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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

HELEN GAZLEY INDIVIDUALLY)	Case No.:
AND AS MOTHER, GENERAL GUARDIAN)	COMPLAINT
OF M.A., A MINOR,)	(Jury Trial Demanded)
<i>Plaintiffs,</i>)	
)	
v.)	
)	
TARGET CORPORATION,)	
WAL-MART, INC.)	
<i>Defendants.</i>)	

COMPLAINT

1
2 Plaintiff Helen Gazley and Plaintiff M.A., pursuant to Fed. R. Civ. P. 17(c)(1)(A), by and
3 through their undersigned counsel, bring this Complaint for damages against Defendant Wal-Mart,
4 Inc., (hereinafter, “Wal-Mart”) and Defendant Target Corporation (hereinafter, “Target”)
5 (collectively, “Defendants”) and in support state the following:

6 1. This is an action brought on behalf of Plaintiffs, Helen Gazley (hereinafter,
7 “Plaintiff Mother”), the mother and guardian of M.A. (hereinafter, “Plaintiff Child”), a minor,
8 arising out of the failure of Defendants to warn about the dangers of prenatal exposure to
9 Paracetamol, also known as Acetaminophen (hereinafter “APAP”) and its propensity to cause
10 attention-deficit/hyperactivity disorder (hereinafter, “ADHD”) in children. As a result, Plaintiffs
11 have suffered permanent injuries and significant pain and suffering, emotional distress, lost wages
12 and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to
13 which they may be legally entitled.

14 2. Defendants entirely failed their duty to adequately warn of the hazards of prenatal
15 exposure to APAP, which was a direct and proximate cause of Plaintiffs’ injuries and associated
16 damages.

STATEMENT OF PARTIES

17
18 3. At all material times, Plaintiffs have been citizens and residents of Alameda,
19 California, and the United States. Plaintiffs are currently citizens and residents of Oakley,
20 California, and the United States.

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

23 5. Target is incorporated in Minnesota, with its principal place of business in
24 Minnesota.

25 6. Defendants are multinational companies involved in the research, development,
26 testing, manufacture, labeling, production, marketing, promotion, and/or sale of APAP through
27 their over-the-counter store brands (hereinafter, the “Store Brand APAP”).
28

1 7. Defendants are individually, and jointly and severally liable to Plaintiffs for
2 damages they suffered, arising from Defendants’ design, manufacture, marketing, labeling,
3 distribution, sale, and placement of the defective Store Brand APAP into the market, effectuated
4 directly and indirectly through their agents, servants, employees, and/or owners, all acting within
5 the course and scope of their agencies, services, employments, and/or ownership.

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

9 **VENUE AND JURISDICTION**

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

12 10. The amount in controversy exceeds \$75,000.

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

15 12. Defendants have and continue to conduct substantial business in the State of
16 California and in this District, distribute the Store Brand APAP in this District, receive substantial
17 compensation and profits from sales of the Store Brand APAP in this District, and have made
18 material omissions and misrepresentations and breaches of warranties in this District, so as to
19 subject Defendants to in personam jurisdiction in this District.

20 13. Defendants are registered to transact business in California.

21 **FACTS COMMON TO ALL COUNTS**

22 **APAP Is Marketed as the Safe Pain Reliever for Pregnant Women,
23 but APAP Can Cause Neurodevelopment Disorders in Children, such as ADHD**

24 13. APAP was initially discovered in the late 1800’s.

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

26 15. APAP is widely used by pregnant women to relieve pain during the term of their
27 pregnancy.
28

1 16. APAP was introduced to the US market in 1955 as the first aspirin-free pain
2 reliever.

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

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

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

8 20. These pregnant women electively choose to take APAP because Defendants have
9 marketed APAP as a safe pain reliever for pregnant women.

10 21. However, increasing experimental and epidemiological research shows that
11 prenatal exposure to APAP alters fetal development, which significantly increases the risks of
12 neurodevelopmental disorders, including but not limited to, ADHD.

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

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

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

19 25. ADHD is a chronic neurodevelopmental disorder resulting in attention difficulty,
20 hyperactivity, and impulsiveness.

21 26. ADHD begins in childhood and persists through adulthood. ADHD contributes to
22 low self-esteem, troubled relationships, and difficulty with school, work, and familial
23 relationships.

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

26 28. Adults with childhood ADHD are expected to earn \$1.25 million less than adults
27 without ADHD over their lifetime, potentially reaching retirement with up to a 75 percent lower
28

1 net worth.

2 29. As of 2019, 8.8% of children had been diagnosed with ADHD, or roughly
3 325,000 children per year.

4 30. Parental awareness and changes in diagnoses do not account for the rapid rise in
5 these diagnoses of neurodevelopmental disorders.

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

8 32. For years, the scientific community has published studies showing that prenatal
9 ingestion of APAP can cause ADHD.

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

13 34. At this time, the overall body of scientific evidence shows that prenatal use of
14 APAP can cause ADHD in the child.

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

20 36. The scientific evidence regarding the risks of in utero exposure of APAP was
21 available to Defendants, and Defendants knew or should have known that prenatal use of APAP
22 can cause ADHD.

23 37. Based on information and belief, Defendants have concealed the prenatal APAP
24 exposure-neurodevelopmental link from consumers, like Plaintiff Mother, in part by not reporting
25 the link to the FDA, which relies on drug manufacturers to bring new information about a drug to
26 the agency's attention.

1 38. Moreover, despite knowing that prenatal use of APAP can cause ADHD,
2 Defendants continue to market the Store Brand APAP as the safe pain reliever for pregnant women,
3 making mothers believe they are choosing a safe drug for even minor aches, pains, and headaches.

4 **Plaintiff Mother Took Store Brand APAP while Pregnant,**
5 **and It Caused ADHD in Plaintiff Child**

6 39. Plaintiff Mother began using the Store Brand APAP in or around June 2007, when
7 she was pregnant with Plaintiff Child, through May 2008, when Plaintiff Child was born.

8 40. During Plaintiff Mother's pregnancy, she took the Store Brand APAP daily to treat
9 migraines and back pain.

10 41. Plaintiff Mother associated these migraines and back pain with her pregnancy.

11 42. Plaintiff Mother purchased and took the Store Brand APAP in Alameda County,
12 California.

13 43. Plaintiff Mother electively took the Store Brand APAP while pregnant.

14 44. Plaintiff Mother believed it was safe for her to take the Store Brand APAP during
15 her pregnancy.

16 45. There is no warning on the Store Brand APAP labels specifically addressing the
17 risks of a child developing ADHD if a mother ingests APAP while pregnant.

18 46. Had Plaintiff Mother known of the risk of taking APAP while pregnant, specifically
19 that it could cause ADHD in her child, she would not have taken the Store Brand APAP.

20 47. Plaintiff Child was born on May 19, 2008.

21 48. Plaintiff Mother started to have concerns about Plaintiff Child's development when
22 he was around six years old.

23 49. Plaintiff Child was diagnosed with ADHD when he was around seven years old.

24 50. Plaintiff Child has behavioral issues because of his ADHD.

25 51. For instance, Plaintiff Child has anxiety and difficulty focusing on basic tasks.

26 52. In addition, Plaintiff Mother has had to leave work early due to accidents caused
27 by Plaintiff Child.

28 53. These issues have a huge impact on Plaintiff Mother and Plaintiff Child.

1 54. Plaintiff Child’s ADHD has placed an incredible mental, physical, emotional, and
2 financial strain on Plaintiff Mother.

3 **ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS**

4 55. Due to Defendants’ acts of fraudulent concealment, Defendants are estopped from
5 relying on any statutes of limitations or repose. Such acts include Defendants’ intentional
6 concealment from Plaintiff Mother and the general public that APAP is defective when there is
7 prenatal exposure, while continuing to market the Store Brand APAP with the adverse effects
8 described in this Complaint.

9 56. Given Defendants’ affirmative actions of concealment by failing to disclose
10 information about the defects known to them but not the public—information over which
11 Defendants had exclusive control—and because Plaintiff Mother could not reasonably have known
12 that the Store Brand APAP was defective, Defendants are estopped from relying on any statutes
13 of limitations that might otherwise be applicable to the claims asserted in this Complaint.

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

15 57. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

16 58. At the time of Plaintiffs’ injuries, the Store Brand APAP was defective and
17 unreasonably dangerous to foreseeable consumers, including Plaintiff Mother, because they lacked
18 an adequate warning.

19 59. At all relevant times, Defendants engaged in the business of testing, developing,
20 designing, manufacturing, marketing, labeling, selling, distributing, and promoting the Store
21 Brand APAP, which was defective and unreasonably dangerous to consumers, including Plaintiff
22 Mother, because they did not contain adequate warnings or instructions concerning the dangerous
23 characteristics of ingesting APAP during pregnancy. These actions were under the ultimate
24 control and supervision of Defendants. At all relevant times, Defendants registered, researched,
25 manufactured, distributed, marketed, labeled, promoted, and sold the Store Brand APAP within
26 this District and aimed the marketing at the ultimate consumer. Defendants were at all relevant
27

1 times involved in the retail and promotion of the Store Brand APAP marketed and sold in this
2 District.

3 60. Defendants had a duty to warn of the risks associated with the use of the Store
4 Brand APAP.

5 61. The Store Brand APAP ingested by Plaintiff Mother during pregnancy was in the
6 same or substantially similar condition as it was when it left possession of the Defendants.

7 62. Defendants expected and intended the Store Brand APAP to reach users such as
8 Plaintiff Mother in the condition in which the Store Brand APAP was sold.

9 63. Plaintiff Mother did not materially alter the Store Brand APAP prior to ingestion.

10 64. Plaintiff Mother ingested the Store Brand APAP as indicated on the Store Brand
11 APAP labels.

12 65. Plaintiff Mother was unaware of the defects and dangers of the Store Brand APAP
13 and was unaware that prenatal exposure increases the risk of brain and behavioral development of
14 children in utero.

15 66. The labels on the Store Brand APAP to consumers lack any warning specific to
16 pregnant women. The information that Defendants did provide or communicate failed to contain
17 relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff
18 Mother to utilize the products safely and with adequate protection, or decide to not ingest the Store
19 Brand APAP at all.

20 67. This alleged failure to warn is not limited to the information contained on the Store
21 Brand APAP' labeling. Defendants were able, in accord with federal law, to comply with relevant
22 state law by disclosing the known risks associated with APAP through other non-labeling
23 mediums, i.e., promotion, advertisements, public service announcements, and/or public
24 information sources. But Defendants did not disclose these known risks through any medium.

25 68. At all relevant times, Defendants had a duty to properly test, develop, design,
26 manufacture, inspect, package, label, market, promote, sell, distribute, maintain, and supply the
27 Store Brand APAP; provide proper warnings for the Store Brand APAP; and take such steps as
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1 necessary to ensure the Store Brand APAP did not cause users and consumers, and their children,
2 to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn
3 Plaintiff Mother of dangers associated with APAP. Defendants, as manufacturers, sellers, and/or
4 distributors of pharmaceutical medication, are held to the knowledge of an expert in the field.

5 69. At the time of manufacture, Defendants could have provided the warnings or
6 instructions regarding the full and complete risks of the Store Brand APAP because Defendants
7 knew or should have known of the unreasonable risks of ADHD associated with prenatal exposure
8 to and/or the use of such products.

9 70. At all relevant times, Defendants failed and deliberately refused to investigate,
10 study, test, or minimize the dangers to consumers of the Store Brand APAP and to those who
11 would foreseeably use or be harmed by the Store Brand APAP, including Plaintiffs.

12 71. Defendants failed to adequately warn consumers, like Plaintiff Mother, about the
13 significant increased risk of neurodevelopmental disorders in children exposed to APAP
14 prenatally, including but not limited to ADHD.

15 72. Defendants failed to adequately inform reasonably foreseeable consumers, like
16 Plaintiff Mother, of the proper usage of the Store Brand APAP.

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

20 74. Plaintiff Mother was exposed to the Store Brand APAP without knowledge of their
21 dangerous characteristics.

22 75. At all relevant times, Plaintiff Mother used and/or was exposed to the use of the
23 Store Brand APAP while using them for their intended or reasonably foreseeable purposes, without
24 knowledge of their dangerous characteristics.

25 76. Plaintiff Mother could not have reasonably discovered the defects and risks
26 associated with the Store Brand APAP prior to or at the time of Plaintiff consuming APAP.

1 Plaintiff Mother relied upon the skill, superior knowledge, and judgment of Defendants to know
2 about and disclose serious health risks associated with using the Store Brand APAP.

3 77. If Plaintiff Mother had been properly warned of the defects, dangers, and risks
4 associated with prenatal exposure to APAP, Plaintiff Mother would have decided to not ingest the
5 Store Brand APAP while pregnant.

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

10 79. As a direct and proximate result of Defendants placing defective Store Brand APAP
11 into the stream of commerce, and Plaintiff Mother's ingestion of the Store Brand APAP during
12 pregnancy, Plaintiff Child was exposed to APAP prenatally, causing him to develop ADHD.

13 80. As a direct and proximate result of Defendants placing defective Store Brand APAP
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 81. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

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

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

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

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

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

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

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

25 89. As such, Defendants breached their duty of reasonable care and failed to exercise
26 ordinary care in the design, research, development, manufacture, testing, marketing, labeling,
27 supply, promotion, advertisement, packaging, sale, and distribution of the Store Brand APAP, in
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1 that Defendants manufactured and produced defective Store Brand APAP, which carry the
2 significantly increased risk of causing neurodevelopmental disorders in children through prenatal
3 exposure to APAP; knew or had reason to know of the defects inherent in the Store Brand APAP;
4 knew or had reason to know that a user's or consumer's use of the Store Brand APAP created a
5 significant risk of harm and unreasonably dangerous side effects; and failed to prevent or
6 adequately warn of these risks and injuries.

7 90. Defendants had a duty to disclose the truth about the risks associated with APAP
8 in their promotional efforts outside of the context of labeling. Defendants were negligent in their
9 promotion of APAP outside of the labeling context by failing to disclose material risk information
10 as part of their promotion and marketing of the Store Brand APAP, including through the internet,
11 television, and print advertisements.

12 91. Despite Defendants' ability and means to investigate, study, and test the Store
13 Brand APAP and to provide adequate warnings, Defendants failed to do so. Indeed, Defendants
14 wrongfully concealed information and further made false and/or misleading statements concerning
15 the safety and use of APAP.

16 92. Defendants' negligence included:

- 17 a. Manufacturing, producing, promoting, formulating, creating, developing,
18 designing, selling, and/or distributing the Store Brand APAP while negligently
19 and/or intentionally concealing and failing to disclose the results of trials, tests, and
20 studies of APAP and the significantly increased risk of causing
21 neurodevelopmental disorders in children through prenatal exposure to APAP, and,
22 consequently, the risk of serious harm associated with human use of APAP during
23 pregnancy;
- 24 b. Failing to undertake sufficient studies and conduct necessary tests to determine
25 whether or not the Store Brand APAP was safe for its intended consumer use and
26 unborn children;
- 27
28

- c. Failing to provide adequate instructions, guidelines, and safety precautions to those persons Defendants could reasonably foresee would use the Store Brand APAP;
- d. Failing to disclose to Plaintiff Mother, users, consumers, and the general public that use of APAP during pregnancy presents severe risks of neurodevelopmental disorders in children exposed to APAP prenatally;
- e. Failing to warn Plaintiff Mother, users, consumers, and the general public that the Store Brand APAP's risk of harm was unreasonable and that there were safer and effective alternative medications or treatments available to Plaintiff Mother and other users and/or consumers;
- f. Representing that the Store Brand APAP was safe for their intended purposes for pregnant women when, in fact, Defendants knew or should have known the Store Brand APAP was not safe for their intended purposes;
- g. Declining to make or propose any changes to the Store Brand APAP's labeling or other promotional materials that would alert users, consumers, and the general public of the risks of APAP, including to pregnant women;
- h. Advertising, marketing, and recommending the use of the Store Brand APAP, while concealing and failing to disclose or warn of the dangers known by Defendants to be caused by the use of or exposure to APAP;
- i. Continuing to disseminate information to their consumers and the general public, which indicates or implies that the Store Brand APAP is not unsafe for pregnant consumer use; and
- j. Continuing the manufacture and sale of the Store Brand APAP with the knowledge that the Store Brand APAP was unreasonably unsafe and dangerous.

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

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

3 95. Defendants' negligence was the proximate cause of Plaintiffs' injuries, i.e., absent
4 Defendants' negligence, Plaintiff Child would not have developed ADHD.

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

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

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

16 98. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

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

20 100. In advertising, marketing, and promoting the Store Brand APAP to consumers, like
21 Plaintiff Mother, Defendants expressly warranted that the Store Brand APAP was safe for use and
22 reasonably fit for their intended purposes. In advertising, marketing, and otherwise promoting the
23 Store Brand APAP, Defendants intended for pregnant consumers to rely upon their representations
24 regarding safety and fitness, in an effort to induce them to purchase and consume the Store Brand
25 APAP during pregnancy to relieve pain.

26 101. Defendants expressly warranted to Plaintiff Mother and pregnant consumers that
27 the Store Brand APAP was safe for ingestion during pregnancy.
28

1 102. 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 Store Brand APAP, including a duty to:

- 4 a. ensure that the Store Brand APAP did not cause users and their unborn children
5 unreasonably dangerous side effects;
- 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 of and
8 exposure to APAP during pregnancy, when making representations to users,
9 consumers, and the general public, including Plaintiff Mother.

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

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

20 105. The representations about the Store Brand APAP, 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.

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

- 26 a. Defendants represented through their labeling, advertising, and marketing materials
27 that the Store Brand APAP was safe, and intentionally withheld and concealed
28

1 information about the risks of serious injury associated with use of APAP and by
2 expressly limiting the risks associated with use within their warnings and labels;
3 and

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

9 107. Plaintiff Mother detrimentally relied on the express warranties and representations
10 of Defendants concerning the safety and/or risk profile of APAP in deciding to purchase the Store
11 Brand APAP. Plaintiff Mother reasonably relied upon Defendants to disclose known defects,
12 risks, dangers, and side effects of APAP. Plaintiff Mother would not have purchased or used the
13 Store Brand APAP had Defendants properly disclosed the risks associated with the Store Brand
14 APAP, either through advertising, labeling, or any other form of disclosure.

15 108. Plaintiff Mother had no knowledge of the falsity or incompleteness of Defendants'
16 statements and representations concerning the Store Brand APAP.

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

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

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

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

4 112. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

5 113. At all material times, Defendants manufactured, marketed, sold, distributed, and
6 otherwise placed the Store Brand APAP into the stream of commerce.

7 114. At all material times, Defendants intended for the Store Brand APAP to be
8 consumed and ingested by pregnant women, like Plaintiff Mother; and Defendants impliedly
9 warranted that the Store Brand APAP and its component parts were of merchantable quality, safe,
10 fit for such use, and adequately tested.

11 115. Defendants were aware that consumers, including Plaintiff Mother, would consume
12 and ingest the Store Brand APAP as directed by the products' labels and promotional materials.
13 Therefore, Plaintiff Mother was a foreseeable user of the Store Brand APAP.

14 116. But Defendants failed to disclose that APAP has dangerous propensities when used
15 as intended and that use of the Store Brand APAP carries an increased risk of developing severe
16 injuries, including Plaintiff Child's injuries.

17 117. The Store Brand APAP was expected to reach, and did in fact reach consumers,
18 including Plaintiff Mother, without substantial change in the condition in which they were
19 manufactured and sold by Defendants.

20 118. Plaintiff Mother was an intended beneficiary of the implied warranties made by
21 Defendants to purchasers of the Store Brand APAP.

22 119. In reliance upon Defendants' implied warranties, Plaintiff Mother used the Store
23 Brand APAP as indicated, and in the foreseeable manner normally intended, recommended,
24 promoted, and marketed by Defendants.

25 120. Defendants breached their implied warranties to Plaintiffs in that the Store Brand
26 APAP was not of merchantable quality, nor were they safe or fit for their intended use or
27 adequately tested.

1 121. The harm caused by the Store Brand APAP far outweighed their benefit, rendering
2 the Store Brand APAP more dangerous than an ordinary consumer or user would expect and more
3 dangerous than alternative products.

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

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

9 123. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

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

13 125. Had Defendants not engaged in the deceptive conduct described in this Complaint,
14 Plaintiff would not have purchased and/or paid for the Store Brand APAP, and Plaintiffs would
15 not have incurred related injury medical costs.

16 126. Defendants engaged in wrongful conduct while at the same time obtaining under
17 false pretenses moneys from Plaintiff for the Store Brand APAP. Those moneys would not have
18 been paid had Defendants not engaged in unfair and deceptive conduct.

19 127. Defendants engaged in the following unfair methods of competition or deceptive
20 acts or practices, which are proscribed by law:

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

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

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

1 128. Plaintiffs were injured by the cumulative nature of Defendants’ conduct. The
2 cumulative effect, directed at patients, physicians, and consumers, was to create demand for and
3 sell the Store Brand APAP. Each aspect of Defendants’ conduct combined to artificially create
4 sales of the Store Brand APAP.

5 129. Defendants had a statutory duty to refrain from unfair or deceptive acts or trade
6 practices in the design, labeling, development, manufacture, promotion, and sale of the Store
7 Brand APAP.

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

11 131. Defendants’ actions, as complained of in this Complaint, constitute unfair
12 competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in violation
13 of the federal and state consumer protection statutes listed below.

14 132. Defendants have engaged in unfair competition, or unfair or deceptive acts or trade
15 practices, or has made false representations under the following statutes:

- 16 • 15 U.S.C. §§ 2301–12 (1982);
- 17 • Cal. Bus & Prof. Code § 17200, *et seq.* (Unfair Competition Law (“UCL”));
- 18 • Cal. Civ. Code § 17500 (False Advertising Law (“FAL”));
- 19 • Cal. Civ. Code § 1750 *et seq.* (Consumer Legal Remedies Act (“CLRA”)).

20 133. To protect consumers against unfair, deceptive, fraudulent, and unconscionable
21 trade and business practices, and false advertising, Defendants, as the suppliers, manufacturers,
22 advertisers, and sellers, are subject to liability under the above legislation enacted against unfair,
23 deceptive, fraudulent, and unconscionable consumer sales practices.

24 134. By knowingly and falsely representing that the Store Brand APAP was fit to be
25 used for the purposes for which they were intended—when in fact they were defective and
26 dangerous—and by other acts alleged, Defendants violated the above statutes, enacted to protect
27 consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices,
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1 and false advertising. The UCL prohibits “any unlawful, unfair, or fraudulent business act or
2 practice and unfair, deceptive, untrue, or misleading advertising and any act prohibited by” Section
3 17500 of the California Business and Professions Code. Section 17500, in turn, prohibits any
4 untrue or misleading statements made in connection with the sale of goods. The CLRA defines as
5 statutorily unlawful certain unfair methods of competition and unfair or deceptive practices. Cal.
6 Civ. Code § 1750 *et seq.*

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

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

14 137. Defendants had actual knowledge of the defective and dangerous conditions of the
15 Store Brand APAP but failed to take any action to cure such defective and dangerous conditions.

16 138. Plaintiff Mother relied upon Defendants’ misrepresentations and omissions in
17 determining which Store Brand APAP (if any) to ingest.

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

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

22 141. As a direct and proximate result of Defendants’ violations of the above-listed
23 legislation, Plaintiffs have sustained economic losses and other damages and are entitled to
24 statutory and compensatory damages in an amount to be proven at trial.

25 **COUNT VI: NEGLIGENT MISREPRESENTATION**

26 142. Plaintiffs incorporate by reference the allegations in all prior paragraphs.
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1 143. Defendants had a duty to accurately and truthfully represent to consumers,
2 including Plaintiff Mother, and the public that the Store Brand APAP had not been adequately
3 tested and found to be a safe and effective treatment for pregnant women. Defendants breached
4 that duty as their representations were false.

5 144. Defendants failed to exercise ordinary care in the representations concerning the
6 Store Brand APAP while Defendants were involved in its manufacture, sale, testing, quality
7 assurance, quality control, and distribution in interstate commerce, because Defendants
8 negligently misrepresented the Store Brand APAP's high risk of unreasonable and dangerous
9 adverse side effects.

10 145. Defendants also breached their duty in representing to Plaintiff Mother that the
11 Store Brand APAP had no serious side effects when ingested during pregnancy.

12 146. As a foreseeable, direct, and proximate result of Defendants' negligent
13 misrepresentations, Defendants knew or had reason to know that the Store Brand APAP had been
14 insufficiently tested or had not been tested at all; and that they lacked adequate and accurate
15 warnings, and created a high risk, or a higher than acceptable reported and represented risk, of
16 adverse side effects. Those side effects include neurodevelopmental disorders in children, such as
17 ADHD.

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

22 **PUNITIVE DAMAGES**

23 148. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

24 149. Defendants failed to adequately test and study the Store Brand APAP to determine
25 and ensure that the Store Brand APAP was safe and effective prior to releasing them for sale for
26 human consumption.

1 150. Further, Defendants continued to manufacture and sell the Store Brand APAP after
2 obtaining knowledge and information that they were defective and unreasonably unsafe in that
3 they did not include adequate warnings.

4 151. Defendants were aware of the probable consequences of the dangerous and
5 defective product, including the risk of neurodevelopmental disorders in children, such as ADHD,
6 when they suffered prenatal exposure.

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

13 153. Defendants' misrepresentations included knowingly withholding material
14 information from consumers and the public, including Plaintiff Mother, concerning the safety and
15 efficacy of the Store Brand APAP, which deprived Plaintiff Mother of vitally necessary
16 information with which to make a fully informed decision about whether to use the Store Brand
17 APAP.

18 154. At all material times, Defendants also knew and recklessly and/or intentionally
19 disregarded the fact that the Store Brand APAP can cause debilitating and life-altering side effects
20 with greater frequency than safer alternative methods, products, and/or treatments. But Defendants
21 recklessly failed to advise the medical community and the general public, including Plaintiff
22 Mother, of that fact.

23 155. At all material times, Defendants intentionally misstated and misrepresented data;
24 and Defendants continue to misrepresent data so as to minimize the perceived risk of injuries and
25 the rate of complications caused by or associated with the Store Brand APAP.

26 156. Notwithstanding the foregoing and the growing body of knowledge and
27 information regarding the true and defective nature of the Store Brand APAP, with its increased
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1 risk of side effects and serious complications, Defendants continue to aggressively market the
2 Store Brand APAP to consumers, including the pregnant community at large, without disclosing
3 the true risk of the complications and side effects.

4 157. When Plaintiff Mother consumed the Store Brand APAP and since then,
5 Defendants have known the Store Brand APAP was defective and unreasonably dangerous without
6 an adequate warning. But Defendants continued to manufacture, produce, assemble, market,
7 distribute, and sell the Store Brand APAP to the pregnant community so as to maximize sales and
8 profits at the expense of the health and safety of expecting mothers in a conscious, reckless, and/or
9 intentional disregard of the likely and foreseeable harm caused by the Store Brand APAP to
10 members of the public, including Plaintiffs.

11 158. At all material times, Defendants have concealed and/or failed to disclose to the
12 public the serious risks and the potential complications associated with the Store Brand APAP, so
13 as to ensure continued and increased sales and profits and to the detriment of the public, including
14 Plaintiffs.

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

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

24 **PRAYER FOR RELIEF**

25 Plaintiffs demand judgment against Defendants, individually, and jointly and severally,
26 and prays for the following relief in accordance with applicable law and equity:
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- i. Compensatory damages to Plaintiffs for past, present, and future damages, including pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;
- ii. Restitution and disgorgement of Defendants' profits;
- iii. Applicable statutory penalties;
- iv. Punitive or enhanced compensatory damages;
- v. Reasonable attorneys' fees as provided by law;
- vi. Past and future costs of all proceedings;
- vii. All ascertainable economic damages;
- viii. Prejudgment interest on all damages as allowed by law; and
- ix. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

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

Dated: September 9, 2022

Respectfully submitted,

/s/ Warren D. Postman

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