAP;

d. Failing to disclose to Plaintiff Mother, users, consumers, and the general public that use of APAP during pregnancy presents severe risks of neurodevelopmental disorders in children exposed to APAP prenatally;

e. Failing to warn Plaintiff Mother, users, consumers, and the general public that the Equate APAP's risk of harm was unreasonable and that there were safer and effective alternative medications or treatments available to Plaintiff Mother and other users and/or consumers;

f. Representing that the Equate APAP was safe for its intended purposes for pregnant women when, in fact, Defendant knew or should have known the Equate APAP was not safe for its intended purposes;

g. Declining to make or propose any changes to the Equate APAP's labeling or other promotional materials that would alert users, consumers, and the general public of the risks of APAP, including to pregnant women;

h. Advertising, marketing, and recommending the use of the Equate APAP, while concealing and failing to disclose or warn of the dangers known by Defendant to be caused by the use of or exposure to APAP;

i. Continuing to disseminate information to its consumers and the general public, which indicates or implies that the Equate APAP is not unsafe for pregnant consumer use; and

j. Continuing the manufacture and sale of the Equate APAP with the knowledge that the Equate APAP was unreasonably unsafe and dangerous.

89. Defendant knew and/or should have known that it was foreseeable that children such as Plaintiff Child would suffer injuries as a result of Defendant's failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of the Equate APAP to consumers, like Plaintiff Mother.

90. Plaintiff Mother did not know the nature and extent of the injuries that could result in her child from the intended use of and/or exposure to APAP prenatally.

91. Defendant's negligence was the proximate cause of Plaintiffs' injuries, i.e., absent Defendant's negligence, Plaintiff Child would not have developed ASD.

92. Defendant's conduct, as described above, was reckless. Defendant regularly risked exposing Plaintiff Mother to the Equate APAP while pregnant with Plaintiff Child, with full knowledge of the dangers of the Equate APAP and that it could cause ASD in Plaintiff Child. Defendant made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting public, including Plaintiff Mother. Defendant's reckless conduct therefore warrants an award of punitive damages.

93. As a direct and proximate result of Defendant placing the defective Equate APAP into the stream of commerce, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT III: BREACH OF EXPRESS WARRANTY

94. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

95. At all material times, Defendant manufactured, marketed, sold, distributed, and otherwise placed into the stream of commerce the Equate APAP. These actions were under the ultimate control and supervision of Defendant.

96. In advertising, marketing, and promoting the Equate APAP to consumers, like Plaintiff Mother, Defendant expressly warranted that the Equate APAP was safe for use and reasonably fit for their intended purposes. In advertising, marketing, and otherwise promoting the Equate APAP, Defendant intended for pregnant consumers to rely upon its representations regarding safety and fitness, in an effort to induce them to purchase and consume the Equate APAP during pregnancy to relieve pain.

97. Defendant expressly warranted to Plaintiff Mother and pregnant consumers that the Equate APAP was safe for ingestion during pregnancy.

98. Defendant had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of the Equate APAP, including a duty to:

a. ensure that the Equate APAP did not cause users and their unborn children unreasonably dangerous side effects;

b. warn of dangerous and potentially incurable side effects; and

c. disclose adverse material facts, such as the true risks associated with the use of and exposure to APAP during pregnancy, when making representations to users, consumers, and the general public, including Plaintiff Mother.

99. Defendant had the ability to properly disclose the risks associated with APAP usage during pregnancy through multiple channels, not just labeling.

100. At all relevant times, Defendant expressly represented and warranted to the purchasers of the Equate APAP, by and through statements made by Defendant in labels, publications, brochures, and other written materials intended for consumers and the general public, that the Equate APAP was safe to human health and the environment, effective, fit, and proper for its intended use. Defendant advertised, labeled, marketed, and promoted the Equate APAP, representing the quality to consumers and the public in such a way as to induce their purchases or use, thereby making an express warranty that the Equate APAP would conform to the representations.

101. The representations about the Equate APAP, as set forth herein, contained or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

102. Defendant breached express representations and warranties made to Plaintiff Mother, with respect to the Equate APAP, including the following:

a. Defendant represented through its labeling, advertising, and marketing materials that the Equate APAP was safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of APAP and by expressly limiting the risks associated with use within its warnings and labels; and

b. Defendant represented that the Equate APAP was safe for use and intentionally concealed information that demonstrated that APAP carries the significantly increased risk of causing neurodevelopmental disorders in children through

prenatal exposure to APAP, and that the Equate APAP, therefore, was not safer than alternatives available on the market.

103. Plaintiff Mother detrimentally relied on the express warranties and representations of Defendant concerning the safety and/or risk profile of APAP in deciding to purchase the Equate APAP. Plaintiff Mother reasonably relied upon Defendant to disclose known defects, risks, dangers, and side effects of APAP. Plaintiff Mother would not have purchased or used the Equate APAP had Defendant properly disclosed the risks associated with the Equate APAP, either through advertising, labeling, or any other form of disclosure.

104. Plaintiff Mother had no knowledge of the falsity or incompleteness of Defendant's statements and representations concerning the Equate APAP.

105. Plaintiff Mother used and/or was exposed to APAP as researched, developed, designed, tested, manufactured, inspected, labeled, distributed, packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by Defendant.

106. Had the warnings, labels, advertisements, or promotional material for the Equate APAP accurately and adequately set forth the true risks associated with the use of such Products, including Plaintiffs' injuries, rather than expressly excluding such information and warranting that the Equate APAP was safe for their intended use, Plaintiffs could have avoided the injuries complained of herein.

107. As a direct and proximate result of Defendant's breach of express warranty, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT IV: BREACH OF IMPLIED WARRANTY

108. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

109. At all material times, Defendant manufactured, marketed, sold, distributed, and otherwise placed the Equate APAP into the stream of commerce.

110. At all material times, Defendant intended for the Equate APAP to be consumed and ingested by pregnant women, like Plaintiff Mother; and Defendant impliedly warranted that the Equate APAP and its component parts were of merchantable quality, safe, fit for such use, and adequately tested.

111. Defendant was aware that consumers, including Plaintiff Mother, would consume and ingest the Equate APAP as directed by the Products' labels and promotional materials. Therefore, Plaintiff was a foreseeable user of the Equate APAP.

112. But Defendant failed to disclose that APAP has dangerous propensities when used as intended and that use of the Equate APAP carries an increased risk of developing severe injuries, including Plaintiff Child's injuries.

113. The Equate APAP was expected to reach, and did in fact reach consumers, including Plaintiff Mother, without substantial change in the condition in which it was manufactured and sold by Defendant.

114. Plaintiff Mother was an intended beneficiary of the implied warranties made by Defendant to purchasers of the Equate APAP.

115. In reliance upon Defendant's implied warranties, Plaintiff Mother used the Equate APAP as indicated, and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.

116. Defendant breached its implied warranties to Plaintiffs in that the Equate APAP was not of merchantable quality, nor was it safe or fit for its intended use or adequately tested.

117. The harm caused by the Equate APAP far outweighed its benefit, rendering the Equate APAP more dangerous than an ordinary consumer or user would expect and more dangerous than alternative products.

118. As a direct and proximate result of Defendant's breach of express warranty, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT V: VIOLATION OF CONSUMER PROTECTION LAWS

119. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

120. Plaintiff Mother purchased and used the Equate APAP for primarily personal use and pain relief during pregnancy, thereby suffering ascertainable losses as a result of Defendant's actions in violation of the consumer protection laws.

121. Had Defendant not engaged in the deceptive conduct described in this Complaint, Plaintiff would not have purchased and/or paid for the Equate APAP, and Plaintiffs would not have incurred related injury medical costs.

122. Defendant engaged in wrongful conduct while at the same time obtaining under false pretenses moneys from Plaintiff for the Equate APAP. Those moneys would not have been paid had Defendant not engaged in unfair and deceptive conduct.

123. Defendant engaged in the following unfair methods of competition or deceptive acts or practices, which are proscribed by law:

A. representing that goods or services have characteristics, ingredients, uses, benefits, or qualities they do not have;

B. advertising goods or services with the intent not to sell them as advertised; and

C. engaging in fraudulent or deceptive conduct creating a likelihood of confusion or misunderstanding.

124. Plaintiffs were injured by the cumulative nature of Defendant's conduct. The cumulative effect, directed at patients, physicians, and consumers, was to create demand for and sell the Equate APAP. Each aspect of Defendant's conduct combined to artificially create sales of the Equate APAP.

125. Defendant had a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Equate APAP.

126. Defendant's deceptive, unconscionable, or fraudulent representations and material omissions to consumers, including Plaintiff Mother, constitute unfair and deceptive acts and trade practices in violation of the federal and state consumer protection statutes listed below.

127. Defendant's actions, as complained of in this Complaint, constitute unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in violation of the federal and state consumer protection statutes listed below.

128. Defendant has engaged in unfair competition, or unfair or deceptive acts or trade practices, or has made false representations under the following statutes:

- 15 U.S.C. §§ 2301–12 (1982); and
- Mo. Rev. Stat. §§ 407.010, *et seq.*

129. To protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising, Defendant, as the supplier, manufacturer, advertiser, and seller, is subject to liability under the above legislation enacted against unfair, deceptive, fraudulent, and unconscionable consumer sales practices.

130. By knowingly and falsely representing that the Equate APAP was fit to be used for the purposes for which it was intended—when in fact it was defective and dangerous—and by other acts alleged, Defendant violated the above statutes, enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising.

131. Defendant's actions and omissions are uncured or incurable, deceptive acts under the above legislation.

132. Defendant had actual knowledge of the defective and dangerous conditions of the Equate APAP but failed to take any action to cure such defective and dangerous conditions.

133. Plaintiff Mother relied upon Defendant's misrepresentations and omissions in determining which Equate APAP (if any) to ingest.

134. Defendant's deceptive, unconscionable, or fraudulent representations and material omissions to consumers constituted unfair and deceptive acts and practices.

135. By reason of the unlawful acts in which Defendant engaged, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

136. As a direct and proximate result of Defendant's violations of the above-listed legislation, Plaintiffs have sustained economic losses and other damages and are entitled to statutory and compensatory damages in an amount to be proven at trial.

COUNT VI: NEGLIGENT MISREPRESENTATION

137. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

138. Defendant had a duty to accurately and truthfully represent to consumers, including Plaintiff Mother, and the public that the Equate APAP had not been adequately tested and found to be a safe and effective treatment for pregnant women. Defendant breached that duty as its representations were false.

139. Defendant failed to exercise ordinary care in the representations concerning the Equate APAP while Defendant was involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendant negligently misrepresented the Equate APAP's high risk of unreasonable and dangerous adverse side effects.

140. Defendant also breached its duty in representing to Plaintiff Mother that the Equate APAP had no serious side effects when ingested during pregnancy.

141. As a foreseeable, direct, and proximate result of Defendant's negligent misrepresentations, Defendant knew or had reason to know that the Equate APAP had been insufficiently tested or had not been tested at all; and that it lacked adequate and accurate warnings, and created a high risk, or a higher than acceptable reported and represented risk, of adverse side effects. Those side effects include neurodevelopmental disorders in children, such as ASD.

142. As a direct and proximate result of Defendant's breach of express warranty, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

PUNITIVE DAMAGES

143. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

144. Defendant failed to adequately test and study the Equate APAP to determine and ensure that the Equate APAP was safe and effective prior to releasing it for sale for human consumption.

145. Further, Defendant continued to manufacture and sell the Equate APAP after obtaining knowledge and information that it was defective and unreasonably unsafe in that it did not include adequate warnings.

146. Defendant was aware of the probable consequences of the dangerous and defective product, including the risk of neurodevelopmental disorders in children, such as ASD, when they suffered prenatal exposure.

147. At all material times, Defendant knew or should have known that the Equate APAP was inherently dangerous with respect to the following: the risk of neurodevelopmental disorders in children, such as ASD, when they suffered prenatal exposure; pain and suffering; loss of life's enjoyment; and unsuccessful treatments to cure the conditions proximately related to the use of the Equate APAP, as well as the other permanent and lasting severe personal injuries.

148. Defendant's misrepresentations included knowingly withholding material information from consumers and the public, including Plaintiff Mother, concerning the safety and efficacy of the Equate APAP, which deprived Plaintiff Mother of vitally necessary information with which to make a fully informed decision about whether to use the Equate APAP.

149. At all material times, Defendant also knew and recklessly and/or intentionally disregarded the fact that the Equate APAP can cause debilitating and life-altering side effects with greater frequency than safer alternative methods, products, and/or treatments. But Defendant recklessly failed to advise the medical community and the general public, including Plaintiff Mother, of that fact.

150. At all material times, Defendant intentionally misstated and misrepresented data; and Defendant continues to misrepresent data so as to minimize the perceived risk of injuries and the rate of complications caused by or associated with the Equate APAP.

151. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true and defective nature of the Equate APAP, with its increased risk of side effects and serious complications, Defendant continues to aggressively market the Equate APAP to consumers, including the pregnant community at large, without disclosing the true risk of the complications and side effects.

152. When Plaintiff Mother consumed the Equate APAP and since then, Defendant has known the Equate APAP was defective and unreasonably dangerous without an adequate warning. But Defendant continued to manufacture, produce, assemble, market, distribute, and sell the Equate APAP to the pregnant community so as to maximize sales and profits at the expense of the health and safety of expecting mothers in a conscious, reckless, and/or intentional disregard of the likely and foreseeable harm caused by the Equate APAP to members of the public, including Plaintiffs.

153. At all material times, Defendant has concealed and/or failed to disclose to the public the serious risks and the potential complications associated with the Equate APAP, so as to ensure continued and increased sales and profits and to the detriment of the public, including Plaintiffs.

154. Defendant's acts and omissions are of such character and nature so as to entitle Plaintiffs to an award of punitive damages in accordance with applicable statutory and common law. Defendant's conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care, raising the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendant individually, and jointly and severally. Plaintiffs also request compensatory damages, punitive damages, or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

Plaintiffs demand judgment against Defendant, individually, and jointly and severally, and prays for the following relief in accordance with applicable law and equity:

i. Compensatory damages to Plaintiffs for past, present, and future damages, including pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;

ii. Restitution and disgorgement of Defendant's profits;

iii. Punitive or enhanced compensatory damages;

iv. Reasonable attorneys' fees as provided by law;

v. Past and future costs of all proceedings;

vi. All ascertainable economic damages;

vii. Prejudgment interest on all damages as allowed by law; and

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

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all issues so triable.

Respectfully submitted,

/s/ Lindsey N. Scarcello
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