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5
6 **UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

7 **TANIA OSUNA, INDIVIDUALLY AND AS**
8 **GUARDIAN AD LITEM OF J.G., MINOR,**
9 **AND E.A., MINOR**

10 **Plaintiff(s),**

11 **v.**

12 **RITE-AID CORPORATION, TARGET**
13 **CORPORATION, AND WALMART, INC.**

14 **Defendants.**

) **Civil Action No.:**

) **COMPLAINT & JURY DEMAND**

) **DEMAND FOR JURY TRIAL**

15 **PLAINTIFF'S ORIGINAL COMPLAINT AND JURY DEMAND**

16 Plaintiff Tania Osuna, individually and as representative of J.G., minor, and E.A., minor,
17 pursuant to Fed. R. Civ. P. 17(c)(1)(A), by and through their undersigned counsel, bring this
18 Complaint for damages against each Defendants Rite-Aid Corporation, Target Corporation, and
19 Walmart, Inc. (hereinafter, "Defendants") and in support, state the following:

20 1. This is an action brought on behalf of Plaintiffs, Tania Osuna (hereinafter,
21 "Plaintiff Mother"), the natural and general guardian and mother of J.G. and E.A. (hereinafter,
22 "Plaintiff Child J.G. and Plaintiff Child E.A."), a minor, arising out of the failure of Defendants
23 to warn about the dangers of prenatal exposure to Paracetamol, also known as Acetaminophen
24 (hereinafter "APAP"). As a result, Plaintiffs have suffered permanent injuries and significant
25 pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of
26 life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

27 2. Defendants entirely failed their duty to adequately warn of the hazards of prenatal
28 exposure to APAP, which was a direct and proximate cause of Plaintiffs' injuries and associated

1 damages.

2 **STATEMENT OF PARTIES**

3 3. At all material times Plaintiffs have been citizens and residents of Riverside
4 County, California.

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

7 5. Target is incorporated in Minnesota with its principal place of business in
8 Minneapolis, Minnesota.

9 6. Walmart is incorporated in Delaware with its principal place of business in
10 Bentonville, Arkansas.

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

14 8. Target is involved in the research, development, testing, manufacture, labeling,
15 production, marketing, promotion, and/or sale of APAP through its over-the-counter store brands,
16 Up&Up Acetaminophen (hereinafter, the “APAP Products”).

17 9. Walmart is involved in the research, development, testing, manufacture, labeling,
18 production, marketing, promotion, and/or sale of APAP through its over-the-counter store brand,
19 Equate Acetaminophen (hereinafter, the “APAP Products”).

20 10. Rite Aid is individually, and jointly and severally liable to Plaintiffs for damages
21 they suffered, arising from Each Defendants’s design, manufacture, marketing, labeling,
22 distribution, sale, and placement of the defective APAP Products into the market, effectuated
23 directly and indirectly through its agents, servants, employees, and/or owners, all acting within
24 the course and scope of its agencies, services, employments, and/or ownership.

25 11. Target is individually, and jointly and severally liable to Plaintiffs for damages
26 they suffered, arising from Each Defendants’s design, manufacture, marketing, labeling,
27 distribution, sale, and placement of the defective APAP Products into the market, effectuated
28

1 directly and indirectly through its agents, servants, employees, and/or owners, all acting within
2 the course and scope of its agencies, services, employments, and/or ownership.

3 12. Walmart is individually, and jointly and severally liable to Plaintiffs for damages
4 they suffered, arising from Each Defendants's design, manufacture, marketing, labeling,
5 distribution, sale, and placement of the defective APAP Products into the market, effectuated
6 directly and indirectly through its agents, servants, employees, and/or owners, all acting within
7 the course and scope of its agencies, services, employments, and/or ownership.

8 13. Rite Aid is vicariously liable for the acts and/or omissions of its employees and/or
9 agents, who were at all material times acting on behalf of Rite Aid and within the scope of its
10 employment or agency.

11 14. Target is vicariously liable for the acts and/or omissions of its employees and/or
12 agents, who were at all material times acting on behalf of Target and within the scope of its
13 employment or agency.

14 15. Walmart is vicariously liable for the acts and/or omissions of its employees and/or
15 agents, who were at all material times acting on behalf of Walmart and within the scope of its
16 employment or agency.

17 **JURISDICTION and VENUE**

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

20 17. The amount in controversy exceeds \$75,000.

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

23 19. Defendants have conducted and continue to conduct substantial business in the
24 State of California and in this District, distribute the APAP Products in this District, receive
25 substantial compensation and profits from sales of the APAP Products in this District, and have
26 made material omissions and misrepresentations and breaches of warranties in this District and
27 caused injuries in this District to Plaintiffs, among others, so as to subject Defendants to in
28 personam jurisdiction in this District. It was foreseeable at all times that Defendants could be

1 haled into court in the State of California for its conduct that caused injuries to citizens of
2 California, like Plaintiffs in this action. An exercise of in personam jurisdiction by this Court
3 over Defendants comports fully with due process and does not offend traditional notions of fair
4 play and substantial justice.

5 20. Defendants is registered to transact business in California.

6 **FACTS COMMON TO ALL COUNTS**

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

8 **ASD/ADHD in Children**

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

11 22. APAP was initially discovered in the late 1800's.

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

15 24. Billions of units of APAP are sold annually in North America alone.

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

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

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

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

23 29. However, scientific and epidemiological research shows that prenatal exposure to
24 APAP alters fetal development significantly increasing the risks of neurodevelopmental
25 disorders, including but not limited to, autism spectrum disorder ("ASD") and attention-
26 deficit/hyperactivity disorder ("ADHD").

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

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

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

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

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

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

13 35. ADHD is a chronic neurodevelopmental disorder resulting in attention difficulty,
14 hyperactivity, and impulsiveness.

15 36. ADHD begins in childhood and persists through adulthood. ADHD contributes to
16 low self-esteem, troubled relationships, and difficulty with school, work, and familial
17 relationships.

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

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

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

25 40. As of 2019, 8.8% of children had been diagnosed with ADHD, or roughly 325,000
26 children per year.

27 41. Parental awareness and changes in diagnoses do not fully account for the rapid rise
28 in these diagnoses.

1 42. Rather, neurotoxic exposures, such as prenatal APAP exposure, partly explain a
2 trending increase in diagnoses.

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

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

8 45. Since 2013, there have been six European birth cohort studies, examining over
9 70,000 mother-child pairs, showing the association between prenatal use of APAP and ASD and
10 ADHD, confirming the results of studies dating back to 1987.

11 46. The overall body of scientific evidence has shown for decades that prenatal use of
12 APAP can cause ASD and ADHD in the child.

13 47. During all relevant times herein, Defendants was engaged in the business of
14 manufacturing and selling the APAP Products in the United States, and the weight of the scientific
15 evidence available showed prenatal exposure to APAP significantly increases the risk of
16 neurodevelopmental disorders in children exposed to APAP prenatally, including but not limited
17 to ASD and ADHD.

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

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

25 **Plaintiff Mother Took APAP Products while Pregnant,**
26 **and It Caused ASD in Plaintiff Child**

27 50. Plaintiff Mother used APAP Products while she was pregnant with Plaintiff Child.

28 51. Over the course of her pregnancy with Plaintiff Child, and during all trimesters,

1 Plaintiff Mother took the APAP Products approximately seven or more times a week for pain
2 relief.

3 52. Plaintiff Mother believed it was safe for her to take APAP Products during her
4 pregnancy.

5 53. Indeed, Plaintiff Mother was instructed by her health care provider(s) to not take
6 ibuprofen or aspirin while pregnant but was informed she could take APAP freely without risk to

7 Plaintiff Child

8 54. Plaintiff Child was born on July 20, 2006.

9 55. Plaintiff Mother started to have concerns about Plaintiff Child's development.
10 Specifically, at that time, Plaintiff exhibited developmental delays and behavioral issues.

11 56. Plaintiff Child has displayed symptoms consistent with an ASD diagnosis since he
12 was a few months old. Specifically, he would cry more than usual and needed a lot of soothing.
13 As he got older, he exhibited more frequent and intense symptoms, including but not limited to
14 avoiding eye contact, tiptoeing instead of crawling, stimming behaviors like clapping, laughing
15 at inappropriate times, avoiding playing with toys, lining up and stacking random items, and
16 compulsively opening and closing drawers.

17 57. Plaintiff Child was diagnosed with Autism at 5 years of age.

18 58. Plaintiff Child has an individualized education plan from his school to manage his
19 ASD symptoms.

20 59. Plaintiff Child requires an immense amount of assistance to complete the normal
21 tasks of his daily life.

22 60. Plaintiff Child's ASD puts an incredible strain on Plaintiff Mother and their
23 family.

24 61. Plaintiff's Mother fears for Plaintiff Child and experiences substantial stress and
25 anxiety due to the challenges associated with Plaintiff Child's ASD.

26 **ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS**

27 62. Due to Defendants' acts of fraudulent concealment, Defendants are estopped from
28 relying on any statutes of limitations or repose. Such acts include Defendants' intentional

1 concealment from Plaintiff Mother and the general public that APAP is defective when there is
2 prenatal exposure, while continuing to market the APAP Products with the adverse effects
3 described in this Complaint.

4 63. Given Defendants' affirmative actions of concealment by failing to disclose
5 information about the defects known to it but not the public—information over which Defendants
6 had exclusive control—and because Plaintiff Mother could not reasonably have known that the
7 APAP Products were defective, Defendants are estopped from relying on any statutes of
8 limitations that might otherwise be applicable to the claims asserted in this Complaint.

9 64. Plaintiffs, in any event, commenced this action within two years of discovering or
10 having reason to discover their causes of action.

11 **CLAIMS FOR RELIEF**

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

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

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

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

27 68. Defendants had a duty to warn of the risks associated with the use of the APAP
28 products during pregnancy.

1 69. The APAP Products ingested by Plaintiff Mother during pregnancy were in the
2 same or substantially similar condition as they were when they left possession of the Defendants.

3 70. Defendants expected and intended the APAP Products to reach users such as
4 Plaintiff Mother in the condition in which the APAP Products were sold.

5 71. Plaintiff Mother did not materially alter the APAP Products prior to ingestion.

6 72. Plaintiff Mother ingested the APAP Products during pregnancy as indicated on the
7 APAP Products' labels.

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

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

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

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

1 knowledge of an expert in the field.

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

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

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

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

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

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

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

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

28 85. If Plaintiff Mother had been properly warned of the defects, dangers, and risks

1 associated with prenatal exposure to APAP, Plaintiff Mother would have decided to not ingest
2 the APAP Products at all. Defendants' failure to properly warn of those defects, dangers, and
3 risks associated with prenatal exposure to APAP was a substantial factor in causing Plaintiffs'
4 injuries and damages.

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

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

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

17 **COUNT II: NEGLIGENCE**

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

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

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

28 92. Defendants knew, or in the exercise of reasonable care should have known, that

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

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

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

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

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

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

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

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

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

14 100. Defendants' negligence included:

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

- 1 d. Failing to disclose to Plaintiff Mother, users, consumers, and the general public
- 2 that use of APAP during pregnancy presents severe risks of
- 3 neurodevelopmental disorders in children exposed to APAP prenatally; and
- 4 e. Failing to warn Plaintiff Mother, users, consumers, and the general public that
- 5 the APAP Products' risk of harm was unreasonable and that there were safer
- 6 and effective alternative medications or treatments available to Plaintiff
- 7 Mother and other users and/or consumers; and
- 8 f. Representing that the APAP Products were safe for their intended purposes for
- 9 pregnant women when, in fact, Defendants knew or should have known the
- 10 APAP Products were not safe for their intended purposes; and
- 11 g. Declining to make or propose any changes to the APAP Products' labeling or
- 12 other promotional materials that would alert users, consumers, and the general
- 13 public of the risks of APAP, including to pregnant women; and
- 14 h. Advertising, marketing, and recommending the use of the APAP Products
- 15 during pregnancy, while concealing and failing to disclose or warn of the
- 16 dangers known by Defendants to be caused by the use of or exposure to APAP;
- 17 and
- 18 i. Continuing to disseminate information to its consumers and the general public,
- 19 which indicates or implies that the APAP Products are not unsafe for pregnant
- 20 consumer use; and
- 21 j. Continuing the manufacture and sale of the APAP Products with the
- 22 knowledge that the APAP Products were unreasonably unsafe and dangerous.

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

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

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

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

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

14

COUNT III: BREACH OF EXPRESS WARRANTY

15
16 106. Plaintiffs restate, reallege, and incorporate by reference each of the allegations set
17 forth in the rest of this Complaint as if fully set forth herein.

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

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

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

1 110. Defendants had a duty to exercise reasonable care in the research, development,
2 design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion,
3 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 their
5 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.

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

12 112. 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, and
16 proper for their intended use during pregnancy. Defendants advertised, labeled, marketed, and
17 promoted the APAP Products, representing the quality to consumers and the public in such a way
18 as to induce their purchases or use during pregnancy, thereby making an express warranty that
19 the APAP Products would conform to the representations.

20 113. 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.

24 114. 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.

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

17 116. Plaintiff Mother had no knowledge of the falsity or incompleteness of
18 Defendants's 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.

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

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

28 119. As a direct and proximate result of Defendants' breach of express warranty,

1 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost
2 wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all
3 damages to which they may be legally entitled.

4 **COUNT IV: BREACH OF IMPLIED WARRANTY**

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

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

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

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

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

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

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

24 127. In reliance upon Defendants' implied warranties, Plaintiff Mother purchased and
25 used the APAP Products as indicated, and in the foreseeable manner normally intended,
26 recommended, promoted, and marketed by Defendants. The failure of the APAP Products to be
27 of merchantable quality, to be safe or fit for their intended use, or to be adequately tested was a
28 substantial factor in causing Plaintiffs' injuries and damages.

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

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

7 130. As a direct and proximate result of Defendants's breach of implied warranties,
8 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost
9 wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all
10 damages to which they may be legally entitled.

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

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

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

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

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

25 135. Defendants engaged in the following unfair methods of competition or deceptive
26 acts or practices, which are proscribed by law:

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

- 1 B. advertising goods or services with the intent not to sell them as
- 2 advertised; and
- 3 C. engaging in fraudulent or deceptive conduct creating a likelihood
- 4 of confusion or misunderstanding.

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

10 137. Defendants had a statutory duty to refrain from unfair or deceptive acts or trade
11 practices in the design, labeling, development, manufacture, promotion, and sale of the APAP
12 Products.

13 138. Defendants’ deceptive, unconscionable, or fraudulent representations and material
14 omissions to consumers, including Plaintiff Mother, constitute unfair and deceptive acts and trade
15 practices in violation of the federal and state consumer protection statutes listed below.

16 139. Defendants’ actions, as complained of in this Complaint, constitute unfair
17 competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in violation
18 of the federal and state consumer protection statutes listed below.

19 140. Defendants has engaged in unfair competition, or unfair or deceptive acts or trade
20 practices, or has made false representations under the following statutes:

- 21 • 15 U.S.C. §§ 2301–12 (1982);
- 22 • Cal. Bus. & Prof. Code § 17200, et seq.;
- 23 • Cal. Civ. Code § 1750 et seq.

24 141. To protect consumers against unfair, deceptive, fraudulent, and unconscionable
25 trade and business practices, and false advertising, Defendants, as the supplier, manufacturer,
26 advertiser, and seller, is subject to liability under the above legislation enacted against unfair,
27 deceptive, fraudulent, and unconscionable consumer sales practices. The California Unfair
28 Competition Law (“UCL”) prohibits “any unlawful, unfair, or fraudulent business act or practice

1 and unfair, deceptive, untrue, or misleading advertising and any act prohibited by” Section 17500
2 of the California Business and Professions Code. Section 17500, in turn, prohibits any untrue or
3 misleading statements made in connection with the sale of goods. The Consumers Legal
4 Remedies Act (“CLRA”) defines as statutorily unlawful certain unfair methods of competition
5 and unfair or deceptive practices. Cal. Civ. Code § 1750 et seq.

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

11 143. Defendants’ actions and omissions are uncured or incurable, deceptive acts under
12 the above legislation.

13 144. Defendants had actual knowledge of the defective and dangerous conditions of the
14 APAP products but failed to take any action to cure such defective and dangerous conditions.

15 145. Plaintiff Mother relied upon Defendants’ misrepresentations and omissions in
16 determining which APAP Products (if any) to ingest.

17 146. Defendants’ deceptive, unconscionable, or fraudulent representations and material
18 omissions to consumers constituted unfair and deceptive acts and practices.

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

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

25 **COUNT VI: NEGLIGENT MISREPRESENTATION**

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

28 150. Defendants had a duty to accurately and truthfully represent to consumers,

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

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

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

16 153. Defendants knew or had reason to know that the APAP Products had been
17 insufficiently tested or had not been tested at all; and that they lacked adequate and accurate
18 warnings, and created a high risk, or a higher than acceptable reported and represented risk, of
19 adverse side effects. Those side effects include neurodevelopmental disorders in children, such
20 as ASD and ADHD. Thus, Defendants lacked reasonable ground for believing the representations
21 to be true and intended for consumers like Plaintiff to rely upon those misrepresentations by
22 purchasing the APAP products for use during pregnancy. Plaintiff Mother justifiably relied upon
23 those misrepresentations in purchasing and using the APAP products while pregnant.
24 Defendants' negligent misrepresentations concerning the safety and/or risk profile of using APAP
25 during pregnancy was a substantial factor in causing Plaintiffs' injuries and damages.

26 154. As a direct and proximate result of Defendants' negligent misrepresentation,
27 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost
28 wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all

1 damages to which they may be legally entitled.

2 **PUNITIVE DAMAGES**

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

5 156. Defendants have acted with malice through despicable conduct that exhibits a
6 willful and conscious disregard for the rights and safety of others, including Plaintiffs, and has
7 acted with oppression in subjecting Plaintiffs to cruel and unjust hardship in conscious disregard
8 of their rights. Further, Defendants have intentionally misrepresented or concealed material facts
9 known to it with the intention of causing injury or otherwise depriving Plaintiffs of their property
10 or legal rights.

11 157. Defendants failed to adequately test and study the APAP Products to determine
12 and ensure that the APAP Products were safe and effective for use during pregnancy before
13 releasing them for sale for human consumption.

14 158. Further, Defendants continued to manufacture and sell the APAP Products and
15 marketed them for use during pregnancy, even after obtaining knowledge and information that
16 the APAP Products were defective and unreasonably unsafe because they, among other things,
17 did not include adequate warnings.

18 159. Defendants was aware of the probable consequences of the dangerous and
19 defective product, including the risk of neurodevelopmental disorders in children, such as ASD
20 and ADHD, when they suffered prenatal exposure.

21 160. At all material times, Defendants knew or should have known that the APAP
22 Products were inherently dangerous with respect to the following: the risk of neurodevelopmental
23 disorders in children, such as ASD and ADHD, when they suffered prenatal exposure; pain and
24 suffering; loss of life's enjoyment; and unsuccessful treatments to cure the conditions proximately
25 related to the use of the APAP Products, as well as the other permanent and lasting severe personal
26 injuries.

27 161. Defendants knowingly withheld material information from consumers and the
28 public, including Plaintiff Mother, concerning the safety and efficacy of the APAP Products

1 during pregnancy, which deprived Plaintiff Mother of vitally necessary information with which
2 to make a fully informed decision about whether to use the APAP Products while pregnant.

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

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

11 164. Notwithstanding the foregoing and the growing body of knowledge and
12 information regarding the true and defective nature of the APAP Products, with their increased
13 risk of side effects and serious complications, Defendants continue to aggressively market the
14 APAP Products to consumers, including the pregnant community at large, without disclosing the
15 true risk of the complications and side effects.

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

23 166. At all material times, Defendants have concealed and/or failed to disclose to the
24 public the serious risks and the potential complications associated with the APAP Products, so as
25 to ensure continued and increased sales and profits and to the detriment of the public, including
26 Plaintiffs.

27 167. Defendants' acts and omissions are of such character and nature so as to entitle
28 Plaintiffs to an award of punitive damages in accordance with applicable statutory and common

1 law. Defendants' conduct shows malice, oppression, or fraud, or that entire want of care, raising
2 the presumption of conscious indifference to consequences of that conduct, thereby justifying an
3 award of punitive damages.

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

8 **PRAYER FOR RELIEF**

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

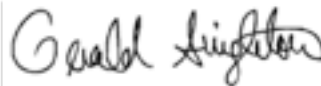
- 11 i. Compensatory damages to Plaintiffs for past, present, and future damages,
12 including pain and suffering for severe and permanent personal injuries
13 sustained by Plaintiffs, permanent impairment, mental pain and suffering,
14 loss of enjoyment of life, health and medical care costs, economic
15 damages, together with interest and costs as provided by law; and
16 ii. Restitution and disgorgement of Defendants' profits; and
17 iii. Punitive or enhanced compensatory damages; and
18 iv. Reasonable attorneys' fees as provided by law; and
19 v. Past and future costs of all proceedings; and
20 vi. All ascertainable economic damages; and
21 vii. Prejudgment interest on all damages as allowed by law; and
22 viii. Such other and further relief as this Court deems just and proper.

23 **DEMAND FOR JURY TRIAL**

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

25 Dated: September 7, 2022

Respectfully submitted,

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