

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

ERIN GIBSON and SHERRY HODGE,
individually and on behalf of those similarly
situated,

Plaintiffs,

v.

PERRIGO COMPANY and RANIR, LLC,

Defendants.

Case No. 1:25-cv-00348

**THIRD AMENDED CLASS ACTION
COMPLAINT**

JURY TRIAL DEMANDED

THIRD AMENDED CLASS ACTION COMPLAINT

Plaintiffs Erin Gibson and Sherry Hodge (“**Plaintiffs**”), by their undersigned counsel, on behalf of themselves and all persons similarly situated who purchased Firefly Mouthrinse for their preschool children, bring this class action lawsuit against Perrigo Company and its subsidiary Ranir, LLC (“**Defendants**”). Plaintiffs allege the following upon information and belief, except for those allegations that pertain to Plaintiffs, which are based on Plaintiffs’ personal knowledge.

INTRODUCTION

1. Defendants manufacture, sell, and distribute a popular kids mouthwash product called Firefly Anticavity Fluoride Rinse (hereafter, “**Firefly Rinse**” or “**Firefly**”). The product is sold by Walmart, and other large retailers.

2. The Firefly container looks like a toy and showcases cartoon characters that are popular among preschool children, including Paw Patrol and Buzz Lightyear. Its colorful blue, pink, and purple liquid comes in sweet candy flavors with sweet candy scents.

3. Every aspect of the packaging is designed to appeal to very young children, including its toy-like appearance, cartoon imagery, bright colored liquid, and candy flavors.



4. Firefly’s toylike appearance, and candy-like nature, conveys the false impression to parents and caregivers that this is a product that is meant for and safe for young children. The reality is that fluoride mouthrinses are *not* safe for young children and virtually all health authorities agree they should *not* be used by children under 6 on an over-the-counter basis.

5. As far back as 1960, it was known that fluoride mouthrinses “should not be employed in children below school age.”¹

6. The U.S. Food and Drug Administration (“FDA”) states that fluoride mouthrinses “are not indicated for use in children under 6 years of age on an [over-the-counter] basis” and “should not be within easy reach of any children.”²

¹ Ingrid Hellstrom, *Fluoride retention following sodium fluoride mouthwashing*, 18 ACTA ODONTOL SCAND 263, 273 (1960).

² FDA, *Anticaries Drug Products for Over-the-Counter Human Use; Final Monograph*, 60 Fed. Reg. 52474, 52486 (Oct. 6, 1995).

7. The American Dental Association (“**ADA**”) states that “Children younger than the age of 6 should not use mouthrinse, unless directed by a dentist, because they may swallow large amounts of the liquid inadvertently.”³

8. The World Health Organization (“**WHO**”) states that fluoride mouthrinses “are not recommended for children below the age of 6 years.”⁴

9. The American Academy of Pediatrics (“**AAP**”) states that fluoride mouth rinses should not be used until a child turns 6 and, even then, only “if the child can reliably swish and spit” and is at high risk of tooth decay.⁵

10. The U.S. Centers for Disease Control and Prevention (“**CDC**”) states that “children aged <6 years should not use fluoride mouthrinse without consultation with a dentist or other health care provider.”⁶

11. Manufacturers of fluoridated dental products are well aware that fluoride mouthrinses are contraindicated for children under six.

12. According to Colgate, the second largest manufacturer of fluoridated dental products in the US, “babies and toddlers should not use [fluoride] mouthrinse” because “children under six may not have fully developed their swallowing reflexes and could swallow the mouthrinse,” which can “lead to side effects like vomiting, intoxication, and nausea.”⁷

³ ADA, *Mouthrinse (Mouthwash) – Key Points*, <https://www.ada.org/resources/ada-library/oral-health-topics/mouthrinse-mouthwash> (last accessed Jan. 13, 2025).

⁴ WORLD HEALTH ORGANIZATION. FLUORIDES AND ORAL HEALTH 33 (1994).

⁵ Melinda B. Clark, et al., *Fluoride Use in Caries Prevention in the Primary Care Setting*, 146 PEDIATRICS e2020034637, Tbl 1 (2020).

⁶ 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, 26 (2001).

⁷ Colgate, *What Parents Should Know About Mouthwash for Children*, <https://www.colgate.com/en-us/oral-health/kids-oral-care/what-parents-should-know-about->

13. Defendants know that fluoride mouthrinses are only recommended for children six and older. On their website (which very few Firefly consumers visit), Defendants disclose that “Firefly’s Anticavity Fluoride Rinse are recommended for children **6 years of age and older**.”⁸ Defendants’ website also provides a “6+ YRS” notation for their rinses.⁹

14. Despite this knowledge, Defendants intentionally target preschool children with this product. In so doing, Defendants are putting the health of millions of children at risk.

15. Firefly has enough fluoride in it to kill a small child. A toddler who ingests just over half of the sweet liquid in the Firefly bottle may suffer severe poisoning, including death. See *infra* ¶¶ 100-103.

16. The risk of toxicity is not limited to children who intentionally drink large quantities of the product. Even small amounts of the rinse can cause symptoms of acute toxicity if ingested.

17. A single 10 mL dose of Firefly Rinse (shown in the photo below¹⁰) contains 2.3 milligrams of fluoride.



[mouthwash-for-children](#) (last accessed Jan. 13, 2025).

⁸ Firefly, *Frequently Asked Questions*, <https://www.fireflytoothbrush.com/pages/faq> (last accessed Jan. 13, 2025).

⁹ Defendants do *not* provide this notation on the package of the Firefly Rinse product.

¹⁰ The 10 mL level is less than half of the dose cup.

18. A toddler who swallows the 10 mL dose can suffer nausea, vomiting, and other early symptoms of acute fluoride toxicity. See *infra* ¶¶ 92-96.

19. There are thousands of poison control reports each year for excess ingestion of fluoride mouthrinse by young children. But these reports represent only a fraction of the total number of incidents. See *infra* ¶¶ 104-107.

20. Another problem with young children using fluoride mouthrinse is that it can cause dental fluorosis.¹¹ Fluorosis is a defect of tooth enamel that is marked by “increased porosity” and “less than normal amounts of calcification in the teeth.”¹² This defect causes visible, and sometimes disfiguring, staining of the enamel. See *infra* ¶¶ 89-91.

21. The FDA recognizes that preschool children who use fluoride mouthrinse are at risk of developing dental fluorosis, but did not require a fluorosis warning *because children under six are not supposed to be using the product*. To quote: “Because fluoride dental rinses and gels are recommended **only** for use in adults and children 6 years of age and older, the agency believes that a warning about discoloration of developing teeth in children under 6 years of age is not needed on an OTC market package.”¹³

22. The health risks of preschool children using fluoride mouthrinse are of such magnitude that scientists have never even attempted to study the potential effect of fluoride mouthrinses on tooth decay in this age group. Therefore, there are no demonstrated benefits from

¹¹ CDC, *About Fluoride*, <https://www.cdc.gov/oral-health/prevention/about-fluoride.html> (“If children repeatedly swallow mouth rinses, they may develop dental fluorosis.”).

¹² 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).

¹³ FDA, *Anticaries Drug Products for Over-the-Counter Use; Tentative Final Monograph; Notice of Proposed Rulemaking*, 59 Fed. Reg. 39854, 39864 (Sept. 30, 1994) (emphasis added).

the use of fluoride mouthrinses for preschool children, particularly in the current context of widespread exposure to fluoride from toothpaste, fluoridated water, and processed foods.

23. Due to the dangers posed by fluoride in mouthrinse form, it is critical that consumers be alerted of the need to take special precautions to avoid ingesting toxic levels of fluoride.

24. By 1960, it was known that “**careful instruction . . . must be provided**” if fluoride mouthrinses are to be used on a daily basis.¹⁴

25. The FDA is concerned that many consumers will not appreciate that fluoride mouthrinses present dangers that are not present with ordinary cosmetic mouthrinses. According to the FDA, “based upon familiarity with cosmetic mouthrinse use, a consumer might overuse and/or misuse an OTC fluoride rinse.”¹⁵

26. Because many consumers will not appreciate the risks posed by fluoride mouthrinse, the FDA has stressed that the “safe” use of fluoride mouthrinse requires “proper labeling.”¹⁶ Towards this end, the FDA specifically commands that the labeling for fluoride mouthrinses “**clearly instructs consumers to read the directions.**”¹⁷

27. In order to ensure consumers read the directions, the FDA requires sellers of fluoride mouthrinse to “prominently” place a notice on the **front label** of the product.¹⁸ The regulation states that “the following statement shall be prominently placed on the principal display panel: ‘IMPORTANT: Read directions for proper use.’” 21 C.F.R. § 355.55.

¹⁴ Hellstrom, *supra* note 1, at 273 (emphasis added).

¹⁵ FDA, *supra* note 2, at 52485.

¹⁶ *Id.*

¹⁷ *Id.* (emphasis added).

¹⁸ *Id.*

28. Defendants are flagrantly violating this regulation.

29. Far from “prominently” displaying the instruction on the Firefly front label, Defendants use a font size for the instruction that is so small that the overwhelming majority of consumers will not even notice that the words are there. And even fewer consumers will be able to read the words, as they are too small to be legible to most, if not all, people.

30. Defendants compound this flagrant violation of federal law by falsely presenting the mouthrinse as a kid-friendly candy-like product.

31. It is well recognized that presenting drugs as “candy-like” products increases the risk of overdose, particularly for young children. In 1997, the *Journal of Public Health Dentistry* published a review, stating “The use of flavored consumer fluoride products increases the possibility that a child will ingest a toxic dose of fluoride.”¹⁹ Others have issued similar recommendations and warnings. See *infra* ¶¶ 116-119.

32. Defendants are aware that their Firefly Rinse is popular among preschool children and their caregivers. The Firefly website contains many glowing reviews of consumers who purchased the product for children under the age of 6.

33. The following are examples of reviews on the Firefly website from caregivers who purchased the rinse for children “**age 1 to 3 years**”:

- a. “My daughter loves Paw Patrol! So this is perfect for her, she asks to brush her teeth every night just so she can use the Mouthwash afterwards. The flavor is great and she does not mind it whatsoever! Loves the Marshall Character on it!”
- b. “I have a 2 1/2 year old and nightly brushing has been a struggle. She loves Paw

¹⁹ 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, 150 (1997).

Patrol, so when I saw this product, I had to get it. She was so excited when she saw it, it was like 3pm, but she asked to brush her teeth right away just so she could get to the mouthwash. She loved the whole look and the cup holder, but most of all she loved the taste.”

- c. “Gifted this to my nephew and he was in love. The mouthwash was very gentle in the teeth but helped keep his breath smelling great and he loved the packaging very friendly. He would stare at the bottle while using the mouthwash.”

34. The following are examples of reviews on the Firefly website from caregivers who purchased the rinse for children “**age 4 to 6 years**”:

- a. “I got these for my boys ages 4 and 3 and this has made brushing their teeth more exciting. Outside of loving the look of the bottle. They love the taste, a little too much actually and I have to remind them it’s not for your drinking pleasure. The 4 year old says his mouth feels fresh which I love. They definitely look forward to brushing with the addition of the mouth wash.”
- b. “My 4 year old literally loves brushing her teeth now knowing she gets to use her paw patrol rinse! It’s so easy to use and she loves the taste ! This product is definitely worth it for the little ones!”
- c. “Our 4 year old loves this mouth wash. Any way that we can make brushing teeth fun, we’ll take and he loves the bottle and the flavor as well. The Buzz Lightyear head on top looks great and makes for added fun during our pre-bedtime routine.”

35. Defendants did not respond to any of the aforementioned reviews to notify the consumers, and those reading their reviews, that Firefly Rinse is only recommended for children 6 and older.

36. The targeting of young children with brightly-colored, candy-flavored fluoride products has been described in peer-reviewed research as a “misleading” marketing practice,²⁰ and is believed to be one of the reasons for the increase in dental fluorosis that has been observed in recent decades.²¹

37. Since the introduction of candy-like fluoride products in the 1980s, the rate of dental fluorosis among U.S. schoolchildren has skyrocketed. In 1986-87, approximately 23% of U.S. children had fluorosis.²² This rate tripled to a staggering 68% of U.S. children by 2015-16.²³

38. Defendants’ deceptive packaging which presents their fluoride mouthrinse as specially formulated to be safe for young children violates the federal and state prohibition against false and misleading labeling, as enshrined in the Federal Food Drug & Cosmetic Act (“**FDCA**”), 21 U.S.C. § 352(a),²⁴ and many state consumer deception statutes, including, but not limited to, the Illinois Consumer Fraud and Deceptive Trade Practices Act (“**ICFA**”), 815 ILCS § 505/2.

39. In addition, Defendants’ failure to prominently display FDA’s required notice on the front label of the Firefly product simultaneously violates 21 C.F.R. § 355.55 and the prohibition on concealment and suppression of material facts under the ICFA, 815 ILCS § 505/2.

²⁰ Corey H. Basch & Sonali Rajan, *Marketing strategies and warning labels on children's toothpaste*, 88 J DENT HYG. 316, 316 (2014).

²¹ Christopher Neurath, et al., *Dental Fluorosis Trends in US Oral Health Surveys: 1986 to 2012*, 4 JDR CLIN TRANS RES. 298, 306 (2019).

²² Keith E. Heller, *Dental caries and dental fluorosis at varying water fluoride concentrations*, 57 J PUBLIC HEALTH DENT. 136, 139 Tbl 5 (1997).

²³ Man Hung et al., *A National Study Exploring the Association Between Fluoride Levels and Dental Fluorosis*, 6 JAMA NETW OPEN. e2318406 (2023).

²⁴ Plaintiffs recognize that there is no private right of action under FDCA and do not assert such a claim here. Instead, Plaintiffs’ allegations that Defendants 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.”).

40. 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 mouthrinse. *See* C.F.R. § 355.50. Plaintiffs seek instead to hold Defendants responsible for the elements of their products that are *not* required by the Monograph *and* which simultaneously violate their obligations under both federal and state law. A judicial finding that these voluntarily added attributes are false, misleading, and/or violative of specific FDCA requirements would be harmonious and not in conflict with the FDCA.²⁵

PARTIES

41. Plaintiff **Erin Gibson** is a citizen of Illinois.

42. Ms. Gibson lives in Chicago, Illinois, which is where she has purchased Firefly Rinse for her minor son A.G.

43. Ms. Gibson began purchasing Firefly Rinse for A.G. in 2021, when her son was four years old. She continued purchasing the product for A.G. until 2024.

44. Ms. Gibson purchased Firefly Rinse for A.G. from a Walmart store located in Chicago. She purchased Firefly Rinses with the Buzz Lightyear and Paw Patrol characters.

45. Ms. Gibson did not purchase the Firefly Rinses at the direction of a dentist, doctor, or health care provider.

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

46. Based on the Firefly packaging, Ms. Gibson believed Firefly Rinse was specially formulated to be safe for young children and would not present any risks to A.G.

47. A.G. enjoyed the cartoon design and candy flavor of the rinse.

48. If Ms. Gibson had known that fluoride mouthrinse is contraindicated for children under 6 years of age, she would not have purchased Firefly rinse or any other fluoride rinse.

49. Plaintiff **Sherry Hodge** is a citizen of Illinois.

50. Ms. Hodge lives in Centralia, Illinois, which is where she has purchased Firefly Rinse for her minor granddaughter H.M.

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

52. Ms. Hodge began purchasing Firefly Rinse for H.M. in or about 2021, when H.M. was about two years old. She continued purchasing Firefly for H.M. for several years.

53. Ms. Hodge purchased Firefly Rinse for H.M. from a Walmart store located in Centralia. One of the Firefly rinses that Ms. Hodge recalls purchasing was the pink-colored version featuring the cartoon image of a young girl.

54. Ms. Hodge did not purchase the Firefly Rinses at the direction of a dentist, doctor, or health care provider.

55. Based on the Firefly packaging, Ms. Hodge believed Firefly Rinse was specially formulated to be safe for young children and would not present any risks to H.M.

56. H.M. enjoyed the cartoon design and candy flavor of the rinse.

57. If Ms. Hodge had known that fluoride mouthrinse is contraindicated for children under 6 years of age, she would not have purchased Firefly rinse or any other fluoride rinse.

58. Defendant **Perrigo Company** is, and at all times mentioned in this Complaint was,

a publicly traded corporation organized and existing under the laws of the State of Delaware with its principal place of business in Allegan, Michigan.

59. Defendant **Ranir, LLC** is, and at all times mentioned in this Complaint was, a publicly traded corporation organized and existing under the laws of the State of Delaware with its principal place of business in Grand Rapids, Michigan.

60. Defendants Perrigo Company and Ranir, LLC are both involved in the manufacture, sale, and distribution of Firefly Rinses.

JURISDICTION AND VENUE

61. 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 defendants are citizens of different states. This court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.

62. This Court has personal jurisdiction over Defendants because the injuries upon which the Plaintiffs’ action are based occurred or arose out of activities that Defendants specifically engaged in within the State of Illinois. Defendants knowingly and intentionally distributed their mouthrinse products for sale in Illinois, and Plaintiffs thereupon purchased Defendants’ mouthrinse products from retail stores located here in Illinois.

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

FACTUAL ALLEGATIONS

A. Fluoride Mouthrinse Poses a Much Greater Risk to Young Children than Adults

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

65. Young children have poorly developed swallowing reflexes and, as a result, swallow a large percentage of the rinse that they put into their mouth. This remains the case even when the child is instructed not to swallow. 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.”²⁶

66. Between mouthrinse and toothpaste, the former poses a greater risk of excess ingestion for young children. This is because fluoride mouthrinses “do not contain an abrasive that can bind some of the fluoride ion and because a child under 6 is more likely to drink a flavored liquid than eat large amounts of toothpaste.”²⁷

67. The lack of a developed swallowing reflex is particularly acute for children under the age of three. In a study designed to estimate exposure from fluoride mouthrinse, “most 2 year old children and some 3 year old children could not perform mouthrinsing with water, but instead quickly swallowed the fluid.”^{28,29}

68. According to the CDC, “studies of the amount of fluoride swallowed by children

²⁶ FDA, *supra* note 13, at 39867.

²⁷ FDA, *supra* note 2, at 52486.

²⁸ FDA, *supra* note 13, at 39867.

²⁹ This study gave the children *water*. The study’s findings would likely have been even more troubling if the children were given *candy-flavored* rinse. When drugs taste and smell like candy, many young children are inclined to swallow it, irrespective of whether they have the necessary reflexes to control doing so. *Cf.*, CDC, *supra* note 6, at 14 (stating that children are “known to swallow toothpaste deliberately when they like its taste”).

aged 3-5 years using such rinses indicated that some young children might swallow substantial amounts.”³⁰

69. Even when ingesting the same amount of mouthrinse as an adult, young children receive a far higher fluoride dose by bodyweight (mg/kg/day) due to their smaller body size.

70. A 2-year-old child of average weight (~12 kg) who ingests a single dose of Firefly³¹ will ingest 0.19 mg/kg of fluoride, which is more than two times higher than 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.”³²

B. Ingesting Fluoride Mouthrinse During Early Childhood Causes Dental Fluorosis

71. Dental fluorosis is “a permanent, mottled discoloration of the teeth”³³ 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.

72. 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.³⁴

³⁰ CDC, *supra*, note 6, at 16.

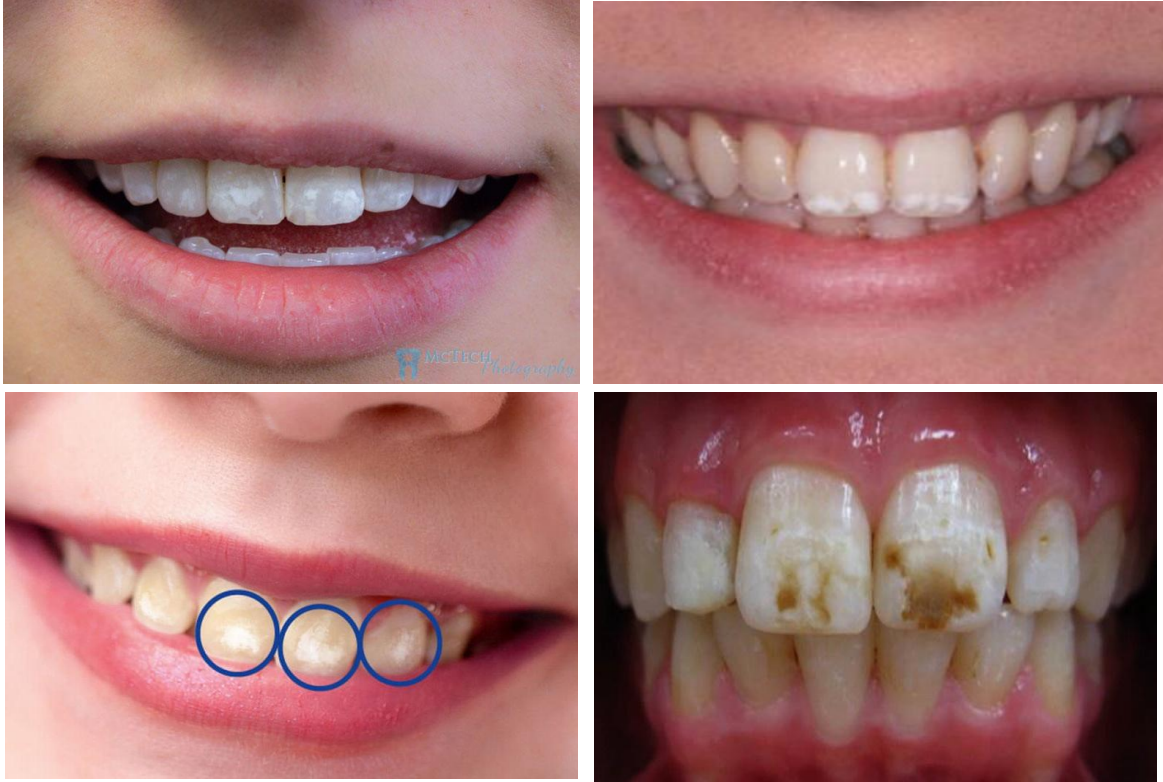
³¹ A single dose is 10 mL. At a concentration of 0.05% sodium fluoride (=0.023% fluoride ion), 10 mL of mouthrinse contains 2.3 mg of fluoride ion.

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

³³ FDA, *supra* note 2, at 52487.

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

73. Dental fluorosis comes in various degrees of severity.³⁵ 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.”³⁶



Photos of Dental Fluorosis

74. 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.”³⁷ In short, “fluoride affects the forming enamel by making it more porous.”³⁸

³⁵ NATIONAL RESEARCH COUNCIL, *supra* note 12, at 103-111.

³⁶ 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).

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

³⁸ Ana Karina Mascarenhas, *Risk factors for dental fluorosis: a review of the recent literature*, 22 PEDIATR DENT. 269, 274 (2000).

75. The CDC agrees that ingesting fluoride mouthrinse can cause fluorosis. According to CDC, “[i]f children repeatedly swallow mouth rinses, they may develop dental fluorosis.”³⁹

76. The ingestion of fluoridated dental products 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.⁴⁰

77. 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).⁴¹

78. 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.”⁴²
- 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

³⁹ CDC, *supra* note 11.

⁴⁰ Hung et al., *supra* note 23.

⁴¹ Susan O. Griffin et al., *Esthetically objectionable fluorosis attributable to water fluoridation*, 30 COMMUNITY DENT ORAL EPIDEMIOL. 199, 202-03 (2002).

⁴² 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).

their peers. A number of children described a reluctance to smile or a lack of confidence.”⁴³

- c. “Fluorosis was associated with increased parental dissatisfaction with overall appearance, color, and blotchiness of their children’s teeth.”⁴⁴
- 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.”⁴⁵
- e. “Our studies of esthetic perceptions of dental fluorosis found that members of the public had strong preferences about variations from normal tooth appearance. For example, all respondents had a preference for teeth with normal color over teeth with mild fluorosis”⁴⁶
- 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).”⁴⁷
- g. “A strong association between fluorosis and parental satisfaction was evident, even

⁴³ 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).

⁴⁴ 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).

⁴⁵ 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).

⁴⁶ Steven M. Levy, *An update on fluorides and fluorosis*, 69 J CAN DENT ASSOC. 286, 287 (2003).

⁴⁷ 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).

at a low level of severity.”⁴⁸

- 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.”⁴⁹
- i. “[O]bservers felt that the appearance would increasingly embarrass the child as the TF score increased.”⁵⁰

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

C. Ingesting Fluoride Mouthrinse Can Cause Stomach Flu Symptoms

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

81. 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.”⁵¹

82. The mechanism by which fluoride causes stomach flu symptoms has been described

⁴⁸ 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).

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

⁵⁰ Paul J. Riordan, *Perceptions of dental fluorosis*, 72 J DENTAL RES 1268, 1268 (1993).

⁵¹ Shulman & Wells, *supra* note 19, at 157.

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.”⁵²

83. 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.”⁵³

84. Symptoms of nausea and gastrointestinal distress have been reported at doses as low as 0.1 mg/kg.⁵⁴ A 2-year-old-child of average weight (~12 kg) will ingest this much fluoride by swallowing just over half of a single 10 mL dose of Firefly Rinse.

85. In *adults*, a one-time ingestion of as little as 3 milligrams of fluoride in one sitting (or the equivalent of 13 mL of Firefly Rinse) has been found to cause “widespread” erosions of the gastric mucosa in the stomach.⁵⁵ 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.

86. If a 2-year-old-child ingests just 5 mL of Firefly mouthrinse, or half of a single dose, the National Capital Poison Center recommends that the child take “Two tablets of chewable

⁵² 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>.

⁵³ *E.g.*, H.G. Eichler, et al., *Accidental ingestion of NaF tablets by children--report of a poison control center and one case*, 20 INT J CLIN PHARMACOL THER TOXICOL. 334 (1982). *Cf.* C.J. Spak, et al., *Studies of human gastric mucosa after application of 0.42% fluoride gel*, 69 J DENT RES. 426 (1990).

⁵⁴ Kenji Akiniwa, *A Re-examination of acute toxicity of fluoride*, 30 FLUORIDE 89 (1997).

⁵⁵ Spak, *supra* note 53.

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.”⁵⁶

87. The Firefly website contains a review from a child who reports suffering gastrointestinal issues after drinking the Firefly Rinse: “I HATE IT. I drank it and had the stinkys the rest of the week and it was not fun.”⁵⁷

D. Half a Bottle of Firefly Rinse Has Enough Fluoride to Kill a Toddler

88. Fluoride is a “protoplasmic poison”⁵⁸ that can kill humans at doses not that much higher than arsenic.⁵⁹ The potency of fluoride’s acute toxicity is why fluoride has been used as the active ingredient in rodenticides (to kill rodents) and insecticides (to kill bugs).⁶⁰ 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.”⁶¹

89. The “Probable Toxic Dose” (“PTD”) for fluoride is 5 mg/kg.⁶² The PTD “is defined

⁵⁶ See <https://triage.webpoisoncontrol.org/> (last accessed Jan. 13, 2025).

⁵⁷ <https://www.fireflytoothbrush.com/products/firefly-toy-story-buzz-anticavity-flouride-rinse-16-oz> (last accessed Jan. 13, 2025).

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

⁵⁹ 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 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.”).

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

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

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

as the dose of ingested fluoride that should trigger immediate therapeutic intervention and hospitalization because of the likelihood of serious toxic consequences.”⁶³ It is the “minimum dose that could cause toxic signs and symptoms, including death, and that should trigger immediate therapeutic intervention and hospitalization.”⁶⁴

90. 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.”⁶⁵

91. A tube of Firefly Mouthwash contains 109 milligrams of fluoride. A 1-year-old-child of average weight (~9 kg) would exceed the PTD if he ingested just 41% of the candy-flavored rinse, while a 2-year-old-child of average weight (~12 kg) would exceed the PTD if he ingested 55%.

92. Each year there are over 4,000 reports to poison control centers related to ingestion of fluoride mouthrinses.⁶⁶ The vast majority of these calls are made on behalf of very young children.

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

⁶³ *Id.*

⁶⁴ *Id.* at 1057.

⁶⁵ *Id.*

⁶⁶ David D. Gummin et al., *2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report*, 59 CLIN TOXICOL (Phila) 1282, 1448 (2020); David D. Gummin et al., *2021 Annual Report of the National Poison Data System© (NPDS) from America's Poison Centers: 39th Annual Report*, 60 CLIN TOXICOL (Phila) 1381, 1581 (2021).

poisonings.”⁶⁷ This is the case even for poisonings that cause outcomes as severe as death.⁶⁸

94. Consistent with the general recognition that poison control data underestimates the true extent and severity of poisonings, the reported number of poisonings from fluoride mouthrinse is also believed to “underestimate” the true extent of fluoride poisonings due to “substantial underreporting” of such incidents.⁶⁹

95. Nevertheless, the FDA has cited the large number of poison control reports for fluoride mouthrinses as a justification for requiring a poison warning on these products.⁷⁰ FDA’s required poison warning states as follows: “Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.” 21 C.F.R. § 355.50(c)(2).

E. Other Health Concerns with Early Life Exposure to Fluoride

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

97. 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.⁷¹ According to the NRC, fluoride has been credibly associated

⁶⁷ 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).

⁶⁸ 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.

⁶⁹ Shulman & Wells, *supra* note 19, at 157.

⁷⁰ FDA, *supra* note 2, at 52486.

⁷¹ NATIONAL RESEARCH COUNCIL, *supra* note 12, at 178-80, 220-22 & 260-66.

with impaired thyroid function in susceptible humans at doses as low as 0.01 to 0.03 mg/kg/day,⁷² which is less than many children will routinely ingest from using fluoride mouthrinse.⁷³

98. 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."⁷⁴ According to the NRC, blood fluoride levels of 0.1 mg/L are credibly associated with this effect.⁷⁵ A preschool child who ingests as little as 1/3 of a single mouthrinse dose will have blood fluoride levels that temporarily approximate or exceed this level.⁷⁶

99. In August of 2024, the National Toxicology Program ("NTP"), which is part of the National Institutes of Health, published a systematic review in which it concluded that excess fluoride exposure is "consistently associated with reduced IQ in children."⁷⁷

100. In January of 2025, NTP scientists published a meta-analysis of 74 human studies on fluoride and IQ in the journal *JAMA Pediatrics*.⁷⁸ 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."

⁷² *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.").

⁷³ A 2-year-old-child of average weight (~12 kg) will ingest 0.03 mg/kg from ingesting just 1/6th of a single 10 mL dose of Firefly rinse.

⁷⁴ *Id.* at 264.

⁷⁵ *Id.*

⁷⁶ See Jan Ekstrand et al., *Plasma fluoride concentrations in pre-school children after ingestion of fluoride tablets and toothpaste*, 17 CRIES RES. 379 (1983).

⁷⁷ 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.

⁷⁸ 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).

101. The NTP has flagged mouthrinse 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.”⁷⁹

102. 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).

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

F. The Problem with Presenting Fluoride Mouthrinse as a Candy-Like Drug

104. 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 fluoridated dental products.

105. 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.”⁸⁰

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

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

⁸⁰ James W. Bawden, et al. *Changing patterns of fluoride intake. Proceedings of the workshop. Part II*, 71 J PUBLIC HEALTH DENT. 1212, 1221 (1992).

flavours . . . should not be encouraged for use by children, as they may lead to an excessive ingestion of fluoride.”⁸¹

107. 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.”⁸²

108. 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.⁸³ Similar studies have not been conducted on candy-flavored mouthrinses. The absence of such studies is likely a result, in part, of the bioethical problem of intentionally exposing preschool children to a product that is contraindicated for this population.

109. According to the FDA, marketing dangerous products to children through the use of candy or food flavoring is a “misleading” marketing tactic that can render a product “misbranded” under the FDCA.⁸⁴

⁸¹ WORLD HEALTH ORGANIZATION, *supra* note 4, at 28.

⁸² Shulman & Wells, *supra* note 19, at 150.

⁸³ 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).

⁸⁴ *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”).

G. FDCA Requirements for Fluoride Mouthrinse

General Requirements

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

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

112. 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 it has additional textual or visual information on the package that is (a) *not* required by the monograph and (b) false and misleading.

Specific Requirements

113. The FDA has issued a Monograph for anti-cavity dental products, including fluoride mouthrinse. 21 C.F.R. §§ 355.50 & 355.55.

114. The FDA requires that all fluoride mouthrinse products provide the following warning: “Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.” 21 C.F.R. § 355.50(c)(2). The FDA requires that the first sentence of this warning be in bold type. *Id.*

115. The FDA requires that fluoride mouthrinses containing 0.05% sodium fluoride⁸⁵ provide the following directions: “Adults and children 6 years of age and older: Use once a day after brushing your teeth with a toothpaste. Vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out. Do not swallow the rinse. Do not eat or drink for 30 minutes

⁸⁵ This is the concentration of Firefly Rinse.

after rinsing. Instruct children under 12 years of age in good rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: Consult a dentist or doctor.” 21 C.F.R. § 355.50(d)(2)(ii).

116. The FDA also requires that “the following statement shall be prominently placed on the principal display panel” of all fluoride mouthrinses: “IMPORTANT: Read directions for proper use.” 21 C.F.R. § 355.55.

Things that the FDA Does Not Require

117. The FDA does not require that fluoride mouthrinses put cartoon characters that appeal to preschool children on the front of the label.

118. The FDA does not require fluoride mouthrinse to be packaged to look like a toy.

119. The FDA does not require fluoride mouthrinse to taste like candy.

120. The FDA does not require fluoride mouthrinse to smell like candy.



H. The Deceptive Attributes of Firefly Rinses

121. Firefly Rinses have the following deceptive attributes which individually and

collectively convey the false and misleading impression that the product is specially formulated to be safe for young children:

- a. The packaging has a toy-like appearance.
- b. The packaging prominently showcases cartoon characters (e.g., Paw Patrol, Buzz Lightyear, etc.) which are very popular with preschool children.
- c. The packaging prominently showcases the candy flavors (Bubble Berry, Wild Melon, Bubble Gum, and Ocean Melon) of the colorful blue, purple, and pink liquid. 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.
- d. The front label conceals the notice that FDA requires, per 21 C.F.R. 355.55, to be “prominently displayed.”

122. Individually and collectively, these deceptive attributes caused Plaintiffs to falsely believe that Firefly Rinse is specially formulated to be safe for young children to use.

123. Plaintiffs relied upon these deceptive attributes, both individually and collectively, in deciding to purchase Firefly Rinse.

124. Had Plaintiffs known that fluoride mouthrinses are contraindicated for children under six due to an unacceptable risk profile, Plaintiffs would *not* have purchased Firefly Rinse, or any other fluoride rinse.

I. Defendants’ Violations of FDCA Requirements

125. Defendants have violated the FDCA in at least two ways.

126. First, Defendants have violated 21 C.F.R. § 355.55 by failing to prominently display on the front label the notice required by the FDA. 21 C.F.R. § 355.55.

127. Second, Defendants have violated 21 U.S.C. § 352(a) by using packaging for

Firefly Rinses that conveys the false and misleading impression that these products are specially formulated to be safe for young children.

J. Reasonable Consumers Are Misled by Defendants' Marketing Tactics

128. Most parents are unaware of the recommended amount of kids' fluoride products that young children should use and the reasons for these recommendations.⁸⁶ This increases the susceptibility of consumers to Defendants' deceptive marketing tactics because the safety, or lack thereof, of fluoride mouthrinse ingestion is not within the ken of most people.

129. Peer-reviewed reports in the scientific literature have described the marketing tactics that Defendants use to sell kids' fluoride toothpastes as "misleading" and "confusing."⁸⁷ These tactics include the use of fruit imagery to depict fluoride products.

130. The fact that Defendant places 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. This is especially so given the small, blurry, hard to read formatting in which Defendant presents this information.

131. In the analogous context of fluoride toothpastes, 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."⁸⁸

132. 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

⁸⁶ Annie Y. Chen, et al., *Appropriate Fluoride Toothpaste Application: Improving Caregiver Compliance*, 40 PEDIATRIC DENT. 412, 415-16 (2018).

⁸⁷ Basch & Rajan, *supra* note 9, at 316; Chen, *supra* note 86, at 416.

⁸⁸ Basch & Rajan, *supra* note 9, at 318.

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).

133. 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 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).”)

K. Defendants’ Deceptive Conduct Caused Economic Injury to Plaintiffs and Class Members

134. Defendants made the false and misleading representations described above to induce parents and caregivers of young children to purchase Firefly Rinse who would not have purchased the product if they knew it is contraindicated for children under six.

135. Defendants were, and remain, unjustly enriched each time parents and caregivers act on Defendants’ false and misleading packaging by purchasing Firefly Rinse for children for whom the drug is contraindicated.

136. Had Plaintiffs known that fluoride mouthrinses are contraindicated for children under 6 due to an unacceptable risk profile, they would not have purchased Firefly Rinse, or any other fluoride rinse, because they would not knowingly have allowed their children to be exposed

to a drug that the FDA considers too dangerous for young children to safely use.

137. Plaintiffs and similarly situated class members have thus suffered injury in fact by losing money on their purchase of a product that they would never have purchased or allowed their children to use had they not been deceived.

138. To the extent that fluoride mouthrinse is considered to have value for children under 6 (which Plaintiffs dispute given the overwhelming evidence of an unacceptable risk profile for this young and vulnerable age group), the value is significantly less than what Plaintiffs and putative class members paid for it. Plaintiffs and class members thereby suffered economic loss by, at a minimum, purchasing the product for far more than its value.

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

CLASS ALLEGATIONS

140. 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, Massachusetts, Minnesota, Missouri, New Jersey, New York, Virginia, Washington State, and Washington D.C., who purchased Firefly Rinse for children under the age of 6 within the applicable statutes of limitation and who did so in the absence of direction from a dentist, doctor, or health care provider.

141. As used herein, the term “Class” shall refer to the aforementioned putative class.

142. Excluded from the Class are Defendant, its parents, subsidiaries, affiliates, officers, and directors; 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.

143. 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.

144. 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.

145. **Numerosity:** The members of the Class are so numerous that joinder of all class members is impracticable. 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.

146. **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 attributes of Firefly Rinse that are not required by the FDA Monograph are false and/or misleading?
- b. Whether Defendants knew or should have known that the packaging of Firefly Rinse is false and/or misleading;
- c. Whether Defendants have violated the state consumer protection statutes alleged herein;
- d. Whether Defendants have violated the FDCA, including 21 C.F.R. § 355.55 and 21 U.S.C. § 352(a);
- 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;

- g. Whether Plaintiffs and Class members are entitled to relief and, if so, the nature of such relief.

147. **Typicality**: Plaintiffs' claims are typical of those of other Class members because, like all members of the Class, Plaintiffs purchased Firefly Rinse for children under 6 and sustained economic loss as a result. Defendants' conduct that gave rise to the claims of Plaintiffs is the same for Plaintiffs and all members of the Class.

148. **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.

149. **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 damages suffered by each individual member of the Class do not justify the burden and expense of individual prosecution of the complex and extensive litigation necessitated by 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 members of the Class 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.⁸⁹

FIRST CAUSE OF ACTION
Deceptive Business Practices in Violation of
Illinois Consumer Fraud and Deceptive Trade Practices Act (815 ILCS 505/1, et seq.)

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

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

152. Plaintiffs and the proposed Class Members are persons within the context of the Illinois Consumer Fraud and Deceptive Trade Practices Act (“ICFA”), 815 ILCS § 505/1(c).

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

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

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

⁸⁹ 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.’”).

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

157. 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.

158. As with other sophisticated corporate entities, Defendants design the labeling and packaging of their Firefly Rinse products with attributes that will entice the target audience (i.e., caregivers of young children) to purchase them. As described in paragraph 121, these attributes include a toy-shaped package with prominently emblazoned cartoon characters that Defendants know are very popular with preschool children.

159. The toy-shaped package of the Firefly Rinse, coupled with the cartoon characters, bright colors, and candy flavors, convey the false pretense, false promise, and misrepresentation that the product is specially formulated to be safe for young children. These deceptive characteristics of the Firefly Rinse product simultaneously violate the FDCA (21 U.S.C. § 352(a)) and ICFA (815 ILCS 505/2).

160. Plaintiffs and the other Illinois Class Members purchased Firefly Rinse for their preschool children based on their reasonable reliance on Defendants’ false and misleading labeling.

161. Plaintiffs and the other Illinois Class Members suffered economic harm as a proximate result of Defendants’ violations of the ICFA by purchasing a product they never would have purchased absent the deceptive practices given FDA’s contraindication and the unacceptable

risk the product poses to young children.

162. Alternatively, to the extent that Firefly Rinse is considered to have value for children six under six despite its contraindication and unacceptable risk profile, Plaintiff and Illinois Class Members were harmed by purchasing a product whose true value, absent the deception, was far less than what they paid.

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

164. Based on Defendants' deceptive acts or practices, Plaintiff 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.

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

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

167. 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.

168. A material fact about fluoride mouthrinse is that the FDA has determined that, given the likelihood consumers will not appreciate the greater dangers of fluoride mouthrinse versus ordinary rinse, it is especially important for consumers to be notified of the importance of reading the directions before using the product. A related material fact is that, due to the heightened risks posed by fluoride mouthrinse, the FDA requires manufacturers of these products

to prominently place a notice on the front label stressing the importance of reading the directions before use.

169. Defendants have concealed and suppressed the aforementioned material facts by placing the FDA-required notice in such a small font on the front label that most consumers will not even see that it is there, let alone be able to read it.

170. The aforementioned concealment and suppression of the directions simultaneously violates the ICFA and FDCA, including 21 U.S.C. § 352(c), 21 C.F.R. § 201.15(a)(4)-(5), and 21 C.F.R. § 355.55.

171. Given Defendant's concealment and suppression of the FDA-required directions, most consumers do not know that Firefly Rinse is contraindicated for children under 6 years of age.

172. Defendants intend for consumers to rely on its concealment and suppression of the directions. Consistent with this intention, consumers do rely on said concealment and suppression.

173. Based on Defendants' concealment and suppression, Plaintiffs did not know there were any age restrictions for Firefly Rinse. Plaintiffs therefore permitted their children to repeatedly use Firefly Rinse before they were six years old.

174. Plaintiffs and the Illinois class members have suffered economic loss as a result of Defendants' violation of the ICFA.

175. Based on Defendants' concealment and suppression of the 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

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

177. Plaintiffs bring this claim on behalf of the Arizona, California, Connecticut, Florida, Hawaii, Idaho, Massachusetts, Minnesota, Missouri, New Jersey, New York, Virginia, Washington State, and Washington D.C. members of the proposed Class.

178. As described above, including but not limited to paragraph 121, Defendants have engaged in deceptive practices in their marketing of Firefly Rinse. Through these deceptive practices, Defendants have conveyed the false and misleading impression that Firefly Rinse is specially formulated to be safe for young children.

179. 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. Massachusetts (ALM GL ch. 93A, *et seq.*);⁹⁰
- h. Minnesota (Minn. Stat. § 325F.68, *et seq.*);
- i. Missouri (Mo. Rev. Stat. § 407.005, *et seq.*);
- j. New Jersey (N.J.S.A. § 56:8-1, *et seq.*);
- k. New York (NY GBL §§ 349-50);

⁹⁰ Plaintiff Gibson served pre-suit notice of her ALM GL ch. 93A claim on January 8, 2025. Plaintiff Hodge served pre-suit notice of her ALM GL ch. 93A claim on January 17, 2025.

- l. Virginia (Va. Code Ann. § 59.1-196, *et seq.*);
- m. Washington (Wash. Rev. Code § 19.86.010, *et seq.*);
- n. Washington D.C. (D.C. Code § 28-3904, *et seq.*)

180. Plaintiffs and the other Class Members purchased Firefly Rinse for their preschool children based on their reasonable reliance on Defendants' false and misleading labeling.

181. Plaintiffs and Class Members suffered economic harm as a proximate result of Defendants' violations of these statutes by purchasing a product they never would have purchased absent the deceptive practices given FDA's contraindication and the unacceptable risk the product poses to young children.

182. Alternatively, to the extent that Firefly Rinse is considered to have value for children six under six despite its contraindication and unacceptable risk profile, Plaintiffs and Class Members were harmed by purchasing a product whose true value, absent the deception, was far less than what they paid.

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

184. Based on Defendants' deceptive acts or 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 Defendants as follows:

- A. Certification of the proposed Class, including appointment of Plaintiffs' counsel as Class counsel and Plaintiff as Class Representative;

- B. An award of compensatory damages in an amount to be determined at trial;
- C. An award of restitution in an amount to be determined at trial;
- D. An award of disgorgement in an amount to be determined at trial;
- E. An award of statutory damages in an amount to be determined at trial, except as to those causes of action where statutory damages are not available by law;
- F. An award of punitive damages in an amount to be determined at trial, except as to those causes of action where punitive damages are not available by law;
- G. An award of treble damages, except as to those causes of action where treble damages are not available by law;
- H. An order requiring Defendants 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 27, 2025

Respectfully Submitted,
SIRI & GLIMSTAD LLP

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