

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS

TANISIER CLAYBORNE, CAMARIA  
BURLEIGH, SHERRY HODGE, ANJU  
GOEL, & JOSH COOK, individually, and  
on behalf of those similarly situated,

Plaintiffs,

v.

COLGATE-PALMOLIVE COMPANY &  
TOM'S OF MAINE, INC.,

Defendants.

Case No. 1:25-cv-04877

**CLASS ACTION COMPLAINT**

**JURY TRIAL DEMANDED**

**CLASS ACTION COMPLAINT**

Plaintiffs Tanisier Clayborne, Camaria Burleigh, Sherry Hodge, Anju Goel, and Josh Cook, (“**Plaintiffs**”), individually and on behalf of all others similarly situated, bring this class action lawsuit against Defendants Colgate-Palmolive Company (“**Colgate**”) and Tom’s of Maine, Inc. (“**Toms**”), based upon Plaintiffs’ personal knowledge as to themselves, the investigation of their counsel, and on information and belief as to all other matters.

**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 presents significant risks to health, particularly for young children.

3. Defendants sell kids-branded toothpastes for preschool children. These toothpastes have the same concentration of fluoride as many adult-strength brands.

4. Defendants know that their fluoride toothpastes, including their “kids” versions, are not safe for young children to swallow. But they deceptively market these Kids products in ways

that lead parents and caregivers to believe they are *extra* safe for children – which Defendants knows is false.

5. 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).

6. 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>

7. The Centers for Disease Control and Prevention (“CDC”) agrees that children under 2 should not use fluoride toothpaste.<sup>2</sup> Defendant Toms concurs with CDC, as evident by the 2+ age notation that Toms places on its kids fluoride toothpastes.

8. 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>3</sup>

9. The American Academy of Pediatrics (“AAP”), American Academy of Pediatric Dentistry (“AAPD”), and the American Dental Association (“ADA”) all agree that children under

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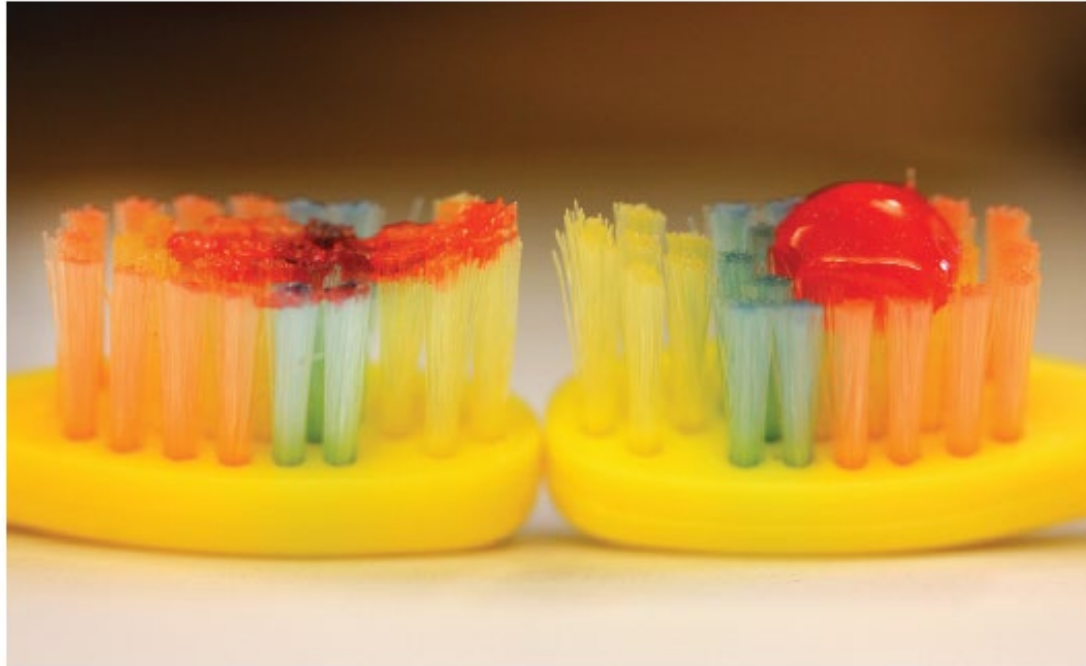
<sup>1</sup> FDA, *Anticaries Drug Products for Over-the-Counter Human Use; Final Monograph*, 60 Fed. Reg. 52474, 52487 (Oct. 6, 1995) (“The agency disagrees with the comments suggesting that the contraindication for children under 2 years of age is unwarranted.”).

<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.”).

<sup>3</sup> *Id.* at 87.

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* ¶¶ 112-114.

10. The following image from the ADA<sup>4</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).

11. Defendant Colgate agrees with the guidelines from the AAP, AAPD, and ADA. On its website, Colgate cites these guidelines when describing the “age-appropriate amounts of toothpaste” that children should use.<sup>5</sup> Colgate has admitted that caregivers of toddlers should “[u]se a smear or rice sized amount of fluoride toothpaste,”<sup>6</sup> and that “[i]t is recommended that

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<sup>4</sup> American Dental Association Council on Scientific Affairs, *Fluoride toothpaste use for young children*, 145 J AM DENT ASSOC. 190, 191 (2014).

<sup>5</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).

<sup>6</sup> Colgate, *Fun Dental Activities for Children*, <https://www.colgate.com/en-us/oral-health/kids->

you use a ‘smear’ (the size of a grain of rice) of fluoride toothpaste as soon as your baby has teeth.”<sup>7</sup>

12. Defendants know that they will sell less toothpaste if parents and caregivers use the safe and recommended amount of fluoride toothpaste, since this will result in very little of its product being used per brushing. Defendants have thus resorted to using marketing tactics that have been described as “misleading” and “aggressive” in order to encourage kids, and their caregivers, to use far more than the safe and recommended amount of fluoride toothpaste.<sup>8</sup>

13. One of the misleading and aggressive marketing tactics that Defendants use is to show “pictures of fruit with flavoring to match,” which signifies “that toothpaste is intended to be consumed as if it were food.”<sup>9</sup>



[oral-care/4-fun-dental-activities-for-children](#) (last accessed Jan. 13, 2025).

<sup>7</sup> 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>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 316.

14. 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 U.S. dental researchers which stated, in part, “The use of flavors that may increase the ingestion of fluoridated dentifrices by young children **should be strongly discouraged.**”<sup>10</sup> Many others have issued similar recommendations and warnings. See *infra* ¶¶ 122-127.

15. It is not just the candy flavoring that increases the ingestion of fluoride toothpaste. The packaging of the product, including cartoon imagery, can also increase a child’s ingestion of the paste. As the National Capital Poison Center has noted, “The flavoring and the pictures of kids’ favorite cartoons on the packaging can make it tempting for kids to eat toothpaste.”<sup>11</sup>



<sup>10</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).

<sup>11</sup> National Capital Poison Center, *My Child Ate Toothpaste: What Should I Do?*, <https://www.poison.org/articles/toothpaste> (last accessed Jan. 13, 2025).

16. In one of its kids fluoride products, Colgate prominently displays the cartoon image of a rainbow unicorn. This image appeals to very young children, and conveys the impression to caregivers that the product is age-appropriate and harmless for young children.

17. Another misleading<sup>12</sup> tactic that Defendants use is to show a visual image of a **full strip** of paste in its marketing materials for kids toothpastes (see examples below). Showing a full strip of paste implies that this is the recommended quantity to use, despite being **eight to ten times more than the safe and recommended amount** for a child under 3, and **three to four times more than the safe and recommended amount** for a child 3 to 6.



<sup>12</sup> Basch & Rajan, *supra* note 8, at 316 (stating that showing “a large swirl of toothpaste . . . directly conflicts with recommendations and warnings for how much toothpaste should be used by a child”).

18. Another deceptive tactic that Colgate uses is to *conceal* FDA’s required warnings and directions by *hiding* them behind a label containing empty space and promotional claims. Colgate uses this deceptive, and unlawful, tactic on its Unicorn Pump product. Only the most diligent consumer will notice there is *any* information hidden beneath the back label, let alone information about the product being potentially poisonous if swallowed.

19. Defendants’ deceptive marketing tactics cause millions of caregivers in the U.S. 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 causes economic loss to consumers by reducing the number of brushings that they receive per tube.

20. Swallowing as little as one full strip of fluoride toothpaste can cause symptoms of acute toxicity in some toddlers, including nausea, stomachache, and vomiting. See *infra* ¶¶ 87-93.

21. 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>13</sup>

22. 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).

23. According to the National Capital Poison Center: “Toothpaste is not meant to be

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



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>14</sup>

24. Children who swallow too much of Defendants’ kids-branded toothpaste can develop a mineralization disorder of their tooth enamel called dental fluorosis.<sup>15</sup> Fluorosis is a defect of tooth enamel that is marked by “increased porosity” and “less than normal amounts of calcification in the teeth.”<sup>16</sup> This disorder causes visible, and sometimes disfiguring, staining of the enamel. See *infra* ¶¶ 75-84.

25. The marketing of fluoride toothpaste as a candy-like product by Defendants and other major toothpaste manufacturers is believed to be one of the reasons for the skyrocketing increase in dental fluorosis that has been observed in recent decades.<sup>17</sup> In the 1980s, an estimated 23% of American children had dental fluorosis.<sup>18</sup> This rate tripled to 68% by 2016.<sup>19</sup>

26. With millions of U.S. children now showing visible signs of excess fluoride

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<sup>14</sup> National Capital Poison Center, *supra* note 11.

<sup>15</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>16</sup> NATIONAL RESEARCH COUNCIL, FLUORIDE IN DRINKING WATER: A SCIENTIFIC REVIEW OF EPA’S STANDARDS 104 (2006); 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>17</sup> Christopher Neurath, et al., *Dental Fluorosis Trends in US Oral Health Surveys: 1986 to 2012*, 4 JDR CLIN TRANS RES. 298, 306 (2019).

<sup>18</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>19</sup> Man Hung et al., *A National Study Exploring the Association Between Fluoride Levels and Dental Fluorosis*, 6 JAMA NETW OPEN. e2318406 (2023).



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* ¶¶ 101-108.

27. Defendants’ marketing tactics simultaneously violate the Federal Food Drug & Cosmetic Act (“**FDCA**”), 21 U.S.C. § 352(a),<sup>20</sup> and many state consumer deception statutes, including the Illinois Consumer Fraud and Deceptive Trade Practices Act, 815 ILCS § 505/2.

28. 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 Defendants under the FDCA and its accompanying regulations, including the FDA Monograph on fluoride toothpaste.<sup>21</sup> See C.F.R. § 355.50. Plaintiffs seek instead to hold Defendants responsible for the elements of their packaging that are *not* required by the Monograph *and* which simultaneously violate their requirements under the FDCA. A judicial finding that these voluntarily added attributes are false and misleading would be harmonious and not in conflict with the FDCA.<sup>22</sup>

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<sup>20</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.”).

<sup>21</sup> For example, Plaintiffs do not seek to require Colgate to disclose that children under 3 should only use a “smear” of paste. Plaintiffs also do not seek to compel Colgate to disclose that ingesting fluoride can cause dental fluorosis, disrupt the endocrine system, and impair neurodevelopment. Although Plaintiffs believe such disclosures would certainly be justified and prudent, Plaintiffs recognize this Court does not have the power to order such measures.

<sup>22</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

**PARTIES**

29. Plaintiff **Tanisier Clayborne** lives in Chicago, Illinois and, at all times relevant to this case, has been a citizen of Illinois.

30. Ms. Clayborne has purchased Unicorn Pump for her son E.S.

31. Ms. Clayborne began purchasing Unicorn Pump for E.S. in approximately 2021, when E.S. was two years old. She continued purchasing Unicorn Pump for E.S. for over two years.

32. E.S. used a full strip of Unicorn Pump on his brush for tooth brushings with Ms. Clayborne's assistance and/or permission.

33. E.S. enjoyed the candy flavor of the paste.

34. E.S. ingested most of the toothpaste that was put in his mouth for the brushings.

35. Based on the packaging of the Unicorn Pump, Ms. Clayborne believed the product was specially formulated to be safe for young children to ingest.

36. Plaintiff **Sherry Hodge** lives in Centralia, Illinois and, at all times relevant to this case, has been a citizen of Illinois.

37. Ms. Hodge has purchased Unicorn Pump for her minor granddaughter H.M.

38. H.M. lives with Ms. Hodge during the summer months, and during most weekends for the remainder of the year.

39. Ms. Hodge began purchasing Unicorn Pump for H.M. in or about 2021 when H.M. was two years old.

40. Ms. Hodge continued purchasing Unicorn Pump for H.M. until she was 5 years old.

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that is not required by federal law.”).

41. H.M. used a full strip of Unicorn Pump on her brush for tooth brushings with Ms. Hodge's assistance and/or permission.

42. H.M. enjoyed the candy flavor of the paste.

43. H.M. ingested most of the toothpaste that was put in her mouth for the brushings.

44. Based on the packaging of Unicorn Pump, Ms. Hodge believed the product was specially formulated to be safe for young children to ingest.

45. Plaintiff **Camaria Burleigh** lives in Carbondale, Illinois and, at all times relevant to this case, has been a citizen of Illinois.

46. Ms. Burleigh has purchased Kids Cavity Protection for her minor daughter Z.J.

47. Ms. Burleigh began purchasing Kids Cavity Protection for Z.J. in approximately December of 2022, when Z.J. was six months old. Ms. Burleigh continued purchasing Kids Cavity Protection for Z.J. until 2024, when she was two years old.

48. From the age of 6 months to 1 year, Ms. Burleigh applied the paste to Z.J.'s erupted teeth with a finger brush. Starting at about 13 months of age, Z.J. began using a kids' toothbrush, to which Ms. Burleigh would apply a full strip of paste for his brushings.

49. Z.J. enjoyed the candy flavor of the paste.

50. Z.J. ingested most of the toothpaste that was put in her mouth for the brushings.

51. Based on the packaging of Kids Cavity Protection, Ms. Burleigh believed the product was specially formulated to be safe for young children to ingest.

52. Plaintiff **Anju Goel** lives in Buffalo Grove, Illinois and, at all times relevant to this case, has been a citizen of Illinois.

53. Ms. Goel has purchased Watermelon Burst for her minor son S.A.

54. Ms. Goel began purchasing Watermelon Burst for S.A. when he was approximately

10 months old in or around January 2020. Ms. Goel continued purchasing Watermelon Burst for S.A. until he was three and a half years old.

55. From 10 months to 2 years of age, S.A. used approximately a half strip of paste on this brush for tooth brushings. From age 2 onwards, S.A. generally used a full strip of paste for tooth brushings. He used these quantities of toothpaste with Ms. Goel's assistance and/or permission.

56. S.A. enjoyed the candy flavor of the paste.

57. S.A. ingested most of the toothpaste that was put in his mouth for the brushings.

58. Based on the packaging of Watermelon Burst, Ms. Goel believed the product was specially formulated to be safe for young children to ingest.

59. Plaintiff **Josh Cook** lives in Rockford, Illinois and, at all times relevant to this case, has been a citizen of Illinois.

60. Mr. Cook has purchased Kids Natural for his daughter Z.C.

61. Mr. Cook began purchasing Kids Natural for Z.C around her second birthday in 2020. Mr. Cook continued purchasing this toothpaste for Z.C. until she was five years old. Mr. Cook recalls purchasing both the watermelon and strawberry flavors of the product.

62. From age 2 onwards, Z.C. used a full strip of the Kids Natural paste on her brush. She used this quantity of toothpaste with Mr. Cook's assistance and/or permission.

63. Z.C. enjoyed the candy flavor of the paste.

64. Z.C. ingested most of the toothpaste that was put in her mouth for the brushings.

65. Based on the packaging of the Kids Natural, Mr. Cook did not believe the toothpaste was harmful for his young child to ingest.

66. Defendant **Colgate** is a Delaware company with its principal place of business in

New York, New York. Colgate manufactures and sells Colgate-branded toothpastes.

67. Defendant **Toms** is a wholly owned subsidiary of Defendant Colgate. It is a Maine company with its principal place of business in Kennebunk, Maine. Tom's manufactures and sells the Tom's of Maine toothpastes that are identified herein.

### **JURISDICTION AND VENUE**

68. 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.

69. This Court has personal jurisdiction over Defendants Colgate and Toms because the injuries upon which the Plaintiffs' claims are based occurred or arose out of activities that Defendants specifically engaged in within the State of Illinois. Defendants knowingly and intentionally distributed their toothpaste products for sale in Illinois and Plaintiffs purchased said products from retail stores located here in Illinois.

70. 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 this District.

### **FACTUAL ALLEGATIONS**

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

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

72. 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>23</sup> Because of this, “ingestion of fluoride from toothpaste is common and often substantial” for young children.<sup>24</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>25</sup>

73. 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>26</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>27</sup> A recent study found that 35% of kids ate toothpaste “frequently” and an additional 22% of kids ate toothpaste “a few times.”<sup>28</sup>

74. Due to their smaller size, young children receive a far higher fluoride dose by

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<sup>23</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>24</sup> Steven M. Levy, *A review of fluoride intake from fluoride dentifrice*, 60 ASDC J DENT CHILD. 115, 115 (1993).

<sup>25</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>26</sup> FDA, *supra* note 1, at 52487.

<sup>27</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>28</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).

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 0.08 mg/kg/day are at risk of developing "severe dental fluorosis."<sup>29</sup>

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

75. Dental fluorosis is "a permanent, mottled discoloration of the teeth"<sup>30</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.

76. 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>31</sup>

77. Dental fluorosis comes in various degrees of severity.<sup>32</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>33</sup>

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<sup>29</sup> ENVIRONMENTAL PROTECTION AGENCY: FLUORIDE: DOSE-RESPONSE ANALYSIS FOR NON-CANCER EFFECTS 107 (2010) (emphasis added).

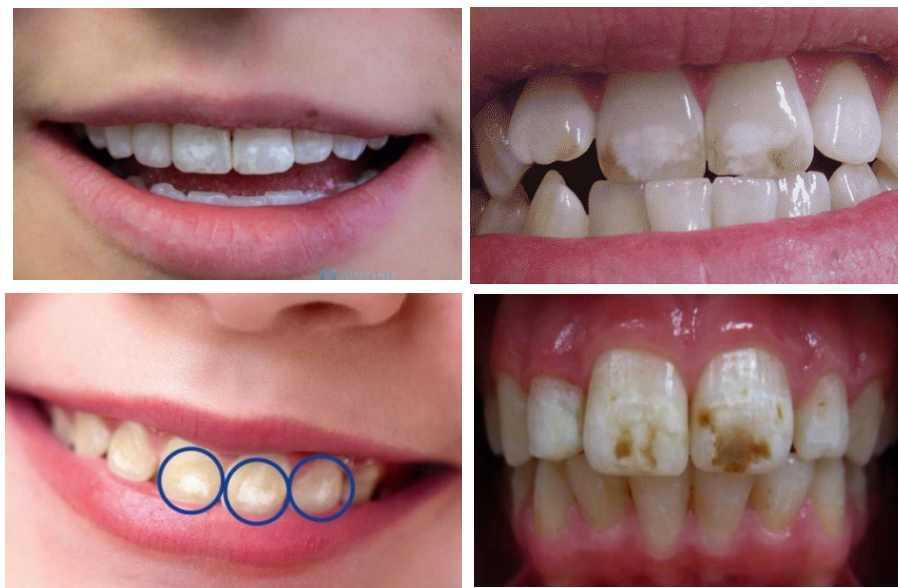
<sup>30</sup> FDA, *supra* note 1, at 52487.

<sup>31</sup> Michael R. Franzman, et al., *Fluoride dentifrice ingestion and fluorosis of the permanent incisors*, 137 J AM DENT ASSOC. 645, 646 (2006).

<sup>32</sup> NATIONAL RESEARCH COUNCIL, *supra* note 16, at 103-111.

<sup>33</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*

78. 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>34</sup> Procter & Gamble, the maker of Crest toothpaste, describes dental fluorosis as a “hypocalcification of tooth enamel” wherein there is “less than normal amounts of calcification in the teeth.”<sup>35</sup> In short, “fluoride affects the forming enamel by making it more porous.”<sup>36</sup>

79. 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>37</sup>

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<sup>34</sup> Brian A. Burt, *The changing patterns of systemic fluoride intake*, 71 J DENT RES. 1228, 1228 (1992).

<sup>35</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>36</sup> Mascarenhas, *supra* note 15, at 269.

<sup>37</sup> American Dental Association Council on Scientific Affairs, *supra* note 4, at 190.

80. 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>38</sup>

81. 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 is not always well controlled, particularly among children aged <3 years.”<sup>39</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>40</sup>

82. 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>41</sup>

83. 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>42</sup>

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<sup>38</sup> Mascarenhas, *supra* note 15, at 274.

<sup>39</sup> CDC, *supra* note 27, at 14.

<sup>40</sup> *Id.*

<sup>41</sup> Hung et al., *supra* note 19.

<sup>42</sup> Susan O. Griffin et al., *Esthetically objectionable fluorosis attributable to water fluoridation*, 30 COMMUNITY DENT ORAL EPIDEMIOL. 199, 202-03 (2002).

84. 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>43</sup>
- 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>44</sup>
- c. “Fluorosis was associated with increased parental dissatisfaction with overall appearance, color, and blotchiness of their children’s teeth.”<sup>45</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>46</sup>
- e. “Our studies of esthetic perceptions of dental fluorosis found that members of

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<sup>43</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).

<sup>44</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>45</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>46</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).

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>47</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>48</sup>
- g. “A strong association between fluorosis and parental satisfaction was evident, even at a low level of severity.”<sup>49</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>50</sup>
- i. “[O]bservers felt that the appearance would increasingly embarrass the child as the TF score increased.”<sup>51</sup>

85. 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.

86. It is too early to determine whether Plaintiffs’ children have suffered dental

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<sup>47</sup> Steven M. Levy, *An update on fluorides and fluorosis*, 69 J CAN DENT ASSOC. 286, 287 (2003).

<sup>48</sup> Carrie B. McKnight, et al., *A pilot study of esthetic perceptions of dental fluorosis vs. selected other dental conditions*, 65 ASDC J DENT CHILD 233, 233 (1998).

<sup>49</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>50</sup> John Spencer, et al., *Water fluoridation in Australia*, 13 COMMUNITY DENT HEALTH 27 (1996).

<sup>51</sup> Paul J. Riordan, *Perceptions of dental fluorosis*, 72 J DENTAL RES 1268, 1268 (1993).

fluorosis as a result of their toothpaste ingestion because their permanent teeth have not yet erupted. (The permanent teeth, not baby teeth, are at risk of fluorosis from toothpaste ingestion.)

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

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

88. 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>52</sup>

89. 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>53</sup>

90. 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>54</sup>

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<sup>52</sup> Jay D. Shulman & Linda M. Wells, *Acute fluoride toxicity from ingesting home-use dental products in children, birth to 6 years of age*, 57 J PUBLIC HEALTH DENT. 150, 157 (1997).

<sup>53</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>54</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,

91. Symptoms of nausea and gastrointestinal distress have been reported at doses as low as 0.1 mg/kg.<sup>55</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.

92. In *adults*, a one-time ingestion of as little as 3 milligrams 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>56</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.

93. If a 1 year-old-child ingests a full strip of Colgate “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>57</sup>

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

94. Fluoride is a “protoplasmic poison”<sup>58</sup> that can kill humans at doses not that much higher than arsenic.<sup>59</sup> The potency of fluoride’s acute toxicity is why fluoride has been used as

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et al., *Studies of human gastric mucosa after application of 0.42% fluoride gel*, 69 J DENT RES. 426 (1990).

<sup>55</sup> Kenji Akiniwa, *A Re-examination of acute toxicity of fluoride*, 30 FLUORIDE 89 (1997).

<sup>56</sup> Spak, *supra* note 54.

<sup>57</sup> See <https://trriage.webpoisoncontrol.org/> (last accessed Jan. 13, 2025).

<sup>58</sup> Editorial, *Chronic fluorine intoxication*, 123 J AM DENT ASSOC. 150, 150 (1943).

<sup>59</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://wwwn.cdc.gov/TSP/MMG/MMGDetails.aspx?mmgid=1424&toxid=3>. This is only

the active ingredient in rodenticides (to kill rodents) and insecticides (to kill bugs).<sup>60</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>61</sup>

95. The “Probable Toxic Dose” (“PTD”) for fluoride is 5 mg/kg.<sup>62</sup> The PTD “is defined as the dose of ingested fluoride that should trigger immediate therapeutic intervention and hospitalization because of the likelihood of serious toxic consequences.”<sup>63</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>64</sup>

96. 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>65</sup>

97. A tube of Colgate’s Watermelon Burst toothpaste contains 143 milligrams of fluoride.<sup>66</sup> A 1 year-old-child of average weight (~9 kg) would need to ingest only 1/3 of the tube

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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>60</sup> KAJ ROHOLM, FLUORINE INTOXICATION: A CLINICAL HYGIENIC STUDY WITH A REVIEW OF THE LITERATURE AND SOME EXPERIMENTAL INVESTIGATIONS 301 (1937).

<sup>61</sup> Herbert B. Baldwin, *The toxic action of sodium fluoride*, 21 J AM CHEM SOC. 517, 521 (1899) (quoting Czrellitzer 1895).

<sup>62</sup> Gary M. Whitford, *Fluoride in dental products: safety considerations*, 66 J DENT RES. 1056, 1056 (1987).

<sup>63</sup> *Id.*

<sup>64</sup> *Id.* at 1057 (emphasis added).

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

<sup>66</sup> Colgate’s Unicorn Pump contains 136 mg of fluoride, Toms’ kids fluoride toothpaste contains 131 to 143 mg of fluoride (depending on the size), and Colgate’s Kid’s Cavity Protection



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.

98. 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>67</sup> The vast majority of these calls are made on behalf of very young children, and hundreds of these calls result in hospitalizations.

99. The number of poisoning incidents from consumer products reported to poison control centers is recognized to “likely underestimate the total incidence and severity of poisonings.”<sup>68</sup> This is the case even for poisonings that cause outcomes as severe as death.<sup>69</sup>

100. 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>70</sup>

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toothpaste contains 84 mg of fluoride.

<sup>67</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).

<sup>68</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>69</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>70</sup> Shulman & Wells, *supra* note 52, at 157.

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

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

102. 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>71</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>72</sup> which is less than many children will ingest from swallowing fluoride toothpaste.<sup>73</sup>

103. Another endocrine effect of fluoride exposure that the NRC flagged is impaired glucose metabolism, which is believed to be caused by fluoride’s “inhibition of insulin production.”<sup>74</sup> According to the NRC, blood fluoride levels of 0.1 mg/L are credibly associated with this effect.<sup>75</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>76</sup>

104. 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

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<sup>71</sup> NATIONAL RESEARCH COUNCIL, *supra* note 16, at 178-80, 220-22 & 260-66.

<sup>72</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>73</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 Colgate’s kids toothpaste products.

<sup>74</sup> *Id.* at 264.

<sup>75</sup> *Id.*

<sup>76</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).

fluoride exposure is “consistently associated with reduced IQ in children.”<sup>77</sup>

105. In January of 2025, NTP scientists published a meta-analysis of 74 human studies on fluoride and IQ in the journal *JAMA Pediatrics*.<sup>78</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.”

106. 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>79</sup>

107. 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).

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

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<sup>77</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>78</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>79</sup> National Toxicology Program, *Fluoride Exposure: Neurodevelopment and Cognition*, <https://ntp.niehs.nih.gov/whatwestudy/assessments/noncancer/completed/fluoride> (last accessed Jan. 13, 2025).

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

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

110. 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>80</sup> According to both the FDA and CDC, children under 2 should only use fluoride toothpaste if directed by a dentist.<sup>81</sup>

111. 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 time the swallowing reflex has developed sufficiently to prevent inadvertent ingestion.”<sup>82</sup>

112. 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>83</sup> The ADA provides the following figure<sup>84</sup> to show what a “smear” and “pea-sized” amount looks like:

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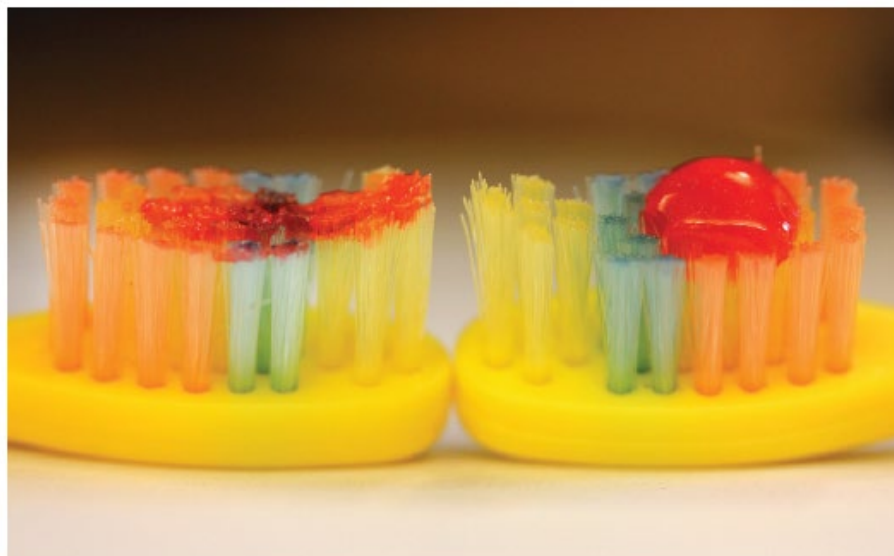
<sup>80</sup> FDA, *supra* note 1, at 52487.

<sup>81</sup> 21 C.F.R. § 355.50(d)(1)(i) (“Children under 2 years of age: Consult a dentist or doctor.”); CDC, *supra* note 28, at 27 (“Parents and caregivers should consult a dentist or other health-care provider before introducing a child aged <2 years to fluoride toothpaste.”).

<sup>82</sup> Thornton-Evans, *supra* note 2, at 87.

<sup>83</sup> ADA, *supra* note 4, at 191.

<sup>84</sup> *Id.* at 191.



**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).

113. 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.

114. The AAP,<sup>85</sup> AAPD,<sup>86</sup> and Colgate itself,<sup>87</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 under 6.

115. 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>88</sup>

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<sup>85</sup> Melinda B. Clark, et al., *Fluoride Use in Caries Prevention in the Primary Care Setting*, 146 PEDIATRICS e2020034637, Tbl 1 (2020).

<sup>86</sup> American Academy of Pediatric Dentistry, Frequently Asked Questions, <https://www.aapd.org/resources/parent/faq/> (last accessed Jan. 13, 2025).

<sup>87</sup> See *supra* ¶ 11.

<sup>88</sup> National Capital Poison Center, *supra* note 11.

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

116. Defendant Colgate is the second largest manufacturer of fluoride toothpaste in the U.S.

117. Colgate 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.

118. As can be seen in the images below, Defendant's national advertisements repeatedly showed full strips of toothpaste on children's toothbrushes.





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

120. Beginning in the 1980s, however, Colgate 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.

121. Dental fluorosis rates among U.S. children have risen sharply since the 1980s, and the marketing efforts that Colgate pioneered are believed to be one of the key reasons why.<sup>89</sup>

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

122. 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.

123. 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>90</sup>

124. 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>91</sup>

125. In 1994, the World Health Organization stated, “the production of candy-like

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<sup>89</sup> Neurath, *supra* note 17, at 306.

<sup>90</sup> Bawden, *supra* note 10, at 1221.

<sup>91</sup> *Introduction to the Workshop*, 22 COMMUNITY DENT ORAL EPIDEMIOL. 140, 142 (1993).



flavours . . . should not be encouraged for use by children, as they may lead to an excessive ingestion of fluoride.”<sup>92</sup>

126. 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>93</sup>

127. Marketing fluoride toothpaste as if it were candy, or food, has been criticized as an “aggressive” and “misleading” marketing tactic.<sup>94</sup> According to Basch and Rajan, “the ubiquitous presence of food pictures and appealing flavors on the toothpaste creates a distinct conflict. While 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>95</sup>

128. 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>96</sup>

129. According to the FDA, marketing dangerous products to children through the use

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<sup>92</sup> WORLD HEALTH ORGANIZATION. FLUORIDES AND ORAL HEALTH 28 (1994).

<sup>93</sup> Shulman & Wells, *supra* note 52, at 150.

<sup>94</sup> Basch & Rajan, *supra* note 8, at 316.

<sup>95</sup> *Id.*

<sup>96</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).

of candy or food flavoring can qualify as a “misleading” marketing tactic that renders a product “misbranded” under the FDCA.<sup>97</sup>

## I. FDCA Requirements for Fluoride Toothpaste

### *General Requirements*

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

131. A drug is misbranded if it has packaging that “is **false or misleading** in any particular.” 21 U.S.C. § 352(a)(1) (emphasis added).

132. A drug is also misbranded if “any word, statement, or other information required . . . to appear on the label or labeling is not **prominently** placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.” 21 U.S.C. § 352(c) (emphasis added).

133. Under the regulations issued pursuant to the FDCA, the warnings and directions on a label will fail to meet the prominence test if there is:

- (4) Insufficiency of label space for the prominent placing of such word, statement, or information, resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;
- (5) Insufficiency of label space for the prominent placing of such word, statement, or information, resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device.

21 C.F.R. § 201.15(a).

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<sup>97</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”).

134. The warnings and directions that FDA requires to be on a label *must* be placed on the “outside container or wrapper of the retail package, or the immediate container label if there is no outside container or wrapper.”<sup>98</sup> 21 C.F.R. 201.66(c)(5) & (6).

135. 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 and the regulations issued pursuant thereto. 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 (a) it makes false and misleading representations that are not approved or required by the Monograph, or (b) it fails to present the warnings and directions required by the Monograph with sufficient prominence.

*Specific Requirements*

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

137. 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.*

138. 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

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<sup>98</sup> The FDA only permits “peel back” labels if the product is “unable to meet the labeling format described in § 201.66(d)(1) through (d)(9), or the modified format authorized under § 201.66(d)(10).” 64 Fed. Reg. 13254 at 13268.

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*

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

140. The FDA does not require fluoride toothpastes to be packaged to look like candy or food products.

141. The FDA does not require fluoride toothpastes to taste like candy or fruit.

142. The FDA does not require fluoride toothpastes to have strong sweet scents.

143. The FDA does not require fluoride toothpastes to have cartoon unicorns with rainbow hair on the front of the product.

144. The FDA does not require fluoride toothpastes to state that they are approved by the ADA.<sup>99</sup>

145. The FDA does not require, and in fact prohibits, companies from hiding the FDA’s required directions and warnings under a label that contains empty space and promotional claims.

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<sup>99</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 23, 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.”).

## J. The Colgate Products at Issue

146. Plaintiffs' claims against Defendant Colgate involve the following three products:

(1) Kids Cavity Protection, (2) Watermelon Burst, and (3) Unicorn Pump.



### Colgate Kids Cavity Protection

147. Colgate's "Kids Cavity Protection" toothpaste contains the same fluoride concentration as Colgate's "Cavity Protection" toothpaste for adults (0.15% fluoride ion by weight).

148. Kids Cavity Protection is Colgate's most popular toothpaste for kids.

149. The following elements of Kids Cavity Protection convey, both individually and collectively, that it is specially formulated to be safe for young children to ingest without need to limit how much of the toothpaste to put on the brush:

- a. The front label of the box, as well as the front label on the product itself, prominently displays the word "KIDS."
- b. The colorful "bubble fruit"-flavored gel inside the tube is indistinguishable in both flavor and scent from 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.
- c. The front label of the box, as well as on the front label of the product itself, prominently advertises that the gel is free of substances that are unhealthy to ingest, including parabens, preservatives, and sugar. This advertised absence of

unhealthy substances further conveys the impression that the gel is not harmful for children to ingest.

- d. The front label of the box, as well as on the front label on the product itself, prominently displays a seal of approval from the ADA, but does not disclose ADA's guideline that children under 3 only use a "smear" of the paste.

150. Kids Cavity Protection magnifies the above deception by providing a visual instruction on the box which implies that a **full strip** of paste is a safe and recommended amount of paste to use. Specifically, the side label of the box shows two steps that are necessary to ensure "a healthy smile." The first step is "BRUSH 2X A DAY" and the second step is to brush "FOR 2 MINUTES." Next to the instruction to "BRUSH 2X A DAY," the label shows a toothbrush with a full heaping strip of paste on it.



151. Studies of misleading marketing strategies used by toothpaste companies have specifically flagged the problem with visually showing full strips of toothpaste. 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>100</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>100</sup> Basch & Rajan, *supra* note 8, at 318.

which may contribute to fluorosis.”<sup>101</sup>

152. As Colgate knows, a full strip of fluoride toothpaste is up to **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.

153. None of the deceptive attributes identified in paragraphs 149 and 150 are required by the FDCA or its accompanying regulations, including the Monograph. Individually and collectively, these voluntary attributes, which Plaintiff Burleigh relied upon, cause reasonable consumers (including Plaintiff) to falsely believe that Kids Cavity Protection is specially formulated to be safe for young children to ingest without need to limit how much paste goes on the brush.

154. Based on this deception, Plaintiff Burleigh permitted her child to regularly use this toothpaste in quantities that, unbeknownst to her, far exceed the safe and recommended amount. She suffered economic loss as a result by obtaining fewer brushings per product.

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<sup>101</sup> Corey H. Basch, et al., *Advertising of toothpaste in parenting magazines*, 38 J COMMUNITY HEALTH. 911, 913 (2013).





**Colgate Watermelon Burst**

155. Colgate has billed its Watermelon Burst product as a “2-in-1 Toothpaste and Anticavity Mouthwash.”<sup>102</sup> Colgate’s description of the product as a mouthwash<sup>103</sup> is a reference to its “liquid gel” composition, which is much less viscous than a normal toothpaste.

156. The following elements of Watermelon Burst deceptively convey, both individually and collectively, that the colorful gel inside the tube is specially formulated to be safe for young children to ingest without need to limit how much toothpaste is put on the brush:

- a. The word “Toothpaste” has a crayon-like rainbow pattern that is clearly and unmistakably directed towards young children, thereby suggesting that the

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<sup>102</sup> See, e.g., <https://www.target.com/p/colgate-2-in-1-kids-toothpaste-and-anticavity-mouthwash-watermelon-burst-4-6oz/-/A-13773703> (last accessed Jan. 13, 2025).

<sup>103</sup> It is a violation of the FDCA for Colgate to market this product as an anticavity mouthwash. This is because the product does not conform to the standard of identity for anticavity mouthwashes, as set forth in FDA’s monograph. See, e.g., 21 C.F.R. § 355(d)(2). Plaintiffs, however, do not base their claims on this violation.

product is specially formulated to be safe for young children.

- b. The product is packaged and presented like a fruit-flavored candy product, from the design of its front label to the sweet candy taste and scent of the gel. The front label shows a heaping green sparkling swirl (that matches the color of the gooey gel inside) flowing from a juicy watermelon, while the gel inside has a sweet candy scent that radiates into the air upon opening the lid. Since fruit and candy are things that children can safely ingest, the fruit- and candy-like elements of the Watermelon Burst product signify that the product is safe for children to ingest.
- c. The front label states that the gel is “SUGAR FREE” which further signifies that the product is healthy, or at least not harmful, to ingest.

157. 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 voluntary attributes, which Plaintiff Goel relied upon, cause reasonable consumers (including Plaintiff) to falsely believe that Watermelon Burst is specially formulated to be safe for young children to ingest without need to limit how much paste goes on the brush.

158. Based on this deception, Plaintiff Goel permitted her child to regularly use this toothpaste in quantities that, unbeknownst to her, far exceed the safe and recommended amount. She suffered economic loss as a result by obtaining fewer brushings per product.



**Colgate Unicorn Pump**

159. Colgate sells a kids-branded “Maximum Cavity Protection” toothpaste in a pump. Although labeled as providing “maximum” cavity protection, this toothpaste contains the same concentration of fluoride (0.15% fluoride ion by weight) as Colgate’s ordinary “Kids Cavity Protection” toothpaste.

160. Colgate has two different label designs for its toothpaste pump. One has a cartoon unicorn design (“Unicorn Pump”) and the other does not have any cartoons (“Regular Pump”).

161. The Regular Pump has a prominent notation on the front label that says it is for “ages 6+.”<sup>104</sup> This notation is not present on the Unicorn Pump, despite the toothpastes containing the same volume and concentration of fluoride, as well as the same green-colored “bubble fruit” flavored toothpaste.

<sup>104</sup> The Regular Pump is not a product that Plaintiffs used, and is thus not a product for which Plaintiffs seek relief.

162. The following elements of the Unicorn Pump product deceptively convey, both individually and collectively, that the colorful gel inside the tube is specially formulated to be safe for young children to ingest without need to limit how much of the toothpaste to put on the brush:

- a. The front label features a cartoon image of a unicorn, which is an image of innocence and purity that conveys a message that the toothpaste is healthy and harmless for young children.
- b. The colorful gel inside the tube has a flavor (“bubble fruit”) that is indistinguishable in both flavor and scent from 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.
- c. The front label does not contain the “6+ YRS” notation that the Regular Pump contains, thus implying that—unlike the Regular Pump—the Unicorn Pump is specially designed to be safe for preschool children.
- d. The front label prominently displays a seal of approval from the ADA, but does not disclose ADA’s guideline that children under 3 should only use a “smear” of the paste.
- e. The back label of the product advertises various promotional claims about the product (“Freshens Breath” and “Helps Reduce Plaque Buildup with Regular Brushing”<sup>105</sup>), but hides FDA’s required warnings and directions. It is only in the fine print that one will see a notation to “Drug Facts” being available if one

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<sup>105</sup> The claim that the paste “reduces plaque buildup” is not an approved indication of fluoride toothpaste under FDA’s monograph. 21 C.F.R. § 350.50(b) & (f).

peels off the back label.

- f. The few consumers who actually see the fine print reference to “Drug Facts” and take the initiative to peel off the label will be frustrated by the messy and cumbersome process that entails. First, the label is difficult to peel back. Second, the back label is connected to the front label and one needs to pull a portion of the front label off in order to fully read the warnings and directions on the back – which results in a disfigured-looking product, as reflected in the photos below. Third, unless one pulls the entire label off the product, one is left with a sticky protruding label coming off the product. Fourth, if one does pull the whole label off, then the directions and warnings will be removed as well, leaving the consumer with a clear plastic tube with no information at all.



163. 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 voluntary attributes, which Plaintiffs Clayborne and Hodge relied upon, cause reasonable consumers (including Plaintiffs) to falsely believe that the Unicorn Pump is specially formulated to be safe for young children to ingest without need to limit how much paste goes on the brush.

164. Based on this deception, Plaintiffs Clayborne and Hodge permitted the children in their care 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. The Tom's Product at Issue**

165. Colgate purchased Toms of Maine in 2006. Prior to Colgate acquiring the company, Toms had developed a reputation for being a “healthy” alternative to mainstream brands of toothpaste. This reputation generated consumer trust in the superior safety of Toms’ products.

166. Upon information and belief, most consumers do not know that Toms is now owned by Colgate. Further, most consumers continue to believe that Toms products are especially safe and healthy products to use.

167. Plaintiffs’ claims against Defendant Tom’s are based on its Kid’s Natural Fluoride Anticavity Toothpaste product (hereafter “Kid’s Natural”).



### **Kid's Natural**

168. Tom's Kid's Natural product comes in various fruit flavors.

169. The following elements of the Kids Natural product deceptively convey, both individually and collectively, that the toothpaste inside the tube is specially formulated to be safe for young children to ingest without need to limit how much of the toothpaste to put on the brush.

- a. The front label prominently displays the word "Kids," thus signifying that the product is specially formulated for children.
- b. The front label prominently features the word "NATURAL" which signifies to a lay consumer that the product is free of toxic ingredients.
- c. The front label prominently displays images of fruit. Since fruit is something that is healthy for kids to eat, the imagery of fruit implies that the product is healthy, or at least not harmful, for young kids to ingest.
- d. The front label provides light-hearted, silly names for the fruit flavors, including



“Silly Strawberry,” “Outrageous Orange Mango,” “Watermelon Wiggle,” “Wild Blueberry,” and “Fruitilicious.” The wording of these flavors implies that this is a harmless product that need not be handled with any serious care.

- e. The front label superimposes cartoon graphics over the fruit. The image of the strawberry, for example, has a superimposed smiley face, while the image of the watermelon has a superimposed face of a cartoon character chewing gum and blowing a bubble. These cartoon graphics further imply that this is a harmless product that need not be handled with any serious care.
- f. The front label of the Kids Natural product states that it is “ADA Accepted,” but does not disclose ADA’s guideline that children under 3 should only use a “smear” of toothpaste.

170. 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 voluntary attributes, which Plaintiff Cook relied upon, cause reasonable consumers (including Plaintiff) to falsely believe that Kids Natural is specially formulated to be safe for young children to ingest without need to limit how much toothpaste is put on the brush.

171. Based on this deception, Plaintiff Cook permitted his child to regularly use this toothpaste in quantities that, unbeknownst to him, far exceed the safe and recommended amount. He suffered economic loss as a result by obtaining fewer brushings per product.

## **L. Reasonable Consumers Are Misled by Defendants' Marketing Tactics**

172. Most parents are unaware of the recommended amount of fluoride toothpaste that young children should use and the reasons for these recommendations.<sup>106</sup> This increases the susceptibility of consumers to Defendants' deceptive marketing tactics as the safety, or lack thereof, of fluoride toothpaste ingestion is not within the ken of most people.

173. Peer-reviewed reports in the scientific literature have described the marketing tactics that Defendants use to sell kids' fluoride toothpastes as "misleading" and "confusing." These tactics include the use of fruit imagery and depictions of full strips of toothpaste.<sup>107</sup>

174. The fact that Defendants place the FDA-required warnings and directions in fine print on the back of the product does not cure the much more prominent representations on the front of the product that run counter to, and undermine, said warnings and directions. Indeed, public health researchers have warned that "the small size and the minimally accessible placement of the warning labels" on the back of kid's fluoride toothpaste tubes "presents a problem for parents and guardians of young children who may miss this important information."<sup>108</sup>

175. 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).

176. As the Seventh Circuit explained in *Bell v. Publix Super Mkts., Inc.*, 982 F.3d 468, 476, 481 (7th Cir. 2020):

Consumer-protection laws do not impose on average consumers an obligation to question the labels they see and to parse them as

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<sup>106</sup> Annie Y. Chen, et al., *Appropriate Fluoride Toothpaste Application: Improving Caregiver Compliance*, 40 PEDIATRIC DENT. 412, 415-16 (2018).

<sup>107</sup> Basch & Rajan, *supra* note 8, at 316; Chen, *supra* note 107, at 416.

<sup>108</sup> Basch & Rajan, *supra* note 8, at 318.

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).”)

#### **M. Defendants’ Deceptive Conduct Caused Economic Injury to Plaintiffs and Class Members**

177. Defendants have engaged in the deceptive conduct described above to (i) obfuscate, distract from, and undermine FDA’s required warnings and directions, (ii) induce people to buy the products 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.

178. Defendants were, and remain, unjustly enriched each time parents and caregivers act on their false and misleading packaging, including when caregivers use more than the safe and recommended amount of Colgate 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 toothpaste 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 paste 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).

179. Adhering to the recommended amount of fluoride toothpaste is not a trivial issue given the toxic effects that can occur when a child ingests more than the recommended amount.

180. Had Plaintiffs not been misled by Defendants' packaging, they would have ensured their children used the recommended amount of paste.

181. As an immediate, direct, and proximate result of Defendants' 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.

182. Consequently, Plaintiffs and the Class Members have suffered injury in fact and lost money as a result of Defendants' wrongful conduct.<sup>109</sup>

### **CLASS ALLEGATIONS**

183. As used herein, the term PRODUCTS refers to the four products identified above, namely: Kids Cavity Protection, Watermelon Burst, Unicorn Pump, and Kids Natural.

184. Pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3), Plaintiffs bring this action on behalf of the following Multi-State Class: All persons in Arizona, California, Connecticut, Florida, Hawaii, Idaho, Illinois, Minnesota, Missouri, New Jersey, New York, Virginia, Washington State, and Washington D.C., who purchased one or more of the PRODUCTS for children aged 0 to 6 years, (B) within the applicable statutes of limitation, and (C) who used more than the recommended amount of paste.

185. Excluded from the Class are Defendants, their parents, subsidiaries, affiliates,

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<sup>109</sup> 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. This does not mean that Plaintiffs' children have not suffered physical harm.

officers, and directors; those who used the recommended amount of toothpaste, despite Defendants' 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.

186. 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.

187. 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.

188. **Numerosity**: The members of the Class are so numerous that joinder of all class members is impracticable. On information and belief, there are, at a minimum, hundreds of thousands 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.

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

- a. Whether the FDCA preempts claims that the voluntarily added components of the PRODUCTS' packaging and labeling are false and/or misleading;
- b. Whether the attributes of the PRODUCTS that are not required by the FDA Monograph are false and/or misleading;
- c. Whether Defendants knew or should have known that the packaging of the

PRODUCTS are false and/or misleading;

- d. Whether Defendants have violated the state consumer protection statutes alleged herein;
- e. Whether Defendants were unjustly enriched;
- f. Whether Plaintiffs and Class members have suffered an ascertainable loss of monies or property or other value as a result of Defendants' deceptive and unlawful conduct; and
- g. Whether Plaintiffs and Class members are entitled to relief and, if so, the nature of such relief.

190. The consumer protection laws in the putative Multi-State Class are materially identical with respect to the causes of action for deceptive trade practices alleged herein. Thus, the same deceptive conduct by Defendant that violates Illinois's Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505, *et seq.*, simultaneously violates the consumer protection laws of the other identified states.

191. **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 aged 0 to 6 years old, used more of the toothpaste than is safe and recommended, and sustained economic loss as a result.

192. **Adequacy**: Plaintiffs will fairly and adequately protect the interests of the Class and have retained counsel that is experienced in litigating complex class actions. Plaintiffs have no interests which conflict with those of the Class. 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.

193. **Superiority**: A class action is superior to any other available means for the fair and efficient adjudication of this controversy for the following reasons:

- a. The economic loss 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 Defendants’ 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 these 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 Defendants’ 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>110</sup>

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<sup>110</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.’”).



**FIRST CAUSE OF ACTION**

**False Pretenses, Promises, and Misrepresentations in Violation of the  
Illinois Consumer Fraud and Deceptive Trade Practices Act  
815 ILCS 505/1, et seq.**

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

195. Plaintiffs bring this claim individually and on behalf of the Illinois members of the Multi-State Class.

196. Plaintiffs 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).

197. Defendants are persons within the context of the ICFA, 815 ILCS § 505/1(c).

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

199. Plaintiffs and Class members are “consumers” who purchased the PRODUCTS for personal, family, or household use within the meaning of the ICFA, 815 ILCS § 505/1(e).

200. The Illinois Consumer Fraud and Deceptive Trade Practices Act (“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 . . . of any material fact.” 815 ILCS 505/2.

201. 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). The defendant, however, must intend for consumers to rely on the aspects of the labeling that are alleged to be deceptive.

202. As with other sophisticated corporate entities, Defendants intentionally design the packaging and labeling of the PRODUCTS, including the false and deceptive elements described in paragraphs 149, 150, 156, 162, and 169 to entice the target audience to purchase said products.

203. Defendants' marketing of the PRODUCTS is deceptive in the following ways, each of which is independently violative of the ICFA:

- a. For all PRODUCTS: As described above, including but not limited to paragraphs 149, 150, 156, 162, and 169, Defendants present the PRODUCTS as specially formulated to be safe for young children to ingest without need to limit the amount of paste that goes on the brush.
- b. For the Kids Cavity Protection product: Defendant Colgate provides a visual instruction to use a full strip of toothpaste which is likely to deceive the consuming public into believing a full strip of toothpaste is a safe, recommended, and age-appropriate amount of paste to use.

204. Defendants intend for consumers to rely on these false pretenses, promises and misrepresentations, whether or not they know these are false and/or misleading.

205. Reasonable consumers rely and act upon said false and misleading representations.

206. Plaintiffs relied on Defendants' deceptive packaging and suffered economic loss as a proximate result of this reliance.

207. Through said violations of the ICFA, Defendants have been unjustly enriched, and continue to be unjustly enriched, by unfairly obtaining money from members of the Class.

208. Based on Defendants' deceptive acts and practices, Plaintiffs and the Illinois Class members are entitled to relief under 815 ILCS §505/10a.

### **SECOND CAUSE OF ACTION**

#### **Concealment and Suppression of Material Facts in Violation of the Illinois Consumer Fraud and Deceptive Trade Practices Act 815 ILCS 505/1, et seq.**

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

210. Plaintiffs bring this claim individually and on behalf of the Illinois members of the

Multi-State Class.

211. The ICFA prohibits “[u]nfair methods of competition and unfair or deceptive acts or practices,” which includes “concealment, suppression or omission of any material fact.” 815 ILCS 505/2.

**Unicorn Pump**

212. Defendant Colgate has violated the ICFA by concealing and suppressing material facts in the packaging of its Unicorn Pump product. Specifically, Colgate has concealed and suppressed all of FDA’s required directions and warnings by hiding said information under a label containing empty space and unapproved promotional claims.

213. The directions and warnings that FDA requires to be present on the packaging for fluoride toothpaste are material facts regarding the risks, and age-appropriate use, of said products.

214. Most consumers, including reasonable consumers, will not know that there are warnings and directions under the back label of the Unicorn Pump. Even fewer consumers, including reasonable consumers, will actually pull off the back label to access this information. This is especially so given (A) the false and misleading representations on the front label which convey the impression that the product is healthy and harmless for young children, (B) the difficulty of pulling off the back label, and (C) the fact that the back label cannot be pulled off without significantly disfiguring the appearance of the product.

215. Colgate’s concealment and suppression of the warnings and directions simultaneously violates Colgate’s obligations under the FDCA. As described above, 21 U.S.C. § 352(c), 21 C.F.R. 201.66(c)(5)-(6), and 21 C.F.R. § 201.15(a)(4)-(5) require that the warnings

and directions be prominently displayed on the immediate container label.<sup>111</sup>

216. While the FDA permits “peel back” labels under limited circumstances, those limited circumstances are not present with the Unicorn Pump product. *See* 21 C.F.R. § 201.66(d)(1) through (d)(10); *see also* 64 Fed. Reg. 13254 at 13268 (permitting peel back labels if the product is “unable to meet the labeling format described in § 201.66(d)(1) through (d)(9), or the modified format authorized under § 201.66(d)(10)).”

217. Colgate’s concealment and suppression of the warnings and directions is prohibited under the FDCA because the immediate container label of the Unicorn Pump is filled with unapproved indications (e.g., “helps reduce plaque buildup”), promotional claims (e.g., “freshens breath”), and *empty space* that cannot be more prominent than the directions and warnings.

218. The lack of justification for Colgate’s concealment and suppression of the warnings and directions is evident by the fact that competitor toothpaste pumps of the same size (Perrigo – Firefly), and *smaller* size (Sanofi - Aquafresh), provide all of the required warnings and directions on the immediate container label without resorting to hidden labels.

219. Defendant intends for consumers to rely on its concealment and suppression of the warnings and directions. Consistent with this intention, consumers do rely on said concealment and suppression.

220. Plaintiffs Clayborne and Hodge did not notice that there were warnings and directions hidden beneath the back label.

221. Plaintiffs Clayborne and Hodge permitted the children in their care to use more toothpaste than safe and recommended based in part on their reasonable reliance on Defendants’

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<sup>111</sup> The Unicorn Pump does not come in a box or other form of wrapping, and thus Colgate has a requirement to place the warnings and directions on the “immediate container label” of the product. 21 C.F.R. 201.66(c).

concealment and suppression of the warnings and directions.

222. Plaintiffs Clayborne and Hodge and the putative Illinois class members have suffered economic loss as a result of Defendant's violation of the ICFA.

223. Based on Defendant's concealment and suppression of the warnings and directions, Plaintiffs Clayborn and Hodge and the Illinois Class members are entitled to relief under 815 ILCS §505/10a.

**Kids Cavity Protection, Unicorn Pump, and Kids Natural**

224. Defendants have concealed and suppressed material facts in violation of the ICFA in the packaging of their Kids Cavity Protection, Unicorn Pump, and Kids Natural products.

225. For each of the aforementioned products, the packaging prominently boasts that the product is approved by the ADA.

226. The FDA does not prohibit showing a seal of approval from the ADA, 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 23, 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.").

227. The Defendants have utilized the ADA seal of approval in a false and misleading way by concealing and suppressing the fact that ADA's recommendation of kids fluoride toothpaste is premised on children under 3 using no more than a smear of paste.

228. ADA's position that children under the age of three should use no more than a smear of toothpaste is a highly material fact to the safe and appropriate use of Defendants' products. By concealing and suppressing this fact, Defendants have engaged in a deceptive act that violates the ICFA.

229. Defendants intend for consumers to rely on their concealment and suppression of the ADA's recommendation regarding the amount of fluoride toothpaste children under 3 should use. Consistent with this intention, consumers do rely on said concealment and suppression.

230. Plaintiffs permitted their children to use more toothpaste than safe and recommended based in part on their reasonable reliance on Defendants' concealment and suppression of ADA's recommendation. Plaintiffs and the putative Illinois class members have suffered economic loss as a result of Defendants' violation of ICFA.

231. Based on Defendants' concealment and suppression of the warnings and directions, Plaintiffs and the Illinois Class members are entitled to relief under 815 ILCS §505/10a.

### **THIRD CAUSE OF ACTION**

#### **Deceptive Business Practices in Violation of Other Similar State Statutes Identified Herein**

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

233. Plaintiffs bring this claim on behalf of the Arizona, California, Connecticut, Florida, Hawaii, Idaho, Minnesota, Missouri, New Jersey, New York, Virginia, Washington State, and Washington D.C. members of the proposed Multi-State Consumer Deception Statute Class.

234. As described above, including but not limited to paragraphs 149, 150, 156, 162, and 169, Defendants have engaged in deceptive practices in its marketing of the PRODUCTS. Through these deceptive practices, Defendants conveyed the false and misleading impressions that these products are specially formulated to be safe for young children to ingest without need to limit how much toothpaste can be put on the brush.

235. Through this deceptive conduct, which violated, and continues to violate, the ICFA (815 ILCS 505/2), Defendants have simultaneously violated, and continue to violate, the following state consumer protection statutes:

- a. Arizona (A.R.S. § 44-1521, *et seq.*);
- b. California (Cal. Bus. & Prof. Code § 17200, *et seq.* & Cal. Civ. Code § 1750, *et seq.*)
- c. Connecticut (Conn. Gen. Stat. § 42-110a, *et seq.*);
- d. Florida (Fla. Stat. § 501.201, *et seq.*);
- e. Hawaii (HRS § 481A-1, *et seq.*);
- f. Idaho (Idaho Code § 48-601, *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. New York (NY GBL §§ 349-50);
- k. Virginia (Va. Code Ann. § 59.1-196, *et seq.*);
- l. Washington (Wash. Rev. Code § 19.86.010, *et seq.*);
- m. Washington D.C. (D.C. Code § 28-3904, *et seq.*)

236. Plaintiffs and the Class Members have permitted their preschool children to use more toothpaste than safe or recommended based on their reasonable reliance on Defendants' false and misleading packaging.

237. Defendants intend for consumers to rely on these false pretenses, promises and misrepresentations, whether or not they know these are false and/or misleading.

238. Reasonable consumers rely and act upon said false and misleading representations.

239. Plaintiffs relied on Defendants' deceptive packaging and suffered economic loss as a proximate result of this reliance.

240. Through said violations of the ICFA, Defendants have been unjustly enriched, and



continue to be unjustly enriched, by unfairly obtaining money from members of the Class.

241. Based on Defendants' deceptive acts and practices, Plaintiffs and the Illinois Class members are entitled to relief under 815 ILCS §505/10a.

242. Plaintiffs and the Class Members have suffered economic harm as a proximate result of Defendants' violations of the aforementioned statutes by using more of the PRODUCTS per brushing than is safe or recommended, and thereby obtaining less brushings per tube of toothpaste.

243. Through its deceptive acts and practices, Defendants have been unjustly enriched, and continue to be unjustly enriched, by unfairly obtaining money from members of the Class.

244. Based on Defendants' 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 Class;
- 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, except as to those causes of action where statutory damages are not available by law;
- 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 treble damages, except as to those causes of action where treble damages are not available by law;

- G. 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;
- 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: May 2, 2025

Respectfully Submitted,

By: /s/ Michael Connett

Michael Connett

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