UNITED STATES DISTRICT COURT
NORTHERN DISTRICT Eastern Division

TANISIER CLAYBORNE, CAMARIA BURLEIGH, SHERRY HODGE, ANJU GOEL, & JOSH COOK, individually, and on behalf of those similarly situated, Plaintiffs, v. COLGATE-PALMOLIVE COMPANY & TOM'S OF MAINE, INC., Defendants.	Case No. 1:25-cv-04877 Hon. Jeffrey I. Cummings ORAL ARGUMENT REQUESTED

PLAINTIFFS' OPPOSITON TO DEFENDANTS COLGATE-PALMOLIVE COMPANY AND TOM'S OF MAINE, INC.'S MOTION TO DISMISS PLAINTIFFS' COMPLAINT OR STRIKE CERTAIN ALLEGATIONS

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INTRODUCTION

This is a case about advertising tactics that Colgate-Palmolive Company and Tom's of Maine, Inc. ("**Defendants**") use to sell fluoride toothpastes to parents of young children. These tactics are not mandatory; the Food & Drug Administration ("**FDA**") does *not* require them. What the FDA does require is that Defendants instruct and warn that fluoride toothpaste is too dangerous to be kept in reach of children, and that careful efforts need to be taken to minimize a young child's ingestion of the paste. The problem is that the Defendants use advertising tactics on the packaging that conveys a much different message, one that runs counter to FDA's directions/warnings. Contrary to FDA's call for caution, Defendants present fluoride toothpaste as a fun, candy-like product that is harmless for young children.

In their motion to dismiss, Defendants predictably argue that the fine print on the back label is a shield against their liability. Defendants argue that all reasonable consumers would read this fine print, would never believe the toothpaste is safe to ingest, and would strictly limit the amount of paste that goes on a child's brush. This argument fails because it flies in the face of *Bell v. Publix Super Mkts., Inc*., 982 F.3d 468 (7th Cir. 2020), which Defendants tellingly fail to mention in their discussion of deception. As the Seventh Circuit made clear, a company cannot evade liability for a deception that it displays on the front label by burying the correct information in the fine print on the back. *See Bell*, 982 F.3d at 476 ("[P]laintiffs' claims survive if they have plausibly alleged that the defendants' front labels likely lead a significant portion of reasonable consumers to falsely believe something that the back labels belie."). Here, the fine print on Defendants' back label conflicts with the safety messaging on the rest of the label, and thus cannot defeat Plaintiff's claims on a Rule 12(b)(6) motion. Defendants' arguments on concealment, preemption, and actual loss are equally unavailing. Their motion should be denied.

FACTUAL BACKGROUND

A. Fluoride Toothpaste Poses Heightened Dangers for Young Children

Fluoride toothpaste is an approved over-the-counter ("OTC") drug for the prevention of tooth decay (aka "caries"). 21 C.F.R. 355.50. Fluoride toothpaste is effective for its indicated use

of caries prevention. ¶ 2.[1] When swallowed, however, fluoride toothpaste presents risks to health, particularly for young children. ¶¶ 2, 71.

Young children are more vulnerable to suffering harm from fluoride toothpaste than adults for a number of reasons. ¶ 71. Children under the age of 6 have poorly developed swallowing reflexes and, as a result, swallow a large percentage of the paste they put in their mouth. ¶ 72. Further, the early years of life are a "critical window of vulnerability" for some of fluoride's adverse effects, including dental fluorosis. ¶¶ 76. Fluorosis is a mineralization defect of tooth enamel that is marked by "increased porosity" and visible discoloration of the teeth. ¶¶ 24, 78, 83-85. The American Dental Association (ADA) and Centers for Disease Control and Prevention (CDC) both recognize that ingestion of fluoride toothpaste during the first 6 years of life (but not after) can cause dental fluorosis. ¶¶ 79, 81.

Fluorosis is not the only health risk from early-life use of fluoride toothpaste. Ingestion of a single strip of fluoride toothpaste can cause stomach flu symptoms, including nausea and upset stomach, in a young child. ¶¶ 20, 87, 91. A toddler who intentionally ingests as little as 1/3 of a tube of kids' fluoride toothpaste can suffer "serious toxic consequences . . . including death." ¶¶ 95, 97. There is also growing concern that early-life fluoride ingestion can cause neurodevelopmental toxicity. ¶¶ 26, 104-107. According to the National Toxicology Program (NTP), excess fluoride exposure during the early years of life is "consistently associated with reduced IQ in children." ¶ 104. Based on the NTP's findings, a federal district court recently concluded that adding fluoride to drinking water for caries prevention "poses an unreasonable risk of reduced IQ in children." ¶ 107.

B. Health Authorities, and Defendants, All Agree that Young Children Should Strictly Limit the Amount of Fluoride Toothpaste that Goes on the Brush

Health authorities in the U.S. agree that the use of fluoride toothpaste for young children should be strictly limited due to the health risks of ingestion. ¶¶ 5-11. According to the FDA and CDC, children under the age of 2 should not use fluoride toothpaste unless directed by a dentist.

[1] As with Defendants' motion, undesignated "¶" citations are to the Complaint. *See* ECF No. 1.

¶¶ 6, 7, 110. Prior to the age of 3, the CDC states that no more than a "smear" (i.e., "rice grain") of fluoride toothpaste should be put on the brush. ¶¶ 8, 111. The ADA, American Academy of Pediatrics (AAP), American Academy of Pediatric Dentistry (AAPD), and National Capital Poison Center (NCPC) all concur with the CDC that children under 3 should use no more than a smear of fluoride toothpaste. ¶¶ 9, 112-115. From age 3 to 6, the CDC, ADA, AAP, and AAPD concur that no more than a "pea-sized" amount of fluoride toothpaste be used. ¶¶ 9, 112, 114.

C. The FDA Requires Warnings on the Dangers of Ingesting Fluoride Toothpaste and the Need to Minimize Swallowing by Young Children

The FDA has issued a monograph for anti-cavity drugs that provide "topical application to the teeth," including fluoride toothpaste ("**Anticaries Monograph**" or "**Monograph**"). 21 C.F.R. 355.1. The Monograph requires that the labeling of fluoride toothpaste disclose the danger of ingesting the paste and the need "to minimize swallowing."[2] 21 C.F.R. § 355.50. The FDA requires the label to state: "keep out of reach of children under 6 years of age," and "get medical help or contact a Poison Control Center" if "more than used for brushing is accidentally swallowed." *Id.* 355.50(c)(1). The FDA also requires that the label inform caregivers to "[i]nstruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing)" and to "[s]upervise children as necessary until capable of using without supervision." *Id.* 355.50(d)(1)(ii).

D. Defendants Present Their Fluoride Toothpastes as Harmless for Young Children

Defendants market adult-strength fluoride toothpastes to caregivers of preschool children, including Kids Cavity Protection ("KCP"), Watermelon Burst ("WB"), Unicorn Pump ("UP"), and Kids Natural ("KN"). ¶¶ 3, 146, 165. Defendants know that fluoride toothpaste presents extra risk for young children and that caregivers should strictly limit the amount of paste that goes on the brush, but their advertising tactics convey the exact *opposite* impression. ¶¶ 4, 12, 149, 150, 156, 162, 169. These tactics include the following:

[2] Defendants assert that "Plaintiffs omit from their allegations the actual warnings and usage instructions on every Product label." Mem. 3. This is false. The Complaint states that Defendants place FDA's required warnings and directions in the fine print on the back (¶ 174), and explains that the Unicorn Pump product hides this information behind an unnecessary label full of promotional claims and empty space (¶¶ 212-14).

1. **Presenting the Products as Specially Formulated for Young Children.** Two of Defendants' products (KCP and KN) have the word "Kids" right in the title,[3] while the other products use graphics that unmistakably identify young children as the target demographic (i.e., the word Toothpaste is written in a crayon-styled, rainbow-colored font on the WB product, and a rainbow-colored unicorn is featured on the UP product).
2. **Showing a Full Strip of Toothpaste on the Brush.** The label of the KCP product shows a full strip of toothpaste on the brush as part of a visual instruction on how to use the product. ¶ 150. The display of a full strip of toothpaste has been specifically criticized as "misleading" by public health researchers because it greatly exceeds the safe and recommended amount of fluoride toothpaste for young children. ¶ 151.
3. **Presenting the Pastes as Candy-Like Products.** Defendants showcase the candy flavors of the pastes on the front label, including "Bubble Fruit," "Watermelon Burst," "Silly Strawberry," "Outrageous Orange Mango," and "Watermelon Wiggle." The use of candy flavors to sell adult-strength fluoride toothpastes has been criticized by public health researchers as another "misleading" marketing tactic that can increase the risk of toxic overdoses. ¶¶ 12-14. Similarly, the FDA has stated that marketing dangerous products with candy- and food-flavoring can render a product misbranded under the FDCA. ¶ 129.
4. **Using Language that Conveys the Impression of a Healthy, Non-Toxic Product.** The labels for three of the products (KCP, WB, and KN) boast of the absence of ingredients that are unhealthy to ingest (e.g., "dye free," "sugar free," "paraben free," "no artificial ingredients"), which implies that the paste itself is not unhealthy to ingest. Defendant Toms compounds this impression by using the word "Natural" in the name of its KN product.
5. **Using Graphics and Words that Disarm Consumers of Any Apprehension of Danger**. Defendants' labels use silly/playful graphics (e.g., a smiling strawberry, a rainbow unicorn,

[3] *See Brady v. Bayer Corp*., 26 Cal. App. 5th 1156, 1170 (2018) (explaining that a descriptive name for a product has a powerful impact on consumer perception because it requires "little thought, little explanation, little effort to build understanding of what the offering actually is").

ribbons of sparkles) and silly/playful words (e.g., "Bubble Fruit," "Silly Strawberry," "Watermelon Wiggle," "Outrageous Orange Mango") that are incongruent with a dangerous product, and which compound the impression of a harmless product for kids.

6. **Boasting of ADA's Approval While Concealing Its Basis.** Defendants boast that their products are approved by the ADA, but conceal that ADA's approval is premised on children under three using no more than a "smear" (or "rice grain") of paste.[4] ¶¶ 224-27.

Most parents are unaware of the recommendations for fluoride toothpastes, which increases their susceptibility to Defendants' deceptive marketing tactics. ¶¶ 172-173. Based on these tactics, Plaintiffs believed Defendants' products are safe for children to ingest in ordinary amounts without need to limit how much paste goes on the brush. ¶¶ 153, 157, 163, 170. As a result, Plaintiffs permitted their children to use toothpaste in quantities that, unbeknownst to them, far exceed the safe and recommended amount. ¶¶ 154, 158, 164, 171. This deception caused economic injury to the Plaintiffs by reducing the number of brushings they got from each tube, which, in turn, unjustly enriched the Defendants. ¶¶ 12, 154, 158, 164, 171, 178.

LEGAL FRAMEWORK

A deceptive label is one which has "a capacity to deceive." *Bober v. Glaxo Wellcome Plc*, 246 F.3d 934, 938 (7th Cir. 2001). Claims of deceptive labeling are "fact intensive" and ordinarily not subject to dismissal under Rule 12(b)(6). *Vanlaningham v. Campbell Soup Co*., 492 F. Supp. 3d 803, 809 (S.D. Ill. 2020). It is only when Plaintiff's theory of deception rests on "unreasonable or fanciful interpretations of labels" that dismissal as a matter of law is warranted. *Bell v. Publix Super Mkts., Inc*., 982 F.3d 468, 477 (7th Cir. 2020). This is a "high bar" for dismissal. *Vanlaningham*, 492 F. Supp. 3d at 809. To survive dismissal under Rule 12(b)(6), "the plaintiffs need only 'nudge[] their claims across the line from conceivable to plausible.'" *Bell*, 982 F.3d at 476 (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

[4] Defendants add language to the fine print that two-year olds should use a "pea-sized" amount of paste (Bladow Decl., Exs A-D), which is *more than two times greater* than a smear (¶ 178) and thus at odds with what ADA approves.

In assessing the plausibility of a deceptive labeling claim, the Seventh Circuit requires that courts focus on "how real consumers understand and react to advertising," which it describes as a "practical and fact-intensive approach to consumer behavior." *Id.* at 476-81. Under this practical approach, the Seventh Circuit has "stressed that ***consumers are likely to exhibit a low degree of care when purchasing low-priced, everyday items***. This low degree of care does not make consumers unreasonable—it makes them human, and even economically rational when search costs and transaction costs are included in the utility calculus. But it also makes them vulnerable to exploitation by unfair and deceptive practices." *Kahn v. Walmart Inc.*, 107 F.4th 585, 597 (7th Cir. 2024) (emphasis added). In applying the reasonable consumer standard, the Seventh Circuit has called on district courts to keep in mind that consumers often have "limited time" and will "rationally use mental shortcuts" when making purchasing decisions. *Id.* at 595. "Many reasonable consumers," the court has noted, "do not instinctively parse every front label or read every back label before placing groceries in their carts." *Bell*, 982 F.3d at 476. The Seventh Circuit has also called on courts to keep in mind that "[l]ots of advertising is aimed at creating positive impressions in buyers' minds . . . subtly by implication and indirection." *Kahn*, 107 F.4th at 595-96.

ARGUMENT

A. Plaintiffs Have Plausibly Pled a False Pretense/Misrepresentation Claim

Plaintiffs' theory of false pretense/misrepresentation *easily* meets the low threshold for Rule 12(b)(6). For starters, consider the type of product at issue. This is not a product, like hand sanitizers or sunscreen, that ordinary consumers know should not go in the mouth, or be swallowed. Instead, this is a product that is *intentionally designed* to go into the *mouth* of *young children*.[5] It is common knowledge, particularly among the targeted consumer (parents), that young children have a tendency to swallow what goes in their mouth. It is not fanciful for parents to believe that a product specifically intended to go into the mouth of young children is safe for their

[5] The fact that the FDA requires an instruction "to minimize swallowing" is evidence that many consumers do not know this. *See Slaten v. Christian Dior, Inc.*, 2023 WL 3437827, 2023 U.S. Dist. LEXIS 83883, at *13 (N.D. Cal. May 12, 2023) ("[T]hat the FDA requires sunscreen labels to tell consumers to reapply suggests many do not know they should do so.").

children to ingest. *See Mirza v. Ignite USA, LLC*, 439 F. Supp. 3d 1058, 1071 (N.D. Ill. 2020) (concluding that reasonable consumers "expect products made for children" to be safe for children).

Rather than dispelling consumers of this illusion, Defendants use marketing tactics to *encourage* it. First, Defendants present the paste as a candy-like product, with flavors such as Bubble Fruit, Watermelon Burst, and Outrageous Orange Mango. Candy is a product kids can safely ingest which invokes light-hearted feelings that are *opposite* to an apprehension of danger. Masking a poisonous product with candy properties thus has the capacity to deceive reasonable consumers into believing it is harmless for children. Second, Defendants use playful and silly graphics and words (e.g., a smiling strawberry, a unicorn with a rainbow tail) that are incongruent with a dangerous product. A product named "silly strawberry" with a cartoon smiley face does not sound to a reasonable consumer like a product that is too dangerous to be left in the reach of children. Third, Defendants boast of the pastes being free of ingredients that are unhealthy to ingest (i.e., dyes, preservatives, sugars, parabens), which implies that the paste itself is not unhealthy to ingest. *See Bell*, 982 F.3d at 479 ("Where a statement or claim is literally true or ambiguous . . . , a plaintiff must prove that the statement implicitly conveys a false impression, is misleading in context, or likely to deceive consumers." (citation omitted) (cleaned up)). Fourth, Defendant Colgate displays a full strip of toothpaste on the toothbrush, despite this being *up to 10 times more than safe and recommended amount* for a child under three.

Plaintiffs' contention that these advertising tactics are deceptive is not fanciful. Indeed, *public health researchers* far removed from the courtroom have long warned that these tactics will encourage unsafe use of fluoride toothpaste. ¶¶ 12-14, 122-127. Further, the use of candy flavors and the visual depiction of full strips of toothpaste have been specifically criticized as "misleading" in the *peer-reviewed academic literature*. ¶¶ 12, 127.

Defendants' attempt to dismiss the case for lack of plausible deception fails for a number of reasons. *First*, Defendants' attempt to absolve their deceptive packaging choices by pointing to the fine print on the back flies in the face of *Bell*. In *Bell*, the Seventh Circuit held that "[P]laintiffs'

claims survive if they have plausibly alleged that the defendants' front labels likely lead a significant portion of reasonable consumers to falsely believe *something that the back labels belie*." *Bell*, 982 F.3d at 476 (emphasis added);[6] *accord Whiteside v. Kimberly Clark Corp*., 108 F.4th 771, 778, 780 (9th Cir. 2024) ("You cannot take away in the back fine print what you gave on the front in large conspicuous print."). To defeat a Rule 12(b)(6) motion, the fine print "must *confirm* the expectations raised on the front, not contradict them." *Brady*, 26 Cal. App. 5th at 1167, 1172. If the fine print "conflict[s] with, rather than confirm[s], a front label claim,' the plaintiff's claim is not defeated."[7] *Moore v. Mars Petcare US, Inc*., 966 F.3d 1007, 1017 (9th Cir. 2020).

Here, the fine print on the back label conflicts with the prominent representations on the front and sides. The fine print warns "Keep out of reach of children," "minimize swallowing," and "get medical help or contact a Poison Control Center" if "more than used for brushing is accidentally swallowed." In contrast, the front and side labels talk about the products' delicious flavors, boasts of the absence of harmful ingredients, and use imagery and words that are more consistent with a fun candy-like product than a poison. The fine print thus contradicts, rather than confirms, the expectations created by the front and cannot be used on a motion to dismiss to defeat Plaintiffs' claim of deception. *Bell*, 982 F.3d at 476; *Moore*, 966 F.3d at 1017.

Defendants' discussion of deception is notably void of any citation to *Bell*. But Defendants do find space to cite two unpublished district court cases from other jurisdictions for the sweeping proposition that reasonable consumers of over-the-counter drugs necessarily read the directions. Mem. at 10-11. In so doing, Defendants fail to heed the repeated admonition from the Seventh

[6] While *Bell* involved a food product, courts have applied the front-back label rule to OTC drugs as well. *E.g., Tobin v. P&G*, 2024 WL 1560050, 2024 U.S. Dist. LEXIS 64831, at *10-15 (N.D. Cal. Apr. 9, 2024)*; Meza v. Coty, Inc*., 2023 WL 3082346, 2023 U.S. Dist. LEXIS 71163, at *20-28 (N.D. Cal. Apr. 24, 2023); *Fagan v. Neutrogena Corp*., 2014 WL 92255, 2014 U.S. Dist. LEXIS 2795, at *4-5 (C.D. Cal. Jan. 8, 2014).

[7] Courts have found that a front label is deceptive even when it has multiple possible meanings (some deceptive, some non-deceptive), so long as it is plausible for a reasonable consumer to view the label as having the deceptive meaning. *E.g*., *Whiteside*, 108 F.4th at 780-81. In *Bell*, for example, the front label had *three* plausible meanings, only one of which was deceptive. *Bell*, 982 F.3d at 475. Although the fine print on the back label clarified the correct meaning, *Bell* held that the fine print did not cure the deception as a matter of law. As *Bell* explained, "[i]t is well established, and critical to the notion of preventing false advertising, that where an advertisement conveys more than one meaning, one of which is false, the advertiser is liable for the misleading variation." *Id.* at 478.

Circuit that "consumers are likely to exhibit a low degree of care when purchasing low-priced, everyday items." *Kahn*, 107 F.4th at 597. This low degree of care for low-cost items, like toothpaste, "does not make consumers unreasonable—it makes them human. . . . But it also makes them vulnerable to exploitation by unfair and deceptive practices." *Id.* Defendants ask this Court to ignore this admonition by the Seventh Circuit and focus instead on an unpublished decision from Arkansas that addressed "One a Day" vitamin gummies. Mem. at 12-13 (citing *Howard v. Bayer Corp.*, 2011 WL 13224118, at *1 (E.D. Ark. July 22, 2011)). In so doing, Defendants ignore a published decision from California that addressed this very same product and, unlike *Howard*, did so in a manner consistent with Seventh Circuit law. *See Brady*, 26 Cal. App. 5th at 1170-75.

In *Brady*, the court rejected the notion that all "reasonable consumers of vitamins are *back-label scrutinizers*." *Id.* at 1174 (emphasis added). The court explained that "[n]ot all reasonable vitamin buyers can be said to be alike as a matter of law," because "the market among reasonable consumers of vitamins is not monolithic." 26 Cal. App. 5th at 1175. As the court explained, "[i]t may well be that engineers and scientists and the vitamin cognoscenti would make such an inquiry. But we are convinced other consumers—knowing they have very little scientific background—would rely upon the representation of a known brand with 70 years of goodwill and credibility behind it." *Id*. In short, the court concluded that "reasonable consumers within [the vitamin] market will represent many different approaches to vitamin purchases." *Id.* at 1175. The fact that *some* reasonable consumers would read the back of the label and thereby discover the deception did not defeat the claim that the front label was deceptive, because other reasonable consumers would *not*.

The same reasoning applies here. Some reasonable consumers will look at the fine print of Defendants' label, and these consumers will likely not permit their children to use more than a pea-sized amount of paste.[8] Other reasonable consumers will *not* read the fine print and will act solely on the deceptive representations on the front and sides. The law commands that this latter group

[8] Even the consumers who read the fine print will *still* be deceived because Defendants have added a statement (one that is *not* required by the FDA) that children two and older should use a pea-sized amount. A pea-sized amount is much more than a rice grain, which is the guideline amount for two-year olds. *See* ¶ 112 and accompanying photo.

of reasonable consumers be afforded a remedy for their loss.

Defendants' other arguments on Plaintiffs' false pretense/misrepresentation claim are equally meritless. First, Defendants mischaracterize the deception that Plaintiffs allege. The deception is not that the toothpastes can be used in "unlimited quantities" (which would include intentionally eating the whole tube) (Mem. 10-11), but that there is no need to "limit how much of the toothpaste to *put on the brush*."[9] ¶¶ 149, 156, 162, 169. Nor are Plaintiffs alleging that they "believe[] toothpaste is food." Mem. 1. Rather, Plaintiffs allege that the presentation of fluoride toothpaste as a candy-like product is a deceptive attribute that, together with the other deceptive attributes, implies a product that is safe for children to ingest in ordinary amounts. Put another way, a reasonable consumer does not expect a product that is too poisonous to be in reach of children to be presented as a silly, candy-like product for kids. Nor does a reasonable consumer expect the label to visually show an amount of paste on the brush that is up to 10 times the safe and recommended amount.

Second, Defendants argue that "[a] reasonable parent will not assume their child can eat toothpaste because of a picture of a unicorn . . . or a strawberry with a smiley face." Mem. 11. Not only does this argument mischaracterize the alleged deception (i.e., Plaintiffs are not claiming they thought the toothpastes could be eaten like food), but by focusing on only one deceptive element *in isolation* Defendants fail to consider the net impression[10] of all deceptive elements together. Thus, even if Defendants were correct that cartoon images by themselves do not imply the products' safety for kids, this says nothing about the *collective* impact of *all* the deceptive elements. *See Williams v. Gerber Prods. Co.*, 552 F.3d 934, 939 n.3 (9th Cir. 2008) (finding that a statement on the label, while not deceptive by itself, "certainly contributes . . . to the deceptive context of the

[9] It is not unreasonable for consumers (most of whom are unfamiliar with the details of fluoride science) to think that a kids toothpaste can be applied to the full strip of a toothbrush. *See* ¶¶ 172-74.

[10] *See FTC v. QT, Inc*., 448 F. Supp. 2d 908, 958 (N.D. Ill. 2006) ("In determining what messages or claims an ad communicates to reasonable consumers, the Court looks to the overall, net impression made by the advertisement to determine whether the net impression is such that the ads would be likely to mislead reasonable consumers.").

packaging as a whole"). While Defendants cite inapposite cases[11] finding that *cartoon* imagery did not convey that the drug at issue was formulated for infants, this does not speak to the collective impact of Defendants' marketing here. Defendants employ this same atomistic approach in their discussion of the full strip image, and their argument fails accordingly. *See* Mem. 12-13.

Third, Defendants summarily assert that the image of a full strip of toothpaste "cannot be reasonably construed as a direction for use" and, in any event, it is "not plausible" that a consumer would rely on a visual image instead of the fine print on the back. Mem. 12. *At best*, Defendants' arguments raise fact-intensive questions about how parents will interpret the full strip image. On one hand, Plaintiffs, *as with public health researchers*, claim that showing a full strip of toothpaste will encourage parents to use more than the safe and recommended amount of toothpaste. *See* ¶¶ 13-14, 127. This is especially so when the full-strip image is part of a set of visual instructions on how to use the toothpaste. ¶ 150. On the other hand, Defendants summarily insist that this is "not plausible." Mem. 12. At this juncture, the material point is that this is a factual dispute and should not be resolved as a matter of law. *See Bell*, 982 F.3d at 480 ("Plaintiffs are entitled to present evidence on how consumers actually understand these labels.").

Finally, to the extent that Defendants are arguing[12] that false pretense/misrepresentation claims require an *express* statement on the label, Defendants are wrong. Defendants cannot deceive consumers with implied messages and then, when challenged in court, point to the absence of express statements as a defense. Were this the law, the laws forbidding deceptive advertising would become a dead letter. *See, e.g.*, *Kahn*, 107 F.4th at 595-97; *Bell*, 982 F.3d at 477-80. Fortunately for consumers a deception need not be expressly stated to be actionable; a false pretense,[13] including an implied falsity, is sufficient. *Bell*, 982 F.3d at 477-80. Plaintiffs' burden here,

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[11] The two cartoon cases that Defendant cites addressed a product where the cartoon image of a baby was accompanied by "**bolded lettering**" that "**prominently**" provided correct and curative information on the **front** label. *See Eidmann v. Walgreen Co.*, 522 F. Supp. 3d 634, 646-47 (N.D. Cal. 2021); *Robinson v. Walgreens Co*., 2022 WL 204360, at *7 (N.D. Ill. Jan. 24, 2022)). No such bolded and prominent information is present on the label of Defendant's products, let alone on the front label. *Eidmann* and *Robinson* do little, therefore, to absolve Defendant of its deceptive packaging.

[12] *See* Mem. 11 (stating that "Plaintiffs do not plausibly allege . . . affirmative misrepresentations . . . .").

[13] While the ICFA does not define "false pretense," it has been defined in other contexts as "any untrue representation, including an implicit one." *United States v. Kucik*, 844 F.2d 493, 499 (7th Cir. 1988).

therefore, is not to show that Defendants' label *expressly* states "fluoride toothpaste is a candy-like product that young children can safely ingest," but to show that Defendants' labels lead a portion of reasonable consumers to falsely believe this. *See id.* at 476 ("[P]laintiffs' claims survive if they have plausibly alleged that the defendants' front labels *likely lead a significant portion of reasonable consumers to falsely believe* something that the back labels belie." (emphasis added)).

B. Plaintiffs Have Plausibly Pled a Concealment/Suppression Claim

In addition to prohibiting false pretenses, the ICFA prohibits the "concealment, suppression, *or* omission of any material fact." 815 ILCS 505/2 (emphasis added). The statute's use of the disjunctive "or" suggests that concealment/suppression require something less than the complete omission of the material fact. A "material fact" concerns "the type of information upon which a buyer would be expected to rely in making a decision whether to purchase." *Connick v. Suzuki Motor Co*., 174 Ill. 2d 482, 505 (1996). Plaintiffs have met that standard here.

First, Plaintiffs allege that Defendant Colgate concealed/suppressed material facts on its Unicorn Pump by hiding FDA's required directions and warnings. ¶¶ 212-18. There can be little dispute that these directions and warnings are material facts. ¶ 213. The only question is whether Defendant Colgate has concealed/suppressed them. Colgate summarily asserts that "nothing is remotely hidden from consumers," because the back label mentions the existence of "drug facts" behind the label. Mem. 14. But, as noted above, the standard is not complete omission. Here, a reasonable jury could conclude that the back label's reference to hidden drug facts is in fine print and much less prominent than the promotional claims that Colgate directs the consumer's attention towards. *See* ¶ 162e,f. A reasonable jury could also conclude that the difficulty and messiness of peeling back the label (a fact that Colgate does not address) will further hinder consumers from accessing the information. ¶ 162f. These facts are sufficient to establish concealment/suppression.

Plaintiffs have a separate claim for concealment/suppression based on Defendants' failure to disclose that ADA's approval of fluoride toothpaste is premised on kids under three using no more than a smear or rice grain of paste. ¶¶ 224-28. Again, there can be little dispute that this is a

material fact as it speaks to the dangers of the product for young children. ¶ 228. Nor is there any dispute that Defendants have concealed/suppressed this information because the label does *not* disclose it at all. *See* Bladow Decl., Exs A, B & D. It matters not if the absence of the ADA guideline "misleads reasonable consumers to use more toothpaste than the directions state" (Mem. 13), because concealment/suppression does not need to separately violate the misrepresentation prong of the ICFA.[14] If this were the law, the ICFA's reference to concealment and suppression would be rendered superfluous and redundant, which violates black letter rules of statutory construction. *See CFTC v. Worth Bullion Grp., Inc.*, 717 F.3d 545, 550 (7th Cir. 2013) ("In the absence of statutory definitions, the court accords words and phrases their ordinary and natural meaning and avoids rendering them meaningless, redundant, or superfluous." (cleaned up)).

C. The FDCA Does Not Expressly Preempt Any of Plaintiffs' Claims

Defendants are wrong that Plaintiffs' claims are expressly preempted. This is clear from the statutory text, regulatory text, and controlling case law in the Seventh Circuit. The rule in *this Circuit* (as opposed to the district court decisions from other jurisdictions that Defendants focus on) is that the FDCA does *not* preempt claims where, as here, (a) Plaintiffs seek to enforce a *state* law requirement that is *identical* to an FDCA requirement, and (b) the deceptive elements at issue are *not required* by the FDA.

Statutory Text: The FDCA prohibits states from establishing "any requirement" regarding OTC drugs "that is different from or in addition to, or that is otherwise not identical with, a requirement under" the Act. 21 U.S.C. § 379r(a). One requirement under the FDCA is that the labeling of a drug cannot be "false and misleading in any particular." 21 U.S.C. § 352(a). This requirement is identical to the prohibition on deceptive labeling found under state consumer protection statutes, including the ICFA. *Gibson v. Albertsons Co*., 754 F. Supp. 3d 793, 808 (N.D. Ill. 2024) ("This federal prohibition against false and misleading labels is 'identical' to the state laws at issue here, which similarly prohibit deceptive mislabeling."). Accordingly, in bringing an

[14] The cases that Defendants cite on this point involved claims that the certification seals were misrepresentations of the facts about the products at issue, not acts of concealment/suppression. *See* Mem. 13.

ICFA claim against Defendant for deceptive labeling, Plaintiffs are holding Defendants to a requirement that is *identical* to what Defendants are already obligated to do under the FDCA.

Regulatory Text: The FDCA's prohibition on false and misleading labeling has been expressly incorporated into FDA's regulations of all OTC drugs, *including fluoride toothpaste*. The first provision in the Anticaries Monograph (21 C.F.R. § 355.1) commands that, to be "generally recognized as safe and effective and not misbranded," fluoride toothpastes *must* comply with the conditions set forth in 21 C.F.R. § 330.1. One of the conditions in § 330.1 is that "[t]he product is labeled in compliance with chapter V," which includes the prohibition on false and misleading labeling. § 330.1(c). Thus, contrary to Defendant's incorrect suggestion to the contrary,[15] the requirement that Plaintiffs seek to enforce (i.e., prohibition on false/misleading labeling) is identical to the requirement that Defendant already has under the Anticaries Monograph itself. 21 C.F.R. § 355.1 (citing 21 C.F.R. § 330.1). A company that uses labeling for fluoride toothpaste that is false and misleading is thus in violation of the *Anticaries Monograph*.

Controlling Case Law: In *Bell v. Publix Super Mkts., Inc*., 982 F.3d 468 (7th Cir. 2020), the Seventh Circuit addressed an FDCA preemption dispute where the defendant complied with all of FDA's specific requirements, but added a representation to the label that FDA had not addressed and which the plaintiffs claimed was deceptive. *Bell* involved a cheese product whose label boasted of being "**100%** grated cheese" despite containing materials that were not cheese. 982 F.3d at 473. The defendant argued that state law challenges to its 100% assertion were preempted because FDA's regulations permitted the product to be described as "grated cheese" and did "not explicitly prohibit" the "100%" descriptor. *Id.* at 483. The Seventh Circuit disagreed. The court held that "[t]he FDCA's preemption provision means that, while states may not require sellers to add further labeling that is not required by federal law, they ***may prevent sellers from voluntarily adding deceptive content that is not required by federal law***." 982 F.3d at 485 (emphasis added). The Seventh Circuit provided the following example to explain its reasoning:

[15] Defendants characterizes the prohibition on false and misleading labeling as somehow separate and distinct from the conditions of the Monograph. Mem. 5-6. But it is *not* because the Monograph *incorporates* this condition.

> Suppose a defendant here labeled its product 'Grated Parmesan Cheese, 100% from Italy.' If the cheese did not actually come from Italy, state-law claims for deceptive advertising would not be preempted simply because the federal standard of identity does not explicitly ban such a statement. Such a result would stretch the FDCA's 'not identical to' language for express preemption beyond its breaking point.

Id.; *accord Souter v. Edgewell Pers. Care Co*., 542 F. Supp. 3d 1083, 1098 (S.D. Cal. 2021) ("[F]ederal law did not require defendants to represent that 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 choices.").

Although *Bell* addressed a food product, its holding "**squarely applies**" to OTC drug cases. *Calchi v. TopCo Assocs., LLC*, 752 F. Supp. 3d 955, 969 (N.D. Ill. 2024) (emphasis added). The *Calchi* court summarized the *Bell* framework for preemption in OTC drug cases as follows:

> A state can't add to the list of disclosure requirements imposed by the FDA. So, if the FDA requires a drug maker to disclose A, B, and C, a state can't add to the list and force a drug maker to disclose A, B, C, and D. . . . But when it comes to what a drug maker can't say, states have a little room to maneuver. A state can't prohibit a drug maker from disclosing A, B, and C if the federal government requires the disclosure of A, B, and C. . . . But if the federal government has not addressed a statement about D, then states can ban a statement about D if the states believe that D is false.

Id. at 969-70; *accord Gibson*, 754 F. Supp. 3d at 808-09 (applying *Bell* to same fact pattern as *Calchi* and finding no preemption).

Consistent with the *Bell* framework, many district courts have rejected preemption defenses in OTC drug cases where, as here, the defendant voluntarily adds an allegedly deceptive representation that the relevant monograph does not require.[16] The one exception in this Circuit is

[16] *See, e.g.*, *Newport v. CVS Pharmacy, Inc*., 757 F. Supp. 3d 931, 936-40 (E.D. Mo. 2024); *Tobin*, 2024 U.S. Dist. LEXIS 64831, at *5-9; *Stephens v. Target Corp*., 694 F. Supp. 3d 1136, 1142-46 (D. Minn. 2023); *Harris v. Supervalu, Inc*., No. 22-cv-2863, ECF No. 35 (N.D. Ill. July 16, 2024); *Davis v. Kroger Co*., 2023 WL 9511156, 2023 U.S. Dist. LEXIS 235055, at *13-21 (C.D. Cal. Sept. 22, 2023); *Zimmerman v. L'Oréal United States, Inc*., 2023 WL 4564552, 2023 U.S. Dist. LEXIS 122875, at *10-12 (N.D. Cal. July 17, 2023); *Slaten*, 2023 U.S. Dist. LEXIS 83883, at *4-9; *Meza* 2023 U.S. Dist. LEXIS 71163, at *10-14; *Lemus v. Rite Aid Corp*., 613 F. Supp. 3d 1269, 1275-76 (C.D. Cal. 2022); *McFall v. Perrigo Co*., 2021 WL 2327936, 2021 U.S. Dist. LEXIS 109451, at *17-29 (C.D. Cal. Apr. 15, 2021); *Souter.*, 542 F. Supp. 3d at 1096-98; *Moreno v. Vi-Jon, Inc*., 2021 WL 807683, 2021 U.S. Dist. LEXIS 40032, at *27-32 (S.D. Cal. Mar. 3, 2021); *Fagan*, 2014 U.S. Dist. LEXIS 2795, at *1-3; *Corra v. Energizer Holdings, Inc*., 962 F. Supp. 2d 1207, 1214-15 (E.D. Cal. 2013).

where the additional content is a *de minimis* alteration to FDA's approved language for the *indication*.[17]

Under the *Bell* framework, Plaintiffs' claims are not preempted because Defendants have voluntarily added advertising content to the label that the FDA has not approved. *See* ¶¶ 107-10. These "advertising choices" by Defendants are not shielded by the FDCA. *See Souter.*, 542 F. Supp. 3d at 1098. Nor does the one exception apply, because the deceptive content is *not* de minimis and does not involve the indication. Plaintiffs' claims are thus *not* expressly preempted.

Defendants' Arguments Are Meritless: Defendants make only one conspicuously brief reference to *Bell*, but manage to spend pages discussing cases from other jurisdictions, including cases that are squarely incompatible with *Bell*. Courts in this Circuit have rightfully shot down similar efforts to eschew *Bell* in favor of cherry-picked cases from other jurisdictions. *See, e.g.*, *Taylor v. Dave's Killer Bread, Inc.*, 2025 WL 71762, 2025 U.S. Dist. LEXIS 5151, at *10 (N.D. Ill. Jan. 10, 2025) (rejecting defendants' citation to "numerous district courts across the country" that found preemption, because "this Court is bound by Seventh Circuit precedent," including *Bell*). This Court should do the same.

Defendants' fleeting attempt to distinguish *Bell* is meritless. *See* Mem. 7. Defendants assert, without explanation, that *Bell* is distinguishable because it involved a product "where FDA regulations were 'silent' on the challenged issue." *Id*. (cleaned up). But, here too, the relevant regulations (i.e., Anticaries Monograph) are silent on the marketing tactics at issue. It matters not that the FDA generally considered the safety of fluoride toothpaste for children. In *Bell*, for example, the FDA had considered the subject matter at issue (i.e., whether grated cheese with non-cheese ingredients can still be described as "grated cheese"). *See* 982 F.3d at 481 (citing 21 C.F.R. § 133.146(c)). *Bell* nevertheless held that state law challenges to defendant's description of its product (which qualified as grated cheese under FDA's regulation) as "100% grated cheese" was

[17] *E.g.*, *Novotney v. Walgreen Co*., 683 F. Supp. 3d 785, 792 (N.D. Ill. 2023); *Wright v. Walmart, Inc*., 688 F. Supp. 3d 794, 805 (S.D. Ill. 2023); *Abron v. Vi-Jon, LLC*, No. 22 C 50238, 2023 U.S. Dist. LEXIS 247459, at *9-13 (N.D. Ill. June 20, 2023).

not preempted. *See* 982 F.3d at 481 (citing 21 C.F.R. § 133.146(c)). There is nothing about the deceptive tactics at issue here that are more "related" to the "subject matter" of the Anticaries Monograph than the deceptive statement at issue in *Bell* was related to the subject matter of FDA's regulation of grated cheese.

Defendants' theory that the FDCA preempts all deceptive statements that are related to the subject matter of a monograph should also be rejected because it leads to absurd results. *See United States v. Vallery*, 437 F.3d 626, 630 (7th Cir. 2006) (explaining that statutes should not be construed in ways that produce "absurd results"). For example, if Defendants' label showed an image of a toddler eating toothpaste with the caption "tastes great!," challenges to that label would be preempted because the FDA considered the safety of fluoride toothpaste and did not prohibit this representation. This absurd result, which is commanded by Defendants' maximalist theory, stretches the scope of preemption "beyond its breaking point." *See Bell*, 982 F.3d at 485; *accord Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 758 (9th Cir. 2015) (rejecting defendant's argument that "the FDA's failure to issue specific regulations on the subject is tantamount to a conscious decision by the agency to permit any use of this term a manufacturer sees fit" because "[b]y this logic, a manufacturer could make any claim—wild, untruthful, or otherwise—about a product whose contents are not addressed by a specific regulation").

Defendants base their maximalist theory of preemption on district court cases from other jurisdictions that are plainly incompatible with the Seventh Circuit's holding in *Bell*.[18] Asking this Court to adopt this maximalist theory of preemption is akin to asking to override *Bell*.

Defendants also rely on cases where plaintiffs were seeking to compel the disclosure of information that is not required under the FDCA.[19] These cases do little to advance Defendants'

[18] Mem. 6-8 (citing *Seale v. GSK Consumer Health, Inc*., 718 F. Supp. 3d 1208 (C.D. Cal. 2024); *Silva v. Haleon US, Inc.*, 758 F. Supp. 3d 1082 (N.D. Cal. 2024); *Goldstein v. Walmart, Inc.*, 673 F. Supp. 3d 95 (S.D.N.Y. 2022); *Wiltz v. Chattem, Inc.*, 2015 WL 3862368 (C.D. Cal. May 8, 2015); *Bowling v. Johnson & Johnson*, 65 F.3d 371 (S.D.N.Y. 2014)).

[19] *See Critcher v. L'Oreal USA, Inc*., 959 F.3d 31, 36 (2d Cir. 2020) (dismissing claim because under Plaintiff's theory "L'Oreal must make an additional disclosure on its packaging"); *Turek v. Gen. Mills, Inc*., 662 F.3d 423, 427 (7th Cir. 2011) (explaining that the "disclaimers that the Plaintiffs wants added to the labeling . . . are not identical to the

argument because Plaintiffs do not seek to compel any such disclosures. ¶ 28.[20] Equally inapposite are cases where plaintiffs were challenging *de minimus* differences between the *indication* statements on the label and those which FDA had approved.[21] The deceptive elements at issue here are *not* de minimis, and deal with *safety*, not efficacy. As one of the cases Defendants cite explains, the structure of the FDCA supports a *less* expansive scope of preemption for *safety* claims, than efficacy claims. *In re Oral Phenylephrine*, 755 F. Supp. 3d 208, 216-17 & n. 4 (E.D.N.Y. 2014).

Lastly, Defendants erroneously state that FDA "already carefully considered" the marketing tactics at issue here. Mem. 6. Defendants do not point to any regulatory history to support this statement *because such history does not exist*.[22] The FDA can hardly be said to have approved marketing tactics that it never considered. But even if the FDA *had* addressed these tactics during its regulatory deliberations (it did not), such discussions would only have preemptive effect if the discussions resulted in an actual rule. *See Stephens*, 694 F. Supp. 3d at 1144-45.

D. The FDCA Does Not Impliedly Preempt Plaintiff's Concealment/Suppression Claim

Plaintiffs' claim that the Unicorn Pump product conceals/suppresses the directions and warnings is not impliedly preempted, contrary to Defendants' contention (Mem. 14-15), because

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[FDA's] labeling requirements"); *Harris v. Topco Assocs., LLC*, 538 F. Supp. 3d 826, 833 (N.D. Ill. 2021) ("Simply put, Harris is asking more than what the TFM requires.").

[20] Plaintiffs' concealment claim regarding the ADA seal of approval (i.e., Defendants concealed ADA's position on the safe amount of toothpaste) does not call for, nor require, compelling a disclosure. The FDA has made clear that if an ADA seal of approval is included on the label, it is subject to the prohibition on deceptive labeling. ¶ 144 n. 99 (citing 50 Fed. Reg. 39867). Thus, because Defendants have voluntarily chosen to show ADA's seal of approval, they have an obligation to do so in a way that is not false and misleading. While states do not have the authority to compel Defendants to disclose ADA's rice grain-recommendation (because such disclosure is not mandated by the FDCA), states *do* have the authority to prohibit Defendants from displaying the ADA seal in ways that are deceptive.

[21] Mem. 5-8 (citing *Silva*, 758 F. Supp. 3d 1082; *In re Oral Phenylephrine*, 755 F. Supp. 3d 208; *Novotney v. Walgreen Co*., 683 F. Supp. 3d 785; *Sapienza v. Albertson's Co., Inc*., 2022 WL 17404919 (D. Mass. Dec. 2, 2022)).

[22] The undersigned Plaintiff's counsel has reviewed the complete rulemaking history of the Anticaries Monograph and found it to be devoid of any discussion of the marketing tactics at issue in this case, including the use of kid-enticing fruit/candy flavors and language conveying a harmless product. *See* https://www.fda.gov/drugs/historical-status-otc-rulemakings/rulemaking-history-otc-anticaries-drug-products (providing the complete rulemaking history for the Anticaries Monograph, with links to every Federal Register document that FDA published regarding it).

the concealment/suppression violates *state* law and is actionable *even if the FDCA did not exist*. To avoid preemption, "[t]he Plaintiffs must be suing for conduct that *violates* the FDCA . . ., but the Plaintiffs must not be suing *because* the conduct violates the FDCA." *Bryant v. Medtronic, Inc*., 623 F.3d 1200, 1204 (8th Cir. 2010). Here, Defendants' concealment/suppression of the directions/warnings violates the FDCA (¶¶ 215-216), but Plaintiffs do not bring their claim *because* of this fact. Instead, Plaintiffs bring the claim because Defendants' conduct separately violates the ICFA's prohibition on concealing/suppressing material facts. *See Moreno v. Vi-Jon, Inc*., 2021 U.S. Dist. LEXIS 40032, at *30 ("Generally, courts have found that claims based on parallel state laws that mirror the relevant sections of the FDCA are not preempted by the Act."). The ICFA's prohibition on concealing/suppressing material facts is "grounded in traditional state law principles of liability," *Taylor*, 2025 U.S. Dist. LEXIS 5151, at *12-13, and "firmly rooted in the states' historic power to protect citizens' health and safety," *Markoff v. Athena Cosmetics, Inc*., 764 F. Supp. 3d 733, 742 (N.D. Ill. 2025) (Wood, J.). In short, holding Defendants accountable for concealing/suppressing material facts about the dangers of fluoride toothpaste is not impliedly preempted because the liability would exist even if the FDCA did not.

E. Plaintiffs Have Plausibly Pled Actual Loss

Defendants rely upon inapposite cases on deceptive pricing for their threadbare argument that Plaintiffs have not alleged actual loss. Mem. 15 (citing *Camasta v. Jos. A. Bank Clothiers, Inc.*, 761 F.3d 732, 739 (7th Cir. 2014) and *Kim v. Carter's Inc.*, 598 F.3d 362, 365 (7th Cir. 2010)). In *Camasta* and *Kim*, the plaintiffs received the "benefit of the bargain" as they did not allege there was anything "defective" about the products. *Camasta*, 761 F.3d at 739-40; *Kim*, 598 F.3d at 365-66. Here, by contrast, Plaintiffs did not receive the "benefit of the bargain" because the products are unsafe, and thereby defective, when used in ways that Defendants' advertising tactics

encourage (i.e., in amounts exceeding the guidelines). Based on this deception, Plaintiffs received up to 10 times less brushings per tube than they would have received had they not been deceived, which is akin to Plaintiffs receiving 1/10th of the bargained-for amount of the products.[23] ¶ 178. This is actual pecuniary harm, which in turn becomes Defendants' unjust financial gain. Consumers have to purchase much more of the product, and Defendants thereby sell much more of it, which is precisely why these deceptive marketing tactics are used. ¶¶ 12, 177-78.[24]

F. The Allegations on Fluoride's Toxicity Are Relevant and Should Not Be Stricken

A motion to strike "inflammatory" allegations under Fed. R. Civ. P. 12(f) "should not be granted unless . . . the language in the pleading has 'no possible relation' to the controversy and is clearly prejudicial." *Volling v. Antioch Rescue Squad*, 999 F. Supp. 2d 991, 1007 (N.D. Ill. 2013) (citation omitted). Defendants have fallen far short of this high bar. Mem. 15. Defendants move to strike allegations describing (a) why young children are more vulnerable to suffering harm from fluoride toothpaste (e.g., ¶¶ 71-76); (b) the ability of fluoride toothpaste to cause dental fluorosis and a description of what fluorosis is (¶¶ 74-86); and (c) the other hazards of ingesting too much fluoride toothpaste (¶¶ 20-21, 24-26, 87-108). The relevance of these allegations does not rest on whether Plaintiffs allege physical harm, because the allegations are relevant to proving the deception. *See In re Aqua Dots Prods. Liab. Litig*., 654 F.3d 748, 750-51 (7th Cir. 2011) (holding that a product's risks are relevant to a false advertising claim even if plaintiffs have not suffered physical injury).

[23] Inherent to the bargain for any consumer good is that the good can be safely used as advertised.

[24] If footnote 9 of Defendants' memorandum is read as a challenge to Plaintiffs' standing, this is a matter for class certification, not a Rule 12(b)(6) motion. *Santiago v. Tesla, Inc*., 757 F. Supp.3d 831, 839 (N.D. Ill. 2024).

Dated: September 12, 2025

Respectfully Submitted,

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