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

14 CHIYAUKAA ARCHER, Individually and as
15 Guardian ad Litem to D.M., a minor,

16 Plaintiffs,

17 v.

18 WALMART INC., TARGET
19 CORPORATION, CVS PHARMACY INC.,
20 AND CVS HEALTH CORPORATION,

21 Defendants.

Case No. 8:22-cv-1644

ORIGINAL COMPLAINT

DEMAND FOR JURY TRIAL

22 **PLAINTIFFS' ORIGINAL COMPLAINT AND JURY DEMAND**

23 Plaintiff Chiyaukaa Archer and Plaintiff D.M., a minor, pursuant to Fed. R. Civ. P.
24 17(c)(1)(A), by and through their undersigned counsel, bring this Complaint for damages against
25 Defendants WALMART INC., TARGET CORP., CVS PHARMACY INC., AND CVS HEALTH
26 CORPORATION (hereinafter, "Defendant(s)") and in support, state the following:

27 1. This is an action brought on behalf of Plaintiffs, Chiyaukaa Archer (hereinafter,
28 "Plaintiff Mother"), the natural and general guardian and mother of D.M., a minor (hereinafter,
"Plaintiff Child"), a minor, arising out of the failure of Defendants to warn about the dangers of
prenatal exposure to Tylenol, also known as Acetaminophen (hereinafter "APAP"). As a result,
Plaintiffs have suffered permanent injuries and significant pain and suffering, emotional distress,

1 lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all
2 damages to which they may be legally entitled.

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

6 **STATEMENT OF PARTIES**

7 3. At all material times Plaintiffs have been citizens and residents of Brea, California,
8 and the United States.

9 4. Walmart Inc. is incorporated in Bentonville, Arkansas with its principal place of
10 business at 702 S.W. 8th Street, Bentonville Arkansas, 72716, USA.

11 5. Target Corp. is a Minnesota corporation with its principal place of business at 1000
12 Nicollet Mall, Minneapolis, Minnesota 55403.

13 6. CVS Pharmacy Inc. and CVS Health Corp. are incorporated in Delaware with their
14 principal places of business at 1 CVS Drive, Woonsocket, Rhode Island, 02895.

15 7. Walmart Inc., Target Corp., CVS Pharmacy Inc., and CVS Health Corp. are involved
16 in the research, development, testing, manufacture, labeling, production, marketing, promotion,
17 and/or sale of APAP through their over-the-counter store brands (hereinafter, the "APAP
18 Products").

19 8. Walmart Inc., Target Corp., CVS Pharmacy Inc., and CVS Health Corp. are
20 individually, and jointly and severally liable to Plaintiffs for damages they suffered, arising from
21 each of Defendant's design, manufacture, marketing, labeling, distribution, sale, and placement of
22 the defective APAP Products into the market, effectuated directly and indirectly through its agents,
23 servants, employees, and/or owners, all acting within the course and scope of its agencies, services,
24 employments, and/or ownership.

25 9. Walmart Inc., Target Corp., CVS Pharmacy Inc., and CVS Health Corp. are
26 vicariously liable for the acts and/or omissions of their employees and/or agents, who were at all
27 material times acting on their behalf and within the scope of their employment or agency.
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2 **VENUE, JURISDICTION, and DIVISIONAL ASSIGNMENT**

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

5 11. The amount in controversy exceeds \$75,000.

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

8 13. Each Defendant has and continues to conduct substantial business in the State of
9 California and in this District, distributes the APAP Products in this District, receives substantial
10 compensation and profits from sales of the APAP Products in this District, and has made material
11 omissions and misrepresentations and breaches of warranties in this District and caused injuries in
12 this District to Plaintiffs, among others, so as to subject each Defendant to in personam jurisdiction
13 in this District. It was foreseeable at all times that each Defendant could be haled into court in the
14 State of California for its conduct that caused injuries to citizens of California, like Plaintiffs in this
15 action. An exercise of in personam jurisdiction by this Court over each Defendant comports fully
16 with due process and does not offend traditional notions of fair play and substantial justice.

17 14. Each Defendant is registered to transact business in California.

18 **FACTS COMMON TO ALL COUNTS**

19 **APAP Is Marketed as the Safe Pain Reliever**

20 **for Pregnant Women, but APAP Can Cause ASD/ADHD in Children**

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

23 16. APAP was initially discovered in the late 1800’s.

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

27 18. Billions of units of APAP are sold annually in North America alone.

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

3 20. Forty to 65% of pregnant women in the United States use APAP during pregnancy.

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

6 22. These pregnant women electively choose to take APAP because Defendants have
7 marketed APAP as a safe pain reliever for pregnant women.

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

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

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

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

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

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

26 29. ADHD is a chronic neurodevelopmental disorder resulting in attention difficulty,
27 hyperactivity, and impulsiveness.

28 30. ADHD begins in childhood and persists through adulthood. ADHD contributes to

1 low self-esteem, troubled relationships, and difficulty with school, work, and familial relationships.

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

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

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

9 34. As of 2019, 8.8% of children had been diagnosed with ADHD, or roughly 325,000
10 children per year.

11 35. Parental awareness and changes in diagnoses do not account for the rapid rise in these
12 diagnoses.

13 36. Rather, neurotoxic exposures, such as prenatal APAP exposure, explain a trending
14 increase in diagnosis.

15 37. For years, the scientific community has published studies showing that prenatal
16 ingestion of APAP can cause ASD and ADHD.

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

20 39. The overall body of scientific evidence has shown that prenatal use of APAP can
21 cause ASD and ADHD in the child.

22 40. During all relevant times herein, Defendants were engaged in the business of
23 manufacturing and selling the APAP Products in the United States, and the weight of the scientific
24 evidence available showed prenatal exposure to APAP significantly increases the risk of
25 neurodevelopmental disorders in children exposed to APAP prenatally, including but not limited to
26 ASD and ADHD.

27 41. At the time Plaintiff Mother was pregnant with Plaintiff Child the scientific evidence
28 regarding the risks of in utero exposure of APAP was available to Defendants, and Defendants knew

1 or should have known that prenatal use of APAP can cause ASD or ADHD.

2 42. Based on information and belief, each Defendant has concealed the prenatal APAP
3 exposure-neurodevelopmental link from consumers, like Plaintiff Mother.

4 43. Moreover, despite knowing that prenatal use of APAP can cause ASD or ADHD,
5 each Defendant continued, and continues, to market APAP Products as safe pain relievers for
6 pregnant women, making mothers believe they are choosing a safe drug for even minor aches, pains,
7 and headaches.

8 **Plaintiff Mother Took APAP Products while Pregnant,**
9 **and It Caused ASD in Plaintiff Child**

10 44. Plaintiff Mother began using the APAP Products in or around May 2008 when she
11 was pregnant with her Plaintiff Child.

12 45. Over the course of her pregnancy, Plaintiff Mother took the APAP Products for pain
13 relief.

14 46. Plaintiff Mother believed it was safe for her to take the APAP Products during her
15 pregnancy.

16 47. Indeed, Plaintiff Mother was instructed to not take ibuprofen or aspirin while
17 pregnant, but was informed she could take APAP freely and without risk.

18 48. There is no warning on the APAP Products' labels specifically addressing the risks
19 of ASD if a mother ingests APAP while pregnant.

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

22 50. Plaintiff Child was born on February 6, 2009.

23 51. Plaintiff Mother started to have concerns about Plaintiff Child's development when
24 he was between two and three years of age based on his development.

25 52. Specifically, at that time, Plaintiff Child exhibited delays in both speech and in
26 socialization.

27 53. Plaintiff Child still has issues using the restroom by himself and is still unable to
28 bathe himself without assistance.

1 54. Plaintiff Child still has difficulty buttoning his shirt and still cannot tie his shoes
2 normally.

3 55. Plaintiff Child has been enrolled in an Individualized Education Program (IEP) in
4 his school district, Applied Behavioral Analysis, Occupational Therapy, and Speech Therapy.

5 56. Plaintiff Child was ultimately diagnosed with ASD in 2015.

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

7 58. Plaintiff Child struggles with major behavioral issues.

8 59. Plaintiff's Mother fears for Plaintiff Child and experiences substantial stress and
9 anxiety due to the challenges associated with Plaintiff Child's ASD.

10 **ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS**

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

16 61. Given each Defendant's affirmative actions of concealment by failing to disclose
17 information about the defects known to it but not the public—information over which Defendant
18 had exclusive control—and because Plaintiff Mother could not reasonably have known that the
19 APAP Products were defective, each Defendant is estopped from relying on any statutes of
20 limitations that might otherwise be applicable to the claims asserted in this Complaint.

21 **CLAIMS FOR RELIEF**

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

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

25 63. At the time of Plaintiffs' injuries, the APAP Products were defective and
26 unreasonably dangerous to foreseeable consumers using the APAP Products in a foreseeable manner
27 during pregnancy, including Plaintiff Mother, because they lacked an adequate warning.
28

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

10 65. Each Defendant had a duty to warn of the risks associated with the use of the APAP
11 products during pregnancy.

12 66. The APAP Products ingested by Plaintiff Mother during pregnancy were in the same
13 or substantially similar condition as they were when they left possession of each Defendant.

14 67. Each Defendant expected and intended the APAP Products to reach users such as
15 Plaintiff Mother in the condition in which the APAP Products were sold.

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

17 69. Plaintiff Mother ingested the APAP Products during pregnancy as indicated on the
18 APAP Products' labels.

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

22 71. The labels on the APAP Products to consumers lack any warning specific to pregnant
23 women. The information that each Defendant did provide or communicate to consumers failed to
24 contain relevant warnings, hazards, and precautions that would have enabled consumers such as
25 Plaintiff Mother to utilize the products safely and with adequate protection during pregnancy, or to
26 decide to not use or ingest the APAP Products at all.

27 72. This alleged failure to warn is not limited to the information contained on the APAP
28 Products' labeling. Each Defendant was able, in accord with federal law, to comply with relevant

1 state law by disclosing the known risks associated with exposure to or use of APAP during
2 pregnancy through other non-labeling mediums, including, but not limited to, promotion,
3 advertisements, public service announcements, and/or public information sources. But each
4 Defendant did not disclose these known risks through any medium.

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

13 74. At the time of manufacture, Each Defendant could have provided the warnings or
14 instructions regarding the full and complete risks of the APAP Products during pregnancy because
15 each Defendant knew or should have known of the unreasonable risks of ASD and ADHD associated
16 with prenatal exposure to and/or the use of such products.

17 75. At all relevant times, Each Defendant failed and deliberately refused to investigate,
18 study, test, or promote the safety of the APAP Products, or to minimize the dangers to consumers
19 of the APAP Products and to those who would foreseeably use or be harmed by the APAP Products,
20 including Plaintiffs.

21 76. Each Defendant failed to adequately warn consumers, like Plaintiff Mother, about
22 the significant increased risk of neurodevelopmental disorders in children exposed to APAP
23 prenatally, including but not limited to ASD and ADHD.

24 77. Each Defendant failed to adequately inform reasonably foreseeable consumers, like
25 Plaintiff Mother, of the proper usage of the APAP Products.

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

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

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

6 88. Each Defendant, directly or indirectly, caused the APAP Products to be sold,
7 distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff Mother. At all relevant
8 times, each Defendant registered, researched, manufactured, distributed, marketed, promoted, and
9 sold the APAP Products within this district and aimed at a consumer market within this district.

10 89. Each Defendant knew, or in the exercise of reasonable care should have known, that
11 the APAP Products were defectively and unreasonably designed and/or manufactured, and/or
12 marketed, and were unreasonably dangerous and likely to injure persons that were prenatally
13 exposed to them. Each Defendant knew or should have known that Plaintiff Mother was unaware
14 of the dangers and defects inherent in the APAP Products when she was ingesting them during her
15 pregnancy with Plaintiff Child.

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

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

27 92. Each Defendant failed to provide any kind of warning to pregnant consumers, like
28 Plaintiff Mother, about the significantly increased risk of causing neurodevelopmental disorders in

1 children through prenatal exposure to APAP.

2 93. Accordingly, at all relevant times, each Defendant knew or, in the exercise of
3 reasonable care, should have known that use of the APAP Products during pregnancy could cause
4 Plaintiffs' injuries, and thus, create a dangerous and unreasonable risk of injury to the users of these
5 products, including Plaintiffs.

6 94. As such, each Defendant breached its duty of reasonable care and failed to exercise
7 ordinary care in the design, research, development, manufacture, testing, marketing, labeling,
8 supply, promotion, advertisement, packaging, sale, and distribution of the APAP Products, in that
9 each Defendant manufactured and produced defective APAP Products, which carry the significantly
10 increased risk of causing neurodevelopmental disorders in children through prenatal exposure to
11 APAP; knew or had reason to know of the defects inherent in the APAP Products; knew or had
12 reason to know that a user's or consumer's use of the APAP Products during pregnancy created a
13 significant risk of harm and unreasonably dangerous side effects; and failed to prevent or adequately
14 warn of these risks and injuries.

15 95. Each Defendant had a duty to disclose the truth about the risks associated with
16 exposure to or use of APAP during pregnancy in its promotional efforts outside of the context of
17 labeling. Each Defendant was negligent in its promotion of APAP outside of the labeling context
18 by failing to disclose material risk information as part of its promotion and marketing of the APAP
19 Products, including through the internet, television, and print advertisements.

20 96. Despite each Defendant's ability and means to investigate, study, and test the APAP
21 Products and to provide adequate warnings regarding use during pregnancy, each Defendant failed
22 to do so. Indeed, each Defendant wrongfully concealed information and further made false and/or
23 misleading statements concerning the safety and use of APAP.

24 97. Each Defendant's negligence included:

- 25 a. Manufacturing, producing, promoting, formulating, creating, developing,
26 designing, selling, and/or distributing the APAP Products while negligently
27 and/or intentionally concealing and failing to disclose the results of trials,
28 tests, and studies of APAP and the significantly increased risk of causing

1 neurodevelopmental disorders in children through prenatal exposure to
2 APAP, and, consequently, the risk of serious harm associated with human
3 use of APAP during pregnancy;

4 b. Failing to undertake sufficient studies and conduct necessary tests to
5 determine whether or not the APAP Products were safe for its intended
6 consumer use and unborn children; and

7 c. Failing to provide adequate instructions, guidelines, and safety precautions
8 to those persons each Defendant could reasonably foresee would use the
9 APAP Products during pregnancy; and

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

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

17 f. Representing that the APAP Products were safe for their intended purposes
18 for pregnant women when, in fact, each Defendant knew or should have
19 known the APAP Products were not safe for their intended purposes; and

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

23 h. Advertising, marketing, and recommending the use of the APAP Products
24 during pregnancy, while concealing and failing to disclose or warn of the
25 dangers known by each Defendant to be caused by the use of or exposure
26 to APAP; and

27 i. Continuing to disseminate information to its consumers and the general
28 public, which indicates or implies that the APAP Products are not unsafe

1 for pregnant consumer use; and

2 j. Continuing the manufacture and sale of the APAP Products with the
3 knowledge that the APAP Products were unreasonably unsafe and
4 dangerous.

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

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

11 100. Each Defendant's negligence was a proximate cause of Plaintiffs' injuries, i.e.,
12 absent each Defendant's negligence, Plaintiff Child would not have developed ASD. That
13 negligence was a substantial factor in causing Plaintiffs' injuries and damages.

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

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

24 **COUNT III: BREACH OF EXPRESS WARRANTY**

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

27 104. At all material times, each Defendant manufactured, marketed, sold, distributed, and
28 otherwise placed into the stream of commerce the APAP Products. These actions were under the

1 ultimate control and supervision of each Defendant.

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

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

10 107. Each Defendant had a duty to exercise reasonable care in the research, development,
11 design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion,
12 sale, and release of the APAP Products, including a duty to:

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

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

21 109. At all relevant times, each Defendant expressly represented and warranted to the
22 purchasers of the APAP Products, by and through statements made by each Defendant in labels,
23 publications, brochures, and other written materials intended for consumers and the general public,
24 that the APAP Products were safe to human health and the environment, effective, fit, and proper
25 for their intended use during pregnancy. Each Defendant advertised, labeled, marketed, and
26 promoted the APAP Products, representing the quality to consumers and the public in such a way
27 as to induce their purchases or use during pregnancy, thereby making an express warranty that the
28 APAP Products would conform to the representations.

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

5 111. Each Defendant breached express representations and warranties made to Plaintiff
6 Mother, with respect to the APAP Products, including the following:

7 a. Each Defendant represented through its labeling, advertising, and
8 marketing materials that the APAP Products were safe for use during
9 pregnancy, and intentionally withheld and concealed information about
10 the risks of serious injury associated with use of APAP and by expressly
11 limiting the risks associated with use during pregnancy within its warnings
12 and labels; and

13 b. Each Defendant represented that the APAP Products were safe for use and
14 intentionally concealed information that demonstrated that APAP carries
15 the significantly increased risk of causing neurodevelopmental disorders
16 in children through prenatal exposure to APAP, and that the APAP
17 Products, therefore, were not safer than alternatives available on the
18 market.

19 112. Plaintiff Mother detrimentally relied on the express warranties and representations
20 of each Defendant concerning the safety and/or risk profile of APAP during pregnancy in deciding
21 to purchase the APAP Products. Plaintiff Mother reasonably relied upon each Defendant to disclose
22 known defects, risks, dangers, and side effects of APAP. Plaintiff Mother would not have purchased
23 or used the APAP Products during pregnancy had each Defendant properly disclosed the risks
24 associated with the APAP Products, either through advertising, labeling, or any other form of
25 disclosure. Each Defendant's breach of the express warranties and representations concerning the
26 safety and/or risk profile of APAP during pregnancy was a substantial factor in causing Plaintiffs'
27 injuries and damages.
28

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

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

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

116. As a direct and proximate result of each 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

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, each Defendant manufactured, marketed, sold, distributed, and otherwise placed the APAP Products into the stream of commerce.

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

120. Each Defendant was 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 each Defendant failed to disclose that APAP has dangerous propensities when

1 used as intended during pregnancy and that use of the APAP Products carries an increased risk of
2 developing severe injuries, including Plaintiff Child's injuries.

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

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

8 124. In reliance upon each Defendant's implied warranties, Plaintiff Mother purchased
9 and used the APAP Products as indicated, and in the foreseeable manner normally intended,
10 recommended, promoted, and marketed by each Defendant. The failure of the APAP Products to
11 be of merchantable quality, to be safe or fit for their intended use, or to be adequately tested was a
12 substantial factor in causing Plaintiffs' injuries and damages.

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

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

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

23 **COUNT V: VIOLATION OF CONSUMER PROTECTION LAWS**

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

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

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

4 131. Each Defendant engaged in wrongful conduct and unlawful while at the same time
5 obtaining under false pretenses moneys from Plaintiff for the APAP Products. Those moneys would
6 not have been paid had each Defendant not engaged in unfair and deceptive conduct. Plaintiffs
7 actually relied upon each Defendant's misrepresentations and deception concerning the APAP
8 Products.

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

- 11 A. representing that goods or services have characteristics, ingredients,
12 uses, benefits, or qualities they do not have; and
- 13 B. advertising goods or services with the intent not to sell them as
14 advertised; and
- 15 C. engaging in fraudulent or deceptive conduct creating a likelihood of
16 confusion or misunderstanding.

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

21 134. Each Defendant had a statutory duty to refrain from unfair or deceptive acts or trade
22 practices in the design, labeling, development, manufacture, promotion, and sale of the APAP
23 Products.

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

27 136. Each Defendant's actions, as complained of in this Complaint, constitute unfair
28 competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in violation

1 of the federal and state consumer protection statutes listed below.

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

- 4 • 15 U.S.C. §§ 2301–12 (1982);
- 5 • Cal. Bus. & Prof. Code § 17200, et seq.;
- 6 • Cal. Civ. Code § 1750 et seq.

7 138. To protect consumers against unfair, deceptive, fraudulent, and unconscionable trade
8 and business practices, and false advertising, each Defendant, as the supplier, manufacturer,
9 advertiser, and seller, is subject to liability under the above legislation enacted against unfair,
10 deceptive, fraudulent, and unconscionable consumer sales practices. The California Unfair
11 Competition Law (“UCL”) prohibits “any unlawful, unfair, or fraudulent business act or practice
12 and unfair, deceptive, untrue, or misleading advertising and any act prohibited by” Section 17500
13 of the California Business and Professions Code. Section 17500, in turn, prohibits any untrue or
14 misleading statements made in connection with the sale of goods. The Consumers Legal Remedies
15 Act (“CLRA”) defines as statutorily unlawful certain unfair methods of competition and unfair or
16 deceptive practices. Cal. Civ. Code § 1750 et seq.

17 139. By knowingly and falsely representing that the APAP Products were fit to be used
18 for the purposes for which they were intended—when in fact they were defective and dangerous
19 when used during pregnancy—and by other acts alleged, each Defendant violated the above statutes,
20 enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and
21 business practices, and false advertising.

22 140. Each Defendant’s actions and omissions are uncured or incurable, deceptive acts
23 under the above legislation.

24 141. Each Defendant had actual knowledge of the defective and dangerous conditions of
25 the APAP products but failed to take any action to cure such defective and dangerous conditions.

26 142. Plaintiff Mother relied upon each Defendant’s misrepresentations and omissions in
27 determining which APAP Products (if any) to ingest.

1 143. Each Defendant's deceptive, unconscionable, or fraudulent representations and
2 material omissions to consumers constituted unfair and deceptive acts and practices.

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

5 145. As a direct and proximate result of each Defendant's violations of the above-listed
6 legislation, Plaintiffs have sustained economic losses and other damages and are entitled to statutory
7 and compensatory damages, including restitution, in an amount to be proven at trial and civil
8 penalties as permitted by law.

9 **COUNT VI: NEGLIGENT MISREPRESENTATION**

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

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

19 148. Each Defendant failed to exercise ordinary care in the representations concerning the
20 APAP Products while each Defendant was involved in its manufacture, sale, testing, quality
21 assurance, quality control, and distribution in interstate commerce, because each Defendant
22 negligently misrepresented the APAP Products' high risk of unreasonable and dangerous adverse
23 side effects when ingested or used during pregnancy.

24 149. Each Defendant also breached its duty in representing to Plaintiff Mother that the
25 APAP Products had no serious side effects when ingested during pregnancy. Each Defendant
26 intended for consumers like Plaintiff Mother to rely upon that representation, and Plaintiff Mother
27 did justifiably rely upon that representation.

1 APAP Products were defective and unreasonably unsafe because they, among other things, did not
2 include adequate warnings.

3 156. Each Defendant was aware of the probable consequences of the dangerous and
4 defective product, including the risk of neurodevelopmental disorders in children, such as ASD and
5 ADHD, when they suffered prenatal exposure.

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

12 158. Each Defendant knowingly withheld material information from consumers and the
13 public, including Plaintiff Mother, concerning the safety and efficacy of the APAP Products during
14 pregnancy, which deprived Plaintiff Mother of vitally necessary information with which to make a
15 fully informed decision about whether to use the APAP Products while pregnant.

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

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

24 161. Notwithstanding the foregoing and the growing body of knowledge and information
25 regarding the true and defective nature of the APAP Products, with their increased risk of side effects
26 and serious complications, each Defendant continues to aggressively market the APAP Products to
27 consumers, including the pregnant community at large, without disclosing the true risk of the
28 complications and side effects.

- ii. Restitution and disgorgement of each Defendant's profits; and
- iii. Applicable statutory penalties; and
- iv. Punitive or enhanced damages; and
- v. Reasonable attorneys' fees as provided by law; and
- vi. Past and future costs of all proceedings; and
- vii. All ascertainable economic damages; and
- viii. Prejudgment interest on all damages as allowed by law; and
- ix. Such other and further relief as this Court deems just and proper.

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

Respectfully submitted,

By: /s/ Ruth Rizkalla

Attorneys for Plaintiff