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 ATTORNEYS FOR PLAINTIFFS

**UNITED STATES DISTRICT COURT
 CENTRAL DISTRICT OF CALIFORNIA**

**NATASHA ANTOINETTE GAMEROZ,
 INDIVIDUALLY AND AS GUARDIAN AD
 LITEM OF M.A.G., MINOR**

Plaintiff(s),

v.

**CVS PHARMACY, INC. and RITE AID,
 CORP.,**

Defendants.

Civil Action No.:

COMPLAINT & JURY DEMAND

DEMAND FOR JURY TRIAL

PLAINTIFFS' ORIGINAL COMPLAINT AND JURY DEMAND

Plaintiff Natasha Antoinette Gameroz, individually and as representative of M.A.G., a minor, pursuant to Fed. R. Civ. P. 17(c)(1)(A), by and through their undersigned counsel, bring this Complaint for damages against Defendants CVS Pharmacy Inc. and Rite Aid, Corp., (hereinafter, "Defendants") and in support, state the following:

1. This is an action brought on behalf of Plaintiffs, Natasha Antoinette Gameroz (hereinafter, "Plaintiff Mother"), the natural and general guardian and mother of M.A.G. (hereinafter, "Plaintiff Child"), a minor, arising out of the failure of Defendants to warn about the dangers of prenatal exposure to Paracetamol, also known as Acetaminophen (hereinafter "APAP"). 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. Defendants entirely failed their 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 Orange, County, California.

4. CVS Pharmacy, Inc. is incorporated in Delaware with its principal place of business in Woonsocket, Rhode Island.

5. Rite Aid, Corp. is incorporated in Delaware with its principal place of business in Camp Hill, Pennsylvania.

6. CVS Pharmacy, Inc. is involved in the research, development, testing, manufacture, labeling, production, marketing, promotion, and/or sale of APAP through its over-the-counter store brand, CVS Health (hereinafter, the “APAP Products”).

7. Rite Aid is involved in the research, development, testing, manufacture, labeling, production, marketing, promotion, and/or sale of APAP through its over-the-counter store brand, Rite Aid Pharmacy (hereinafter, the “APAP Products”).

8. CVS Pharmacy, Inc. is individually, and jointly and severally liable to Plaintiffs for damages they suffered, arising from Each Defendant’s design, manufacture, marketing, labeling, distribution, sale, and placement of the defective APAP Products 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.

9. Rite Aid, Corp. is individually, and jointly and severally liable to Plaintiffs for damages they suffered, arising from Each Defendant’s design, manufacture, marketing, labeling, distribution, sale, and placement of the defective APAP Products 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.

10. CVS Pharmacy, Inc. 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 CVS Pharmacy, Inc. and within the scope of its employment or agency.

11. Rite Aid, Corp. 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 Rite Aid, Corp. and within the scope of its employment or agency.

JURISDICTION and VENUE

12. This Court has subject-matter jurisdiction under 28 U.S.C. § 1332(a), based on complete diversity of citizenship between Plaintiffs and Defendants. *See supra* ¶¶ 3–4.

13. The amount in controversy exceeds \$75,000.

14. 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.

15. Defendants have conducted and continue to conduct substantial business in the State of California and in this District, distribute the APAP Products in this District, receive substantial compensation and profits from sales of the APAP Products in this District, and have made material omissions and misrepresentations and breaches of warranties in this District and caused injuries in this District to Plaintiffs, among others, so as to subject Defendants to in personam jurisdiction in this District. It was foreseeable at all times that Defendants could be haled into court in the State of California for their conduct that caused injuries to citizens of California, like Plaintiffs in this action. An exercise of in personam jurisdiction by this Court over Defendants comports fully with due process and does not offend traditional notions of fair play and substantial justice.

16. Defendants are registered to transact business in California.

FACTS COMMON TO ALL COUNTS

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

ASD/ADHD in Children

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

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

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

4 20. Billions of units of APAP are sold annually in North America alone.

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

7 22. Forty to 65% of pregnant women in the United States use APAP during
8 pregnancy.

9 23. Based upon information and belief, a majority of women who use APAP during
10 pregnancy do so electively for the treatment of headaches, muscle pain, back pain, and
11 discomfort.

12 24. These pregnant women electively choose to take APAP because Defendants have
13 marketed APAP as a safe pain reliever for pregnant women.

14 25. However, scientific and epidemiological research shows that prenatal exposure
15 to APAP alters fetal development significantly increasing the risks of neurodevelopmental
16 disorders, including but not limited to, autism spectrum disorder (“ASD”) and attention-
17 deficit/hyperactivity disorder (“ADHD”).

18 26. Undisturbed development of the human brain in utero is vital to the health and
19 wellness of a child’s development. The human brain is vulnerable and extremely sensitive in
20 utero. During this sensitive time-period in utero, certain chemicals have been found to cause
21 permanent brain injury at low exposure levels.

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

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

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

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

5 31. ADHD is a chronic neurodevelopmental disorder resulting in attention difficulty,
6 hyperactivity, and impulsiveness.

7 32. ADHD begins in childhood and persists through adulthood. ADHD contributes
8 to low self-esteem, troubled relationships, and difficulty with school, work, and familial
9 relationships.

10 33. Treatments for ADHD, include, but are not limited to, chronic medication usage
11 and various therapies. Treatment for ADHD lasts a lifetime, as there is no cure.

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

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

17 36. As of 2019, 8.8% of children had been diagnosed with ADHD, or roughly
18 325,000 children per year.

19 37. Parental awareness and changes in diagnoses do not fully account for the rapid
20 rise in these diagnoses.

21 38. Rather, neurotoxic exposures, such as prenatal APAP exposure, partly explain a
22 trending increase in diagnoses.

23 39. For decades, beginning in 1987, the scientific community has published studies
24 showing that prenatal ingestion of APAP can cause ASD and ADHD.

25 40. A 2019 meta-analysis of studies from 1987 to 2016, with relative risks ranging
26 from 1.16 to 1.34, found statistically significant nineteen percent (19%) increased risk of ASD
27 in children whose mothers took APAP during pregnancy.
28

1 41. Since 2013, there have been six European birth cohort studies, examining over
2 70,000 mother-child pairs, showing the association between prenatal use of APAP and ASD and
3 ADHD, confirming the results of studies dating back to 1987.

4 42. The overall body of scientific evidence has shown for decades that prenatal use
5 of APAP can cause ASD and ADHD in the child.

6 43. During all relevant times herein, Defendants were engaged in the business of
7 manufacturing and selling the APAP Products in the United States, and the weight of the
8 scientific evidence available showed prenatal exposure to APAP significantly increases the risk
9 of neurodevelopmental disorders in children exposed to APAP prenatally, including but not
10 limited to ASD and ADHD.

11 44. At the time Plaintiff Mother was pregnant with Plaintiff Child the scientific
12 evidence regarding the risks of in utero exposure of APAP was available to Defendants, and
13 Defendants knew or should have known that prenatal use of APAP can cause ASD or ADHD.

14 45. Moreover, despite scientific evidence that prenatal use of APAP can cause ASD
15 or ADHD, Defendants continued and continue, to market APAP Products as safe pain relievers
16 for pregnant women, making mothers believe they are choosing a safe drug for even minor
17 aches, pains, and headaches.

18 **Plaintiff Mother Took APAP Products while Pregnant,**
19 **and It Caused ASD in Plaintiff Child**

20 46. Plaintiff Mother used APAP Products while she was pregnant with Plaintiff
21 Child.

22 47. During her pregnancy with Plaintiff Child, Plaintiff Mother took the APAP
23 Products approximately two to three times a week for pain and discomfort relief.

24 48. Plaintiff Mother believed it was safe for her to take APAP Products during her
25 pregnancy.

26 49. Indeed, Plaintiff Mother was instructed by her health care provider(s) to not take
27 ibuprofen or aspirin while pregnant but was informed she could take APAP freely without risk
28 to Plaintiff Child.

1 50. There is no warning on the APAP Products' labels specifically addressing the
2 risks of ASD if a mother ingests APAP while pregnant.

3 51. Had Plaintiff Mother known of the risk of ASD in her child from taking APAP
4 while pregnant, she would not have taken the APAP Products.

5 52. Plaintiff Child was born on April 27, 2012.

6 53. Plaintiff Mother started to have concerns about Plaintiff Child's development
7 when Plaintiff Child was one and a half years old. Specifically, at that time, Plaintiff Child
8 exhibited developmental delays, he would flail his arms, spin around, stare at things, would not
9 make eye contact, and would throw temper tantrums.

10 54. Plaintiff Child was diagnosed with autism when he was in the first grade.

11 55. Plaintiff Child exhibits development delays and is being provided an
12 individualized education plan for ASD from his school.

13 56. Plaintiff Child requires an immense amount of assistance to complete the normal
14 tasks of his daily life.

15 57. Plaintiff Child's ASD puts an incredible strain on Plaintiff Mother and their
16 family.

17 58. Plaintiff's Mother fears for Plaintiff Child and experiences substantial stress and
18 anxiety due to the challenges associated with Plaintiff Child's ASD.

19
20 **ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS**

21 59. Due to Defendants' acts of fraudulent concealment, Defendants are estopped
22 from relying on any statutes of limitations or repose. Such acts include Defendants' intentional
23 concealment from Plaintiff Mother and the general public that APAP is defective when there is
24 prenatal exposure, while continuing to market the APAP Products with the adverse effects
25 described in this Complaint.

26 60. Given Defendants' affirmative actions of concealment by failing to disclose
27 information about the defects known to it but not the public—information over which
28 Defendants had exclusive control—and because Plaintiff Mother could not reasonably have

1 known that the APAP Products were defective, Defendants are estopped from relying on any
2 statutes of limitations that might otherwise be applicable to the claims asserted in this
3 Complaint.

4 61. Plaintiffs, in any event, commenced this action within two years of discovering
5 or having reason to discover their causes of action.

6 **CLAIMS FOR RELIEF**

7 **COUNT I: STRICT LIABILITY – FAILURE TO WARN**

8 62. Plaintiffs restate, reallege, and incorporate by reference the allegations set forth
9 in the rest of this Complaint as if fully set forth herein.

10 63. At the time of Plaintiffs' injuries, the APAP Products were defective and
11 unreasonably dangerous to foreseeable consumers using the APAP Products in a foreseeable
12 manner during pregnancy, including Plaintiff Mother, because they lacked an adequate warning.

13 64. At all relevant times, Defendants engaged in the business of testing, developing,
14 designing, manufacturing, marketing, labeling, selling, distributing, and promoting the APAP
15 Products, which were defective and unreasonably dangerous to consumers, including Plaintiff
16 Mother, because they did not contain adequate warnings or instructions concerning the
17 dangerous characteristics of ingesting APAP during pregnancy. These actions were under the
18 ultimate control and supervision of Defendants. At all relevant times, Defendants registered,
19 researched, manufactured, distributed, marketed, labeled, promoted, and sold the APAP
20 Products within this District and aimed the marketing at the ultimate consumer. Defendants
21 were at all relevant times involved in the retail and promotion of the APAP Products marketed
22 and sold in this District.

23 65. Defendants had a duty to warn of the risks associated with the use of the APAP
24 products during pregnancy.

25 66. The APAP Products ingested by Plaintiff Mother during pregnancy were in the
26 same or substantially similar condition as they were when they left possession of the
27 Defendants.
28

1 67. Defendants expected and intended the APAP Products to reach users such as
2 Plaintiff Mother in the condition in which the APAP Products were sold.

3 68. Plaintiff Mother did not materially alter the APAP Products prior to ingestion.

4 69. Plaintiff Mother ingested the APAP Products during pregnancy as indicated on
5 the APAP Products' labels.

6 70. Plaintiff Mother was unaware of the defects and dangers of the APAP Products
7 during pregnancy and was specifically unaware that prenatal exposure increases the risk of brain
8 and behavioral development of children in utero.

9 71. The labels on the APAP Products to consumers lack any warning specific to
10 pregnant women. The information that Defendants did provide or communicate to consumers
11 failed to contain relevant warnings, hazards, and precautions that would have enabled
12 consumers such as Plaintiff Mother to utilize the products safely and with adequate protection
13 during pregnancy, or to decide to not use or ingest the APAP Products at all.

14 72. This alleged failure to warn is not limited to the information contained on the
15 APAP Products' labeling. Defendants were able, in accord with federal law, to comply with
16 relevant state law by disclosing the known risks associated with exposure to or use of APAP
17 during pregnancy through other non-labeling mediums, including, but not limited to, promotion,
18 advertisements, public service announcements, and/or public information sources. But
19 Defendants did not disclose these known risks through any medium.

20 73. At all relevant times, Defendants had a duty to properly test, develop, design,
21 manufacture, inspect, package, label, market, promote, sell, distribute, maintain, and supply the
22 APAP Products; provide proper warnings for the APAP Products; and take such steps as
23 necessary to ensure the APAP Products did not cause users and consumers, and their children,
24 to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn
25 Plaintiff Mother of dangers associated with exposure to or use of APAP during pregnancy.
26 Defendants, as manufacturers, sellers, and/or distributors of pharmaceutical medication, are held
27 to the knowledge of experts in the field.
28

1 74. At the time of manufacture, Defendants could have provided the warnings or
2 instructions regarding the full and complete risks of the APAP Products during pregnancy
3 because Defendants knew or should have known of the unreasonable risks of ASD and ADHD
4 associated with prenatal exposure to and/or the use of such products.

5 75. At all relevant times, Defendants failed and deliberately refused to investigate,
6 study, test, or promote the safety of the APAP Products, or to minimize the dangers to
7 consumers of the APAP Products and to those who would foreseeably use or be harmed by the
8 APAP Products, including Plaintiffs.

9 76. Defendants failed to adequately warn consumers, like Plaintiff Mother, about the
10 significant increased risk of neurodevelopmental disorders in children exposed to APAP
11 prenatally, including but not limited to ASD and ADHD.

12 77. Defendants failed to adequately inform reasonably foreseeable consumers, like
13 Plaintiff Mother, of the proper usage of the APAP Products.

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

17 79. Plaintiff Mother was exposed to the APAP Products during pregnancy without
18 knowledge of their dangerous characteristics.

19 80. At all relevant times, Plaintiff Mother used and/or was exposed to the use of the
20 APAP Products while using them for their intended or reasonably foreseeable purposes during
21 pregnancy, without knowledge of their dangerous characteristics.

22 81. Plaintiff Mother could not have reasonably discovered the defects and risks
23 associated with the APAP Products prior to or at the time of Plaintiff consuming APAP during
24 pregnancy. Plaintiff Mother relied upon the skill, superior knowledge, and judgment of
25 Defendants to know about and disclose serious health risks associated with using the APAP
26 Products.

27 82. If Plaintiff Mother had been properly warned of the defects, dangers, and risks
28 associated with prenatal exposure to APAP, Plaintiff Mother would have decided to not ingest

1 the APAP Products at all. Defendants' failure to properly warn of those defects, dangers, and
2 risks associated with prenatal exposure to APAP was a substantial factor in causing Plaintiffs'
3 injuries and damages.

4 83. Defendants are liable to Plaintiffs for injuries caused by Defendants' negligent or
5 willful failure, as described above, to provide adequate warnings or other relevant information
6 and data regarding the appropriate use of the APAP Products and the risks associated with the
7 use of APAP.

8 84. As a direct and proximate result of Defendants placing defective APAP Products
9 into the stream of commerce, and Plaintiff Mother's foreseeable use and ingestion of the APAP
10 Products during pregnancy, Plaintiff Child was exposed to APAP prenatally, causing him to
11 develop ASD.

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

16 **COUNT II: NEGLIGENCE**

17 86. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
18 set forth in the rest of this Complaint as if fully set forth herein.

19 87. Although Defendants had a duty to use reasonable care in testing, developing,
20 designing, manufacturing, marketing, labeling, selling, distributing, promoting, and preparing
21 written instructions and warnings for the APAP Products, Defendants failed to do so.

22 88. Defendants, directly or indirectly, caused the APAP Products to be sold,
23 distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff Mother. At all
24 relevant times, Defendants registered, researched, manufactured, distributed, marketed,
25 promoted, and sold the APAP Products within this district and aimed at a consumer market
26 within this district.

27 89. Defendants knew, or in the exercise of reasonable care should have known, that
28 the APAP Products were defectively and unreasonably designed and/or manufactured, and/or

1 marketed, and were unreasonably dangerous and likely to injure persons that were prenatally
2 exposed to them. Defendants knew or should have known that Plaintiff Mother was unaware of
3 the dangers and defects inherent in the APAP Products when she was ingesting them during her
4 pregnancy with Plaintiff Child.

5 90. At all relevant times, Defendants had a duty to exercise reasonable care in the
6 marketing, advertisement, promotion, and sale of the APAP Products. Defendants' duty of care
7 owed to consumers and the general public included providing accurate, true, and correct
8 information concerning the risks of using APAP during pregnancy and appropriate, complete,
9 and accurate warnings concerning the potential adverse effects of APAP and, in particular, the
10 significantly increased risk of causing neurodevelopmental disorders in children through
11 prenatal exposure to APAP.

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

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

19 93. Accordingly, at all relevant times, Defendants knew or, in the exercise of
20 reasonable care, should have known that use of the APAP Products during pregnancy could
21 cause Plaintiffs' injuries, and thus, create a dangerous and unreasonable risk of injury to the
22 users of these products, including Plaintiffs.

23 94. As such, Defendants breached their duty of reasonable care and failed to exercise
24 ordinary care in the design, research, development, manufacture, testing, marketing, labeling,
25 supply, promotion, advertisement, packaging, sale, and distribution of the APAP Products, in
26 that Defendants manufactured and produced defective APAP Products, which carry the
27 significantly increased risk of causing neurodevelopmental disorders in children through
28 prenatal exposure to APAP; knew or had reason to know of the defects inherent in the APAP

1 Products; knew or had reason to know that a user's or consumer's use of the APAP Products
2 during pregnancy created a significant risk of harm and unreasonably dangerous side effects;
3 and failed to prevent or adequately warn of these risks and injuries.

4 95. Defendants had a duty to disclose the truth about the risks associated with
5 exposure to or use of APAP during pregnancy in its promotional efforts outside of the context
6 of labeling. Defendants were negligent in their promotion of APAP outside of the labeling
7 context by failing to disclose material risk information as part of its promotion and marketing of
8 the APAP Products, including through the internet, television, and print advertisements.

9 96. Despite Defendants' ability and means to investigate, study, and test the APAP
10 Products and to provide adequate warnings regarding use during pregnancy, Defendants failed
11 to do so. Indeed, Defendants wrongfully concealed information and further made false and/or
12 misleading statements concerning the safety and use of APAP.

13 97. Defendants' negligence included:

- 14 a. Manufacturing, producing, promoting, formulating, creating, developing,
15 designing, selling, and/or distributing the APAP Products while negligently
16 and/or intentionally concealing and failing to disclose the results of trials,
17 tests, and studies of APAP and the significantly increased risk of causing
18 neurodevelopmental disorders in children through prenatal exposure to
19 APAP, and, consequently, the risk of serious harm associated with human
20 use of APAP during pregnancy; and
- 21 b. Failing to undertake sufficient studies and conduct necessary tests to
22 determine whether or not the APAP Products were safe for their intended
23 consumer use and unborn children; and
- 24 c. Failing to provide adequate instructions, guidelines, and safety precautions to
25 those persons Defendants could reasonably foresee would use the APAP
26 Products during pregnancy; and
- 27
28

- 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; and
- e. Failing to warn Plaintiff Mother, users, consumers, and the general public that the APAP Products' 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; and
- f. Representing that the APAP Products were safe for their intended purposes for pregnant women when, in fact, Defendants knew or should have known the APAP Products were not safe for their intended purposes; and
- g. Declining to make or propose any changes to the APAP Products' labeling or other promotional materials that would alert users, consumers, and the general public of the risks of APAP, including to pregnant women; and
- h. Advertising, marketing, and recommending the use of the APAP Products during pregnancy, while concealing and failing to disclose or warn of the dangers known by Defendants to be caused by the use of or exposure to APAP; and
- i. Continuing to disseminate information to its consumers and the general public, which indicates or implies that the APAP Products are not unsafe for pregnant consumer use; and
- j. Continuing the manufacture and sale of the APAP Products with the knowledge that the APAP Products were unreasonably unsafe and dangerous.

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

99. 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.

100. Defendants' negligence was a proximate cause of Plaintiffs' injuries, i.e., absent Defendants' negligence, Plaintiff Child would not have developed ASD. That negligence was a substantial factor in causing Plaintiffs' injuries and damages.

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

102. As a direct and proximate result of Defendants placing the defective APAP Products 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

103. Plaintiffs restate, reallege, and incorporate by reference each of the allegations set forth in the rest of this Complaint as if fully set forth herein.

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

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

106. Defendants expressly warranted to Plaintiff Mother and pregnant consumers that the APAP Products were safe for ingestion during pregnancy.

1 107. Defendants had a duty to exercise reasonable care in the research, development,
2 design, testing, packaging, manufacture, inspection, labeling, distributing, marketing,
3 promotion, sale, and release of the APAP Products, including a duty to:

- 4 a. ensure that the APAP Products during pregnancy did not cause users and
5 their unborn children unreasonably dangerous side effects; and
6 b. warn of dangerous and potentially incurable side effects; and
7 c. disclose adverse material facts, such as the true risks associated with the use
8 of and exposure to APAP during pregnancy, when making representations to
9 users, consumers, and the general public, including Plaintiff Mother.

10 108. Defendants had the ability to properly disclose the risks associated with APAP
11 usage during pregnancy through multiple channels, not just labeling.

12 109. At all relevant times, Defendants expressly represented and warranted to the
13 purchasers of the APAP Products, by and through statements made by Defendants in labels,
14 publications, brochures, and other written materials intended for consumers and the general
15 public, that the APAP Products were safe to human health and the environment, effective, fit,
16 and proper for their intended use during pregnancy. Defendants advertised, labeled, marketed,
17 and promoted the APAP Products, representing the quality to consumers and the public in such
18 a way as to induce their purchases or use during pregnancy, thereby making an express warranty
19 that the APAP Products would conform to the representations.

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

24 111. Defendants breached express representations and warranties made to Plaintiff
25 Mother, with respect to the APAP Products, including the following:

- 26 a. Defendants represented through their labeling, advertising, and marketing
27 materials that the APAP Products were safe for use during pregnancy, and
28 intentionally withheld and concealed information about the risks of serious

1 injury associated with use of APAP and by expressly limiting the risks
2 associated with use during pregnancy within its warnings and labels; and

3 b. Defendants represented that the APAP Products were safe for use and
4 intentionally concealed information that demonstrated that APAP carries the
5 significantly increased risk of causing neurodevelopmental disorders in
6 children through prenatal exposure to APAP, and that the APAP Products,
7 therefore, were not safer than alternatives available on the market.

8 112. Plaintiff Mother detrimentally relied on the express warranties and
9 representations of Defendants concerning the safety and/or risk profile of APAP during
10 pregnancy in deciding to purchase the APAP Products. Plaintiff Mother reasonably relied upon
11 Defendants to disclose known defects, risks, dangers, and side effects of APAP. Plaintiff
12 Mother would not have purchased or used the APAP Products during pregnancy had
13 Defendants properly disclosed the risks associated with the APAP Products, either through
14 advertising, labeling, or any other form of disclosure. Defendants' breach of the express
15 warranties and representations concerning the safety and/or risk profile of APAP during
16 pregnancy was a substantial factor in causing Plaintiffs' injuries and damages.

17 113. Plaintiff Mother had no knowledge of the falsity or incompleteness of
18 Defendants' statements and representations concerning the APAP Products and could not have
19 taken reasonable steps to notify Defendants of those matters or to seek repair or other remedies.

20 114. Plaintiff Mother used and/or was exposed to APAP during pregnancy as
21 researched, developed, designed, tested, manufactured, inspected, labeled, distributed,
22 packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by
23 Defendants.

24 115. Had the warnings, labels, advertisements, or promotional material for the APAP
25 Products accurately and adequately set forth the true risks associated with the use of such
26 Products during pregnancy, including Plaintiffs' injuries, rather than expressly excluding such
27 information, and warranting that the APAP Products were safe for their intended use, Plaintiffs
28 could have avoided the injuries complained of herein.

116. As a direct and proximate result of Defendants' 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

117. Plaintiffs restate, reallege, and incorporate by reference each of the allegations set forth in the rest of this Complaint as if fully set forth herein.

118. At all material times, Defendants manufactured, marketed, sold, distributed, and otherwise placed the APAP Products into the stream of commerce.

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

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

121. But Defendants failed to disclose that APAP has dangerous propensities when used as intended during pregnancy and that use of the APAP Products carries an increased risk of developing severe injuries, including Plaintiff Child's injuries.

122. The APAP Products were expected to reach, and did in fact reach consumers, including Plaintiff Mother, without substantial change in the condition in which they were manufactured and sold by Defendants.

123. Plaintiff Mother was an intended beneficiary of the implied warranties made by Defendants to purchasers of the APAP Products, including Plaintiff Mother.

124. In reliance upon Defendants' implied warranties, Plaintiff Mother purchased and used the APAP Products as indicated, and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants. The failure of the APAP Products to be of merchantable quality, to be safe or fit for their intended use, or to be adequately tested was a

substantial factor in causing Plaintiffs' injuries and damages.

125. Defendants breached their implied warranties to Plaintiffs in that the APAP Products were not of merchantable quality, nor were they safe or fit for their intended use or adequately tested.

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

127. As a direct and proximate result of Defendants' breach of implied warranties, 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

128. Plaintiffs restate, reallege, and incorporate by reference each of the allegations set forth in the rest of this Complaint as if fully set forth herein.

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

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

131. Defendants engaged in wrongful and unlawful conduct, while at the same time, obtaining under false pretenses moneys from Plaintiff Mother for the APAP Products. Those moneys would not have been paid had Defendants not engaged in unfair and deceptive conduct. Plaintiffs actually relied upon Defendants' misrepresentations and deception concerning the APAP Products.

132. Defendants 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.

133. Plaintiffs were injured by the cumulative nature of Defendants' conduct. The cumulative effect, directed at patients, physicians, and consumers, was to create demand for and sell the APAP Products. Each aspect of Defendants' conduct combined to artificially create sales of the APAP Products, including to Plaintiff Mother who did, in fact, purchase the APAP Products.

134. Defendants 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 APAP Products.

135. Defendants' 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.

136. Defendants' 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.

137. Defendants have 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);
- Cal. Bus. & Prof. Code § 17200, et seq.;
- Cal. Civ. Code § 1750 et seq.

138. To protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising, Defendants, as the suppliers, manufacturers,

1 advertisers, and sellers, are subject to liability under the above legislation enacted against unfair,
2 deceptive, fraudulent, and unconscionable consumer sales practices. The California Unfair
3 Competition Law (“UCL”) prohibits “any unlawful, unfair, or fraudulent business act or
4 practice and unfair, deceptive, untrue, or misleading advertising and any act prohibited by”
5 Section 17500 of the California Business and Professions Code. Section 17500, in turn,
6 prohibits any untrue or misleading statements made in connection with the sale of goods. The
7 Consumers Legal Remedies Act (“CLRA”) defines as statutorily unlawful certain unfair
8 methods of competition and unfair or deceptive practices. Cal. Civ. Code § 1750 et seq.

9 139. By knowingly and falsely representing that the APAP Products were fit to be
10 used for the purposes for which they were intended—when in fact they were defective and
11 dangerous when used during pregnancy—and by other acts alleged, Defendants violated the
12 above statutes, enacted to protect consumers against unfair, deceptive, fraudulent, and
13 unconscionable trade and business practices, and false advertising.

14 140. Defendants’ actions and omissions are uncured or incurable, deceptive acts under
15 the above legislation.

16 141. Defendants had actual knowledge of the defective and dangerous conditions of
17 the APAP products but failed to take any action to cure such defective and dangerous
18 conditions.

19 142. Plaintiff Mother relied upon Defendants’ misrepresentations and omissions in
20 determining which APAP Products (if any) to ingest.

21 143. Defendants’ deceptive, unconscionable, or fraudulent representations and
22 material omissions to consumers constituted unfair and deceptive acts and practices.

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

25 145. As a direct and proximate result of Defendants’ violations of the above-listed
26 legislation, Plaintiffs have sustained economic losses and other damages and are entitled to
27 statutory and compensatory damages, including restitution, in an amount to be proven at trial
28 and civil penalties as permitted by law.

COUNT VI: NEGLIGENT MISREPRESENTATION

146. Plaintiffs restate, reallege, and incorporate by reference each of the allegations set forth in the rest of this Complaint as if fully set forth herein.

147. Defendants had a duty to accurately and truthfully represent to consumers, including to Plaintiff Mother and to the public, that the APAP Products had not been adequately tested and found to be a safe and effective treatment for pregnant women. Defendants breached that duty as their representations of the safety of the APAP Products were false. Defendants intended for consumers like Plaintiff Mother to rely upon that representation, and Plaintiff Mother did justifiably rely on Defendants' misrepresentations concerning the APAP Products' high risk of unreasonable and dangerous adverse side effects when ingested or used during pregnancy.

148. Defendants failed to exercise ordinary care in the representations concerning the APAP Products while Defendants were involved in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the APAP Products' high risk of unreasonable and dangerous adverse side effects when ingested or used during pregnancy.

149. Defendants also breached their duty in representing to Plaintiff Mother that the APAP Products had no serious side effects when ingested during pregnancy. Defendants intended for consumers like Plaintiff Mother to rely upon that representation, and Plaintiff Mother did justifiably rely upon that representation.

150. Defendants knew or had reason to know that the APAP Products had been insufficiently tested or had not been tested at all; and that they 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 and ADHD. Thus, Defendants lacked reasonable ground for believing the representations to be true and intended for consumers like Plaintiff to rely upon those misrepresentations by purchasing the APAP products for use during pregnancy. Plaintiff Mother justifiably relied upon those misrepresentations in purchasing and using the APAP products

1 while pregnant. Defendants' negligent misrepresentation concerning the safety and/or risk
2 profile of using APAP during pregnancy was a substantial factor in causing Plaintiffs' injuries
3 and damages.

4 151. As a direct and proximate result of Defendants' negligent misrepresentation,
5 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress,
6 lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all
7 damages to which they may be legally entitled.

8 **PUNITIVE DAMAGES**

9 152. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
10 set forth in the rest of this Complaint as if fully set forth herein.

11 153. Defendants have acted with malice through despicable conduct that exhibits a
12 willful and conscious disregard for the rights and safety of others, including Plaintiffs, and has
13 acted with oppression in subjecting Plaintiffs to cruel and unjust hardship in conscious disregard
14 of their rights. Further, Defendants have intentionally misrepresented or concealed material
15 facts known to them with the intention of causing injury or otherwise depriving Plaintiffs of
16 their property or legal rights.

17 154. Defendants failed to adequately test and study the APAP Products to determine
18 and ensure that the APAP Products were safe and effective for use during pregnancy before
19 releasing them for sale for human consumption.

20 155. Further, Defendants continued to manufacture and sell the APAP Products and
21 marketed them as safe for use during pregnancy, even after obtaining knowledge and
22 information that the APAP Products were defective and unreasonably unsafe because they,
23 among other things, did not include adequate warnings.

24 156. Defendants were aware of the probable consequences of the dangerous and
25 defective product, including the risk of neurodevelopmental disorders in children, such as ASD
26 and ADHD, when they suffered prenatal exposure.

27 157. At all material times, Defendants knew or should have known that the APAP
28 Products were inherently dangerous with respect to the following: the risk of

1 neurodevelopmental disorders in children, such as ASD and ADHD, when they suffered
2 prenatal exposure; pain and suffering; loss of life's enjoyment; and unsuccessful treatments to
3 cure the conditions proximately related to the use of the APAP Products, as well as the other
4 permanent and lasting severe personal injuries.

5 158. Defendants knowingly withheld material information from consumers and the
6 public, including Plaintiff Mother, concerning the safety and efficacy of the APAP Products
7 during pregnancy, which deprived Plaintiff Mother of vitally necessary information with which
8 to make a fully informed decision about whether to use the APAP Products while pregnant.

9 159. At all material times, Defendants also knew and recklessly and/or intentionally
10 disregarded the fact that the APAP Products, when used during pregnancy, can cause
11 debilitating and life-altering side effects with greater frequency than safer alternative methods,
12 products, and/or treatments. But Defendants recklessly failed to advise the medical community
13 and the general public, including Plaintiff Mother, of that fact.

14 160. At all material times, Defendants intentionally misstated and misrepresented
15 data; and Defendants continue to misrepresent data so as to minimize the perceived risk of
16 injuries and the rate of complications caused by or associated with the APAP Products.

17 161. Notwithstanding the foregoing and the growing body of knowledge and
18 information regarding the true and defective nature of the APAP Products, with their increased
19 risk of side effects and serious complications, Defendants continue to aggressively market the
20 APAP Products to consumers, including the pregnant community at large, without disclosing
21 the true risk of the complications and side effects.

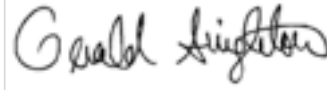
22 162. When Plaintiff Mother consumed the APAP Products and since then, Defendants
23 have known the APAP Products were defective and unreasonably dangerous without an
24 adequate warning. But Defendants continued to manufacture, produce, assemble, market,
25 distribute, and sell the APAP Products to the pregnant community so as to maximize sales and
26 profits at the expense of the health and safety of expecting mothers in a conscious, reckless,
27 and/or intentional disregard of the likely and foreseeable harm caused by the APAP Products to
28 members of the public, including Plaintiffs.

DEMAND FOR JURY TRIAL

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

Dated: October 10, 2022

Respectfully submitted,



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