

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS**

PATRICIA GURROLA, ALEJANDRO  
ARREOLA, BRITINI BROUGHTON,  
EILEEN AVILES, COURTNEY  
DESCHAMP, YVONNE LAMENDOLA,  
SUSHMADAVI LAKERAM, &  
GERMAINE DOLLISME, individually and  
on behalf of those similarly situated,

Plaintiffs,

v.

THE PROCTER & GAMBLE COMPANY,

Defendant.

Case No. 1:25-cv-00358

**CLASS ACTION COMPLAINT**

**JURY TRIAL DEMANDED**

**CLASS ACTION COMPLAINT**

Plaintiffs Patricia Gurrola, Alejandro Arreola, Britini Broughton, Eileen Aviles, Courtney Deschamp, Yvonne Lamendola, Sushmadavi Lakeram, and Germaine Dollisme (“**Plaintiffs**”), individually and on behalf of all others similarly situated who purchased Crest “Kids” Toothpaste, bring this class action lawsuit against defendant The Procter & Gamble Company (“**Defendant**”). Plaintiffs allege the following upon information and belief, except for those allegations that pertain to Plaintiffs, which are based on Plaintiffs’ personal knowledge.

**INTRODUCTION**

1. In the United States, most toothpaste contains an ingredient which makes the paste unsafe for children to swallow: Fluoride.
2. Fluoride helps prevent cavities when applied *topically* to the teeth. When *ingested*, fluoride can present significant risks to health, particularly for young children.
3. Defendant sells kids-branded **Crest** toothpastes for preschool children. These toothpastes have the same concentration of fluoride as many adult-strength brands.

4. Defendant knows its fluoride toothpastes, including its “kids” versions, are not safe for young children to swallow. But it deceptively markets these Kids products in ways that lead parents and caregivers to believe they are formulated to be *extra* safe for children – which Defendant knows is false.

5. Defendant is the largest manufacturer of fluoride toothpaste in the United States and millions of parents across this country have been deceived, and continue to be deceived, by its deceptive marketing.

6. The Food & Drug Administration (“FDA”) states that fluoride-containing toothpastes need to be kept “**out of reach of children under 6 years of age,**” and that caregivers who purchase fluoride toothpaste for children under 6 need to supervise the child’s brushing in order “**to minimize swallowing.**” 21 C.F.R. § 355.50(c)(1) & (d)(1) (second emphasis added).

7. Children under two years of age have little ability to “minimize swallowing” due to poorly developed swallowing reflexes at this young age. Because of this, the FDA considers fluoride toothpaste to be generally contraindicated for children under the age of 2.<sup>1</sup>

8. The Centers for Disease Control and Prevention (“CDC”) agrees that children under 2 should not use fluoride toothpaste.<sup>2</sup>

9. Defendant agrees with CDC and FDA that fluoride toothpaste is contraindicated for children under the age of 2. Defendant’s Crest website (“Website”) thus only offers a fluoride-

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<sup>1</sup> Anticaries Drug Products for Over-the-Counter Human Use; Final Monograph, 60 Fed. Reg. 52474, 52487 (Oct. 6, 1995) (“The agency disagrees with the comments suggesting that the contraindication for children under 2 years of age is unwarranted.”).

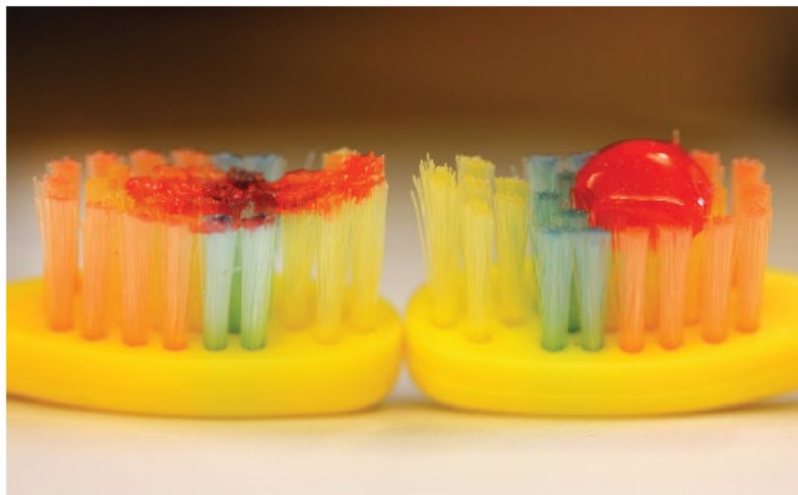
<sup>2</sup> Gina Thornton-Evans, et al., *Use of Toothpaste and Toothbrushing Patterns Among Children and Adolescents - United States, 2013-2016*, 68 MMWR MORB MORTAL WKLY REP. 87, 87 (2019) (“CDC recommends that children begin using fluoride toothpaste at age 2 years.”).

free toothpaste for children under 2.<sup>3</sup>

10. For children who begin brushing their teeth at 2, the CDC states they should use no more than a “smear” of fluoride toothpaste, which is akin to a “rice grain” amount of paste, until they turn 3. From age 3 to 6, the CDC states that children should use no more than a “pea-sized” amount of paste.<sup>4</sup>

11. The American Academy of Pediatrics (“AAP”), American Academy of Pediatric Dentistry (“AAPD”), and the American Dental Association (“ADA”) all agree that children under 3 should use no more than a “smear” of fluoride toothpaste, and they further agree that children ages 3 to 6 should use no more than a “pea-sized” amount of paste. See *infra* ¶¶ 126-128.

12. The following image from the ADA<sup>5</sup> shows what a “smear” (left) and “pea-sized” (right) amount of toothpaste looks like:



**Figure.** The toothbrush on the left shows a smear of toothpaste (0.1 milligram of fluoride) and the one on the right a pea-sized amount (0.25 mg of fluoride).

<sup>3</sup> See <https://crest.com/en-us/oral-care-products/kids> (last accessed Jan. 13, 2025).

<sup>4</sup> Thornton-Evans, et al., *supra* note 2, at 87 (“Children aged <3 years should use a smear the size of a rice grain, and children aged >3 years should use no more than a pea-sized amount (0.25 g) until age 6 years, by which time the swallowing reflex has developed sufficiently to prevent inadvertent ingestion.”)

<sup>5</sup> American Dental Association Council on Scientific Affairs, *Fluoride toothpaste use for young children*, 145 J AM DENT ASSOC. 190, 191 (2014).

13. Given how tiny a “smear” is, Defendant knows that disclosing this guideline to caregivers will cause apprehension about the safety of its kid’s fluoride toothpaste. Defendant also knows that if caregivers follow this guideline, consumers will get many more brushings per tube and, thereby, Defendant will sell less of its product. Defendant, therefore, does not disclose the “smear” guideline on any of its Crest kid’s toothpastes.

14. Instead of disclosing the “smear” guideline, Defendant’s Website states that its kid’s fluoride toothpaste is only for kids who are “3+ Years.”<sup>6</sup>

15. Consistent with its Website, Defendant places a prominent age notation of “3+ YRS” on the front label of all its kid’s Crest fluoride toothpastes with one glaring exception. Defendant does **not** provide the 3+ YRS age notation for its highest selling kids fluoride toothpaste: KID’S Crest Cavity Protection (hereafter, “**KID’S CREST ONE**”).

16. There is nothing about KID’S CREST ONE that makes it safer for kids to ingest than Defendant’s other kids toothpastes. KID’S CREST ONE has the same fluoride concentration, same flavors, same sparkle colors, and same sweet scents as Defendant’s 3+ YRS products.



<sup>6</sup> See <https://tinyurl.com/CrestforKids> (last accessed Jan. 13, 2025).

17. Despite Defendant's knowledge that children under 3 should only use a tiny "smear" of toothpaste, Defendant's KID'S CREST ONE packaging shows a **full strip** of toothpaste. The full strip is shown on the front and side of the product's box as well as on the front label of the product itself. In total, Defendant includes three images of full strips of toothpaste on each unit sold.<sup>7</sup>

18. A full strip of toothpaste is at least **eight to ten times more than the safe and recommended amount** of fluoride toothpaste for children under 3.

19. Showing full strips of fluoride toothpaste in advertising and packaging has been described as an "aggressive" and "misleading" marketing tactic in peer-reviewed dental literature.<sup>8</sup> As one study noted, showing "a large swirl of toothpaste . . . directly conflicts with recommendations and warnings for how much toothpaste should be used by a child."<sup>9</sup> Another study noted that "the power of a visual image" of a full strip of paste can overwhelm the fine print on the back of the label and "result in children's and parents' use of toothpaste at levels higher than recommended."<sup>10</sup> Defendant is well aware of this.

20. In 2023, Defendant launched a new "color changing" toothpaste for kids: KID'S Crest Advanced (hereafter, "**KID'S CREST TWO**"). As with KID'S CREST ONE, KID'S CREST TWO depicts full strips of toothpaste on the front and sides of the box, as well as on the

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<sup>7</sup> This is for the regular-sized Sparkle Fun version of KIDS CREST ONE which is, by far, the highest selling iteration of this product line.

<sup>8</sup> Corey H. Basch & Sonali Rajan, *Marketing strategies and warning labels on children's toothpaste*, 88 J DENT HYG. 316, 316 (2014).

<sup>9</sup> *Id.* at 318.

<sup>10</sup> Corey H. Basch, et al., *Advertising of toothpaste in parenting magazines*, 38 J COMMUNITY HEALTH. 911, 913 (2013).

front of the product itself.



21. KID'S CREST TWO magnifies this deception by showing a full strip of paste as a *visual instruction* on how to use the product, which is located right on the side label of the product's box (as can be seen in the following photo):



22. Defendant also emphasizes this visual instruction in its online promotional materials for KID'S CREST TWO, including on various retail websites (e.g., Amazon, Target, etc) where Defendant sells many units of the product:



23. Another misleading tactic that Defendant uses to sell its Crest kids toothpaste is to present the products as if they are candy. The packaging of KID'S CREST ONE and KID'S CREST TWO promotes the paste's candy flavors ("bubble gum" and "sparkle fun") and Defendant imbues the paste with a flavor, color, and scent that is indistinguishable from candy.

24. It is well recognized that presenting drugs as "candy-like" products increases the risk of overdose, particularly for young children. This problem has long been specifically flagged in the context of fluoride toothpaste. In 1992, the *Journal of Public Health Dentistry* published a consensus statement from dental researchers which read, in part, "The use of flavors that may increase the ingestion of fluoridated dentifrices by young children **should be strongly discouraged.**"<sup>11</sup> Others have issued similar recommendations and warnings. See *infra* ¶¶ 136-141.

<sup>11</sup> James W. Bawden, et al. *Changing patterns of fluoride intake. Proceedings of the workshop. Part II*, 71 J PUBLIC HEALTH DENT. 1212, 1221 (1992) (emphasis added).

25. Defendant's deceptive marketing tactics cause millions of caregivers to unwittingly permit and encourage their children to use far more toothpaste than is recommended or safe. Not only does this pose significant health risks for children, it reduces the number of brushings that families receive per tube, causing economic loss to consumers and unjust enrichment to Defendant.

26. In 2019, the CDC published the results of a nationwide survey of children's toothbrushing habits, and reported that over 50% of 3-6-year-old children are using at least twice the recommended amount of toothpaste.<sup>12</sup>

27. Swallowing as little as one full strip of fluoride toothpaste can cause symptoms of acute toxicity in a 1-year-old child, including nausea, vomiting, and headache. See *infra* ¶¶ 101-107. Defendant is aware of this problem. Defendant's Vice President, Jim Schwartz, once told a journalist: "Our own kid swallowed some toothpaste and threw up."<sup>13</sup>

28. As one pediatric dentist explained, "It does not take much toothpaste to cause a problem in a very small child. For this reason, it is extremely important to keep toothpaste out of reach of small children and behind childproofed drawers or cabinets. The symptoms that follow are nausea and vomiting that progresses to seizures and muscle spasms. It can potentially lead to death if left untreated."<sup>14</sup>

29. The FDA instructs that "if more [fluoride toothpaste] than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away." 21 C.F.R. § 355.50(c)(1).

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<sup>12</sup> Thornton-Evans, *supra* note 2, at 88-89.

<sup>13</sup> Elaine Porterfield, *Hazards lurk in toothpaste tube*, THE NEWS TRIBUNE (Tacoma, Washington), Apr. 5, 1994.

<sup>14</sup> Milling Pediatric Dentistry, *Help! My Child Ate Toothpaste!*, <https://www.simmonsyoung.com/PediatricDentalBlog/help-my-child-ate-toothpaste/> (last accessed Jan. 13, 2025).



30. According to the National Capital Poison Center: “Toothpaste is not meant to be swallowed, but it happens a lot. A child who has eaten toothpaste is a common reason parents call Poison Control. Kids find the flavors and sweetness of toothpaste irresistible. Often, a child is found sucking the paste out of the tube or is found with the paste smeared all over themselves (and the room!).”<sup>15</sup>

31. Children who swallow too much of Defendant’s “kid’s” toothpaste can develop a mineralization disorder of their tooth enamel called dental fluorosis.<sup>16</sup> Defendant describes fluorosis as a “hypocalcification of tooth enamel” that is marked by “less than normal amounts of calcification in the teeth.”<sup>17</sup> This disorder causes visible, and sometimes disfiguring, staining of the enamel. See *infra* ¶¶ 98-100.

32. Despite Defendant’s knowledge that its “kid’s” fluoride toothpaste causes a mineralization disorder of tooth enamel, the label of KID’S CREST ONE deceptively states that it is “**GENTLE ON TOOTH ENAMEL.**”<sup>18</sup>

33. The marketing of fluoride toothpaste as a candy-like product, which Defendant played a lead role in pioneering, is believed to be one of the reasons for the increase in dental fluorosis that has been observed in recent decades.<sup>19</sup>

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<sup>15</sup> National Capital Poison Center, *My Child Ate Toothpaste: What Should I Do?*, <https://www.poison.org/articles/toothpaste> (last accessed Jan. 13, 2025).

<sup>16</sup> Ana Karina Mascarenhas, *Risk factors for dental fluorosis: a review of the recent literature*, 22 PEDIATR DENT. 269, 274 (2000) (“Based on the number of well-conducted case control studies, and the strength of the associations seen in the various studies, the risk of fluorosis from early use of fluoride toothpaste is no longer a controversial issue.”).

<sup>17</sup> Crest, *Dental Fluorosis: Causes, Treatments & Prevention*, <https://crest.com/en-us/oral-care-tips/tooth-enamel/dental-fluorosis-causes-treatments-prevention> (last accessed Jan. 13, 2025).

<sup>18</sup> This is for the regular-sized Sparkle Fun version of KIDS CREST ONE which is, by far, the highest selling iteration of this product line.

<sup>19</sup> Christopher Neurath, et al., *Dental Fluorosis Trends in US Oral Health Surveys: 1986 to 2012*,

34. Defendant first began selling candy-like and colorful fluoride toothpastes in the mid-1980s.<sup>20</sup> Since that time, the rate of dental fluorosis among U.S. schoolchildren has skyrocketed. In 1986-87, approximately 23% of U.S. children had fluorosis.<sup>21</sup> This rate tripled to a staggering 68% of U.S. children by 2015-16.<sup>22</sup>

35. With millions of U.S. children showing visible signs of excess fluoride exposure (dental fluorosis), there is growing concern about other chronic health conditions that fluoride may be causing, including neurodevelopmental disorders and endocrine disruption. In August of 2024, the prestigious National Toxicology Program (NTP) concluded that excess fluoride exposure is associated with IQ deficits, and, in September 2024, a federal district court concluded that the addition of fluoride to drinking water “poses an unreasonable risk of reduced IQ in children.” See *infra* ¶¶ 118-122.

36. Plaintiffs bring this action to hold Defendant accountable for the false and misleading labeling of its products, which puts the health of millions of children at risk. Defendant’s misleading marketing of KIDS CREST ONE and KIDS CREST TWO violates the Federal Food Drug & Cosmetic Act (“FDCA”), 21 U.S.C. § 352(a),<sup>23</sup> and many state warranty

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4 JDR CLIN TRANS RES. 298, 306 (2019).

<sup>20</sup> See Jesus Sanchez, *New Flavors Appeal to Youthful Palates: Children Fill Gap in Toothpaste Market*, L.A. TIMES, Sept. 25, 1987 (“Dental experts, for the most part, are not too excited about the new toothpaste tastes. Alson J. McCaslin, president of the American Academy of Pediatric Dentistry, said: ‘This is a new marketing technique to get a larger share of the market without doing anything really new.’”).

<sup>21</sup> Keith E. Heller, *Dental caries and dental fluorosis at varying water fluoride concentrations*, 57 J PUBLIC HEALTH DENT. 136, 139 Tbl 5 (1997).

<sup>22</sup> Man Hung et al., *A National Study Exploring the Association Between Fluoride Levels and Dental Fluorosis*, 6 JAMA NETW OPEN. e2318406 (2023).

<sup>23</sup> Plaintiffs recognize that there is no private right of action under FDCA and do not assert such a claim here. Instead, Plaintiffs’ allegations that Defendant violated the requirements of the FDCA serve as a prerequisite for their state law claims. See, e.g., *In re Beyond Meat, Inc.*, No. 23 C 669, 2024 U.S. Dist. LEXIS 30397, at \*21 (N.D. Ill. Feb. 21, 2024) (“[T]o avoid preemption, a state

and consumer deception statutes, including, but not limited to, the Illinois Consumer Fraud and Deceptive Trade Practices Act, 815 ILCS § 505/2, California Unfair Competition Act, Cal. Bus. & Prof. Code § 17200, and New York General Business Law §§ 349-50.

37. Plaintiffs do not seek to impose any requirement that goes beyond, is not identical to, or is different from, the requirements that are imposed on Defendant under the FDCA and its accompanying regulations, including the FDA Monograph on fluoride toothpaste.<sup>24</sup> See C.F.R. § 355.50. Plaintiffs seek instead to hold Defendant responsible for the elements of its products that are *not* required by the Monograph *and* which simultaneously violate the FDCA's requirements. A judicial finding that these voluntarily added attributes are false and misleading would be harmonious and not in conflict with the FDCA.<sup>25</sup>

### PARTIES

38. Plaintiff **Patricia Gurrola** is a citizen of Illinois and lives in Chicago. Ms. Gurrola has purchased KID'S CREST ONE for her minor daughter I.K, and both KID'S CREST ONE and KID'S CREST TWO for her minor son G.K.

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law claim related to misleading labeling must allege a violation of the FDCA or its regulations.”).

<sup>24</sup> For example, Plaintiffs do not seek to require Defendant to disclose that children under 3 should only use a “smear” of paste, or that Defendant add a “3+ YRS” notation on the label. Nor do Plaintiffs seek to compel Defendant to disclose that ingesting fluoride can cause dental fluorosis, disrupt the endocrine system, or impair neurodevelopment. Although Plaintiffs believe such disclosures would be justified and prudent, Plaintiffs recognize this Court does not have the power to order such measures.

<sup>25</sup> See, e.g., *Bell v. Publix Super Mkts., Inc.*, 982 F.3d 468, 485 (7th Cir. 2020) (“The FDCA’s preemption provision means that, while states may not require sellers to add further labeling that is not required by federal law, they may prevent sellers from voluntarily adding deceptive content that is not required by federal law.”); *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 758 (9th Cir. 2015) (“FDA regulations do not require Hain to label its products as ‘All Natural’ or ‘Pure Natural.’ If Astiana’s suit ultimately requires Hain to remove these allegedly misleading advertising statements from its product labels, such a result does not run afoul of the FDCA, which prohibits ‘requirement[s]’ that are ‘different from,’ ‘in addition to,’ or ‘not identical with’ federal rules.”).

39. Ms. Gurrola has purchased KID'S CREST ONE and KID's CREST TWO for I.K. and G.K. from CVS, Walgreens, and Mariano's in Cook County.

40. Ms. Gurrola began purchasing KID'S CREST ONE for I.K. in approximately 2023 when she was 1 year old. She continued purchasing this product for I.K. until 2024, when she was 2 years old.

41. Ms. Gurrola began purchasing KID'S CREST ONE for G.K. in approximately 2020 when he was 1 year old. She continued purchasing the paste for G.K. until switching over to KID's CREST TWO in 2023. Ms. Gurrola purchased KID'S CREST TWO for G.K. until 2024.

42. Since they began brushing with Defendant's toothpaste at 1 year of age, both G.K. and I.K. have used full strips of paste with Ms. Gurrola's assistance and/or permission.

43. Both G.K. and I.K. enjoyed the candy flavor of Defendant's paste.

44. Based on the packaging of KID'S CREST ONE and KID'S CREST TWO, Ms. Gurrola believed the product was specially formulated to be safe for young children to ingest.

45. Plaintiff **Alejandro Arreola** is a citizen of Illinois and lives in Chicago. Mr. Arreola purchased KID'S CREST TWO for his minor daughter N.A.

46. Mr. Arreola has purchased KID'S CREST TWO in Walmart's and/or Jewel-Osco in Chicago.

47. Mr. Arreola began purchasing KID'S CREST TWO for N.A. in 2023 when she was about 4 years old. He continued purchasing this product for N.A. until 2024 when N.S. was 5 years old.

48. With Mr. Arreola's assistance and/or permission, N.A. used a full strip of paste on her brush for brushings.

49. N.A. enjoyed the candy flavor and color-changing properties of Defendant's paste.

50. Based on the packaging of KID'S CREST TWO, Mr. Arreola believed the product was specially formulated to be safe for young children to ingest.

51. Plaintiff **Britini Broughton** is a citizen of Chicago and lives in Kankakee. Ms. Broughton purchased KID'S CREST TWO for her minor daughter A.B. while living in Bourbonnais, Illinois.

52. Ms. Broughton has purchased KID'S CREST TWO from various stores, including Walmart, Walgreens, and/or Kroger in Bourbonnais.

53. Ms. Broughton began purchasing KID'S CREST TWO for A.B. in early 2024 when A.B. was 3 years old. She purchased the product for A.B. through to the late summer of 2024.

54. With Ms. Broughton's assistance and/or permission, A.B. used a full strip of paste on her brush for brushings.

55. A.B. enjoyed the candy flavor of Defendant's paste.

56. Based on the packaging of KID'S CREST TWO, Ms. Broughton believed the product was specially formulated to be safe for young children to ingest.

57. Plaintiff **Eileen Aviles** lives in Suisun City, California and is a citizen of California. Ms. Aviles purchased KID'S CREST ONE for her minor daughter I.A.C.

58. Ms. Aviles began purchasing KID'S CREST ONE for I.A.C. in approximately 2022 when she was 2 years old. She continued purchasing this product for I.A.C. until 2024 when I.A.C. was 4 years old.

59. With Ms. Aviles's assistance and/or permission, I.A.C. used a full strip of paste on her brush for brushings.

60. I.A.C. enjoyed the candy flavor of Defendant's paste.

61. Based on the packaging of KID'S CREST ONE, Ms. Aviles believed the product

was specially formulated to be safe for young children to ingest.

62. Plaintiff **Courtney Deschamp** lives in Santa Clarita, California and is a citizen of California. Ms. Deschamp purchased KID'S CREST ONE for her minor daughter L.D.

63. Ms. Deschamp began purchasing KID'S CREST ONE for L.D. in approximately 2022 when she was 1.5 years old. She continued purchasing this product for L.D. until 2024, when L.K. was 3 years old.

64. With Ms. Deschamp's assistance and/or permission, L.D. used a full strip of paste on her brush for brushings.

65. L.D. enjoyed the candy flavor of Defendant's paste.

66. Based on the packaging of KID'S CREST ONE, Ms. Deschamp believed the product was specially formulated to be safe for young children to ingest.

67. Plaintiff **Yvonne Lamendola** lives in Oxnard, California and is a citizen of California. Ms. Lamendola purchased KID'S CREST TWO for her minor daughter K.L.

68. Ms. Lamendola began purchasing KID'S CREST TWO for K.L. in approximately 2023 when she was 4 years old. She continued purchasing this product for K.L. until 2024, when she was 5 years old.

69. With Ms. Lamendola's assistance and/or permission, K.L. used at least a half strip of paste for each of her brushings.

70. K.L. enjoyed the candy flavor of Defendant's paste.

71. Based on the packaging of KID'S CREST TWO, Ms. Lamendola believed the product was specially formulated to be safe for young children to ingest.

72. Plaintiff **Sushmadavi Lakeram** lives in Queens Village, New York and is a citizen of New York. Ms. Lakeram purchased KID'S CREST ONE for her minor son C.L.

73. Ms. Lakeram began purchasing KID'S CREST ONE for C.L. in approximately 2020 when he was 1.5 years old. She continued purchasing this product for C.L. until 2024, when he was 5 years old.

74. With Ms. Lakeram's assistance and/or permission, C.L. used a full strip of paste on his brush for brushings.

75. C.L. enjoyed the candy flavor of Defendant's paste.

76. Based on the packaging of KID'S CREST ONE, Ms. Lakeram believed the product was specially formulated to be safe for young children to ingest.

77. Plaintiff **Germaine Dollisme** lives in Utica, New York and is a citizen of New York. Ms. Dollisme purchased KID'S CREST TWO for her minor son S.D.G.

78. Ms. Dollisme began purchasing KID'S CREST TWO for S.D.G. in approximately 2023 when he was 4 years old. She continued purchasing this product for S.D.G. until 2024, when he was 5 years old.

79. With Ms. Dollisme's assistance and/or permission, S.D.G. used a full strip of paste on his brush for brushings.

80. S.D.G. enjoyed the candy flavor of Defendant's paste.

81. Based on the packaging of KID'S CREST TWO, Ms. Dollisme believed the product was specially formulated to be safe for young children to ingest.

82. Defendant **The Procter & Gamble Company** is a publicly traded corporation organized and existing under the laws of Ohio, with its principal place of business in Cincinnati, Ohio. Defendant manufactures and sells various brands of toothpaste, including Crest.

### **JURISDICTION AND VENUE**

83. This Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. §1332(d)(2) and the Class Action Fairness Act of 2005 (“CAFA”), because (i) there are 100 or more class members; (ii) there is an aggregate amount in controversy exceeding \$5,000,000, exclusive of interest and costs; and (iii) there is minimal diversity because at least one member of the class and defendant are citizens of different states. This court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.

84. This Court has personal jurisdiction over Defendant Procter & Gamble Company because the injuries upon which the Illinois Plaintiffs’ action are based occurred or arose out of activities that Defendant specifically engaged in within the State of Illinois. Plaintiffs purchased Defendant’s toothpaste products from retail stores located here in Illinois; Defendant knowingly and intentionally distributed its toothpaste products for sale in Illinois; and Defendant accomplished this, in part, through operation of a distribution center in Chicago.

85. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claims occurred in the State of Illinois, including within Cook County.

### **FACTUAL ALLEGATIONS**

#### **A. Fluoride Toothpaste Poses a Much Greater Risk to Young Children than Adults**

86. For a multitude of reasons, young children are more vulnerable to suffering harm from fluoride toothpaste than adolescents and adults.

87. Young children have poorly developed swallowing reflexes and, as a result, swallow a large percentage of the paste that they put into their mouth. As the FDA has explained, “Children under 6 years of age . . . have not developed control of their swallowing reflex and are



not able to hold the fluoride preparation in their mouth and then expectorate properly.”<sup>26</sup> Because of this, “ingestion of fluoride from toothpaste is common and often substantial” for young children.<sup>27</sup> As summarized in the *Journal of Public Health Dentistry*, “[v]irtually all authors have noted that some children could ingest more fluoride from [toothpaste] alone than is recommended as a total daily fluoride ingestion.”<sup>28</sup>

88. Young children are also at greater risk from fluoride toothpaste because they “cannot be expected to rationally interpret and consistently follow the instructions involving proper toothbrushing.”<sup>29</sup> When toothpaste tastes and smells like candy, for example, young children will want to swallow it, irrespective of what the fine print on the label says. As noted by the CDC, children are “known to swallow toothpaste deliberately when they like its taste.”<sup>30</sup> A recent study found that 35% of kids ate toothpaste “frequently” and an additional 22% of kids ate toothpaste “a few times.”<sup>31</sup>

89. Due to their smaller size, young children receive a far higher fluoride dose by bodyweight (mg/kg/day) than adults, even when ingesting the same amount of paste. A 1 year old child of average weight (~9 kg) who ingests a single strip of toothpaste will exceed EPA’s reference dose (0.08 mg/kg/day) for fluoride. According to EPA, children who ingest more than

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<sup>26</sup> FDA, *Anticaries Drug Products for Over-the-Counter Use; Tentative Final Monograph; Notice of Proposed Rulemaking*, 59 Fed. Reg. 39854, 39867 (Sept. 30, 1985).

<sup>27</sup> Steven M. Levy, *A review of fluoride intake from fluoride dentifrice*, 60 ASDC J DENT CHILD. 115, 115 (1993).

<sup>28</sup> Steven M. Levy & Nupur Guha-Chowdhury, *Total fluoride intake and implications for dietary fluoride supplementation*, 59 J PUBLIC HEALTH DENT. 211, 216-17 (1999).

<sup>29</sup> FDA, *supra* note 1, at 52487.

<sup>30</sup> CDC, *Recommendations for using fluoride to prevent and control dental caries in the United States. Centers for Disease Control and Prevention*, 50 MMWR RECOMM REP. 1, 14 (2001).

<sup>31</sup> Roger K. Celeste & Patricia Blaya Luz, *Independent and Additive Effects of Different Sources of Fluoride and Dental Fluorosis*, 38 PEDIATR DENT. 233, 235 Tbl 2 (2016).

0.08 mg/kg/day are at risk of developing “severe dental fluorosis.”<sup>32</sup>

### **B. Ingesting Fluoride Toothpaste During Early Childhood Causes Dental Fluorosis**

90. Dental fluorosis is “a permanent, mottled discoloration of the teeth”<sup>33</sup> that is caused by ingesting too much fluoride while the teeth are still developing. Once the teeth have finished forming, fluoride can no longer cause fluorosis. Ergo, only young children are at risk of developing this condition.

91. The first six years of life are the critical window of vulnerability for developing dental fluorosis, with fluoride exposures during the first 3 years of life being the most significant for causing fluorosis of the upper front teeth, which are the most cosmetically important teeth.<sup>34</sup>

92. Dental fluorosis comes in various degrees of severity.<sup>35</sup> The mild forms of fluorosis cause “permanent white lines or streaks” on the teeth, whereas the severe forms of fluorosis cause “brown, gray, or black patches and pits, typically on top of an irregular tooth surface.”<sup>36</sup>



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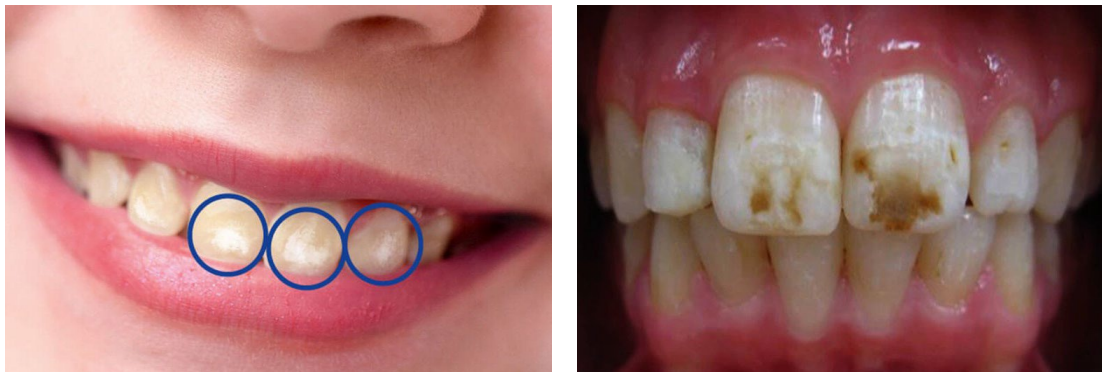
<sup>32</sup> ENVIRONMENTAL PROTECTION AGENCY: FLUORIDE: DOSE-RESPONSE ANALYSIS FOR NON-CANCER EFFECTS 107 (2010),

<sup>33</sup> FDA, *supra* note 1, at 52487.

<sup>34</sup> Michael R. Franzman, et al., *Fluoride dentifrice ingestion and fluorosis of the permanent incisors*, 137 J AM DENT ASSOC. 645, 646 (2006).

<sup>35</sup> NATIONAL RESEARCH COUNCIL, FLUORIDE IN DRINKING WATER: A SCIENTIFIC REVIEW OF EPA’S STANDARDS 104 (2006).

<sup>36</sup> Colgate, *Causes of Brown Spots on the Teeth*, <https://www.colgate.com/en-us/oral-health/adult-oral-care/brown-spots-on-teeth-causes> (last accessed Jan. 13, 2025).



*Photos of Dental Fluorosis*

93. Microscopically, “dental fluorosis is a condition of permanent hypomineralized change, with increased surface and sub-surface enamel porosity resulting from excess fluoride reaching the developing tooth prior to eruption.”<sup>37</sup> In short, “fluoride affects the forming enamel by making it more porous.”<sup>38</sup>

94. It is well established that ingesting fluoride toothpaste can cause dental fluorosis. The American Dental Association states that “ingesting pea-sized amounts or more [of fluoride toothpaste] can lead to mild fluorosis.”<sup>39</sup>

95. According to a review in the journal *Pediatric Dentistry* “[b]ased on the number of well-conducted case control studies, and the strength of the associations seen in the various studies, the risk of fluorosis from early use of fluoride toothpaste is no longer a controversial issue.”<sup>40</sup>

96. The CDC agrees that fluoride toothpaste causes fluorosis: “Fluoride toothpaste contributes to the risk for enamel fluorosis because the swallowing reflex of children aged <6 years

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<sup>37</sup> Brian A. Burt, *The changing patterns of systemic fluoride intake*, 71 J DENT RES. 1228, 1228 (1992).

<sup>38</sup> Mascarenhas, *supra* note 16, at 269.

<sup>39</sup> American Dental Association Council on Scientific Affairs, *supra* note 5, at 190.

<sup>40</sup> Mascarenhas, *supra* note 16, at 274.

is not always well controlled, particularly among children aged <3 years.”<sup>41</sup> The CDC states that the risk of developing fluorosis from using fluoride toothpaste is greatest for children under the age of two: “Children who begin using fluoride toothpaste at age <2 years are at higher risk for enamel fluorosis than children who begin later or who do not use fluoride toothpaste at all.”<sup>42</sup>

97. The ingestion of fluoride toothpaste is considered to be a key reason for the skyrocketing prevalence of dental fluorosis in the US. In the 1940s, dental fluorosis was a rare condition that was generally found only in areas with elevated fluoride in water. Since that time, with the advent of water fluoridation programs and fluoridated dental products, the rate of dental fluorosis has steadily increased. The most recent national survey from the CDC, conducted in 2015-2016, found that 68.2% of children now have some form of dental fluorosis.<sup>43</sup>

98. Dental fluorosis, even in its “mild” forms, is recognized to be cosmetically objectionable when present on a child’s upper front teeth (i.e., maxillary anterior teeth).<sup>44</sup>

99. The following are some findings from the peer-reviewed dental literature regarding the disfiguring effects of “mild” fluorosis:

- a. “Mild and moderate dental fluorosis had a negative aesthetic effect on the studied population, leading to a strong desire to seek dental treatment to change the appearance of affected teeth.”<sup>45</sup>

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<sup>41</sup> CDC, *supra* note 30, at 14.

<sup>42</sup> *Id.*

<sup>43</sup> Hung et al., *supra* note 22.

<sup>44</sup> Susan O. Griffin et al., *Esthetically objectionable fluorosis attributable to water fluoridation*, 30 COMMUNITY DENT ORAL EPIDEMIOL. 199, 202-03 (2002).

<sup>45</sup> Frederico Omar Gleber-Netto, et al. *Assessment of aesthetic perception of mild and moderate dental fluorosis levels among students from the Federal University of Minas Gerais-UFMG, Brazil*, 9 ORAL HEALTH PREV DENT 339, 339 (2011).

- b. “The key finding to emerge from this study was the negative psychosocial impact reported by some children with untreated enamel defects . . . . Over half of the children stated that they had been subject to unkind remarks about their teeth by their peers. A number of children described a reluctance to smile or a lack of confidence.”<sup>46</sup>
- c. “Fluorosis was associated with increased parental dissatisfaction with overall appearance, color, and blotchiness of their children’s teeth.”<sup>47</sup>
- d. “The pupils’ feedback was extremely useful, revealing that they believed the ‘marks’ on the teeth to be due to poor oral hygiene, despite a preliminary tutorial which indicated this was not the case.”<sup>48</sup>
- e. “Our studies of esthetic perceptions of dental fluorosis found that members of the public had strong preferences about variations from normal tooth appearance. For example, all respondents had a preference for teeth with normal color over teeth with mild fluorosis . . . .”<sup>49</sup>
- f. “Results show that not only is fluorosis noticeable, but it may be more of an esthetic concern than the other conditions (e.g. isolated opacities, tetracycline staining, or various types of malocclusion).”<sup>50</sup>

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<sup>46</sup> H.D. Rodd, et al., *Seeking children's perspectives in the management of visible enamel defects*, 21 Int J Paediatr Dent. 89, 93 (2011); see also Zoe Marshman, et al., *The impact of developmental defects of enamel on young people in the UK*, 37 COMMUNITY DENT ORAL EPIDEMIOL. 45 (2008).

<sup>47</sup> Steven M. Levy, et al., *Factors associated with parents’ esthetic perceptions of children’s mixed dentition fluorosis and demarcated opacities*, 27 PEDIATR DENT. 486, 486 (2005).

<sup>48</sup> Maura Edwards, et al., *An assessment of teenagers’ perceptions of dental fluorosis using digital stimulation and web-based testing*, 33 COMMUNITY DENT ORAL EPIDEMIOL. 298, 305(2005).

<sup>49</sup> Steven M. Levy, *An update on fluorides and fluorosis*, 69 J CAN DENT ASSOC. 286, 287 (2003).

<sup>50</sup> Carrie B. McKnight, et al., *A pilot study of esthetic perceptions of dental fluorosis vs. selected*

- g. “A strong association between fluorosis and parental satisfaction was evident, even at a low level of severity.”<sup>51</sup>
- h. “South Australian children 10- to 17-years-old were able to recognize very mild and mild fluorosis and register changes in satisfaction with the colour and appearance of teeth. Even mild changes were associated with psycho-behavioural impacts.”<sup>52</sup>
- i. “[O]bservers felt that the appearance would increasingly embarrass the child as the TF score increased.”<sup>53</sup>

100. Due to the objectionable appearance of fluorosis, many people with the condition pay for cosmetic treatment (e.g., abrasion of the tooth surface in mild cases, and veneers in severe cases). This treatment can be expensive and beyond the financial means for some families.

### **C. Ingesting Fluoride Toothpaste Can Cause Stomach Flu Symptoms**

101. Ingesting too much fluoride toothpaste can cause symptoms of acute toxicity that mimic the symptoms of stomach flu, including nausea, upset stomach, and vomiting.

102. According to a review in the *Journal of Public Health Dentistry*, “Parents or caregivers may not notice the symptoms associated with mild fluoride toxicity or may attribute them to colic or gastroenteritis, particularly if they did not see the child ingest fluoride. Similarly, because of the nonspecific nature of mild to moderate symptoms, a physician’s differential diagnosis is unlikely to include fluoride toxicity without a history of fluoride ingestion.”<sup>54</sup>

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*other dental conditions*, 65 ASDC J DENT CHILD 233, 233 (1998).

<sup>51</sup> James A. Lalumandier & R. Gary Rozier, *Parents’ satisfaction with children’s tooth color: fluorosis as a contributing factor*, 129 J AM DENT ASSOC. 1000, 1003 (1998).

<sup>52</sup> John Spencer, et al., *Water fluoridation in Australia*, 13 COMMUNITY DENT HEALTH 27 (1996).

<sup>53</sup> Paul J. Riordan, *Perceptions of dental fluorosis*, 72 J DENTAL RES 1268, 1268 (1993).

<sup>54</sup> Jay D. Shulman & Linda M. Wells, *Acute fluoride toxicity from ingesting home-use dental*

103. The mechanism by which fluoride causes stomach flu symptoms has been described as follows: “When above normal amounts of fluoride are ingested, the fluoride combines with hydrochloric acid in the stomach and forms hydrofluoric acid. As a result, the hydrofluoric acid has a burning effect on the gastric lining causing gastrointestinal (GI) symptoms such as nausea, vomiting, abdominal cramping, and discomfort.”<sup>55</sup>

104. As with all toxicants, the dose of fluoride that causes symptoms of acute toxicity varies considerably across the population, with some children being much more vulnerable, and other children being much more resistant, than the “average child.”<sup>56</sup>

105. Symptoms of nausea and gastrointestinal distress have been reported at doses as low as 0.1 mg/kg.<sup>57</sup> A 1 year-old-child of average weight (~9 kg) will ingest this much fluoride by swallowing as little as one full strip of fluoride toothpaste.

106. In *adults*, a one-time ingestion of as little as 3 milligrams of fluoride in one sitting (or the equivalent of about 3 strips of fluoride toothpaste) has been found to cause “widespread” erosions of the gastric mucosa in the stomach.<sup>58</sup> The dose that causes erosions in the stomach of children has not been studied (due to ethical constraints) but will almost certainly be less than 3 mg due to lower bodyweight and smaller stomach space.

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*products in children, birth to 6 years of age*, 57 J PUBLIC HEALTH DENT. 150, 157 (1997).

<sup>55</sup> Mary D. Cooper & Connie M. Kracher, *Are our patients guzzling too much fluoride?*, RDH MAGAZINE, Feb. 1, 1997, <https://www.rdhmag.com/patient-care/rinses-pastes/article/16406858/are-our-patients-guzzling-too-much-fluoride>.

<sup>56</sup> E.g., H.G. Eichler, et al., *Accidental ingestion of NaF tablets by children--report of a poison control center and one case*, 20 INT J CLIN PHARMACOL THER TOXICOL. 334 (1982). Cf. C.J. Spak, et al., *Studies of human gastric mucosa after application of 0.42% fluoride gel*, 69 J DENT RES. 426 (1990).

<sup>57</sup> Kenji Akiniwa, *A Re-examination of acute toxicity of fluoride*, 30 FLUORIDE 89 (1997).

<sup>58</sup> Spak, *supra* note 56.

107. If a 1-year-old-child ingests a full strip of Crest “kids” fluoride toothpaste, the National Capital Poison Center recommends that the child take “Two tablets of chewable calcium or calcium plus vitamin D supplement,” “Four ounces of milk,” or “One tablespoon of liquid antacid containing magnesium or aluminum” in order to help prevent “nausea, vomiting, diarrhea.”<sup>59</sup>

#### **D. 1/3 of a Tube of “Kids” Fluoride Toothpaste Has Enough Fluoride to Kill a Toddler**

108. Fluoride is a “protoplasmic poison”<sup>60</sup> that can kill humans at doses not that much higher than arsenic.<sup>61</sup> The potency of fluoride’s acute toxicity is why fluoride has been used as the active ingredient in rodenticides (to kill rodents) and insecticides (to kill bugs).<sup>62</sup> As far back as 1895, it was observed that “sodium fluoride is an active poison for micro-organisms of all kinds, algae, and nerves and muscles of the higher organisms.”<sup>63</sup>

109. The “Probable Toxic Dose” (“PTD”) for fluoride is 5 mg/kg.<sup>64</sup> The PTD “is defined as the dose of ingested fluoride that should trigger immediate therapeutic intervention and

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<sup>59</sup> See <https://triage.webpoisoncontrol.org/> (last accessed Jan. 13, 2025).

<sup>60</sup> Editorial, *Chronic fluorine intoxication*, 123 J AM DENT ASSOC. 150, 150 (1943).

<sup>61</sup> The CDC states that “[a]s little as 1–2.5 mg/kg of arsenic trioxide is a potentially fatal dose.” CDC, *Medical Management Guidelines for Arsenic (As) and Inorganic Arsenic Compounds*, <https://www.cdc.gov/TSP/MMG/MMGDetails.aspx?mmgid=1424&toxid=3>. This is only slightly lower than the potentially fatal dose of fluoride (5 mg/kg), as discussed below. See also Floyd DeEds, *Fluorine in relation to bone and tooth development*, 33 J AM DENT ASSOC. 568, 570 (1936) (“Such a comparison of toxicity data suggests that fluorine, lead and arsenic belong to the same group, as far as ability to cause some symptom of toxicity in minute dosage is concerned.”).

<sup>62</sup> KAJ ROHOLM, *FLUORINE INTOXICATION: A CLINICAL HYGIENIC STUDY WITH A REVIEW OF THE LITERATURE AND SOME EXPERIMENTAL INVESTIGATIONS* 301 (1937).

<sup>63</sup> Herbert B. Baldwin, *The toxic action of sodium fluoride*, 21 J AM CHEM SOC. 517, 521 (1899) (quoting Czrellitzer 1895).

<sup>64</sup> Gary M. Whitford, *Fluoride in dental products: safety considerations*, 66 J DENT RES. 1056, 1056 (1987).



hospitalization because of the likelihood of serious toxic consequences.”<sup>65</sup> It is the “minimum dose that could cause toxic signs and symptoms, including death, and that should trigger immediate therapeutic intervention and hospitalization.”<sup>66</sup>

110. Due to person-to-person variations in sensitivity to fluoride toxicity, not all people who ingest 5 mg/kg will experience significant toxicity. But, “if it is even suspected that 5.0 mg/kg or more of fluoride has been ingested, then it should be assumed that an emergency exists. Appropriate therapeutic measures and hospitalization should be instituted immediately.”<sup>67</sup>

111. A tube of KID’S CREST ONE contains 143 milligrams of fluoride.<sup>68</sup> A 1 year-old-child of average weight (~9 kg) would need to ingest only 1/3 of the tube to exceed the PTD, while a 2-year-old-child of average weight (~12 kg) would need to ingest only 42% of the product to exceed the PTD.

112. Each year there are between 10,000 and 15,000 calls to poison control centers as a result of excess ingestion of fluoride toothpaste.<sup>69</sup> The vast majority of these calls are made on behalf of very young children, and hundreds of these calls result in hospitalizations.

113. The number of poisoning incidents from consumer products reported to poison control centers is recognized to “likely underestimate the total incidence and severity of

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<sup>65</sup> *Id.*

<sup>66</sup> *Id.* at 1057.

<sup>67</sup> *Id.*

<sup>68</sup> Defendant’s KID’S CREST TWO toothpaste contains approximately 130 mg of fluoride.

<sup>69</sup> David D. Gummin et al., *2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report*, 59 CLIN TOXICOL (Phila) 1282, 1448 (2020); David D. Gummin et al., *2021 Annual Report of the National Poison Data System© (NPDS) from America's Poison Centers: 39th Annual Report*, 60 CLIN TOXICOL (Phila) 1381, 1581 (2021).

poisonings.”<sup>70</sup> This is the case even for poisonings that cause outcomes as severe as death.<sup>71</sup>

114. Consistent with the general recognition that poison control data underestimates the true extent and severity of poisonings, the number of poisonings from fluoride toothpaste is also believed to “underestimate” the true extent of fluoride poisonings due to “substantial underreporting” of such incidents.<sup>72</sup>

#### **E. Other Health Concerns with Early Life Exposure to Fluoride**

115. Acute toxicity and dental fluorosis are not the only health concerns with excess ingestion of fluoride.

116. In 2006, the National Research Council (“NRC”) of the National Academies of Science published a comprehensive review of fluoride toxicology which concluded, among other things, that excess fluoride exposure weakens bone, damages the brain, and disrupts the endocrine system, including the thyroid gland.<sup>73</sup> According to the NRC, fluoride has been credibly associated with impaired thyroid function in susceptible humans at doses as low as 0.01 to 0.03 mg/kg/day,<sup>74</sup> which is less than many children will ingest from swallowing fluoride toothpaste.<sup>75</sup>

117. Another endocrine effect of fluoride exposure that the NRC flagged is impaired

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<sup>70</sup> Arthur Chang, et al., *Cleaning and Disinfectant Chemical Exposures and Temporal Associations with COVID-19 — National Poison Data System, United States, January 1, 2020–March 31, 2020*, 69 MMWR MORB MORTAL WKLY REP. 16 496, 496-97 (2020).

<sup>71</sup> Christopher Hoyte, Medical Director of the Rocky Mountain Poison Center, Presentation to FDA Workshop “Defining ‘Candy-Like’ Nonprescription Drug Products,” Oct. 30, 2023, p. 232.

<sup>72</sup> Shulman & Wells, *supra* note 54, at 157.

<sup>73</sup> NATIONAL RESEARCH COUNCIL, *supra* note 35, at 178-80, 220-22 & 260-66.

<sup>74</sup> *Id.* at 263 (“In humans, effects on thyroid function were associated with fluoride exposures of 0.05-0.13 mg/kg/day when iodine intake was adequate and 0.01-0.03 mg/kg/day when iodine intake was inadequate.”).

<sup>75</sup> A 2-year-old-child of average weight (~12 kg) will ingest 0.04 mg/kg from ingesting just half of a full strip of Defendant’s kids toothpaste products.

glucose metabolism, which is believed to be caused by fluoride’s “inhibition of insulin production.”<sup>76</sup> According to the NRC, blood fluoride levels of 0.1 mg/L are credibly associated with this effect.<sup>77</sup> A preschool child who ingests a full strip of fluoride toothpaste will have blood fluoride levels that temporarily approximate or exceed this level.<sup>78</sup>

118. In August of 2024, the National Toxicology Program (“NTP”), which is part of the National Institutes of Health, published a systematic review in which it concluded that excess fluoride exposure is “consistently associated with reduced IQ in children.”<sup>79</sup>

119. In January of 2025, NTP scientists published a meta-analysis of 74 human studies on fluoride and IQ in the journal *JAMA Pediatrics*.<sup>80</sup> The NTP analysis “found inverse associations and a dose-response relationship between fluoride measurements in urine and drinking water and children’s IQ across the large multicountry epidemiological literature.”

120. The NTP has flagged toothpaste as a source of childhood fluoride exposure that could contribute to the risk of neurodevelopmental problems. According to the NTP, “children may be getting more fluoride than they need because they now get fluoride from many sources including treated public water, water-added foods and beverages, teas, *toothpaste*, floss, and mouthwash, and the combined total intake of fluoride may exceed safe amounts.”<sup>81</sup>

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<sup>76</sup> *Id.* at 264.

<sup>77</sup> *Id.*

<sup>78</sup> See Jan Ekstrand et al., *Plasma fluoride concentrations in pre-school children after ingestion of fluoride tablets and toothpaste*, 17 *CARIES RES.* 379 (1983).

<sup>79</sup> NATIONAL TOXICOLOGY PROGRAM, NTP MONOGRAPH ON THE STATE OF THE SCIENCE CONCERNING FLUORIDE EXPOSURE AND NEURODEVELOPMENT AND COGNITION: A SYSTEMATIC REVIEW. Available online at [https://ntp.niehs.nih.gov/sites/default/files/2024-08/fluoride\\_final\\_508.pdf](https://ntp.niehs.nih.gov/sites/default/files/2024-08/fluoride_final_508.pdf).

<sup>80</sup> Kyla Taylor et al., *Fluoride exposure and children’s IQ scores: A systematic review and meta-analysis*, *JAMA PED.* doi: 10.1001/jamapediatrics.2024.5542 (published online on Jan. 6, 2025).

<sup>81</sup> National Toxicology Program, *Fluoride Exposure: Neurodevelopment and Cognition*,

121. On September 24, 2024, after hearing extensive expert testimony about NTP's findings and other recent research, the Honorable Judge Edward Chen from the U.S. District Court for the Northern District of California concluded that the addition of fluoride to drinking water "poses an unreasonable risk of reduced IQ in children." *Food & Water Watch, Inc. v. United States EPA*, No. 17-cv-02162-EMC, 2024 U.S. Dist. LEXIS 172635, at \*4 (N.D. Cal. Sep. 24, 2024).

122. Judge Chen's detailed 80-page decision, along with the NRC and NTP reports, further highlights the need to limit children's ingestion of fluoride.

#### **F. The Undisputed Need to Limit a Child's Use and Ingestion of Fluoride Toothpaste**

123. U.S. health authorities, and the Defendant itself, agree caregivers should strictly limit the amount of fluoride toothpaste that young children use.

124. The FDA states that fluoride toothpaste is contraindicated for children under 2 because "[c]hildren under 2 years of age do not have control of their swallowing reflex and do not have the skills to expectorate the toothpaste properly."<sup>82</sup> According to both the FDA and CDC, children under 2 should only use fluoride toothpaste if directed by a dentist.<sup>83</sup>

125. When children first begin using fluoride toothpaste, CDC states that caregivers should only put a "smear" of paste on the brush, and this should remain the practice until the child turns 3. To quote: "Children aged <3 years should use a smear the size of a rice grain, and children aged >3 years should use no more than a pea-sized amount (0.25 g) until age 6 years, by which

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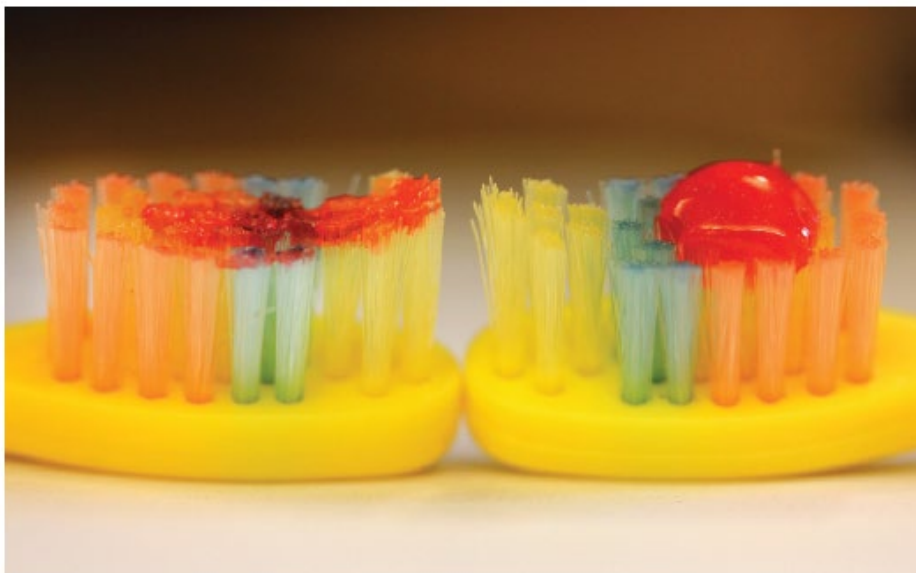
<https://ntp.niehs.nih.gov/whatwestudy/assessments/noncancer/completed/fluoride> (last accessed Jan. 13, 2025).

<sup>82</sup> FDA, *supra* note 1, at 52487,

<sup>83</sup> 21 C.F.R. § 355.50(d)(1)(i) ("Children under 2 years of age: Consult a dentist or doctor."); CDC, *supra* note 30, at 27 ("Parents and caregivers should consult a dentist or other health-care provider before introducing a child aged <2 years to fluoride toothpaste.").

time the swallowing reflex has developed sufficiently to prevent inadvertent ingestion.”<sup>84</sup>

126. The American Dental Association agrees that caregivers should put “no more than a smear or the size of a grain of rice” of fluoride toothpaste on the brush for children under 3, and “no more than a pea-sized amount” for children 3 to 6.<sup>85</sup> The ADA provides the following figure<sup>86</sup> to show what a “smear” and “pea-sized” amount looks like:



**Figure.** The toothbrush on the left shows a smear of toothpaste (0.1 milligram of fluoride) and the one on the right a pea-sized amount (0.25 mg of fluoride).

127. As ADA states in the above figure, a smear of paste represents 0.1 mg of fluoride, or approximately 0.1 grams of paste, while a pea-sized amount represents 0.25 mg of fluoride, or approximately 0.25 grams of paste.

128. The AAP,<sup>87</sup> AAPD,<sup>88</sup> and other major manufacturers of fluoride toothpaste,

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<sup>84</sup> Thornton-Evans, *supra* note 2, at 87.

<sup>85</sup> ADA, *supra* note 5, at 191.

<sup>86</sup> *Id.*

<sup>87</sup> Melinda B. Clark, et al., *Fluoride Use in Caries Prevention in the Primary Care Setting*, 146 PEDIATRICS e2020034637, Tbl 1 (2020).

<sup>88</sup> American Academy of Pediatric Dentistry, *Frequently Asked Questions*, <https://www.aapd>.

including Colgate,<sup>89</sup> agree with the ADA that fluoride toothpaste use should be limited to a “smear” for children under 3, and a “pea-sized” amount for children 3 to 6.

129. The National Capital Poison Center, which works to prevent poisonings from fluoride toothpaste, states: “For children under 3 years of age, only use a smear or the size of a grain of rice of fluoride toothpaste for brushing, starting when the first tooth appears.”<sup>90</sup>

**G. Defendant’s Extensive and Longstanding Marketing Efforts Helped Shape Consumer Perceptions on the Safe and Age-Appropriate Amount of Fluoride Toothpaste for Young Children**

130. Defendant is the largest manufacturer of fluoride toothpaste in the U.S.

131. Defendant engaged in extensive marketing efforts for decades, including prominent advertisements on national tv and major print media, to promote the use of fluoride toothpaste for young children. These advertisements played a key role in implanting the idea that a full strip of fluoride toothpaste is a safe and age-appropriate amount of toothpaste for young children to use.

132. As can be seen in the images below, Defendant’s national advertisements repeatedly showed full strips of toothpaste on children’s toothbrushes, and made representations that stressed the harmlessness and safety of early-life fluoride exposure (including showing a tube of Crest fluoride toothpaste in a baby bottle with the words “The sooner the better”).

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[org/resources/parent/faq/](#) (last accessed Jan. 13, 2025).

<sup>89</sup> Colgate, *Pediatric Guidelines for Using Toothpaste in Young Children*, <https://www.colgate.com/en-us/oral-health/kids-oral-care/pediatric-guidelines-for-using-toothpaste-in-young-children> (last accessed Jan. 13, 2025); Colgate, *Pediatric Guidelines for Using Toothpaste in Young Children*, <https://www.colgate.com/en-us/oral-health/kids-oral-care/pediatric-guidelines-for-using-toothpaste-in-young-children> (last accessed Jan. 13, 2025); Colgate, *Best Toothpaste for Kids with Cavities*, <https://www.colgate.com/en-us/oral-health/kids-oral-care/best-toothpaste-for-kids-with-cavities> (last accessed Jan. 13, 2025).

<sup>90</sup> National Capital Poison Center, *supra* note 15.

Introducing  
Cavity-Fighting Like You've  
Never Seen Before.

If your kids complain that brushing isn't fun, give them a toothpaste that is. New Sparkle Crest For Kids. It's the only gel that not only tastes great, but it actually sparkles. And once your kids try it, they'll see brushing in a different light. Which means you'll probably see them brushing longer and more often with Sparkle Crest For Kids. It contains the same cavity-fighting formula as regular Crest, which over the years has prevented more cavities than all other toothpastes combined. And you'll also see something else. Terrific checkups. The dentists' choice for fighting cavities.

Shown to be an effective decay preventive dentifrice that can be of significant value when used in a conscientiously applied program of oral hygiene and regular professional care. Council on Dental Therapeutics, American Dental Association. © 1999, The Procter & Gamble Company.

**SHE'S ABOUT TO GIVE A TOOTH IN TROUBLE A SECOND CHANCE.**

A squeeze of Crest on that toothbrush can make a difference. Because even if your kid has the start of decay right now, it may not be too late with Advanced Formula Crest with Fluoristat. And Crest offers dramatic evidence to prove it. You see, when your kids eat, acids can form and attack minerals that keep teeth healthy. Normally, those minerals are replaced; when too many are lost, a weak area forms. Left unchecked, this could become a cavity.

But Crest's fluoride penetrates—helping replace those minerals and actually reverse the early decay process. All this doesn't mean your kids can neglect their teeth and then brush-brush-brush. It does mean your kids' teeth can have a second chance—from the very first time they brush with Crest. And what a difference that can make.

**THE MOST A TOOTH PASTE CAN DO**

Crest has been shown to be an effective decay preventive dentifrice that can be of significant value when used in a conscientiously applied program of oral hygiene and regular professional care. Council on Dental Therapeutics, American Dental Association. © 1999, The Procter & Gamble Company.

**The sooner the better.**

Baby's first tooth. Precious, but vulnerable. As soon as it emerges from the gums, it's exposed to mouth acids. Ripe for decay. And decay, if left unchecked in baby teeth, can eventually create problems for permanent ones. It sounds a bit scary, it doesn't have to be. All it takes is care. And that includes Crest. Crest is well suited for protecting those baby teeth. Because Crest's fluoride strengthens the teeth—making them much more resistant to the mouth acids that weaken them. Crest has been proven effective against cavities in test after test for more than 25 years. Naturally, a teething baby or even a small child cannot be expected to brush his own teeth. But you can—and must. Of course, diet is important, too. And sweets should be limited. Finally, there's the family dentist. The one person who can truly tell if your child's teeth are healthy and growing properly. And, hopefully, if you've been conscientious—and used Crest—those routine checkups will always be routine. No, it's never too early for good dental health. But it's never too late, either.

**We're working to make cavities a thing of the past.**

Shown to be an effective decay preventive dentifrice that can be of significant value when used in a conscientiously applied program of oral hygiene and regular professional care. Council on Dental Therapeutics, American Dental Association. © 1999, The Procter & Gamble Company.

Introducing  
**New Crest Gel.**

The only gel with Fluoristat, Advanced Formula Crest's proven cavity-fighting system.

**KIDS LOVE THE FLAVOR. MOMS LOVE THE FIGHT.**

Now there's a gel as tough on cavities as Crest... because it is Crest New Crest Gel. It's the only gel with Fluoristat, the cavity fighting system found only in Advanced Formula Crest—so your best Crest checkups may be ahead of you. Now your family has three great cavity fighting weapons from Crest. Regular, Mint, and New Crest Gel. So choose your weapon, Mom.

Crest has been shown to be an effective decay preventive dentifrice that can be of significant value when used in a conscientiously applied program of oral hygiene and regular professional care. Council on Dental Therapeutics, American Dental Association. © 1999, The Procter & Gamble Company.

Defendant's Print Advertisements



*Still Shots from Defendant's TV Advertisements*

133. Prior to the 1980s, Defendant did not use candy flavors or cartoon imagery to market its toothpastes to young children. Upon information and belief, Defendant recognized that such marketing efforts would be grossly irresponsible.

134. Beginning in the 1980s, however, Defendant abandoned its prior restraint and began adding features to its packaging to further expand its share of the children's market, including the addition of candy flavors, bright sparkling colors, and cartoon imagery.

135. Dental fluorosis rates among U.S. children have risen sharply since the 1980s, and the marketing efforts that Defendant pioneered are believed to be one of the key reasons why.<sup>91</sup>

<sup>91</sup> Neurath, *supra* note 19, at 306.



## H. The Problem with Presenting Fluoride Toothpaste as a Candy-Like Drug

136. It is well recognized that presenting drugs as “candy-like” products increases the risk of overdose, particularly for young children. This problem has long been specifically flagged in the context of fluoride toothpaste.

137. In 1992, the *Journal of Public Health Dentistry* published a consensus statement which read, in part, “The use of flavors that may increase the ingestion of fluoridated dentifrices by young children should be strongly discouraged.”<sup>92</sup>

138. In 1993, a consensus statement from Canadian dental researchers stated, in part: “Manufacturers should be discouraged from marketing toothpastes which, because of their taste or appeal, encourage swallowing or excessive use.”<sup>93</sup>

139. In 1994, the World Health Organization stated, “the production of candy-like flavours . . . should not be encouraged for use by children, as they may lead to an excessive ingestion of fluoride.”<sup>94</sup>

140. In 1997, the *Journal of Public Health Dentistry* published a review, which stated “The use of flavored consumer fluoride products increases the possibility that a child will ingest a toxic dose of fluoride.”<sup>95</sup>

141. Marketing fluoride toothpaste as if it were candy, or food, has been criticized as an “aggressive” and “misleading” marketing tactic.<sup>96</sup> According to Basch and Rajan, “the ubiquitous presence of food pictures and appealing flavors on the toothpaste creates a distinct conflict. While

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<sup>92</sup> Bawden, *supra* note 11, at 1221.

<sup>93</sup> *Introduction to the Workshop*, 22 COMMUNITY DENT ORAL EPIDEMIOLOG. 140, 142 (1993).

<sup>94</sup> WORLD HEALTH ORGANIZATION. FLUORIDES AND ORAL HEALTH 28 (1994).

<sup>95</sup> Shulman & Wells, *supra* note 54, at 150.

<sup>96</sup> Basch & Rajan, *supra* note 8, at 316.

the labels warn the consumer to use only a pea-sized amount and note that toothpaste is not intended to be swallowed, many toothpastes simultaneously boast pictures of fruit with flavoring to match - a common signal to a child that toothpaste is intended to be consumed as if it were food.”<sup>97</sup>

142. Studies have empirically tested, and confirmed, that adding candy flavor to toothpaste increases the amount of paste that children add to their brush, as well as the amount of toothpaste that they ingest.<sup>98</sup>

143. According to the FDA, marketing dangerous products to children through the use of candy or food flavoring can qualify as a “misleading” marketing tactic that renders a product “misbranded” under the FDCA.<sup>99</sup>

## **I. FDCA Requirements for Fluoride Toothpaste**

### *General Requirements*

144. The FDCA prohibits companies from selling over-the-counter drugs that are “misbranded.” 21 U.S.C. § 331(a).

145. A drug is misbranded if it has packaging that “is **false or misleading** in any

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<sup>97</sup> *Id.* at 316.

<sup>98</sup> Steven M. Levy, et al., *A pilot study of preschoolers' use of regular-flavored dentifrices and those flavored for children*, 14 PEDIATR DENT. 388 (1992); Steven M. Adair, et al., *Comparison of the use of a child and an adult dentifrice by a sample of preschool children*, 19 PEDIATR DENT. 99 (1997); Claudia A. Kobayashi, et al., *Factors influencing fluoride ingestion from dentifrice by children*, 39 COMMUNITY DENT ORAL EPIDEMIOL. 426 (2011); Carrie A. Strittholt, et al., *A randomized clinical study to assess ingestion of dentifrice by children*, 75 REGUL TOXICOL PHARMACOL. 66 (2016).

<sup>99</sup> *E.g.*, FDA Warning Letter to Electric Lotus, LLC, Nov. 29, 2018, available at: <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/electric-lotus-llc-568710-11292018> (warning liquid tobacco companies that their use of candy flavoring is “misleading” and “increases the likelihood that children will ingest the product as a food”).

particular.” 21 U.S.C. § 352(a)(1) (emphasis added).

146. An over-the-counter drug is “not misbranded” if it satisfies “each of the conditions contained in any applicable monograph” **and** is “labeled in compliance” with 21 U.S.C. § 352. 21 C.F.R. § 330.1(c)(1). Thus, a drug can meet each of the conditions of an applicable Monograph and still be misbranded if it has textual or visual representations on the label that are not required by the Monograph and which are “false and misleading in any particular.”

*Specific Requirements*

147. The FDA has issued a Monograph for anti-cavity dental products, including fluoride toothpaste. 21 C.F.R. § 355.50.

148. The FDA requires that all fluoride toothpastes provide the following warning: “Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.” 21 C.F.R. § 355.50(c)(1). The FDA requires that the first sentence of this warning be in bold type. *Id.*

149. The FDA requires that all fluoride toothpastes provide the following directions: “Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 2 years of age: Consult a dentist or doctor.” 21 C.F.R. § 355.50(d)(1)(i).

*Things that the FDA Does Not Require*

150. The FDA does not require the label of fluoride toothpastes to depict full strips of toothpaste.

151. The FDA does not require fluoride toothpastes to be presented as candy-like

products.

152. The FDA does not require fluoride toothpastes to have cartoon imagery that directly appeals to young children on the front of the product.

153. The FDA does not require fluoride toothpastes to state that they are approved by the ADA.<sup>100</sup>

#### J. The Defendant's Products at Issue

154. Plaintiffs' claims in this case involve the following two products: (1) KID'S CREST ONE and (2) KID'S CREST TWO (collectively, "the Products").

#### KID'S CREST ONE



<sup>100</sup> The FDA does not prohibit showing ADA's seal of approval, but the agency has made clear that the inclusion of this seal is subject to the prohibition on false or misleading labeling. *See* FDA, *supra* note 26, at 39868 ("As with other statements differing from the wording in the monograph, the ADA's approval statement and seal may appear on product labeling subject to the prohibitions in 21 USC 352(a) against false or misleading labeling.").

155. KID'S CREST ONE is Defendant's most popular toothpaste for kids. While the labeling stresses that it is a "KID'S" toothpaste, it contains the same fluoride concentration (0.243% sodium fluoride) as Defendant's adult-branded "Cavity Protection" toothpaste.<sup>101</sup>

156. While KID'S CREST ONE comes in several shapes and sizes, the front label of the product is false and misleading across each and every iteration of the product.

157. The following attributes, present on each and every variation of KID'S CREST ONE, individually and collectively convey the false and misleading impressions that (a) the product is specially formulated to be safe for young children to ingest, and (b) a full strip is a safe and age-appropriate amount of paste for a child under 6 to use:

- a. The front label of the product prominently displays the word KID'S in rainbow-colored crayon font.
- b. Contrary to all other Crest-branded kids fluoride toothpastes that Defendant sells, KID'S CREST ONE does not have a "3+ YRS" notation, thus implying that the product is specially formulated to be safe for children under 3.
- c. The front label of the product prominently displays an image of a **full strip** of toothpaste, despite the fact that Defendant knows this is **8 to 10 times more than the safe and recommended amount** for a <3 year old, and **3 to 4 times more than the safe and recommended amount** for a 3-6 year old.
- d. The toothpaste in the tube has a bright blue (sparkle fun) or bright pink (bubble gum) color, and a taste and smell that is essentially identical to candy. Since candy is something that children can safely ingest, the candy-like element of the product signifies the safety of the product for children to ingest.

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<sup>101</sup> See <https://smartlabel.pg.com/en-us/00037000512066.html> (last accessed Jan. 13, 2025).

158. None of the deceptive attributes identified in the foregoing paragraph are required by the FDCA or its accompanying regulations, including the Monograph. Individually and collectively, these deceptive attributes lead reasonable consumers to believe, and did lead Plaintiffs to believe, that KID'S CREST ONE is specially formulated to be safe for young children to ingest, and that a full strip of toothpaste is a safe and age-appropriate amount of toothpaste for a child under 6 to use.

159. The regular-sized version of KID'S CREST ONE comes in two flavors: Sparkle Fun and Bubble Gum. The Bubble Gum-flavored product comes in a stand-up tube and is not sold in a box. The Sparkle Fun-flavored product, which is, by far, the highest-selling iteration of KID'S CREST ONE, comes in a regular tube and is sold in a box.

160. The box that contains the regular-sized Sparkle Fun version of KID'S CREST ONE has the following elements which further magnify the deception identified in paragraph 151:

- a. Prominent emblazonment of the word KID'S on all six sides of the box.
- b. Prominent display of a full strip of toothpaste on two sides of the box.
- c. Prominent display of ADA's seal of approval on three sides of the box, without any disclosure of ADA's guideline that children under three should use no more than a "smear" of fluoride toothpaste.
- d. A statement on one side of the box which, in bold letters, reads: "**GENTLE ON TOOTH ENAMEL.**" This despite the fact that the Defendant knows this product will cause many children to develop a mineralization disorder of tooth enamel called dental fluorosis which Defendant admits will cause teeth to have "less than normal amounts of calcification in the teeth."<sup>102</sup>

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<sup>102</sup> Crest, *supra* note 17.

161. None of the deceptive attributes on the box that are identified in the foregoing paragraph, and which further magnify the deception described in paragraph 157, are required by the FDCA or its accompanying regulations, including the Monograph.

162. Plaintiffs relied upon each of the aforementioned deceptive attributes, both individually and collectively, in purchasing the KID'S CREST ONE product. These deceptive attributes caused Plaintiffs to falsely believe that KID'S CREST ONE is safe for their young children to ingest, and that a full strip of toothpaste is a safe and age-appropriate amount of paste for a child under 6 to use.

163. Based on this deception, Plaintiffs permitted their preschool children to regularly use this toothpaste in quantities that, unbeknownst to them, far exceed the safe and recommended amount. They suffered economic loss as a result by obtaining fewer brushings per product.

#### KID'S CREST TWO



164. KID'S CREST TWO has the same fluoride concentration (0.243% sodium fluoride) as Defendant's adult-branded Cavity Protection toothpaste.

165. KID'S CREST TWO is sold in a box and comes with a prominent 3+ YRS notation.

166. The following attributes, present on each variation of KID'S CREST TWO, individually and collectively convey the false and misleading impressions that (a) the product is specially formulated to be safe for young children to ingest, and (b) a full strip amount of the paste

is a safe and age-appropriate amount of paste for a child under 6 to use:

- a. The front label of the product, as well as 4 sides of the box, prominently display the word KID'S in rainbow-colored crayon font.
- b. The toothpaste gel has a taste and smell that is essentially identical to candy-flavored bubble gum. It also has a function that is similar to Gobstopper candy, where the blue color of the gel transforms to pink in the child's mouth after a certain period of time. Since candy is something that children can safely ingest, the candy-like element of the product signifies the safety of the product for children to ingest.
- c. The front label of the product, as well as three sides of the box, prominently display an image of a **full strip** of toothpaste, despite the fact that Defendant knows this is **3 to 4 times more than the safe and recommended amount** for a 3-6 year old.
- d. One side of the box provides both written and **visual instructions** for how to use the toothpaste. The visual instructions show a full strip of toothpaste next to the words "KEEP BRUSHING!"



167. None of the deceptive attributes identified in the foregoing paragraph are required by the FDCA or its accompanying regulations, including the Monograph. Individually and collectively, these deceptive attributes lead reasonable consumers to believe, and did lead Plaintiffs



to believe, that KIDS CREST TWO is specially formulated to be safe for young children to ingest, and that a full strip of toothpaste is a safe and age-appropriate amount of paste for a child under 6 to use.

168. Based on this deception, Plaintiffs permitted their preschool children to regularly use this toothpaste in quantities that, unbeknownst to them, far exceed the safe and recommended amount. They suffered economic loss as a result by obtaining fewer brushings per product.

#### **K. Defendant's Violation of the FDCA**

169. Defendant's false and misleading labeling, described above, violates the FDCA's prohibition on false and misleading labeling.<sup>103</sup> 21 U.S.C. § 352(a).

170. Defendant's violation of 21 U.S.C. § 352(a) is not cured by Defendant's inclusion of FDA's required warnings and instructions in the fine print on the back of the label.

171. Courts have recognized that false and misleading representations on the front of a label are not cured or absolved by including correct information in the fine print on the back, even when the fine print provides all of the requisite information required by the FDA. *See, e.g., Cooper v. Anheuser-Busch, LLC*, 553 F. Supp. 3d 83, 107-08 (S.D.N.Y. 2021) (citing cases).

172. As the Ninth Circuit explained in *Williams v. Gerber Prods. Co.*, 552 F.3d 934, 939-40 (9th Cir. 2008):

We disagree with the district court that reasonable consumers should be expected to look beyond misleading representations on the front of the box to discover the truth from the ingredient list in small print on the side of the box. The ingredient list on the side of the box appears to comply with FDA regulations and certainly serves some purpose. We do not think that the FDA requires an ingredient list so

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<sup>103</sup> Plaintiffs recognize that there is no private right of action under FDCA and do not assert such a claim here. Instead, Plaintiffs' allegations that Defendant violated the requirements of the FDCA serve as a prerequisite for their state law claims. *See, e.g., In re Beyond Meat, Inc.*, No. 23 C 669, 2024 U.S. Dist. LEXIS 30397, at \*21 (N.D. Ill. Feb. 21, 2024) (“[T]o avoid preemption, a state law claim related to misleading labeling must allege a violation of the FDCA or its regulations.”).

that manufacturers can mislead consumers and then rely on the ingredient list to correct those misinterpretations and provide a shield for liability for the deception. Instead, reasonable consumers expect that the ingredient list contains more detailed information about the product that confirms other representations on the packaging.

173. The Seventh Circuit has endorsed the Ninth Circuit’s approach. In *Bell v. Publix Super Mkts., Inc.*, 982 F.3d 468, 476, 481 (7th Cir. 2020), the court explained:

Consumer-protection laws do not impose on average consumers an obligation to question the labels they see and to parse them as lawyers might for ambiguities, especially in the seconds usually spent picking a low-cost product. *See, e.g., Danone, US, LLC v. Chobani, LLC*, 362 F. Supp. 3d 109, 123 (S.D.N.Y. 2019) (“[A] parent walking down the dairy aisle in a grocery store, possibly with a child or two in tow, is not likely to study with great diligence the contents of a complicated product package, searching for and making sense of fine-print disclosures . . . . Nor does the law expect this of the reasonable consumer. . . . We doubt it would surprise retailers and marketers if evidence showed that many grocery shoppers make quick decisions that do not involve careful consideration of all information available to them. *See, e.g., U.S. Food & Drug Admin., Guidance for Industry: Letter Regarding Point of Purchase Food Labeling* (Oct. 2009) (“FDA’s research has found that with [Front of Package] labeling, people are less likely to check the Nutrition Facts label on the information panel of foods (usually, the back or side of the package).”)

**L. Defendant’s Deceptive Conduct Caused Economic Injury to Plaintiffs and Class Members**

174. Defendant made the false and misleading representations described above to (i) obfuscate, distract from, and undermine FDA’s required warnings and directions, (ii) induce people to buy the Products for young children who otherwise would not have done so if they had correct information; (iii) induce people to pay more for the Products than they would have paid if they had correct information; and (iv) induce parents, caregivers, and children to use more of the Products per brushing than recommended.

175. Defendant was, and remains, unjustly enriched each time parents and caregivers act

on Defendant's false and misleading packaging, including when caregivers use more than the safe and recommended amount of Defendant's toothpaste for a young child. For example:

- a. A parent of a 2-year-old who applies a full strip (0.75-1 grams) of KID'S CREST ONE to the brush will obtain 8 to 10 times *less* brushings per tube than a parent who applies the recommended smear of paste (0.1 grams).
- b. A parent of a 3-year old who applies a full strip of KID'S CREST TWO will obtain 3 to 4 times fewer brushings per tube of paste than a parent who uses the recommended pea-sized amount of paste (0.25 grams).

176. Had Plaintiffs known and appreciated the truth about the Products, they would have ensured their child used the recommended amount of paste.

177. As an immediate, direct, and proximate result of Defendant's false and misleading representations, Plaintiffs and the Class Members purchased more of the Products, and/or paid more per brushing, than they would have if they had known the truth.

178. Consequently, Plaintiffs and the Class Members have suffered injury in fact and lost money as a result of Defendant's wrongful conduct.

179. Plaintiffs do not seek recovery for any personal injuries that they or their children may have suffered from using the Products, including any emotional harm stemming therefrom.

#### **CLASS ALLEGATIONS**

180. Pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3), Plaintiffs bring this action on behalf of the following classes:

- c. **Nationwide Implied Warranty Class:** All persons in the United States who (A) purchased KID'S CREST ONE for children aged 0 to 6 years and/or purchased KID'S CREST TWO for children aged 3 to 6 years, (B) within the applicable

statutes of limitation, and (C) who used more than the recommended amount of paste.

- d. **Multi-State Consumer Deception Statute Class:** All persons in Arizona, California, Connecticut, Florida, Hawaii, Idaho, Illinois, Massachusetts, Minnesota, Missouri, New Jersey, New York, Virginia, Washington State, and Washington D.C., who (A) purchased KID’S CREST ONE for children aged 0 to 6 years and/or purchased KID’S CREST TWO for children aged 3 to 6 years, (B) within the applicable statutes of limitation, and (C) who used more than the recommended amount of paste.
- e. **Alternative Multi-State Consumer Deception Statute Class:** All persons in California, Illinois, and New York who (A) purchased KID’S CREST ONE for children aged 0 to 6 years and/or purchased KID’S CREST TWO for children aged 3 to 6 years, (B) within the applicable statutes of limitation, and (C) who used more than the recommended amount of paste.

181. As used herein, the term “Class,” although used in the singular, shall refer to each of the aforementioned putative classes.

182. Excluded from the Class are Defendant, its parents, subsidiaries, affiliates, officers, and directors; those who used the recommended amount of toothpaste, despite Defendant’s deceptive practices; those who purchased the Products for resale; those who make a timely election to be excluded from the classes, and the judge to whom the case is assigned and any immediate family members thereof.

183. The Class Period begins on the date established by the Court’s determination of any applicable statute of limitations, after consideration of any tolling, discovery, knowing

concealment, and accrual issues, and ending on the date of entry of judgment.

184. Plaintiffs reserve the right to amend the definition of the Class if discovery or further investigation reveals that the Class should be expanded or otherwise modified.

185. **Numerosity**: The members of the Class are so numerous that joinder of all class members is impracticable. On information and belief, there are millions of Class Members. Class Members may be notified of the pendency of this action by recognized, Court-approved notice dissemination methods, which may include U.S. mail, electronic mail, Internet postings, and/or published notice.

186. **Predominance of Common Questions of Law and Fact**: Questions of law and fact common to the members of the Class that predominate over questions that may affect individual class members include, but are not limited to the following:

- a) Whether the attributes that Defendant has voluntarily added to the Products are false and/or misleading;
- b) Whether Defendant knew or should have known that the marketing was false and/or misleading;
- c) Whether Defendant has breached the implied warranty of merchantability;
- d) Whether Defendant has violated the state consumer protection statutes alleged herein;
- e) Whether Defendant was unjustly enriched;
- f) Whether Plaintiffs and the Class members have suffered an ascertainable loss of monies or property or other value as a result of Defendant's acts and omissions of material facts; and
- g) Whether Plaintiffs and the Class members are entitled to monetary damages and, if so, the nature of such relief.

187. **Typicality:** Plaintiffs' claims are typical of those of other Class members because, like all members of the Class, Plaintiffs purchased the Products with the false and misleading packaging for children under 6, used more of the toothpaste than is safe and recommended, and sustained economic loss as a result.

188. Defendant's conduct that gave rise to the claims of Plaintiffs and Class members is the same for Plaintiffs and all members of the putative Class.

189. **Adequacy:** Plaintiffs will fairly and adequately protect the interests of the Class and have retained counsel that is experienced in litigating complex class actions.

190. Plaintiffs have no interests which conflict with those of the Class.

191. Plaintiffs and counsel are aware of their fiduciary responsibilities to the Class members and are determined to diligently discharge those duties by vigorously seeking the maximum possible recovery for Class members.

192. **Superiority:** A class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no materially significant difficulties are likely to be encountered in the management of this class action.

- a. The damages suffered by each individual member of the Class do not justify the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendant's conduct;
- b. Even if individual members of the Class had the resources to pursue individual litigation, it would pose a crushing burden on the court system for the cases to be litigated on an individual basis;
- c. Absent a class action mechanism, Plaintiffs and Class members will continue to suffer harm as a result of Defendant's unlawful conduct because individual

litigation is wholly impractical and cost prohibitive; and

- d. This action presents no difficulty that would impede its management by the Court as a class action.<sup>104</sup>

**FIRST CAUSE OF ACTION**  
**Breach of Implied Warranty of Merchantability**

193. Plaintiffs incorporate the preceding paragraphs as if fully written herein.

194. Plaintiffs bring this claim on behalf of themselves and all members of the Nationwide Implied Warranty Class.

195. All states have adopted Article 2 of the Uniform Commercial Code (UCC), or a materially identical equivalent,<sup>105</sup> which imposes upon Defendant a duty requiring that the products it sells are fit for their ordinary purpose and conform to the promises or affirmations of fact made on the products' packaging. This implied warranty of merchantability is part of the basis of the bargain between Defendant, on the one hand, and Plaintiffs and Class members, on the other.

196. A good is not "merchantable" for purposes of the implied warranty of merchantability if it is (A) not fit for the ordinary purpose for which the product is sold, or (B)

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<sup>104</sup> Each claimant's eligibility for relief can be determined through self-identifying affidavits, a mechanism that courts have widely endorsed in cases, such as the one at bar, involving low-priced consumer goods. *See, e.g., Beaton v. SpeedyPC Software*, 907 F.3d 1018, 1030 (7th Cir. 2018); *Mullins v. Direct Dig., Ltd. Liab. Co.*, 795 F.3d 654, 658 (7th Cir. 2015); *Langan v. Johnson & Johnson Consumer Cos.*, 897 F.3d 88 (2d Cir. 2018); *Benson v. Newell Brands, Inc.*, No. 19 C 6836, 2021 U.S. Dist. LEXIS 220986, at \*30-32 (N.D. Ill. Nov. 16, 2021); *Hasemann v. Gerber Prods. Co.*, No. 15-CV-2995 (MKB) (RER), 2019 U.S. Dist. LEXIS 28770, at \*53-54 (E.D.N.Y. Feb. 20, 2019); *Suchanek v. Sturm Foods, Inc.*, 311 F.R.D. 239, 259-60 (S.D. Ill. 2015); *Brown v. Hain Celestial Grp., Inc.*, No. C 11-03082 LB, 2014 U.S. Dist. LEXIS 162038, at \*29-30 (N.D. Cal. Nov. 18, 2014); *Cf. Pella Corp. v. Saltzman*, 606 F.3d 391, 396 (7th Cir. 2010) ("Under Rule 23, district courts are permitted to 'devise imaginative solutions to problems created by the presence in a class action litigation of individual damages issues.'").

<sup>105</sup> Louisiana is the only state that has not adopted Article 2 of the UCC, but it has codified a materially equivalent warranty law. *See* La.C.C. Art. 2550, *et seq.*

does not conform to the promises or affirmations of fact made on its packaging.

197. KIDS CREST ONE and KIDS CREST TWO are goods contemplated by Article 2 of the U.C.C.

198. The purchase of KIDS CREST ONE and KIDS CREST TWO by Plaintiffs and Class members constitute sales of goods under the U.C.C. and corresponding state statutes.

199. Defendant is a merchant of kids fluoride toothpaste.

200. The ordinary purpose for which KIDS CREST ONE and KIDS CREST TWO are sold is as a toothpaste that can be safely used to brush a young child's teeth.

201. Based on Defendant's packaging of its KIDS CREST ONE and KIDS CREST TWO toothpastes (see, e.g., *supra* ¶¶ 157, 160, & 166), Defendant impliedly warranted that a full strip of Defendant's toothpaste is a safe and age-appropriate amount for a child under 6 to use.

202. At all times relevant to this Complaint, KIDS CREST ONE and KIDS CREST TWO was not merchantable because it did not conform to the promises and affirmations of fact set forth in the labeling of the product. Contrary to the visual representations on these products, a full strip of toothpaste is not a safe or age-appropriate amount of toothpaste for children under 6 to use because it is **8 to 10 times more than the safe and recommended amount** for a <3 year old, and **3 to 4 times more than the safe and recommended amount** for a 3-6 year old.

203. Because KIDS CREST ONE and KIDS CREST TWO failed to conform to the promises or affirmations of fact on its packaging, Defendant breached the implied warranty of merchantability.

204. In reliance upon Defendant's skill and judgment and the implied warranty that a full strip of KIDS CREST ONE and KIDS CREST TWO is a safe and age-appropriate amount of toothpaste for children under 6 to use, Plaintiffs and Class members permitted their young children



to use far more toothpaste per brushing than is actually safe and recommended.

205. As a proximate result of Defendant's breach of the implied warranty of merchantability, Plaintiffs and Class members suffered economic damages by obtaining less brushings per tube of Defendant's toothpaste, and thereby paying more money per brushing.

206. Because KIDS CREST ONE and KIDS CREST TWO are still being sold and are violative of the implied warranty of merchantability, the number of injured Class members continues to grow.

207. Plaintiffs have provided Defendant with the requisite pre-suit notice of claim demanding Defendant take remedial action. Defendant, however, has failed to remediate its breach.

208. Through its breach of the implied warranty of merchantability, Defendant has been unjustly enriched, and continues to be unjustly enriched, by unfairly obtaining money from members of the Class.

209. Based on Defendant's breach of the implied warranty of merchantability, Plaintiffs and the members of the Nationwide Implied Warranty Class are entitled to relief.

**SECOND CAUSE OF ACTION**  
**Deceptive Acts and Practices in Violation of the**  
**Illinois Consumer Fraud and Deceptive Trade Practices Act**  
**815 ILCS 505/1, et seq.**

210. Plaintiffs incorporate the preceding paragraphs as if fully written herein.

211. Plaintiffs Patricia Gurrola, Alejandro Arreola, and Britini Broughton bring this claim individually and on behalf of the Illinois Class members for the proposed Multi-State Consumer Deception Statute classes.

212. Plaintiffs Gurrola, Arreola and Broughton and other Class Members are persons within the context of the Illinois Consumer Fraud and Deceptive Trade Practices Act ("ICFA"),

815 ILCS § 505/1(c).

213. Defendant is a person within the context of the ICFA, 815 ILCS § 505/1(c).

214. At all times relevant hereto, Defendant was engaged in trade or commerce as defined under the ICFA, 815 ILCS § 505/1(f).

215. Plaintiffs Gurrola, Arreola and Broughton and the proposed Class are “consumers” who purchased the products identified herein for personal, family, or household use within the meaning of the ICFA, 815 ILCS § 505/1(e).

216. The ICFA prohibits “[u]nfair methods of competition and unfair or deceptive acts or practices,” which includes “the use or employment of any . . . false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact.” 815 ILCS 505/2.

217. A “claim for ‘deceptive’ business practices under the [ICFA] does not require proof of intent to deceive.” *Wigod v. Wells Fargo Bank, N.A.*, 673 F.3d 547, 575 (7th Cir. 2012) (citation omitted).

218. Defendant has violated, and continues to violate, the ICFA by using deceptive acts and practices to sell KIDS CREST ONE and KIDS CREST TWO. As described above, including but not limited to paragraphs 157, 160, and 166, Defendant’s labeling of these products conveys the false pretense, false promise, and misrepresentation that (a) these products are specially formulated to be safe for young children to ingest, and (b) a full strip of fluoride toothpaste is a safe and age-appropriate amount for children under 6 to use.

219. Defendant has also violated the concealment and suppression prongs of the ICFA by stating on the label of KIDS CREST ONE that the product is approved by the ADA while omitting ADA’s recommendation that children under 3 only use a “smear” (i.e., “rice grain”)

amount of toothpaste.

220. Plaintiffs and the other Illinois Class Members have permitted their preschool children to use more toothpaste than safe or recommended based on their reasonable reliance on Defendant's false and misleading labeling.

221. Plaintiffs and Class Members suffered economic damages as a proximate result of Defendant's violations of the ICFA by using more of the product per brushing than is safe or recommended and thereby obtaining less brushings per tube of toothpaste.

222. Through its violations of the ICFA, Defendant has been unjustly enriched, and continues to be unjustly enriched, by unfairly obtaining money from members of the Class.

223. Based on Defendant's deceptive acts and practices, Plaintiffs Gurrola, Arreola and Broughton and the Illinois Class members are entitled to relief under 815 ILCS §505/10a.

**THIRD CAUSE OF ACTION**  
**Deceptive Business Practices in Violation of**  
**California's Unfair Competition Law**  
**Cal. Bus. & Prof. Code §§ 17200**

224. Plaintiffs incorporate the preceding paragraphs as if fully written herein.

225. Plaintiffs Eileen Aviles, Courtney Deschamp, and Yvonne Lamendola bring this claim individually and on behalf of the California Class members for the proposed Multi-State Consumer Deception Statute classes.

226. California's Unfair Competition Law ("UCL") prohibits "fraudulent" acts or practices, which the statute defines to include any act or practice that is likely to deceive members of the consuming public. Cal. Bus. & Prof. Code §17200. An intention to defraud is not a necessary element for demonstrating a fraudulent business practice under the UCL.

227. Defendant has violated, and continues to violate, the "fraudulent" prong of the UCL by using deceptive acts and practices to sell KIDS CREST ONE and KIDS CREST TWO. As

described above, including but not limited to paragraphs 157, 160, and 166, Defendant's labeling is likely to deceive members of the consuming public to believe that (a) these products are specially formulated to be safe for young children to ingest, and (b) a full strip of fluoride toothpaste is a safe and age-appropriate amount for children under 6 to use.

228. Plaintiffs and the other California Class Members have permitted their preschool children to use more toothpaste than safe or recommended based on their reasonable reliance on Defendant's false and misleading labeling.

229. Plaintiffs and Class Members suffered economic damages as a proximate result of Defendant's violations of the UCL by using more of the product per brushing than is safe or recommended, and thereby obtaining less brushings per tube of toothpaste.

230. Through its deceptive acts and practices, Defendant has been unjustly enriched, and continues to be unjustly enriched, by unfairly obtaining money from members of the Class.

231. Based on Defendant's deceptive acts and practices, Plaintiffs Aviles, Deschamp, and Lamendola and the California Class members are entitled to relief under the UCL.

**FOURTH CAUSE OF ACTION**  
**Deceptive Business Practices in Violation of**  
**New York General Business Law §§ 349 & 350**

232. Plaintiffs incorporate the preceding paragraphs as if fully written herein.

233. Plaintiffs Sushmadavi Lakeram and Germaine Dollisme bring this claim individually and on behalf of the New York Class members for the proposed Multi-State Consumer Deception Statute classes.

234. New York General Business Law ("GBL") prohibits "deceptive acts or practices in the conduct of any business, trade, or commerce or in the furnishing of any service in this state." GBL § 349. GBL also prohibits "[f]alse advertising in the conduct of any business, trade or

commerce.” GBL § 350. GBL defines false advertising as including “labeling” of a product that is “misleading in a material respect.” *Id.* § 350a(1).

235. Defendant has violated, and continues to violate, GBL §§ 349-50 by using deceptive labeling for KIDS CREST ONE and KIDS CREST TWO. As described above, including but not limited to paragraphs 157, 160, and 166, this deceptive labeling conveys the false and misleading impression that (a) these products are specially formulated to be safe for young children to ingest, and (b) a full strip of fluoride toothpaste is a safe and age-appropriate amount for children under 6 to use.

236. Plaintiffs and the other New York Class Members have permitted their preschool children to use more toothpaste than safe or recommended based on their reasonable reliance on Defendant’s false and misleading labeling.

237. Plaintiffs and Class Members suffered economic damages as a proximate result of Defendant’s violations of GBL §§ 349-50 by using more of the product per brushing than is safe or recommended, and thereby obtaining less brushings per tube of toothpaste.

238. Through its deceptive acts and practices, Defendant has been unjustly enriched, and continues to be unjustly enriched, by unfairly obtaining money from members of the Class.

239. Based on Defendant’s deceptive acts and practices, Plaintiffs Lakeram and Dollisme and the New York Class members are entitled to relief under the GBL §§ 349-50.

**FIFTH CAUSE OF ACTION**  
**Deceptive Business Practices in Violation of**  
**Other Similar State Statutes Identified Herein**

240. Plaintiffs incorporate the preceding paragraphs as if fully written herein.

241. Plaintiffs bring this claim on behalf of the Arizona, Connecticut, Florida, Hawaii, Idaho, Massachusetts, Minnesota, Missouri, New Jersey, Virginia, Washington State, and

Washington D.C. members of the proposed Multi-State Consumer Deception Statute Class.

242. As described above, including but not limited to paragraphs 157, 160, and 166, Defendant has engaged in deceptive practices in its marketing of KIDS CREST ONE and KIDS CREST TWO. Through these deceptive practices, Defendant has conveyed the false and misleading impression that (a) these products are specially formulated to be safe for young children to ingest, and (b) a full strip of fluoride toothpaste is a safe and age-appropriate amount for children under 6 to use.

243. Through this deceptive conduct, which violated, and continues to violate, the ICFA (815 ILCS 505/2), the UCL (Cal. Bus. & Prof. Code §17200), and NY GBL §§ 349-50, Defendant has simultaneously violated, and continues to violate, the following state consumer protection statutes:

- a. Arizona (A.R.S. § 44-1521, *et seq.*);
- b. Connecticut (Conn. Gen. Stat. § 42-110a, *et seq.*);
- c. Florida (Fla. Stat. § 501.201, *et seq.*);
- d. Hawaii (HRS § 481A-1, *et seq.*);
- e. Idaho (Idaho Code § 48-601, *et seq.*);
- f. Massachusetts (ALM GL ch. 93A, *et seq.*);
- g. Minnesota (Minn. Stat. § 325F.68, *et seq.*);
- h. Missouri (Mo. Rev. Stat. § 407.005, *et seq.*);
- i. New Jersey (N.J.S.A. § 56:8-1, *et seq.*);
- j. Virginia (Va. Code Ann. § 59.1-196, *et seq.*);
- k. Washington (Wash. Rev. Code § 19.86.010, *et seq.*);
- l. Washington D.C. (D.C. Code § 28-3904, *et seq.*)

244. Plaintiffs have provided Defendant with the requisite pre-suit notice of claim under ALM GL ch 93A, *et seq.* demanding that Defendant take remedial action. Defendant has failed to take said action.

245. Plaintiffs and the other Class Members have permitted their preschool children to use more toothpaste than safe or recommended based on their reasonable reliance on Defendant's false and misleading labeling.

246. Plaintiffs and Class Members suffered economic damages as a proximate result of Defendant's violations of the aforementioned statutes by using more of the product per brushing than is safe or recommended, and thereby obtaining less brushings per tube of toothpaste.

247. Through its deceptive acts and practices, Defendant has been unjustly enriched, and continues to be unjustly enriched, by unfairly obtaining money from members of the Class.

248. Based on Defendant's deceptive acts and practices, Plaintiffs and the Class members are entitled to relief under the aforementioned state statutes.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs, on behalf of themselves and those similarly situated, respectfully request that the Court enter judgment against Defendant as follows:

- A. Certification of the proposed Nationwide Implied Warranty Class and Multi-State Consumer Deception State Class, including appointment of Plaintiffs' counsel as Class counsel and Plaintiffs as Class Representatives;
- B. An award of compensatory damages in an amount to be determined at trial;
- C. An award of restitution in an amount to be determined at trial;
- D. An award of disgorgement in an amount to be determined at trial;
- E. An award of statutory damages in an amount to be determined at trial, except as to

- those causes of action where statutory damages are not available by law;
- F. An award of punitive damages in an amount to be determined at trial, except as to those causes of action where punitive damages are not available by law;
- G. An award of treble damages, except as to those causes of action where treble damages are not available by law;
- H. An order requiring Defendant to pay both pre- and post-judgment interest on any amounts awarded;
- I. For reasonable attorneys' fees and the costs of suit incurred; and
- J. For such further relief as this Court may deem just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiffs hereby demand a trial by jury on all Counts and as to all issues.

Dated: January 13, 2025

Respectfully Submitted,

By: /s/ Michael Connett

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