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11		S DISTRICT COURT RICT OF CALIFORNIA
12	CHEYENNE VERBISH, ERICA	Case No. 3:25-cv-00426
13	DOUTHERD, ASHLEY CHERRY, TAMBRA RECEK, CHARLOTTE	
14	LAZAR, CAMARIA BURLEIGH, TANISIER CLAYBORNE, SHERRY	CLASS ACTION COMPLAINT
15	HODGE, ANJU GOEL, JOSH COOK, CYNTHIA RIVERA, MEGAN	JURY TRIAL DEMANDED
16 17	CRATSLEY, CHARLENE ROSEBORO & TIARRA HOOK, individually, and on behalf of those similarly situated,	
18	Plaintiffs,	
19	V.	
20	COLGATE-PALMOLIVE COMPANY,	
21	Defendant.	
22		
23		outherd, Ashley Cherry, Tambra Recek, Charlotte
24	Lazar, Camaria Burleigh, Tanisier Clayborn	e, Sherry Hodge, Anju Goel, Josh Cook, Cynthia
25	Rivera, Megan Cratsley, Charlene Roseboro,	and Tiarra Hook ("Plaintiffs"), individually and on
26	behalf of all others similarly situated, bring t	his class action lawsuit against defendant Colgate-
27	Palmolive Company ("Colgate" or "Defendar	nt") based upon Plaintiffs' personal knowledge as to
28	themselves, the investigation of their counsel,	and on information and belief as to all other matters.
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1	<b>INTRODUCTION</b>
2	1. In the United States, most toothpaste contains an ingredient which makes the paste
3	unsafe for children to swallow: Fluoride.
4	2. Fluoride helps prevent cavities when applied <i>topically</i> to the teeth. When <i>ingested</i> ,
5	fluoride presents significant risks to health, particularly for young children.
6	3. Defendant Colgate sells kids-branded toothpastes for preschool children. These
7	toothpastes have the same concentration of fluoride as many adult-strength brands.
8	4. Defendant knows its fluoride toothpastes, including its "kids" versions, are not safe
9	for young children to swallow. But it deceptively markets these Kids products in ways that lead
10	parents and caregivers to believe they are <i>extra</i> safe for children – which Defendant knows is false.
11	5. The Food & Drug Administration ("FDA") states that fluoride-containing
12	toothpastes need to be kept "out of reach of children under 6 years of age," and that caregivers
13	who purchase fluoride toothpaste for children under 6 need to supervise the child's brushing in
14	order "to minimize swallowing." 21 C.F.R. § 355.50(c)(1) & (d)(1) (second emphasis added).
15	6. Children under two years of age have little ability to "minimize swallowing," due to
16	poorly developed swallowing reflexes at this young age. Because of this, the FDA considers
17	fluoride toothpaste to be generally contraindicated for children under the age of 2.1
18	7. The Centers for Disease Control and Prevention (" <b>CDC</b> ") agrees that children under
19	2 should not use fluoride toothpaste. <sup>2</sup>
20	8. For children who begin brushing their teeth at 2, the CDC states they should use no
21	more than a "smear" of fluoride toothpaste, which is akin to a "rice grain" amount of paste, until
22	they turn 3. From age 3 to 6, the CDC states that children should use no more than a "pea-sized"
23	
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25	<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
26	contraindication for children under 2 years of age is unwarranted.").
27	<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)
28	("CDC recommends that children begin using fluoride toothpaste at age 2 years.").
	2
	PLAINTIFFS' CLASS ACTION COMPLAINT

1 amount of paste.<sup>3</sup>

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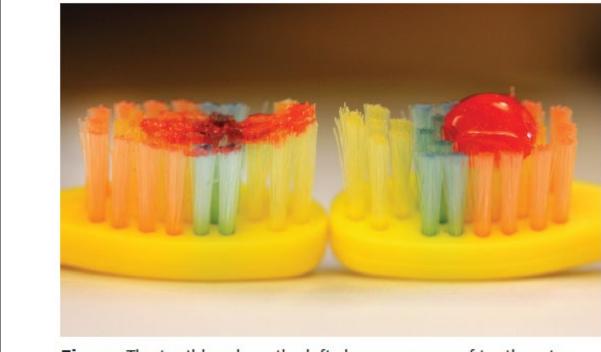
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9. The American Academy of Pediatrics ("AAP"), American Academy of Pediatric
Dentistry ("AAPD"), and the American Dental Association ("ADA") all agree that children under
3 should use no more than a "smear" of fluoride toothpaste, and they further agree that children
ages 3 to 6 should use no more than a "pea-sized" amount of paste. See *infra* ¶¶ 164-166.

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. Colgate *agrees* with the guidelines from the AAP, AAPD, and ADA. On its website,

22 Colgate cites these guidelines when describing the "age-appropriate amounts of toothpaste" that

23 children should use.<sup>5</sup> Colgate has admitted that caregivers of toddlers should "[u]se a smear or rice

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<sup>&</sup>lt;sup>3</sup> *Id.* at 87.

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

 <sup>&</sup>lt;sup>5</sup> Colgate, *Pediatric Guidelines for Using Toothpaste in Young Children*, <u>https://www.colgate.com/en-us/oral-health/kids-oral-care/pediatric-guidelines-for-using-</u>
 <u>toothpaste-in-young-children</u> (last accessed Jan. 13, 2025).

sized amount of fluoride toothpaste,"<sup>6</sup> and that "[i]t is recommended that you use a 'smear' (the 1 size of a grain of rice) of fluoride toothpaste as soon as your baby has teeth."<sup>7</sup> 2

3 12. Colgate knows that it will sell less toothpaste if parents and caregivers use the safe 4 and recommended amount of fluoride toothpaste, since this will result in very little of its product 5 being used per brushing. Colgate has thus resorted to using marketing tactics that have been 6 described as "misleading" and "aggressive" in order to encourage kids, and their caregivers, to use 7 far more than the safe and recommended amount of fluoride toothpaste.<sup>8</sup>

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13. One of the misleading and aggressive marketing tactics that Colgate uses is to show "pictures of fruit with flavoring to match," which is a common signal to a child that toothpaste is intended to be consumed as if it were food."9 10



oral-care/best-toothpaste-for-kids-with-cavities (last accessed Jan. 13, 2025).

<sup>9</sup> *Id.* at 316. 28

<sup>26</sup> <sup>8</sup> Corey H. Basch & Sonali Rajan, Marketing strategies and warning labels on children's toothpaste, 88 J DENT HYG. 316, 316 (2014). 27

1 14. It is well recognized that presenting drugs as "candy-like" products increases the 2 risk of overdose, particularly for young children. This problem has long been specifically flagged 3 in the context of fluoride toothpaste. In 1992, the *Journal of Public Health Dentistry* published a 4 consensus statement from U.S. dental researchers which stated, in part, "The use of flavors that 5 may increase the ingestion of fluoridated dentifrices by young children **should be strongly** 6 **discouraged**."<sup>10</sup> Many others have issued similar recommendations and warnings. See *infra* ¶¶ 7 168-174.

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

12 16. In one of its kids fluoride products, Colgate prominently displays the cartoon image
13 of a rainbow unicorn. This image appeals to very young children, and can entice a child to use and
14 ingest more of the product.

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26 <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>27</sup> <sup>11</sup> National Capital Poison Center, *My Child Ate Toothpaste: What Should I Do?*,
 <u>https://www.poison.org/articles/toothpaste</u> (last accessed Jan. 13, 2025).

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17. Another misleading<sup>12</sup> marketing tactic that Colgate uses is to show a visual image of a **full strip** of paste on the packaging of its Kids Cavity Protection brand. Showing a full strip of paste on the package 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.



18. Another deceptive tactic that Colgate uses is to *conceal* FDA's required warnings and directions by *hiding* them behind a label containing 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. Colgate's 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 reduces the number of brushings that families receive per tube, causing economic loss to consumers and unjust enrichment to Defendant.
  - 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* ¶¶ 139-45.
  - 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

<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").

1 if left untreated."<sup>13</sup>

2 22. The FDA instructs that "if more [fluoride toothpaste] than used for brushing is
3 accidentally swallowed, get medical help or contact a Poison Control Center right away." 21 C.F.R.
4 § 355.50(c)(1).

5 23. According to the National Capital Poison Center: "Toothpaste is not meant to be 6 swallowed, but it happens a lot. A child who has eaten toothpaste is a common reason parents call 7 Poison Control. Kids find the flavors and sweetness of toothpaste irresistible. Often, a child is found 8 sucking the paste out of the tube or is found with the paste smeared all over themselves (and the 9 room!)."<sup>14</sup>

10 24. Children who swallow too much of Defendant's kids-branded toothpaste can 11 develop a mineralization disorder of their tooth enamel called dental fluorosis.<sup>15</sup> Fluorosis is a 12 defect of tooth enamel that is marked by "increased porosity" and "less than normal amounts of 13 calcification in the teeth."<sup>16</sup> This disorder causes visible, and sometimes disfiguring, staining of the 14 enamel. See *infra* ¶ 136-138.

15 25. The marketing of fluoride toothpaste as a candy-like product by Colgate and other
16 major toothpaste manufacturers is believed to be one of the reasons for the increase in dental
17 fluorosis that has been observed in recent decades.<sup>17</sup>

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<sup>21</sup> <sup>14</sup> National Capital Poison Center, *supra* note 11.

 <sup>19
 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).

 <sup>&</sup>lt;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>&</sup>lt;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*, <u>https://crest.com/en-us/oral-care-tips/tooth-enamel/dental-fluorosis-causes-treatments-prevention</u> (last accessed Jan. 13, 2025).

<sup>&</sup>lt;sup>27</sup>
<sup>17</sup> Christopher Neurath, et al., *Dental Fluorosis Trends in US Oral Health Surveys: 1986 to 2012*,
<sup>28</sup>
<sup>4</sup> JDR CLIN TRANS RES. 298, 306 (2019).

Colgate first began selling candy-like fluoride toothpastes in the mid-1980s.<sup>18</sup> Since
 that time, the rate of dental fluorosis among U.S. schoolchildren has skyrocketed. In 1986-87,
 approximately 23% of U.S. children had fluorosis.<sup>19</sup> This rate tripled to a staggering 68% of U.S
 children by 2015-16.<sup>20</sup>

5 27. With millions of U.S. children showing visible signs of excess fluoride exposure 6 (dental fluorosis), there is growing concern about other chronic health conditions that fluoride may 7 be causing, including neurodevelopmental disorders and endocrine disruption. In August of 2024, 8 the prestigious National Toxicology Program (NTP) concluded that excess fluoride exposure is 9 associated with IQ deficits, and, in September 2024, a federal district court concluded that the 10 addition of fluoride to drinking water "poses an unreasonable risk of reduced IQ in children." See 11 *infra* ¶ 156-160.

28. Plaintiffs bring this action to hold Colgate accountable for the false, misleading, and
unlawful labeling of its products, which puts the health of millions of children at risk. Colgate's
marketing tactics violate the Federal Food Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 352(a),<sup>21</sup>
and many state consumer deception statutes, including, but not limited to, California's Unfair
Competition Act, Cal. Bus. & Prof. Code § 17200, the Illinois Consumer Fraud and Deceptive
Trade Practices Act, 815 ILCS § 505/2, and New York General Business Law §§ 349-50. Colgate
is also violating the FDCA through its concealment of FDA's required warnings and directions on

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 <sup>&</sup>lt;sup>18</sup> See Jesus Sanchez, New Flavors Appeal to Youthful Palates: Children Fill Gap in Toothpaste Market, L.A. TIMES, Sept. 25, 1987 ("Dental experts, for the most part, are not too excited about the new toothpaste tastes. Alson J. McCaslin, president of the American Academy of Pediatric Dentistry, said: 'This is a new marketing technique to get a larger share of the market without doing anything really new.'").

<sup>&</sup>lt;sup>19</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>&</sup>lt;sup>20</sup> Man Hung et al., A National Study Exploring the Association Between Fluoride Levels and Dental Fluorosis, 6 JAMA NETW OPEN. e2318406 (2023).

<sup>&</sup>lt;sup>21</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.").

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1	the Unicorn Pump product. 21 U.S.C. § 352(c), 21 C.F.R. § 355.50(c)(1) & (d)(1), 21 C.F.R. §	
2	201.15(a)(4)-(5), & 21 C.F.R. 201.66(c)(5)-(6).	
3	29. Plaintiffs do not seek to impose any requirement that goes beyond, is not identical	
4	to, or is different from, the requirements that are imposed on Defendant under the FDCA and its	
5	accompanying regulations, including the FDA Monograph on fluoride toothpaste. <sup>22</sup> See C.F.R. §	
6	355.50. Plaintiffs seek instead to hold Colgate responsible for the elements of its packaging that are	
7	not required by the Monograph and which simultaneously violate its requirements under the FDCA.	
8	A judicial finding that these voluntarily added attributes are false, misleading, and/or violative of	
9	specific FDCA requirements would be harmonious and not in conflict with the FDCA. <sup>23</sup>	
10	PARTIES	
11	30. Plaintiff <b>Cheyenne Verbish</b> lives in Santa Rosa, California and, at all times relevant	
12	to this case, has been a citizen of California.	
13	31. Ms. Verbish has purchased Colgate Kids Cavity Protection toothpaste ("Kids	
14	Cavity Protection") for her minor son K.K.	
15	32. Ms. Verbish began purchasing Kids Cavity Protection for K.K. in approximately	
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17	<sup>22</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	
18	fluoride can cause dental fluorosis, disrupt the endocrine system, and impair neurodevelopment. Although Plaintiffs believe such disclosures would certainly be justified and prudent, Plaintiffs	
19	recognize this Court does not have the power to order such measures.	
20	<sup>23</sup> See, e.g., Ebner v. Fresh, Inc., 838 F.3d 958, 965 (9th Cir. 2016) ("[T]he state-law duty that Plaintiff seeks to enforce under the Sherman Law is identical to Fresh's federal duty under the	
21	FDCA: the duty to avoid false or misleading labeling." (citation omitted)); Astiana v. Hain Celestial	
22	<i>Grp., Inc.</i> , 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	
23	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	
24	'not identical with' federal rules."); <i>Bell v. Publix Super Mkts., Inc.</i> , 982 F.3d 468, 485 (7th Cir. 2020) ("The FDCA's preemption provision means that, while states may not require sellers to add	
25	further labeling that is not required by federal law, they may prevent sellers from voluntarily adding	
26	deceptive content that is not required by federal law."); <i>Souter v. Edgewell Pers. Care Co.</i> , 542 F. Supp. 3d 1083, 1098 (S.D. Cal. 2021) ("[F]ederal law did not require Defendants to represent that	
27	their hand wipes kill 99.99 percent of germs or that they are 'hypoallergenic' and 'gentle.' Instead, these were advertising choices that Defendants made, and Plaintiff is simply challenging those	
28	choices.").	
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1	2022 when K	K.K. was a year old. Ms. Verbish continued purchasing Kids Cavity Protection for K.K.
2	until he was	three years old.
3	33.	Ms. Verbish purchased Kids Cavity Protection for K.K. from various retail stores in
4	Santa Rosa, i	including Target and Safeway.
5	34.	From the age of 1 onwards, K.K. used a full strip of Kids Cavity Protection paste on
6	his brush for	tooth brushings with Ms. Verbish's assistance and/or permission.
7	35.	K.K. enjoyed the candy flavor of the paste.
8	36.	Based on the packaging of Kids Cavity Protection, Ms. Verbish believed the product
9	was specially	v formulated to be safe for young children to ingest.
10	37.	Plaintiff Erica Doutherd lives in Rancho Cordova, California and, at all times
11	relevant to th	is case, has been a citizen of California.
12	38.	Ms. Doutherd has purchased Colgate Watermelon Burst Toothpaste ("Watermelon
13	Burst") for h	ner minor daughter E.B.
14	39.	Ms. Doutherd purchased a package of three units of Watermelon Burst for E.B. in
15	January 2024	, when E.B. was two years old.
16	40.	Ms. Doutherd purchased Watermelon Burst from Sam's Club online.
17	41.	E.B. used a full strip of Watermelon Burst for tooth brushings, and an additional
18	amount to br	ush his tongue. He did so with Ms. Doutherd's assistance and/or permission.
19	42.	E.B. enjoyed the candy flavor of the paste.
20	43.	Based on the packaging of Watermelon Burst, Ms. Doutherd believed the product
21	was specially	v formulated to be safe for young children to ingest.
22	44.	Plaintiff Ashley Cherry lives in Bakersfield, California and, at all times relevant to
23	this case, has	been a citizen of California.
24	45.	Ms. Cherry has purchased Colgate's unicorn-themed Maximum Cavity Protection
25	toothpaste pu	amp ("Unicorn Pump") for her minor daughter G.C.
26	46.	Ms. Cherry began purchasing Unicorn Pump for G.C. in approximately 2020, when
27	G.C. was a y	ear old. Ms. Cherry continued purchasing Unicorn Pump for G.C. for over four years.
28	47.	Ms. Cherry purchased Unicorn Pump from Walmart in Bakersfield, and she may
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1	have also pur	chased it at the Dollar Store as well.
2	48.	At the age of 1, G.C. used a quarter strip of paste. Her usage of the paste steadily
3	increased with	th age. By age 2, G.C. was typically using a half strip, and by age 3 she was using a
4	full strip. G.O	C. used these quantities of paste with Ms. Cherry's assistance and/or permission.
5	49.	G.C. enjoyed the candy flavor of the paste.
6	50.	Based on the packaging of Unicorn Pump, Ms. Cherry believed the product was
7	specially for	nulated to be safe for young children to ingest.
8	51.	Plaintiff Tambra Recek lives in Fresno, California and, at all times relevant to this
9	case, has bee	n a citizen of California.
10	52.	Ms. Recek has purchased Unicorn Pump for her minor daughter L.F.
11	53.	Ms. Recek began purchasing Unicorn Pump for L.F. in approximately 2022, when
12	L.F. was two	years old. She continued purchasing Unicorn Pump for L.F. until L.F. was three years
13	old.	
14	54.	L.F. used a full strip of Unicorn Pump on her brush for tooth brushings with Ms.
15	Recek's assis	stance and/or permission.
16	55.	L.F. enjoyed the candy flavor of the paste.
17	56.	Based on the packaging of Unicorn Pump, Ms. Recek believed the product was
18	specially for	nulated to be safe for young children to ingest.
19	57.	Plaintiff Charlotte Lazar lives in Los Angeles, California and at all times relevant
20	to this case h	as been a citizen of California.
21	58.	Ms. Lazar has purchased Toms of Maine's "natural" kids fluoride toothpaste ("Kids
22	Natural") fo	r her minor son D.L.
23	59.	Ms. Lazar began purchasing Kids Natural for D.L. around his second birthday in
24	2020. Ms. L	azar continued purchasing this toothpaste for D.L. until he was five years old. Ms.
25	Lazar recalls	purchasing the strawberry flavor of the product from the Whole Foods store in
26	Brentwood, O	California.
27	60.	D.L. typically used a half to full strip of the Kids Natural paste on his brush. He did
28	so with Ms. I	Lazar's with assistance and/or permission.
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1	61.	D.L. enjoyed the candy flavor of the paste.
2	62.	Based on the packaging of Kids Natural, Ms. Lazar believed the product was
3	specially form	nulated to be safe for young children to ingest.
4	63.	Plaintiff Camaria Burleigh lives in Carbondale, Illinois and, at all times relevant
5	to this case, h	has been a citizen of Illinois.
6	64.	Ms. Burleigh has purchased Kids Cavity Protection for her minor daughter Z.J.
7	65.	Ms. Burleigh began purchasing Kids Cavity Protection for Z.J. in approximately
8	December of	2022, when Z.J. was six months old. Ms. Burleigh continued purchasing Kids Cavity
9	Protection fo	r Z.J. until 2024, when she was two years old.
0	66.	From the age of 6 months to 1 year, Ms. Burleigh applied the paste to Z.J.'s erupted
1	teeth with a f	inger brush. Starting at about 13 months of age, Z.J. began using a kids' toothbrush,
2	to which Ms.	Burleigh would apply a full strip of paste for his brushings.
3	67.	Z.J. enjoyed the candy flavor of the paste.
4	68.	Based on the packaging of Kids Cavity Protection, Ms. Burleigh believed the
5	product was	specially formulated to be safe for young children to ingest.
6	69.	Plaintiff Tanisier Clayborne lives in Chicago, Illinois and, at all times relevant to
7	this case, has	been a citizen of Illinois.
8	70.	Ms. Clayborne has purchased Unicorn Pump for her son E.S.
9	71.	Ms. Clayborne began purchasing Unicorn Pump for E.S. in approximately 2021,
0	when E.S. wa	as two years old. She continued purchasing Unicorn Pump for E.S. for over two years.
1	72.	E.S. used a full strip of Unicorn Pump on his brush for tooth brushings with Ms.
2	Clayborne's	assistance and/or permission.
3	73.	E.S. enjoyed the candy flavor of the paste.
24	74.	Based on the packaging of the Unicorn Pump, Ms. Clayborne believed the product
5	was specially	formulated to be safe for young children to ingest.
6	75.	Plaintiff Sherry Hodge lives in Centralia, Illinois and, at all times relevant to this
7	case, has bee	n a citizen of Illinois.
8	76.	Ms. Hodge has purchased Unicorn Pump for her minor granddaughter H.M. 12

1	77.	H.M. lives with Ms. Hodge during the summer months, and during most weekends	
2	for the remainder of the year.		
3	78.	Ms. Hodge began purchasing Unicorn Pump for H.M. in or about 2021 when H.M.	
4	was two year	s old.	
5	79.	Ms. Hodge continued purchasing Unicorn Pump for H.M. until she was 5 years old.	
6	80.	H.M. used a full strip of Unicorn Pump on her brush for tooth brushings with Ms.	
7	Hodge's assis	stance and/or permission.	
8	81.	H.M. enjoyed the candy flavor of the paste.	
9	82.	Based on the packaging of Unicorn Pump, Ms. Hodge believed the product was	
10	specially form	nulated to be safe for young children to ingest.	
11	83.	Plaintiff Anju Goel lives in Buffalo Grove, Illinois and, at all times relevant to this	
12	case, has been	n a citizen of Illinois.	
13	84.	Ms. Goel has purchased Watermelon Burst for her minor son S.A.	
14	85.	Ms. Goel began purchasing Watermelon Burst for S.A. when he was approximately	
15	10 months ol	d in or around January 2020. Ms. Goel continued purchasing Watermelon Burst for	
16	S.A. until he	was three and a half years old.	
17	86.	From 10 months to 2 years of age, S.A. used approximately a half strip of paste on	
18	this brush for	r tooth brushings. From age 2 onwards, S.A. generally used a full strip of paste for	
19	tooth brushings. He used these quantities of toothpaste with Ms. Goel's assistance and/or		
20	permission.		
21	87.	S.A. enjoyed the candy flavor of the paste.	
22	88.	Based on the packaging of Watermelon Burst, Ms. Goel believed the product was	
23	specially form	nulated to be safe for young children to ingest.	
24	89.	Plaintiff Josh Cook lives in Rockford, Illinois and, at all times relevant to this case,	
25	has been a cit	tizen of Illinois.	
26	90.	Mr. Cook has purchased Kids Natural for his daughter Z.C.	
27	91.	Mr. Cook began purchasing Kids Natural for Z.C around her second birthday in	
28	2020. Mr. Co	ook continued purchasing this toothpaste for Z.C. until she was five years old. Mr.	
		13	
		PLAINTIFFS' CLASS ACTION COMPLAINT	

1	Cook recalls purchasing both the watermelon and strawberry flavors of the product.
2	92. From age 2 onwards, Z.C. used a full strip of the Kids Natural paste on her bru
3	She used this quantity of toothpaste with Mr. Cook's assistance and/or permission.
4	93. Z.C. enjoyed the candy flavor of the paste.
5	94. Based on the packaging of the Kids Natural, Mr. Cook did not believe the toothpa
6	was harmful for his young child to ingest.
7	95. Plaintiff <b>Cynthia Rivera</b> lives in Staten Island, New York and, at all times releva
8	to this case, has been a citizen of New York.
9	96. Ms. Rivera has purchased Kids Cavity Protection for her minor son N.R. and min
10	daughter M.M.
11	97. Ms. Rivera has continually purchased Kids Cavity Protection for N.R. and M.
12	since they turned two years old. M.M. turned two in 2022, while N.R turned two in 2020.
13	98. Both N.R. and M.M. always used a full strip of paste when they brushed. They a
14	so with Ms. Rivera's assistance and/or permission.
15	99. Both N.R. and M.M. enjoyed the candy flavor of the paste.
16	100. Based on the packaging of Kids Cavity Protection, Ms. Rivera believed the produ
17	was specially formulated to be safe for young children to ingest.
18	101. Plaintiff Charlene Roseboro lives in Rego Park, New York and, at all tin
19	relevant to this case, has been a citizen of New York.
20	102. Ms. Roseboro has purchased Watermelon Burst for her minor son K.M.
21	103. Ms. Roseboro began purchasing Watermelon Burst for K.M. in 2022 when he w
22	a year old, and continued purchasing it for him until he was three.
23	104. K.M. used a full strip of Watermelon Burst on his brush for tooth brushings. He
24	so with Ms. Roseboro's assistance and/or permission.
25	105. K.M. enjoyed the candy flavor of the paste.
26	106. Based on the packaging of Watermelon Burst, Ms. Roseboro believed the production
27	was specially formulated to be safe for young children to ingest.
28	107. Plaintiff Megan Cratsley lives in Little Valley, New York and, at all times releva
	<u> </u>
	PLAINTIFFS' CLASS ACTION COMPLAINT

I	Case 3:25-cv-00426 Document 1 Filed 01/13/25 Page 15 of 54
1	to this case, has been a citizen of New York.
2	108. Ms. Cratsley has purchased Unicorn Pump for her minor daughter A.C.R.
3	109. Ms. Cratsley began purchasing Unicorn Pump for A.C.R. in approximately 2021,
4	when A.C.R. was two years old. She continued purchasing Unicorn Pump for A.C.R. until 2023,
5	when A.C.R. was four years old.
6	110. A.C.R. initially used a half strip of Unicorn Pump on her brush, but, by the time she
7	was three years old, A.C.R. was using a full strip. She used these quantities of toothpaste with Ms.
8	Cratsley's assistance and/or permission.
9	111. A.C.R. enjoyed the candy flavor of the paste.
10	112. Based on the packaging of Unicorn Pump, Ms. Cratsley believed the product was
11	specially formulated to be safe for young children to ingest.
12	113. Plaintiff Tiarra Hook lives in Albany, New York and, at all times relevant to this
13	case, has been a citizen of New York.
14	114. Ms. Hook has purchased Kids Natural for her minor son G.C.
15	115. Ms. Hook began purchasing Kids Natural for G.C. in approximately 2020 when he
16	was two years old. Ms. Hook continued purchasing this toothpaste for G.C. until just prior to his
17	fifth birthday in 2023.
18	116. G.C. used a full strip of paste on this brush with Ms. Hook's assistance and/or
19	permission.
20	117. G.C. enjoyed the candy flavor of the paste.
21	118. Based on the packaging of Kids Natural, Ms. Hook believed the product was
22	specially formulated to be safe for young children to ingest.
23	119. Defendant <b>Colgate</b> is a publicly traded corporation organized and existing under the
24	laws of the State of Delaware, having its principal place of business at 300 Park Avenue, New
25	York, NY 10022. In addition to manufacturing and selling Colgate-branded toothpastes, Colgate
26	manufactures and sells the Toms of Maine toothpastes that are identified herein.
27	JURISDICTION AND VENUE
28	120. This Court has subject matter jurisdiction over this case pursuant to 28 U.S.C.
	15 PLAINTIFFS' CLASS ACTION COMPLAINT

\$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.

6 121. This Court has personal jurisdiction over Defendant Colgate-Palmolive Company
7 because the injuries upon which the California Plaintiffs' action are based occurred or arose out of
8 activities that Defendant specifically engaged in within the State of California. Plaintiffs purchased
9 Defendant's toothpaste products from retail stores located here in California; Defendant knowingly
10 and intentionally distributed its toothpaste products for sale in California; and Defendant
11 accomplished this, in part, through operation of a distribution center in Riverside, California.

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

15

#### **DIVISIONAL ASSIGNMENT**

16 123. Assignment of this case to the San Francisco Division is proper pursuant to Civil
17 Local Rule 3-2(c) because a substantial part of the events or omissions giving rise to Plaintiff
18 Cheyenne Verbish's claims occurred in Sonoma County, California.

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21

A. Fluoride Toothpaste Poses a Much Greater Risk to Young Children than Adults124. For a multitude of reasons, young children are more vulnerable to suffering harm

**FACTUAL ALLEGATIONS** 

22 from fluoride toothpaste than adolescents and adults.

125. 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>24</sup> Because of this,

<sup>24</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).

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"ingestion of fluoride from toothpaste is common and often substantial" for young children.<sup>25</sup> As 1 2 summarized in the Journal of Public Health Dentistry, "[v]irtually all authors have noted that some 3 children could ingest more fluoride from [toothpaste] alone than is recommended as a total daily 4 fluoride ingestion."26

Young children are also at greater risk from fluoride toothpaste because they "cannot 5 126. 6 be expected to rationally interpret and consistently follow the instructions involving proper toothbrushing."<sup>27</sup> When toothpaste tastes and smells like candy, for example, young children will 7 8 want to swallow it, irrespective of what the fine print on the label says. As noted by the CDC, 9 children are "known to swallow toothpaste deliberately when they like its taste."<sup>28</sup> A recent study found that 35% of kids ate toothpaste "frequently" and an additional 22% of kids ate toothpaste "a 10 few times."29 11

Due to their smaller size, young children receive a far higher fluoride dose by 12 127. 13 bodyweight (mg/kg/day) than adults, even when ingesting the same amount of paste. A 1 year old 14 child of average weight (~9 kg) who ingests a single strip of toothpaste will exceed EPA's reference 15 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>30</sup> 16

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

- Dental fluorosis is "a permanent, mottled discoloration of the teeth"<sup>31</sup> that is caused 128.
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<sup>25</sup> Steven M. Levy, A review of fluoride intake from fluoride dentifrice, 60 ASDC J DENT CHILD. 20 115, 115 (1993).

21 <sup>26</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). 22

- <sup>27</sup> FDA, *supra* note 1, at 52487. 23
- <sup>28</sup> CDC, Recommendations for using fluoride to prevent and control dental caries in the United 24 States. Centers for Disease Control and Prevention, 50 MMWR RECOMM REP. 1, 14 (2001).

<sup>29</sup> Roger K. Celeste & Patricia Blaya Luz, Independent and Additive Effects of Different Sources of 25 Fluoride and Dental Fluorosis, 38 PEDIATR DENT. 233, 235 Tbl 2 (2016). 26

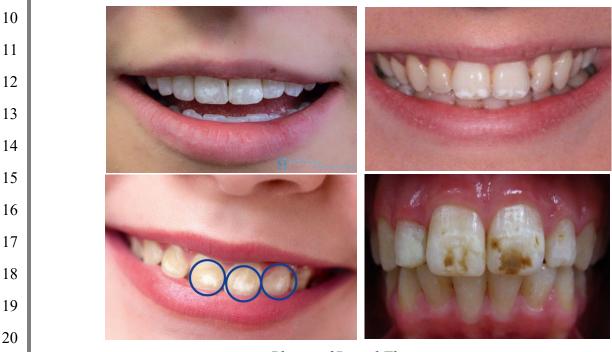
<sup>30</sup> Environmental Protection Agency: Fluoride: Dose-Response Analysis for Non-CANCER EFFECTS 107 (2010), 27

<sup>31</sup> FDA, *supra* note 1, at 52487. 28

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.

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>32</sup>

7 130. Dental fluorosis comes in various degrees of severity.<sup>33</sup> The mild forms of fluorosis
8 cause "permanent white lines or streaks" on the teeth, whereas the severe forms of fluorosis cause
9 "brown, gray, or black patches and pits, typically on top of an irregular tooth surface."<sup>34</sup>



Photos of Dental Fluorosis 21 131. Microscopically, "dental fluorosis is a condition of permanent hypomineralized 22 change, with increased surface and sub-surface enamel porosity resulting from excess fluoride 23 24 25 <sup>32</sup> Michael R. Franzman, et al., *Fluoride dentifrice ingestion and fluorosis of the permanent* incisors, 137 J AM DENT ASSOC. 645, 646 (2006). 26 <sup>33</sup> NATIONAL RESEARCH COUNCIL, *supra* note 16, at 103-111. 27 <sup>34</sup> Colgate, Causes of Brown Spots on the Teeth, https://www.colgate.com/en-us/oral-health/adultoral-care/brown-spots-on-teeth-causes (last accessed Jan. 13, 2025). 28 18 PLAINTIFFS' CLASS ACTION COMPLAINT

reaching the developing tooth prior to eruption."<sup>35</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>36</sup> In short, "fluoride affects the forming enamel
 by making it more porous."<sup>37</sup>

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>38</sup>

8 133. According to a review in the journal *Pediatric Dentistry* "[b]ased on the number of
9 well-conducted case control studies, and the strength of the associations seen in the various studies,
10 the risk of fluorosis from early use of fluoride toothpaste is no longer a controversial issue."<sup>39</sup>

11 134. The CDC agrees that fluoride toothpaste causes fluorosis: "Fluoride toothpaste 12 contributes to the risk for enamel fluorosis because the swallowing reflex of children aged <6 years 13 is not always well controlled, particularly among children aged <3 years."<sup>40</sup> The CDC states that 14 the risk of developing fluorosis from using fluoride toothpaste is greatest for children under the age 15 of two: "Children who begin using fluoride toothpaste at age <2 years are at higher risk for enamel 16 fluorosis than children who begin later or who do not use fluoride toothpaste at all."<sup>41</sup>

17 135. The ingestion of fluoride toothpaste is considered to be a key reason for the 18 skyrocketing prevalence of dental fluorosis in the US. In the 1940s, dental fluorosis was a rare 19 condition that was generally found only in areas with elevated fluoride in water. Since that time, 20 with the advent of water fluoridation programs and fluoridated dental products, the rate of dental

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- <sup>36</sup> Crest, Dental Fluorosis: Causes, Treatments & Prevention, <u>https://crest.com/en-us/oral-care-tips/tooth-enamel/dental-fluorosis-causes-treatments-prevention (last accessed Jan. 13, 2025).
  </u>
  - <sup>37</sup> Mascarenhas, *supra* note 15, at 269.
- <sup>25</sup> <sup>38</sup> American Dental Association Council on Scientific Affairs, *supra* note 4, at 190.
- <sup>26</sup> <sup>39</sup> Mascarenhas, *supra* note 15, at 274.
- 27 <sup>40</sup> CDC, *supra* note 28, at 14.
- $28 \quad {}^{41} Id.$

<sup>22 &</sup>lt;sup>35</sup> Brian A. Burt, *The changing patterns of systemic fluoride intake*. 71 J DENT RES. 1228, 1228 (1992).

1	fluorosis has steadily increased. The most recent national survey from the CDC, conducted in 2015-
2	2016, found that 68.2% of children now have some form of dental fluorosis. <sup>42</sup>
3	136. Dental fluorosis, even in its "mild" forms, is recognized to be cosmetically
4	objectionable when present on a child's upper front teeth (i.e., maxillary anterior teeth). <sup>43</sup>
5	137. The following are some findings from the peer-reviewed dental literature regarding
6	the disfiguring effects of "mild" fluorosis:
7	a. "Mild and moderate dental fluorosis had a negative aesthetic effect on the
8	studied population, leading to a strong desire to seek dental treatment to
9	change the appearance of affected teeth." <sup>44</sup>
10	b. "The key finding to emerge from this study was the negative psychosocial
11	impact reported by some children with untreated enamel defects Over
12	
13	half of the children stated that they had been subject to unkind remarks about
14 15	their teeth by their peers. A number of children described a reluctance to
15 16	smile or a lack of confidence." <sup>45</sup>
10	c. "Fluorosis was associated with increased parental dissatisfaction with
18	overall appearance, color, and blotchiness of their children's teeth."46
19	d. "The pupils' feedback was extremely useful, revealing that they believed the
20	$^{42}$ Hung et al., <i>supra</i> note 20.
21 22	<sup>43</sup> Susan O. Griffin et al., <i>Esthetically objectionable fluorosis attributable to water fluoridation</i> , 30 COMMUNITY DENT ORAL EPIDEMIOL. 199, 202-03 (2002).
23 24	<ul> <li><sup>44</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).</li> </ul>
25 26	<sup>45</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).
27 28	<sup>46</sup> Steven M. Levy, et al., <i>Factors associated with parents' esthetic perceptions of children's mixed dentition fluorosis and demarcated opacities</i> , 27 PEDIATR DENT. 486, 486 (2005).
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1 'marks' on the teeth to be due to poor oral hygiene, despite a preliminary 2 tutorial which indicated this was not the case."47 3 e. "Our studies of esthetic perceptions of dental fluorosis found that members 4 of the public had strong preferences about variations from normal tooth 5 appearance. For example, all respondents had a preference for teeth with 6 normal color over teeth with mild fluorosis . . . . "48 7 "Results show that not only is fluorosis noticeable, but it may be more of an 8 f. 9 esthetic concern than the other conditions (e.g. isolated opacities, 10 tetracycline staining, or various types of malocclusion)."49 11 "A strong association between fluorosis and parental satisfaction was g. 12 evident, even at a low level of severity."50 13 h. "South Australian children 10- to 17-years-old were able to recognize very 14 mild and mild fluorosis and register changes in satisfaction with the colour 15 16 and appearance of teeth. Even mild changes were associated with psycho-17 behavioural impacts."51 18 "[O]bservers felt that the appearance would increasingly embarrass the child i. 19 as the TF score increased."52 20 21 <sup>47</sup> Maura Edwards, et al., An assessment of teenagers' perceptions of dental fluorosis using digital 22 stimulation and web-based testing, 33 COMMUNITY DENT ORAL EPIDEMIOL. 298, 305(2005). 23 <sup>48</sup> Steven M. Levy, An update on fluorides and fluorosis, 69 J CAN DENT ASSOC. 286, 287 (2003). 24 <sup>49</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). 25 <sup>50</sup> James A. Lalumandier & R. Gary Rozier, *Parents' satisfaction with children's tooth color:* 26 fluorosis as a contributing factor, 129 J AM DENT ASSOC. 1000, 1003 (1998). 27 <sup>51</sup> John Spencer, et al., *Water fluoridation in Australia*, 13 COMMUNITY DENT HEALTH 27 (1996). <sup>52</sup> Paul J. Riordan, *Perceptions of dental fluorosis*, 72 J DENTAL RES 1268, 1268 (1993). 28 21

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

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

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

140. 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>53</sup>

12 141. The mechanism by which fluoride causes stomach flu symptoms has been described
13 as follows: "When above normal amounts of fluoride are ingested, the fluoride combines with
14 hydrochloric acid in the stomach and forms hydrofluoric acid. As a result, the hydrofluoric acid has
15 a burning effect on the gastric lining causing gastrointestinal (GI) symptoms such as nausea,
16 vomiting, abdominal cramping, and discomfort."<sup>54</sup>

17 142. As with all toxicants, the dose of fluoride that causes symptoms of acute toxicity
18 varies considerably across the population, with some children being much more vulnerable, and
19 other children being much more resistant, than the "average child."<sup>55</sup>

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143. Symptoms of nausea and gastrointestinal distress have been reported at doses as low

<sup>23 &</sup>lt;sup>53</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>&</sup>lt;sup>54</sup> Mary D. Cooper & Connie M. Kracher, Are our patients guzzling too much fluoride?, RDH
 MAGAZINE, Feb. 1, 1997, <u>https://www.rdhmag.com/patient-care/rinses-pastes/article/16406858/are-our-patients-guzzling-too-much-fluoride</u>.

<sup>&</sup>lt;sup>55</sup> E.g., H.G. Eichler, et al., Accidental ingestion of NaF tablets by children--report of a poison control center and one case, 20 INT J CLIN PHARMACOL THER TOXICOL. 334 (1982). Cf. C.J. Spak, et al., Studies of human gastric mucosa after application of 0.42% fluoride gel, 69 J DENT RES. 426 (1990).

as 0.1 mg/kg.<sup>56</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.

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>57</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.

8 145. If a 1 year-old-child ingests a full strip of Colgate "kids" fluoride toothpaste, the
9 National Capital Poison Center recommends that the child take "Two tablets of chewable calcium
10 or calcium plus vitamin D supplement," "Four ounces of milk," or "One tablespoon of liquid
11 antacid containing magnesium or aluminum" in order to help prevent "nausea, vomiting,
12 diarrhea."<sup>58</sup>

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

146. Fluoride is a "protoplasmic poison"<sup>59</sup> that can kill humans at doses not that much higher than arsenic.<sup>60</sup> The potency of fluoride's acute toxicity is why fluoride has been used as the active ingredient in rodenticides (to kill rodents) and insecticides (to kill bugs).<sup>61</sup> As far back as 1895, it was observed that "sodium fluoride is an active poison for micro-organisms of all kinds,

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<sup>21</sup> <sup>58</sup> See <u>https://triage.webpoisoncontrol.org/</u>(last accessed Jan. 13, 2025).

28 LITERATURE AND SOME EXPERIMENTAL INVESTIGATIONS 301 (1937).

<sup>&</sup>lt;sup>56</sup> Kenji Akiniwa, A Re-examination of acute toxicity of fluoride, 30 FLUORIDE 89 (1997).

<sup>20 &</sup>lt;sup>57</sup> Spak, *supra* note 55.

<sup>&</sup>lt;sup>22</sup> <sup>59</sup> Editorial, *Chronic fluorine intoxication*, 123 J AM DENT ASSOC. 150, 150 (1943).

<sup>&</sup>lt;sup>60</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*, <u>https://wwwn.cdc.gov/TSP/MMG/MMGDetails.aspx?mmgid=1424&toxid=3</u>. This is only slightly
lower than the potentially fatal dose of fluoride (5 mg/kg), as discussed below. *See also* Floyd DeEds, *Fluorine in relation to bone and tooth development*, 33 J AM DENT ASSOC. 568, 570 (1936)
("Such a comparison of toxicity data suggests that fluorine, lead and arsenic belong to the same group, as far as ability to cause some symptom of toxicity in minute dosage is concerned.").
<sup>61</sup> KAJ ROHOLM, FLUORINE INTOXICATION: A CLINICAL HYGIENIC STUDY WITH A REVIEW OF THE

algae, and nerves and muscles of the higher organisms."<sup>62</sup>

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2	147. The "Probable Toxic Dose" (" <b>PTD</b> ") for fluoride is 5 mg/kg. <sup>63</sup> The PTD "is defined
3	as the dose of ingested fluoride that should trigger immediate therapeutic intervention and
4	hospitalization because of the likelihood of serious toxic consequences." <sup>64</sup> It is the "minimum dose
5	that could cause toxic signs and symptoms, including <i>death</i> , and that should trigger immediate
6	therapeutic intervention and hospitalization."65
7	148. Due to person-to-person variations in sensitivity to fluoride toxicity, not all people
8	who ingest 5 mg/kg will experience significant toxicity. But, "if it is even suspected that 5.0 mg/kg
9	or more of fluoride has been ingested, then it should be assumed that an emergency exists.
10	Appropriate therapeutic measures and hospitalization should be instituted immediately."66
11	149. A tube of Colgate's Watermelon Burst toothpaste contains 143 milligrams of
12	fluoride. <sup>67</sup> A 1 year-old-child of average weight (~9 kg) would need to ingest only 1/3 of the tube
13	to exceed the PTD, while a 2 year-old-child of average weight (~12 kg) would need to ingest only
14	42% of the product to exceed the PTD.
15	150. Each year there are between 10,000 and 15,000 calls to poison control centers as a
16	result of excess ingestion of fluoride toothpaste. <sup>68</sup> The vast majority of these calls are made on
17	behalf of very young children, and hundreds of these calls result in hospitalizations.
18 19	<sup>62</sup> Herbert B. Baldwin, <i>The toxic action of sodium fluoride</i> , 21 J AM CHEM Soc. 517, 521 (1899) (quoting Czrellitzer 1895).
19 20	<ul> <li><sup>63</sup> Gary M. Whitford, <i>Fluoride in dental products: safety considerations</i>, 66 J DENT RES. 1056, 1056 (1987).</li> </ul>
21	$^{64}$ Id.
22	<sup>65</sup> <i>Id.</i> at 1057 (emphasis added).
23	<sup>66</sup> <i>Id</i> .
24	<sup>67</sup> Colgate's Unicorn Pump contains 136 mg of fluoride, Toms of Maine kids fluoride toothpaste contains 131 to 143 mg of fluoride (depending on the size), and Colgate's Kid's Cavity Protection
25	toothpaste contains 84 mg of fluoride.
26	<sup>68</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)
27	1282, 1448 (2020); David D. Gummin et al., 2021 Annual Report of the National Poison Data System <sup>©</sup> (NPDS) from America's Poison Centers: 39th Annual Report, 60 CLIN TOXICOL (Phila)
28	1381, 1581 (2021).
	24 DIADITIES? CLASS ACTION COMPLADIT
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1 151. The number of poisoning incidents from consumer products reported to poison 2 control centers is recognized to "likely underestimate the total incidence and severity of poisonings."<sup>69</sup> This is the case even for poisonings that cause outcomes as severe as death.<sup>70</sup> 3 4 Consistent with the general recognition that poison control data underestimates the 152. 5 true extent and severity of poisonings, the number of poisonings from fluoride toothpaste is also 6 believed to "underestimate" the true extent of fluoride poisonings due to "substantial underreporting" of such incidents.71 7 8 E. Other Health Concerns with Early Life Exposure to Fluoride 9 Acute toxicity and dental fluorosis are not the only health concerns with excess 153. ingestion of fluoride. 10 11 In 2006, the National Research Council ("NRC") of the National Academies of 154. Science published a comprehensive review of fluoride toxicology which concluded, among other 12 things, that excess fluoride exposure weakens bone, damages the brain, and disrupts the endocrine 13 system, including the thyroid gland.<sup>72</sup> According to the NRC, fluoride has been credibly associated 14 with impaired thyroid function in susceptible humans at doses as low as 0.01 to 0.03 mg/kg/day,<sup>73</sup> 15 16 which is less than many children will ingest from swallowing fluoride toothpaste.<sup>74</sup> 17 155. 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 18 19 20 <sup>69</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, 21 69 MMWR MORB MORTAL WKLY REP. 16 496, 496-97 (2020). 22 <sup>70</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. 23 <sup>71</sup> Shulman & Wells, *supra* note 53, at 157. 24 <sup>72</sup> NATIONAL RESEARCH COUNCIL, *supra* note 16, at 178-80, 220-22 & 260-66. 25 <sup>73</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 26 was inadequate."). 27 <sup>74</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. 28 25

1	production."75 According to the NRC, blood fluoride levels of 0.1 mg/L are credibly associated
2	with this effect. <sup>76</sup> A preschool child who ingests a full strip of fluoride toothpaste will have blood
3	fluoride levels that temporarily approximate or exceed this level. <sup>77</sup>
4	156. In August of 2024, the National Toxicology Program ("NTP"), which is part of the
5	National Institutes of Health, published a systematic review in which it concluded that excess
6	fluoride exposure is "consistently associated with reduced IQ in children."78
7	157. In January of 2025, NTP scientists published a meta-analysis of 74 human studies
8	on fluoride and IQ in the journal JAMA Pediatrics. <sup>79</sup> The NTP analysis "found inverse associations
9	and a dose-response relationship between fluoride measurements in urine and drinking water and
10	children's IQ across the large multicountry epidemiological literature."
11	158. The NTP has flagged toothpaste as a source of childhood fluoride exposure that
12	could contribute to the risk of neurodevelopmental problems. According to the NTP, "children may
13	be getting more fluoride than they need because they now get fluoride from many sources including
14	treated public water, water-added foods and beverages, teas, toothpaste, floss, and mouthwash, and
15	the combined total intake of fluoride may exceed safe amounts."80
16	159. On September 24, 2024, after hearing extensive expert testimony about NTP's
17	findings and other recent research, the Honorable Judge Edward Chen from the U.S. District Court
18	for the Northern District of California concluded that the addition of fluoride to drinking water
19	"poses an unreasonable risk of reduced IQ in children." Food & Water Watch, Inc. v. United States
20	$^{75}$ <i>Id.</i> at 264.
21	<sup>76</sup> Id.
22	<sup>77</sup> See Jan Ekstrand et al., <i>Plasma fluoride concentrations in pre-school children after ingestion of fluoride tablets and toothpaste</i> , 17 CARIES RES. 379 (1983).
23 24	<sup>78</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.
25	<sup>79</sup> Kyla Taylor et al., <i>Fluoride exposure and children's IQ scores: A systematic review and meta-</i>
26	analysis, JAMA PED. doi: 10.1001/jamapediatrics.2024.5542 (published online on Jan. 6, 2025).
27 28	<sup>80</sup> National Toxicology Program, <i>Fluoride Exposure: Neurodevelopment and Cognition</i> , <u>https://ntp.niehs.nih.gov/whatwestudy/assessments/noncancer/completed/fluoride (last accessed Jan. 13, 2025)</u> .
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*EPA*, No. 17-cv-02162-EMC, 2024 U.S. Dist. LEXIS 172635, at \*4 (N.D. Cal. Sep. 24, 2024).

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

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**F.** The Undisputed Need to Limit a Child's Use and Ingestion of Fluoride Toothpaste 161. U.S. health authorities, and Colgate itself, agree caregivers should strictly limit the

5 161. U.S. health authorities, and Colgate itself, agree caregivers sho
6 amount of fluoride toothpaste that young children use.

7 162. The FDA states that fluoride toothpaste is contraindicated for children under 2
8 because "[c]hildren under 2 years of age do not have control of their swallowing reflex and do not
9 have the skills to expectorate the toothpaste properly."<sup>81</sup> According to both the FDA and CDC,
10 children under 2 should only use fluoride toothpaste if directed by a dentist.<sup>82</sup>

11 163. When children first begin using fluoride toothpaste, CDC states that caregivers 12 should only put a "smear" of paste on the brush, and this should remain the practice until the child 13 turns 3. To quote: "Children aged <3 years should use a smear the size of a rice grain, and children 14 aged >3 years should use no more than a pea-sized amount (0.25 g) until age 6 years, by which 15 time the swallowing reflex has developed sufficiently to prevent inadvertent ingestion."<sup>83</sup>

16 164. 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>84</sup> The ADA provides the following figure<sup>85</sup>
to show what a "smear" and "pea-sized" amount looks like:

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- 22
- 23  $\frac{1}{81}$  FDA, *supra* note 1, at 52487,
- <sup>82</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.").</li>
- <sup>26</sup><sup>83</sup> Thornton-Evans, *supra* note 2, at 87.
- 27 <sup>84</sup> ADA, *supra* note 4, at 191.

28 <sup>85</sup> *Id.* at 191.

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2	Figure. The toothbrush on the left shows a smear of toothpaste
3	(0.1 milligram of fluoride) and the one on the right a pea-sized amount (0.25 mg of fluoride).
4	
5	165. As ADA states in the above figure, a smear of paste represents 0.1 mg of fluoride,
6	or approximately 0.1 grams of paste, while a pea-sized amount represents 0.25 mg of fluoride, or
7	approximately 0.25 grams of paste.
8	166. The AAP, <sup>86</sup> AAPD, <sup>87</sup> and Colgate itself, <sup>88</sup> agrees 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.
_	167. The National Capital Poison Center, which works to prevent poisonings from
2	fluoride toothpaste, states: "For children under 3 years of age, only use a smear or the size of a
3	grain of rice of fluoride toothpaste for brushing, starting when the first tooth appears."89
4	<sup>86</sup> Melinda B. Clark, et al., <i>Fluoride Use in Caries Prevention in the Primary Care Setting</i> , 146
5	PEDIATRICS e2020034637, Tbl 1 (2020).
6	<sup>87</sup> American Academy of Pediatric Dentistry, Frequently Asked Questions, <u>https://www.aapd.org/resources/parent/faq/</u> (last accessed Jan. 13, 2025).
7	<sup>88</sup> See supra ¶ 11.
8	<sup>89</sup> National Capital Poison Center, <i>supra</i> note 11.
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G. Defendant's Extensive and Longstanding Marketing Efforts Helped Shape Consumer Perceptions on the Safe and Age-Appropriate Amount of Fluoride

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1 171. Prior to the 1980s, Defendant did not use candy flavors or cartoon imagery to market 2 its toothpastes to young children. Upon information and belief, Defendant recognized that such 3 marketing efforts would be grossly irresponsible. 4 Beginning in the 1980s, however, Defendant abandoned its prior restraint and began 172. 5 adding features to its packaging to further expand its share of the children's market, including the 6 addition of candy flavors, bright sparkling colors, and cartoon imagery. 7 173. Dental fluorosis rates among U.S. children have risen sharply since the 1980s, and the marketing efforts that Defendant pioneered are believed to be one of the key reasons why.<sup>90</sup> 8 9 H. The Problem with Presenting Fluoride Toothpaste as a Candy-Like Drug 10 It is well recognized that presenting drugs as "candy-like" products increases the 174. 11 risk of overdose, particularly for young children. This problem has long been specifically flagged 12 in the context of fluoride toothpaste. 13 175. In 1992, the Journal of Public Health Dentistry published a consensus statement 14 which read, in part, "The use of flavors that may increase the ingestion of fluoridated dentifrices by young children should be strongly discouraged."91 15 16 In 1993, a consensus statement from Canadian dental researchers stated, in part: 176. 17 "Manufacturers should be discouraged from marketing toothpastes which, because of their taste or appeal, encourage swallowing or excessive use."92 18 19 In 1994, the World Health Organization stated, "the production of candy-like 177. 20 flavours . . . should not be encouraged for use by children, as they may lead to an excessive ingestion of fluoride."93 21 22 In 1997, the Journal of Public Health Dentistry published a review, which stated 178. "The use of flavored consumer fluoride products increases the possibility that a child will ingest a 23 24 25 <sup>90</sup> Neurath, *supra* note 17, at 306. 26 <sup>91</sup> Bawden, *supra* note 10, at 1221. <sup>92</sup> Introduction to the Workshop, 22 COMMUNITY DENT ORAL EPIDEMIOL. 140, 142 (1993). 27 <sup>93</sup> World Health Organization. Fluorides and Oral Health 28 (1994). 28 30 PLAINTIFFS' CLASS ACTION COMPLAINT

1	toxic dose of fluoride."94
2	179. Marketing fluoride toothpaste as if it were candy, or food, has been criticized as an
3	"aggressive" and "misleading" marketing tactic.95 According to Basch and Rajan, "the ubiquitous
4	presence of food pictures and appealing flavors on the toothpaste creates a distinct conflict. While
5	the labels warn the consumer to use only a pea-sized amount and note that toothpaste is not intended
6	to be swallowed, many toothpastes simultaneously boast pictures of fruit with flavoring to match -
7	a common signal to a child that toothpaste is intended to be consumed as if it were food."96
8	180. Studies have empirically tested, and confirmed, that adding candy flavor to
9	toothpaste increases the amount of paste that children add to their brush, as well as the amount of
10	toothpaste that they ingest. <sup>97</sup>
11	181. According to the FDA, marketing dangerous products to children through the use of
12	candy or food flavoring can qualify as a "misleading" marketing tactic that renders a product
13	"misbranded" under the FDCA. <sup>98</sup>
14	I. FDCA Requirements for Fluoride Toothpaste
15	General Requirements
16	182. The FDCA prohibits companies from selling over-the-counter drugs that are
17	"misbranded." 21 U.S.C. § 331(a).
18	
19	$^{94}$ Shulman & Wells, <i>supra</i> note 53, at 150.
20	<ul> <li><sup>95</sup> Basch &amp; Rajan, <i>supra</i> note 8, at 316.</li> <li><sup>96</sup> Id.</li> </ul>
21	<sup>97</sup> Steven M. Levy, et al., A pilot study of preschoolers' use of regular-flavored dentifrices and those
22	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
23	(1997); Claudia A. Kobayashi, et al., Factors influencing fluoride ingestion from dentifrice by
24	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
25	PHARMACOL. 66 (2016). <sup>98</sup> E.g. EDA Warning Letter to Electric Lotus LLC Nov 29 2018 available at
26	https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-
27	<u>letters/electric-lotus-llc-568710-11292018</u> (warning liquid tobacco companies that their use of candy flavoring is "misleading" and "increases the likelihood that children will ingest the product
28	as a food").
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1	183. A drug is misbranded if it has packaging that "is false or misleading in any
2	particular." 21 U.S.C. § 352(a)(1) (emphasis added).
3	184. A drug is also misbranded if "any word, statement, or other information required
4	. to appear on the label or labeling is not <b>prominently</b> placed thereon with such conspicuousness
5	(as compared with other words, statements, designs, or devices, in the labeling) and in such terms
6	as to render it likely to be read and understood by the ordinary individual under customary
7	conditions of purchase and use." 21 U.S.C. § 352(c) (emphasis added).
8	185. Under the regulations issued pursuant to the FDCA, the warnings and directions on
9	a label will fail to meet the prominence test if there is:
10	(4) Insufficiency of label space for the prominent placing of such word, statement, or
11	information, resulting from the use of label space for any word, statement, design, or device
12	which is not required by or under authority of the act to appear on the label;
13	(5) Insufficiency of label space for the prominent placing of such word, statement, or
14	information, resulting from the use of label space to give materially greater conspicuousness
15	to any other word, statement, or information, or to any design or device.
16	21 C.F.R. § 201.15(a).
17	186. The warnings and directions that FDA requires to be on a label <i>must</i> be placed on
18	the "outside container or wrapper of the retail package, or the immediate container label if there is
19	no outside container or wrapper."99 21 C.F.R. 201.66(c)(5) & (6).
20	187. An over-the-counter drug is "not misbranded" if it satisfies "each of the conditions
21	contained in any applicable monograph" and is "labeled in compliance" with 21 U.S.C. § 352 and
22	the regulations issued pursuant thereto. 21 C.F.R. § 330.1(c)(1). Thus, a drug can meet each of the
23	conditions of an applicable Monograph and still be misbranded if (a) it has labeling that is not
24	required by the Monograph that is false and misleading, or (b) it fails to present the warnings and
25	directions required by the Monograph with sufficient prominence.
26	
27	<sup>99</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 §
28	201.66(d)(10)." 64 Fed. Reg. 13254 at 13268.

1	Specific Requirements
2	188. The FDA has issued a Monograph for anti-cavity dental products, including fluoride
3	toothpaste. 21 C.F.R. § 355.50.
4	189. The FDA requires that all fluoride toothpastes provide the following warning: "Keep
5	out of reach of children under 6 years of age. If more than used for brushing is accidentally
6	swallowed, get medical help or contact a Poison Control Center right away." 21 C.F.R. §
7	355.50(c)(1). The FDA requires that the first sentence of this warning be in bold type. <i>Id</i> .
8	190. The FDA requires that all fluoride toothpastes provide the following directions:
9	"Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal
10	or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age
11	in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until
12	capable of using without supervision. Children under 2 years of age: Consult a dentist or doctor."
13	21 C.F.R. § 355.50(d)(1)(i).
14	Things that the FDA Does <u>Not</u> Require
15	191. The FDA does not require the label of fluoride toothpastes to depict full strips of
16	toothpaste.
17	192. The FDA does not require fluoride toothpastes to be packaged to look like candy or
18	food products.
19	193. The FDA does not require fluoride toothpastes to taste like candy or fruit.
20	194. The FDA does not require fluoride toothpastes to have strong sweet scents.
21	195. The FDA does not require fluoride toothpastes to have cartoon unicorns with
22	rainbow hair on the front of the product.
23	196. The FDA does not require fluoride toothpastes to state that they are approved by the
24	ADA. <sup>100</sup>
25	$\frac{100}{100} \text{ The EDA} = \frac{1}{100} \frac{1}{100$
26	<sup>100</sup> The FDA does not prohibit showing ADA's seal of approval, but the agency has made clear that the inclusion of this seal is subject to the prohibition on false or misleading labeling. <i>See</i> FDA,
27	<i>supra</i> note 24, 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
28	in 21 USC 352(a) against false or misleading labeling.").
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1 197. The FDA does not require, and in fact prohibits, companies from hiding the FDA's 2 required directions and warnings under a label that contains empty space and promotional claims. 3 J. The Colgate Products at Issue 4 198. Plaintiffs' claims in this case involve the following four Colgate products: (1) Kids 5 Cavity Protection, (2) Watermelon Burst, (3) Unicorn Pump, and (4) Kids Natural (collectively, 6 "the Products"). 7 8 9 oaraben 10 OZ (76 g) 11 **Colgate Kids Cavity Protection** 12 199. Colgate's "Kids Cavity Protection" toothpaste contains the same fluoride 13 concentration as Colgate's "Cavity Protection" toothpaste for adults (0.15% fluoride ion by 14 weight). 15 200. Kids Cavity Protection is Colgate's most popular toothpaste for kids. 16 201. The following elements of Kids Cavity Protection convey, both individually and 17 collectively, that it is specially formulated to be safe for young children to ingest without need to 18 limit how much of the toothpaste to put on the brush: 19 a. The front label of the box, as well as the front label on the product itself, 20 prominently displays the word "KIDS." 21 b. The colorful "bubble fruit"-flavored gel inside the tube is indistinguishable 22 in both flavor and scent from candy. Since candy is something that children 23 can safely ingest, the candy-like element of the product signifies the safety 24 of the product for children to ingest. 25 c. The front label of the box, as well as on the front label of the product itself, 26 prominently advertises that the gel is free of substances that are unhealthy to 27 ingest, including parabens, preservatives, and sugar. This advertised absence 28 34 PLAINTIFFS' CLASS ACTION COMPLAINT

of unhealthy substances 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.

202. 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.

9 203. The side label of the box shows two steps that are necessary to ensure "a healthy
10 smile." The first step is "BRUSH 2X A DAY" and the second step is to brush "FOR 2 MINIUTES."
11 Next to the instruction to "BRUSH 2X A DAY," the label shows a toothbrush with a full heaping
12 strip of paste on it.



204. 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>101</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, which may contribute
to fluorosis." <sup>102</sup>

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<sup>101</sup> Basch & Rajan, *supra* note 8, at 318.

<sup>27</sup>
<sup>102</sup> Corey H. Basch, et al., *Advertising of toothpaste in parenting magazines*, 38 J COMMUNITY
<sup>28</sup>
<sup>102</sup> HEALTH. 911, 913 (2013).

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205. As Colgate knows, a full strip of fluoride toothpaste is up to 8 to 10 times more 2 than the safe and recommended amount for a <3 year old, and 3 to 4 times more than the safe 3 and recommended amount for a 3-6 year old.

206. None of the deceptive attributes identified in paragraphs 201 to 203 are required by the FDCA or its accompanying regulations, including the Monograph. Individually and collectively, these deceptive attributes, which Plaintiffs relied upon, caused Plaintiffs 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.

9 207. Based on this deception, which Plaintiffs relied upon, Plaintiffs permitted their 10 toddlers and preschool children to regularly use this toothpaste in quantities that, unbeknownst to 11 them, far exceed the safe and recommended amount. They suffered economic loss as a result by 12 obtaining fewer brushings per product.



25 **Colgate Watermelon Burst** 26 208. Colgate has billed its Watermelon Burst product as a "2-in-1 Toothpaste and 27 28 36 PLAINTIFFS' CLASS ACTION COMPLAINT

Anticavity Mouthwash."<sup>103</sup> Colgate's description of the product as a mouthwash<sup>104</sup> is a reference
 to its "liquid gel" composition, which is much less viscous than a normal toothpaste.

209. The following elements of the Watermelon Burst 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 word "Toothpaste" has a crayon-like rainbow pattern that is clearly and unmistakably directed towards young children, thereby suggesting that the product is specially formulated to be safe for young children.

9 b. The product is packaged and presented like a fruit-flavored candy product, 10 from its front label to its sweet watermelon taste and scent. The front label shows a heaping green sparkling swirl (that matches the color of the gooey 11 12 gel inside) flowing from a juicy watermelon, while the gel inside has a sweet 13 flavor and a sweet scent that radiates into the air. Since fruit and candy is something that children can safely ingest, the fruit- and candy-like elements 14 15 of the Watermelon Burst product signify that the product is safe for children 16 to ingest.

c. The front label states that the gel is "SUGAR FREE" which signifies that the
product is healthy, or at least not harmful, to ingest.

19 210. None of the deceptive attributes identified in the foregoing paragraph are required
20 by the FDCA or its accompanying regulations, including the Monograph. Individually and
21 collectively, these deceptive attributes, which Plaintiffs relied upon, caused Plaintiffs to falsely
22 believe that the Watermelon Burst product is specially formulated to be safe for young children to
23 ingest without need to limit how much paste goes on the brush.

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<sup>25 &</sup>lt;sup>103</sup> See, e.g., <u>https://www.target.com/p/colgate-2-in-1-kids-toothpaste-and-anticavity-mouthwash-watermelon-burst-4-60z/-/A-13773703</u> (last accessed Jan. 13, 2025).

<sup>&</sup>lt;sup>104</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.

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

5 6 7 8 9 10 11	Colorate       Maximum       Colorate       Maximum       Colorate       Maximum       Colorate       Maximum       Colorate       Maximum       Colorate       Maximum       Colorate
12 13 14 15 16	CULLE FAXED COLLE FAXED COLL
17	Colgate Unicorn Pump
18	212. Colgate sells a kids-branded "Maximum Cavity Protection" toothpaste in a pump.
19	Although labeled as providing "maximum" cavity protection, this toothpaste contains the same
20	concentration of fluoride (0.15% fluoride ion by weight) as Colgate's ordinary "Kids Cavity
21	Protection" toothpaste.
22	213. Colgate has two different label designs for its toothpaste pump. One has a cartoon
23	unicorn design ("Unicorn Pump") and the other does not have any cartoons ("Regular Pump").
24	214. The Regular Pump has a prominent notation on the front label that says it is for "ages
25	6+." <sup>105</sup> This notation is not present on the Unicorn Pump, despite the toothpastes containing the
26	same volume and concentration of fluoride, as well as the same green-colored "bubble fruit"
27 28	<sup>105</sup> The Regular Pump is not a product that Plaintiffs used, and is thus not a product for which Plaintiffs seek relief.

1 flavored toothpaste.

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2 215. The following elements of the Unicorn Pump product deceptively convey, both
3 individually and collectively, that the colorful gel inside the tube is specially formulated to be safe
4 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.

12 c. The front label does not contain the "6+ YRS" notation that the Regular
13 Pump contains, thus implying that—unlike the Regular Pump—the Unicorn
14 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 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>106</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 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

<sup>27</sup>
<sup>106</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).

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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 photo 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.



216. None of the deceptive attributes identified in the foregoing paragraph are required by the FDCA or its accompanying regulations, including the Monograph. Individually and collectively, these deceptive attributes, which Plaintiffs relied upon, caused 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.

217. Based on this deception, which Plaintiffs relied upon, Plaintiffs permitted their toddlers and preschool children to regularly use this toothpaste in quantities that, unbeknownst to them, far exceed the safe and recommended amount. They suffered economic loss as a result by

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obtaining fewer brushings per product.



### **Kids Natural**

218. Colgate sells a "natural" brand of toothpaste under the "Toms of Maine" brand. 219. Colgate purchased Toms of Maine in 2006. Prior to Colgate taking over the company, Toms of Maine 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 of Maine products.

220. Upon information and belief, most consumers do not know that Toms of Maine is now a Colgate product. Further, most consumers believe that Toms of Maine products are especially safe and healthy products to use.

Colgate sells its Kids Natural toothpaste under the Toms of Maine brand. This 221. "natural" product comes in various fruit flavors.

222. The following elements of the Kids Natural product deceptively convey, both 24 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. 26

The front label prominently displays the word "Kids," thus signifying that a. the product is specially formulated for children.

1	b.	The front label prominently features the word "NATURAL" which signifies
2		that the product is free of toxic ingredients.
3	c.	The front label prominently displays images of fruit. Since fruit is something
4		that is healthy for kids to eat, the imagery of fruit implies that the product is
5		healthy, or at least not harmful, for young kids to ingest.
6	d.	The front label provides light-hearted, silly names for the fruit flavors,
7		including "Silly Strawberry," "Outrageous Orange Mango," "Watermelon
8		Wiggle," "Wild Blueberry," and "Fruitilicious." The wording of these
9		flavors implies that this is a harmless product that need not be handled with
10		any serious care.
11	e.	The front label superimposes cartoon graphics over the fruit. The image of
12		the strawberry, for example, has a superimposed smiley face, while the
13		image of the watermelon has a superimposed face of a cartoon character
14		chewing gum and blowing a bubble. These cartoon graphics further imply
15		that this is a harmless product that need not be handled with any serious care.
16	f.	The front label of the Kids Natural product states that it is "ADA Accepted,"
17		but does not disclose ADA's guideline that children under 3 should only use
18		a "smear" of toothpaste.
19	223. None	of the deceptive attributes identified in the foregoing paragraph are required
20	by the FDCA or its	s accompanying regulations, including the Monograph. Individually and
21	collectively, these de	eceptive attributes, which Plaintiffs relied upon, caused Plaintiffs to falsely
22	believe that Kids Nat	tural is specially formulated to be safe for young children to ingest without
23	need to limit how mu	ch of the toothpaste to put on the brush.
24	224. Based	on this deception, which Plaintiffs relied upon, Plaintiffs permitted their
25	toddlers and preschoo	ol children to regularly use this toothpaste in quantities that, unbeknownst to
26	them, far exceed the	safe and recommended amount. They suffered economic loss as a result by
27	obtaining fewer brush	nings per product.

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#### K. Colgate's Violations of FDCA Requirements

225. Colgate has violated FDA's requirements in several important and material ways. 226. First Colgate has violated 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) by not disclosing the required warnings and directions on the immediate container label of its Unicorn Pump product.<sup>107</sup> There is no legal justification for Colgate's concealment of this information because: (A) the back label is filled with unapproved indications (e.g., "helps reduce plaque buildup"), promotional claims (e.g., "freshens breath"), and *empty space* that cannot, and should not, be more prominent than the directions and warnings; and (B) competitor toothpaste pumps of the same size (Perrigo - Firefly), or smaller size (Sanofi -Aquafresh), provide all of the required warnings and directions on the immediate container label without resorting to hidden labels.

12 227. Second, as described above, Colgate has included false and misleading 13 representations on the front and sides of the label which violate 21 U.S.C. § 352(a). This violation 14 is not cured by Colgate's inclusion of the requisite warnings and instructions in the fine print on the back of the label.<sup>108</sup> 15

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228. The Ninth Circuit has 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

18 back, even when the fine print provides all of the requisite information required by the FDA.:

19 We disagree with the district court that reasonable consumers should be expected to look beyond misleading representations on the front 20 of the box to discover the truth from the ingredient list in small print on the side of the box. The ingredient list on the side of the box 21 appears to comply with FDA regulations and certainly serves some purpose. We do not think that the FDA requires an ingredient list so 22 that manufacturers can mislead consumers and then rely on the ingredient list to correct those misinterpretations and provide a shield 23 for liability for the deception. Instead, reasonable consumers expect that the ingredient list contains more detailed information about the 24 product that confirms other representations on the packaging.

25 <sup>107</sup> The Unicorn Pump does not come in a box or other form of wrapping, and thus Defendant has a requirement to place the warnings and directions on the "immediate container label" of the 26 product. 21 C.F.R. 201.66(c).

<sup>27</sup> <sup>108</sup> The language that Colgate uses for the directions is not verbatim to the language in the Monograph. Plaintiffs' do not, however, challenge Colgate on these differences. 28

Williams v. Gerber Prods. Co., 552 F.3d 934, 939-40 (9th Cir. 2008). Accord Bell v. Publix Super Mkts., Inc., 982 F.3d 468, 476 (7th Cir. 2020); Cooper v. Anheuser-Busch, LLC, 553 F. Supp. 3d 83, 107-08 (S.D.N.Y. 2021) (citing cases).

229. Colgate's violations of the FDCA were relied upon by Plaintiffs and were individually and collectively a material cause of their excess use of the product, and resulting economic loss.

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#### L. Colgate's Deceptive Conduct Caused Economic Injury to Plaintiffs and Class Members

230. Colgate has engaged in the deceptive and unlawful conduct described above to (i) obfuscate, distract from, and undermine FDA's required warnings and directions, (ii) induce people 12 to buy the Products for young children who otherwise would not have done so if they had correct 13 information; (iii) induce people to pay more for the Products than they would have paid if they had 14 correct information; and (iv) induce parents, caregivers, and children to use more of the Products 15 per brushing than recommended.

16 231. Colgate was, and remains, unjustly enriched each time parents and caregivers act on 17 Colgate's false and misleading packaging, including when caregivers use more than the safe and 18 recommended amount of Colgate toothpaste for a young child. For example: 19

- a. A parent of a 2-year-old who applies a full strip (0.75-1 grams) of toothpaste 20 to the brush will obtain 8 to 10 times *less* brushings per tube than a parent 21 who applies the recommended smear of paste (0.1 grams). 22
- b. A parent of a 3-year old who applies a full strip of paste will obtain 3 to 4 23 times fewer brushings per tube of paste than a parent who uses the 24 recommended pea-sized amount of paste (0.25 grams). 25

#### 232. Had Plaintiffs known and appreciated the truth about the Products, they would have 26 ensured their child used the recommended amount of paste. 27

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As an immediate, direct, and proximate result of Defendant's false and misleading, 233.

1	representations, Plaintiffs and the Class Members purchased more of the Products, and/or paid more			
2	per brushing, than they would have if they had known the truth.			
3	234. Consequently, Plaintiffs and the Class Members have suffered injury in fact and lost			
4	money as a result of Defendant's wrongful conduct.			
5	235. Plaintiffs do not seek recovery for any personal injuries that they or their children			
6	may have suffered from using the Products, including any emotional harm stemming therefrom.			
7	CLASS ALLEGATIONS			
8	236. Pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3), Plaintiffs bring this			
9	action on behalf of the following Classes:			
10	a. Multi-State Class: All persons in the States of California, Illinois, and New			
11	York who (A) purchased Kids Cavity Protection, Unicorn Pump, and			
12	Watermelon Burst for children aged 0 to 6 years and/or purchased Kids			
13	Natural for children 2 to 6 years, (B) within the applicable statutes of			
14	limitation and (C) who used more than the recommended amount of paste. <sup>109</sup>			
15	b. California Unicorn Pump Subclass: All persons in the State of California			
16	who purchased the Unicorn Pump for children aged 0 to 6 years within the			
17	applicable statute of limitations and who used more than the recommended			
18	amount of paste.			
19	237. As used herein, the term "Class," although used in the singular, shall refer to each			
20	of the aforementioned putative classes.			
21	238. Excluded from the Class are Defendant, its parents, subsidiaries, affiliates, officers,			
22	and directors; those who used the recommended amount of toothpaste, despite Colgate's deceptive			
23	practices; those who purchased the Products for resale; those who make a timely election to be			
24	excluded from the Classes, and the judge to whom the case is assigned and any immediate family			
25	members thereof.			
26	239. The Class Period begins on the date established by the Court's determination of any			
27 28	<sup>109</sup> As described above, the Products are: 1) Kids Cavity Protection; (2) Unicorn Pump; (3) Watermelon Burst; and (4) Toms Natural Kids Fluoride.			
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	PLAINTIFFS' CLASS ACTION COMPLAINT			

applicable statute of limitations, after consideration of any tolling, discovery, knowing
 concealment, and accrual issues, and ending on the date of entry of judgment.

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

5 241. <u>Numerosity</u>: The members of the Class are so numerous that joinder of all class 6 members is impracticable. On information and belief, there are, at a minimum, hundreds of 7 thousands of Class Members. Class Members may be notified of the pendency of this action by 8 recognized, Court-approved notice dissemination methods, which may include U.S. mail, 9 electronic mail, Internet postings, and/or published notice.

10 242. <u>Predominance of Common Questions of Law and Fact</u>: Questions of law and
11 fact that are common to the members of the Class predominate over questions that are specific to
12 individual members. These common questions of law and fact include, but are not limited to, the
13 following:

a. Whether the attributes of the Products that are not required by the FDA
Monograph are false and/or misleading;

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- b. Whether Defendant knew or should have known that the packaging of the Products is false and/or misleading;
- c. Whether Defendant has violated the state consumer protection statutes alleged herein;
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   d. Whether Defendant has violated the FDCA, including 21 U.S.C. § 352(a),

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   21 U.S.C. § 352(c), 21 C.F.R. § 201.15(a)(4)-(5), and 21 C.F.R.

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   201.66(c)(5)-(6);
  - e. Whether Defendant was unjustly enriched;
  - f. Whether Plaintiffs and Class members have suffered an ascertainable loss of monies or property or other value as a result of Defendant's deceptive and unlawful conduct; and
  - g. Whether Plaintiffs and Class members are entitled to monetary damages and, if so, the nature of such relief.

1 243. The consumer protection laws in the three states of the putative Multi-State 2 Consumer Class are materially identical with respect to the causes of action for deceptive trade 3 practices alleged herein. Thus, the same deceptive conduct by Defendant that violates California's 4 Unfair Competition Law, CAL. BUS. & PROF. CODE §§ 17200, et seq., simultaneously violates 5 Illinois's Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505, et seq., and New 6 York's Consumer Protection from Deceptive Acts and Practices Act, N.Y. GEN. BUS. LAW §§ 349 7 & 350. Additionally, the same conduct by Defendant that constitutes unjust enrichment under 8 California law, also constitutes unjust enrichment under Illinois and New York law.

9 244. <u>Typicality</u>: Plaintiffs' claims are typical of those of other Class Members because,
10 like all members of the Class, Plaintiffs purchased the Products with the false and misleading
11 packaging for children aged 0 to 6 years old, used more of the toothpaste than is safe and
12 recommended, and sustained economic loss as a result.

13 245. <u>Adequacy</u>: Plaintiffs will fairly and adequately protect the interests of the Class and
 14 have retained counsel that is experienced in litigating complex class actions. Plaintiffs have no
 15 interests which conflict with those of the Class. Plaintiffs and counsel are aware of their fiduciary
 16 responsibilities to the Class members and are determined to diligently discharge those duties by
 17 vigorously seeking the maximum possible recovery for Class members.

18 246. <u>Superiority</u>: A class action is superior to any other available means for the fair and
19 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 Defendant's conduct;
- b. Even if individual members of the Class had the resources to pursue individual
  litigation, it would pose a crushing burden on the court system for these cases to
  be litigated on an individual basis;
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c. Absent a class action mechanism, Plaintiffs and Class members will continue to

suffer harm as a result of Defendant's unlawful conduct because indivi	dual		
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>			
FIRST CAUSE OF ACTION Deceptive Business Practices in Violation of California's Unfair Competition Law Cal. Bus. & Prof. Code §§ 17200			
247. Plaintiffs incorporate the preceding paragraphs as if fully written herein.			
248. Plaintiffs Cheyenne Verbish, Erica Doutherd, Ashley Cherry, Tambra Recek,	and		
Charlottle Lazar bring this claim individually and on behalf of the California members of the Multi-			
State Class.			
249. California's Unfair Competition Law ("UCL") prohibits "fraudulent" act	s or		
practices, which the statute defines to include any act or practice that is likely to deceive members			
of the consuming public. Cal. Bus. & Prof. Code §17200. An intention to defraud is not a necessary			
element for demonstrating a fraudulent business practice under the UCL.			
250. Defendant's marketing of the Products is deceptive in the following ways, each of			
which is independently violative of the UCL:			
a. For all Products: As described above, including but not limited to paragr	aphs		
201, 202, 203, 209, 215, and 222, Defendant presents the Products as			
specially formulated to be safe for young children to ingest without need to			
<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. <i>See, e.g., Beaton v. SpeedyPC Software</i> , 907 F.3d 1018, 1030 (7th Cir. 2018); <i>Mullins v. Direct Dig., Ltd. Liab. Co.</i> , 795 F.3d 654, 658 (7th Cir. 2015); <i>Langan v. Johnson &amp; Johnson Consumer Cos.</i> , 897 F.3d 88 (2d Cir. 2018); <i>Benson v. Newell Brands, Inc.</i> , No. 19 C 6836, 2021 U.S. Dist. LEXIS 220986, at *30-32 (N.D. III. Nov. 16, 2021); <i>Hasemann v. Gerber Prods. Co.</i> , No. 15-CV-2995 (MKB) (RER), 2019 U.S. Dist. LEXIS 28770, at *53-54 (E.D.N.Y. Feb. 20, 2019); <i>Suchanek v. Sturm Foods, Inc.</i> , 311 F.R.D. 239, 259-60 (S.D. III. 2015); <i>Brown v. Hain Celestial Grp., Inc.</i> , No. C 11-03082 LB, 2014 U.S. Dist. LEXIS 162038, at *29-30 (N.D. Cal. Nov. 18, 2014); <i>Cf. Pella Corp. v. Saltzman</i> , 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."").			
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PLAINTIFFS' CLASS ACTION COMPLAINT			

1	limit the amount of paste that goes on the brush.			
2	b. For all Products, except for Colgate Watermelon Burst: Defendant boast			
3	that the product is approved by the ADA without disclosing that ADA states			
4	children under 3 should use no more than a smear of paste. This is likely to			
5	further deceive the consuming public into believing there is no need to limit			
6	the amount of paste that goes on the brush.			
7	c. For the Kids Cavity Protection product: Defendant provides a visual			
8	instruction to use a full strip of toothpaste which is likely to deceive the			
9	consuming public into believing a full strip of toothpaste is a safe,			
10	recommended, and age-appropriate amount of paste to use.			
11	251. Plaintiffs and the other California Class Members have permitted their preschool			
12	children to use more toothpaste than safe and recommended based on their reasonable reliance on			
13	Defendant's aforementioned deceptive labeling. Plaintiffs and the California Class Members have			
14	thus obtained less brushings per tube of toothpaste as a proximate result of Defendant's violations			
15	of the UCL.			
16	252. Through its deceptive acts and practices, Defendant has been unjustly enriched, and			
17	continues to be unjustly enriched, by unfairly obtaining money from members of the Class.			
18	253. Based on Defendant's deceptive acts and practices, Plaintiffs and the Californi			
19	Class members are entitled to relief under the UCL.			
20	SECOND CAUSE OF ACTION			
21	"Unlawful" Business Practices in Violation of California's Unfair Competition Law Cal. Bus. & Prof. Code §§17200, <i>et seq</i> .			
22	254. Plaintiffs incorporate the preceding paragraphs as if fully written herein.			
23	255. Plaintiffs Ashley Cherry and Tambra Recek bring this claim individually and on			
24	behalf of the California Unicorn Pump Subclass.			
25	256. The UCL defines unfair business competition to include any "unlawful" act. Cal.			
26	Bus. & Prof. Code § 17200.			
27	257. A business act or practice is "unlawful" if it violates any established state or federal			
28	law. See Graham v. Bank of Am., N.A., 226 Cal. App. 4th 594, 610 (2014) ("By proscribing 'any			
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unlawful' business act or practice, the UCL borrows rules set out in other laws and makes violations
 of those rules independently actionable. A violation of another law is a predicate for stating a cause
 of action under the UCL's unlawful prong." (quotations and citations omitted)).

4 258. As described above, including but not limited to paragraphs 215(f) and 226, 5 Defendant has violated the "unlawful" prong of the UCL by failing to place the FDA-required 6 warnings and directions on the immediate container label of the Unicorn Pump product. Rather 7 than place these warnings and directions on the immediate container label, Colgate hides this 8 information under a label full of unapproved indications, promotional claims and empty space. This 9 unjustifiable concealment of FDA's required warnings and directions is a violation of 21 U.S.C. § 10 352(c), 21 C.F.R. § 201.15(a), and 21 C.F.R. 201.66(c)(5)-(6), and thereby a violation of the UCL. 11 259. Plaintiffs and the other California Class Members have permitted their preschool 12 children to use more toothpaste than the safe and recommended amount based on their reasonable 13 reliance on Defendant's unlawful labeling. Plaintiffs and the California Class Members have thus 14 obtained less brushings per tube of toothpaste as a proximate result of Defendant's violations of the 15 UCL. 16 260. Through its unlawful acts and practices, Defendant has been unjustly enriched, and 17 continues to be unjustly enriched, by unfairly obtaining money from members of the Class. 18 261. Based on Defendant's unlawful acts and practices, Plaintiff and the California Class 19 members are entitled to relief under the UCL. 20 THIRD CAUSE OF ACTION Unfair Business Practices in Violation of California's Unfair Competition Law 21 Cal. Bus. & Prof. Code §§17200, et seq. 22 262. Plaintiffs incorporate the preceding paragraphs as if fully written herein. 23 263. Plaintiffs Cheyenne Verbish, Erica Doutherd, Ashley Cherry, Tambra Recek, and 24 Charlottle Lazar bring this claim individually and on behalf of the California members of the Multi-25 State Class. 26 264. The UCL defines unfair business competition to include any "unfair" act or practice. 27 Cal. Bus. & Prof. Code § 17200. 28

1 265. A business act or practice is "unfair" under the UCL if the reasons and motives of 2 the alleged wrongdoer are outweighed by the gravity of the harm to the alleged victims. 3 266. Defendant utilizes its sophisticated knowledge on marketing and social psychology 4 to prey upon unsophisticated consumers with implied messaging which persuasively encourages 5 behavior that Defendant knows will place a vulnerable population (young children) in harm's way. 6 267. Defendant's marketing tactics, which violate its legal requirements under both state 7 and federal law, jeopardize the health of millions of American children, and cause widespread 8 economic injury to consumers. 9 Although fluoride toothpaste can prevent cavities, U.S. health authorities are in 268. 10 universal agreement that this benefit can be obtained using a smear (i.e., "rice grain") of paste up 11 through age 3, and a pea-sized amount of paste from 3 to 6. 12 269. There is no adequate justification for Colgate to entice young children to use and 13 ingest more than the safe and recommended amount of toothpaste, particularly when doing so 14 places the children at risk of harm. 15 Defendant's aforementioned conduct is unfair under the UCL. 270. 16 271. Plaintiffs and the other California Class Members have permitted their preschool 17 children to use more toothpaste than the safe and recommended based on their reasonable reliance 18 on Defendant's unfair acts and practices. Plaintiffs and the California Class Members have thus 19 obtained less brushings per tube of toothpaste as a proximate result of Defendant's violations of the 20 UCL. 21 272. Through its unfair acts and practices, Defendant has been unjustly enriched, and 22 continues to be unjustly enriched, by unfairly obtaining money from members of the Class. 23 273. Based on Defendant's unfair acts and practices, Plaintiff and the California Class 24 members are entitled to relief under the UCL. 25 FOURTH CAUSE OF ACTION **Deceptive Trade Practices in Violation of the** 26 **Illinois Consumer Fraud and Deceptive Trade Practices Act** 815 ILCS 505/1, et seq. 27 274. Plaintiffs incorporate the preceding paragraphs as if fully written herein. 28 51 PLAINTIFFS' CLASS ACTION COMPLAINT

1 275. Plaintiffs Camaria Burleigh, Tanisier Clayborne, Sherry Hodge, Anju Goel, and 2 Josh Cook bring this claim individually and on behalf of the Illinois members of the Multi-State 3 Class. 276. The Illinois Consumer Fraud and Deceptive Trade Practices Act ("ICFA") prohibits 4 5 "[u]nfair methods of competition and unfair or deceptive acts or practices," which includes "the 6 use or employment of any . . . false pretense, false promise, misrepresentation or the concealment, 7 suppression or omission of any material fact." 815 ILCS 505/2. 8 277. A "claim for 'deceptive' business practices under the [ICFA] does not require proof 9 of intent to deceive." Wigod v. Wells Fargo Bank, N.A., 673 F.3d 547, 575 (7th Cir. 2012) (citation 10 omitted). 278. For the reasons identified above, including but not limited to paragraph 250, 11 12 Defendant has violated, and continues to violate, the ICFA. 13 279. Plaintiffs and the other Illinois Class Members have permitted their preschool 14 children to use more toothpaste than safe and recommended based on their reasonable reliance on 15 Defendant's deceptive labeling. Plaintiffs and the California Class Members have thus obtained 16 less brushings per tube of toothpaste as a proximate result of Defendant's violations of the ICFA. 17 280. Through its violations of the ICFA, Defendant has been unjustly enriched, and 18 continues to be unjustly enriched, by unfairly obtaining money from members of the Class. 19 Based on Defendant's deceptive acts and practices, Plaintiffs and the Illinois Class 281. 20 members are entitled to relief under 815 ILCS §505/10a. 21 FIFTH CAUSE OF ACTION **Deceptive Business Practices in Violation of** 22 New York General Business Law §§ 349 & 350 23 282. Plaintiffs incorporate the preceding paragraphs as if fully written herein. 24 283. Plaintiffs Cynthia Rivera, Megan Cratsley, Charlene Roseboro, and Tiarra Hook 25 bring this claim individually and on behalf of the New York members of the Multi-State Class. 26 New York General Business Law ("GBL") prohibits "deceptive acts or practices in 284. 27 the conduct of any business, trade, or commerce or in the furnishing of any service in this state." 28 52 PLAINTIFFS' CLASS ACTION COMPLAINT

1	NY GBL § 349. GBL also prohibits "[f]alse advertising in the conduct of any business, trade or			
2	commerce." NY GBL § 350. GBL defines false advertising as including "labeling" of a product			
3	that is "misleading in a material respect." Id. § 350a(1).			
4	285.	For the reasons identified above, including but not limited to paragraph 250,		
5	Defendant has violated, and continues to violate, GBL §§ 349-50.			
6	286.	Plaintiffs and the other New York Class Members have permitted their preschool		
7	children to us	se more toothpaste than safe and recommended based on their reasonable reliance on		
8	Defendant's	deceptive labeling. Plaintiffs and the California Class Members have thus obtained		
9	less brushing	s per tube of toothpaste as a proximate result of Defendant's violations of NY GBL		
10	§§ 349-50.			
11	287.	Through its deceptive and misleading acts and practices, Defendant has been		
12	unjustly enri	ched, and continues to be unjustly enriched, by unfairly obtaining money from		
13	members of the Class.			
14	288.	Based on Defendant's unlawful acts and practices, Plaintiffs and the New York		
15	Class membe	ers are entitled to relief under NY GBL §§ 349-50.		
16		PRAYER FOR RELIEF		
17	WHEREFORE, Plaintiffs, on behalf of themselves and those similarly situated,			
18	respectfully r	equest that the Court enter judgment against Defendant as follows:		
19	А.	Certification of the proposed Class and Subclass, including appointment of		
20		Plaintiffs' counsel as Class counsel and Plaintiffs as Class Representatives;		
21	В.	An award of compensatory damages in an amount to be determined at trial;		
22	C.	An award of restitution in an amount to be determined at trial;		
23	D.	An award of disgorgement of profits in an amount to be determined at trial;		
24	E.	An award of statutory damages in an amount to be determined at trial, except as to		
25		those causes of action where statutory damages are not available by law;		
26	F.	An award of punitive damages in an amount to be determined at trial, except as to		
27		those causes of action where punitive damages are not available by law;		
28	G.	An award of treble damages, except as to those causes of action where treble		
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		PLAINTIFFS' CLASS ACTION COMPLAINT		

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1		damages are not available by	
2	Н.		t to pay both pre- and post-judgment interest on any
3		amounts awarded;	
4	I.	For reasonable attorneys' fee	es and the costs of suit incurred; and
5	J.	For such further relief as this	Court may deem just and proper.
6		<b>DEMAND</b>	FOR JURY TRIAL
7	Plain	tiffs hereby demand a trial by ju	ury on all Counts and as to all issues.
8	Dated: Janu	ary 13, 2025	Respectfully Submitted,
9			By: <u>/s/ Michael Connett</u>
10			Michael Connett, SBN 300314 SIRI & GLIMSTAD LLP
11			700 S. Flower St., Suite 1000 Los Angeles, CA 90017
12			mconnett@sirillp.com
13			Tel: (888) 747-4529
14			Aaron Siri ( <i>pro hac vice</i> to be sought) Elizabeth A. Brehm ( <i>pro hac vice</i> to be
15			sought) SIRI & GLIMSTAD LLP
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