

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

SHELLY BENSON and LISA CAPARELLIL,
individually and on behalf of all others
similarly situated,

Plaintiffs,

v.

NEWELL BRANDS INC. and
NUK USA LLC,

Defendants.

CASE NO.

CLASS ACTION

COMPLAINT

JURY TRIAL DEMANDED

Plaintiffs Shelly Benson and Lisa Caparellil (“Plaintiffs”), by their undersigned counsel, bring this class action complaint against Defendants Newell Brands Inc. and NUK USA LLC (collectively, “Defendants”), individually and on behalf of all others similarly situated, and allege upon personal knowledge as to their acts and experiences, and as to all other matters, upon information and belief, including the investigation conducted by Plaintiffs’ attorneys.

NATURE OF THIS ACTION

1. This is a consumer protection class action arising out of Defendants’ false and misleading advertising of its “orthodontic” pacifiers. Defendants’ deceptive marketing practices include: (1) the deceptive misrepresentation that its pacifiers are “orthodontic,” which is deceptive and misleading to reasonable consumers; and (2) the omission of material facts concerning the risks associated with pacifier use by children over the age of 24 months.

2. As more fully described below, prolonged pacifier use by children over the age of 24 months can cause significant harm by interfering with the proper development of their teeth and orofacial structures. Children who use pacifiers to continue non-nutritive sucking habits past the age of 24 months have an increased risk of dental malocclusions—deviations from the ideal

occlusion (the relation between the upper jaw and teeth and lower jaw and teeth)—of primary teeth, which, in turn, may interfere with a child’s chewing, swallowing, speech, and jaw development and function. Dental malocclusions and teeth misalignment may also have a significant adverse effect on a child’s psychosocial development, self-image, and social well-being.

3. Defendants manufacture, market, distribute, and sell a line of “orthodontic” pacifiers throughout Illinois and nationwide. Defendants’ “orthodontic” pacifiers come in a variety of styles, colors, and sizes. Defendants’ product packaging prominently displays an age range or age minimum for each size. According to the product packaging and labeling, the largest pacifiers in Defendants’ line of “orthodontic” pacifiers are for children aged 18 to 36 months, or for children 18 months and older.

4. “Orthodontics” is the branch of dentistry that corrects teeth and jaws that are positioned improperly. Through marketing, advertising statements, and misleading use of the term “orthodontic,” Defendants affirmatively represent to reasonable consumers that their pacifiers are beneficial for dental health or alignment of the teeth and jaws. In addition, Defendants represent that their pacifiers are (1) safe for children over the age of 24 months, and (2) beneficial to children over the age of 24 months.

5. There is no FDA-approved or widely accepted definition of an “orthodontic” pacifier. Defendants’ advertisement and use of the term “orthodontic” pacifier is misleading to a reasonable consumer and is an affirmative representation that the products promote healthy oral and orofacial development in children, including children over the age of 24 months. Defendants’ use of the term “orthodontic” is designed to induce consumers to pay a premium price and to buy products that do not perform as promised for their children while wrongly believing that those

products are not only harmless, but that they enhance their child's oral and orofacial health. Despite their false and misleading marketing practices, Defendants' "orthodontic" pacifiers do not eliminate the various dental malocclusions caused by prolonged pacifier use. Defendants' "orthodontic" pacifiers cannot and do not support the healthy oral and orofacial development of children 24 months or older. Indeed, they do not provide any material orthodontic benefit for children of any age.

6. On their product packaging and in their marketing and advertising, Defendants fail to disclose the material fact that prolonged pacifier use by children 24 months or older is detrimental to oral and orofacial health and development, or that such use increases the risk of developing numerous forms of dental malocclusions and teeth misalignment.

7. Defendants' "orthodontic" pacifiers put children at an increased risk of numerous types of dental malocclusions, are harmful to children over the age of 24 months, and do not support or improve children's oral or orofacial health and development.

8. Through false, misleading and deceptive advertisements, Defendants have violated Illinois' consumer protection statute by: (1) representing that their "orthodontic" pacifiers promote healthy oral and orofacial development in children and (2) failing to clearly and conspicuously disclose the material fact that use of Defendants' "orthodontic" pacifiers by children 24 months or older increases the risk of malocclusions and misalignment of primary teeth.

9. Plaintiffs assert claims for injunctive relief and restitution arising from Defendants' false, misleading, and deceptive advertising and Defendants' failure to disclose the material risks of use of their products by children over the age of 24 months. Plaintiffs allege violations of Illinois' Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 502/1, *et seq.* ("Illinois Consumer Fraud Act").

10. Plaintiffs bring this action on behalf of themselves and a Class of similarly situated consumers who purchased an “orthodontic” pacifier manufactured by Defendants, as well as a Subclass of consumers who purchased an “orthodontic” pacifier manufactured by Defendants that was labeled for use by children 24 months or older and used by a child aged 24 months or older, during the class period.

11. Plaintiffs, for themselves and for the Class, bring this suit to halt Defendants’ dissemination of false and misleading representations, to correct the false and misleading perception that Defendants’ representations have created in the minds of reasonable consumers, to ensure that appropriate disclosures and warnings are placed on Defendants’ products in the future, and to obtain redress for those who have purchased Defendants’ “orthodontic” pacifiers.

12. Plaintiffs, for themselves and for the Class, seek injunctive and other equitable relief, damages, restitution, and costs of suit and reasonable attorneys’ fees.

JURISDICTION AND VENUE

13. The Court has original jurisdiction under 28 U.S.C. § 1332(d)(2) because the matter in controversy, exclusive of interests and costs, exceeds the sum or value of \$5,000,000 and is a class action in which there are in excess of 100 class members, and some of the members of the class are citizens of states different from Defendants.

14. This Court has personal jurisdiction over Defendants because Defendants conduct business in Illinois. Defendants have marketed, promoted, distributed, and sold the “orthodontic” pacifiers at issue in Illinois, rendering exercise of jurisdiction by Illinois courts permissible.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(a) and (b) because a substantial part of the events and omissions giving rise to Plaintiffs’ claims occurred in this district.

PARTIES

16. Plaintiff Shelly Benson (“Plaintiff Benson”) is a citizen of Illinois and, at all relevant times to this action, resided in Elgin, Illinois.

17. In approximately January 2018, Plaintiff Benson purchased one of Defendants’ “orthodontic” pacifiers for her child at Walmart located in Elgin, Illinois, for approximately \$8.99. The packaging on the pacifier purchased by Plaintiff Benson had the following prominently displayed in the top right corner of the packaging: “18-36 m,” clearly indicating that the pacifier was intended for use by a child over the age of 24 months. Plaintiff Benson purchased the pacifier for her child who was approximately 24 months at the time of purchase. Defendants failed to disclose clearly and conspicuously the material facts that, contrary to Defendants’ advertising and marketing statements, the pacifier was not an orthodontic product and that prolonged pacifier use by children aged 24 months or older is associated with an increased risk of various malocclusions of children’s primary teeth. Plaintiff Benson would not have purchased Defendants’ “orthodontic” pacifier for use by her child at age 24 months or would have paid less for the pacifier but for Defendants’ misrepresentations and omissions of material facts. By purchasing the falsely advertised product without any warning about risks associated with the use of that product by children over the age of 24 months, Plaintiff Benson suffered injury-in-fact and lost money.

18. The NUK “orthodontic” pacifier Plaintiff Benson purchased, like all of Defendants’ pacifiers at issue, is neither an orthodontic product nor safe for use by children over the age of 24 months. Plaintiff Benson purchased the NUK “orthodontic” pacifier because she believed, based on the representations made by Defendants, that the “orthodontic” pacifier would improve dental health outcomes, including oral and orofacial health and development. Had Plaintiff Benson known the truth about Defendants’ misrepresentations and omissions at the time of purchase,

Plaintiff would not have purchased Defendants' "orthodontic" pacifier for her child who was 24 months old at the time of the purchase or would have paid less for the pacifier.

19. Plaintiff Lisa Caparellil ("Plaintiff Caparellil") is a citizen of Illinois and, at all times relevant to this action, resided in Plainfield, Illinois.

20. In approximately December 2018 or January 2019, Plaintiff Caparellil purchased one of Defendants' "orthodontic" pacifiers for her child at Walmart located in Plainfield, Illinois for approximately \$8.99. The packaging on the pacifier purchased by Plaintiff Caparellil had the following prominently displayed in the top right corner of the packaging: "18-36 m," clearly indicating that the pacifier was intended for use by a child over the age of 24 months. Plaintiff Caparellil purchased the pacifier for her child who was approximately four years old at the time of purchase. Defendants failed to disclose clearly and conspicuously the material facts that, contrary to Defendants' advertising and marketing statements, the pacifier was not an orthodontic product and that prolonged pacifier use by children aged 24 months or older is associated with an increased risk of various malocclusions of children's primary teeth. Plaintiff Caparellil would not have purchased Defendants' "orthodontic" pacifier for use by her child who was nearly four years of age or would have paid less for the pacifier but for Defendants' misrepresentations and omissions of material facts. By purchasing the falsely advertised product without any warning about risks associated with the use of that product by children over the age of 24 months, Plaintiff Caparellil suffered injury-in-fact and lost money.

21. The NUK "orthodontic" pacifier Plaintiff Caparellil purchased, like all of Defendants' pacifiers at issue, is neither an orthodontic product nor safe for use by children over the age of 24 months. Plaintiff Caparellil purchased the NUK "orthodontic" pacifier because she believed, based on the representations made by Defendants, that the "orthodontic" pacifier would

improve dental health outcomes, including oral and orofacial health and development. Had Plaintiff Caparellil known the truth about Defendants' misrepresentations and omissions at the time of purchase, Plaintiff Caparellil would not have purchased Defendants' "orthodontic" pacifier for her child who was nearly four years old at the time of the purchase or would have paid less for the pacifier.

22. Defendant Newell Brands Inc. is a Delaware corporation with its principal place of business located at 221 River Street, Hoboken, New Jersey 07030. The NUK brand of pacifiers was originally marketed and sold by the Gerber Products Company. In or about October 2008, Nestle sold part of its Gerber business to Total S.A., which owned various businesses including Mapa Spontex, a global manufacturer and distributor of baby care and home care products. In or about April 2010, Jarden Corporation acquired Mapa Spontex from Total S.A., including Total S.A.'s Gerber business segment, which included NUK pacifiers. In or about December 2015, Newell Rubbermaid acquired Jarden Corporation. When the acquisition closed in or about April 2016, the combined corporation was renamed Newell Brands Inc.

23. Defendant NUK USA LLC is a wholly owned subsidiary of Newell Brands Inc., the principal place of business of which is located at 728 Booster Boulevard, Reedsburg, Wisconsin 54959. Defendant NUK USA LLC is a distributor of NUK pacifiers in the United States, including in Illinois and this district.

24. Defendants Newell Brands Inc. and NUK USA LLC (collectively, "NUK") have marketed, advertised, and sold NUK pacifiers, including NUK "orthodontic" pacifiers, in Illinois, this district, and throughout the United States.

FACTUAL ALLEGATIONS

I. Defendants' Line of "Orthodontic" Pacifiers

25. NUK manufactures, markets, distributes, and sells a line of "orthodontic" pacifiers. The "orthodontic" pacifiers at issue are sold at various brick-and-mortar retail and grocery stores, including Target, Walgreens, CVS, Walmart, buybuyBaby, and Safeway. Defendants' "orthodontic" pacifiers are also sold online through the websites of the same retailers, as well as on Amazon and other online retailers.

26. Defendants' "orthodontic" pacifiers at issue are sold under the NUK[®] brand name (collectively, the "Orthodontic Pacifiers") and include the following products, as well as any other NUK[®] branded "orthodontic" pacifiers:

- NUK[®] Orthodontic Pacifiers
- NUK[®] Space[™] Orthodontic Pacifiers
- NUK[®] Latex Orthodontic Pacifiers
- NUK[®] Sports Orthodontic Pacifiers
- NUK[®] Confetti Orthodontic Pacifiers
- NUK[®] Fashion Orthodontic Pacifiers
- NUK[®] Sensitive[™] Orthodontic Pacifiers
- NUK[®] Juicy Orthodontic Pacifiers.

II. Defendants' False and Deceptive Advertising

27. Defendants, through their advertisements, including on the Orthodontic Pacifiers' packaging and labeling, have consistently conveyed to consumers in Illinois and throughout the United States that their Orthodontic Pacifiers are safe for use by children 24 months and older and

that they promote healthy oral and orofacial development for children of all ages.

28. Defendants' use of the word "orthodontic" conveys to reasonable consumers that the Orthodontic Pacifiers improve dental health outcomes by correcting teeth and jaws that are positioned improperly. This representation is false and misleading because the Orthodontic Pacifiers do not benefit dental health in this manner.

29. Defendants display an age range or minimum age on the packaging of each Orthodontic Pacifier. The age range or minimum age is prominently displayed on the top right corner of each pacifier package. According to the product packaging and labeling, the largest of Defendants' Orthodontic Pacifiers are for children aged 18 to 36 months (labeled as "18-36 m"), or for children 18 months and older (labeled as "18+ m"). These age ranges or minimum ages (with no maximum age) are intended to induce consumers to purchase NUK's Orthodontic Pacifiers for children 24 months or older. Defendants' advertising statements on the product packaging falsely convey to consumers that the Orthodontic Pacifiers are safe for use by children 24 months and older.

30. In addition to the misleading age ranges or minimum ages, the packaging for some of NUK's Orthodontic Pacifiers at issue here, including but not limited to those labeled for use by children 18 months and older, include the following statements:

- "Orthodontic Pacifier"
- "Soothes and calms baby better"
- "100% baby approved orthodontic shape"
- "Naturally Fits Baby's Mouth for Healthy Oral Development"

31. The product packaging for all of NUK's Orthodontic Pacifiers refers consumers to Defendant NUK USA LLC's website: www.nuk-usa.com. Defendants' online advertising

statements on that website corroborate the misleading nature of the product packaging. A product webpage for each of NUK's Orthodontic Pacifiers is available on the website, and each webpage for the Orthodontic Pacifier at issue here, labeled for use by children between the ages of 18 and 36 months and identified as such on the website, includes the following statements:

- “NUK®’s asymmetrical nipple naturally fits baby’s palate and is now improved to allow for more room for a natural sucking motion, reduce pressure on teeth and jaw, and helps prevent teeth misalignment.”
- “ideal for your child aged 18-36 months”
- “Orthodontic nipple shape is asymmetrical with a scooped bottom: Flatter to allow more room for natural sucking motion, slimmer to reduce pressure on jaw and teeth, and narrower to help prevent teeth misalignment”

32. In addition, on its website, www.nuk-usa.com, NUK claims that it makes a “truly orthodontic pacifier, which fits baby’s mouth better with its unique top and bottom shape,” and which “promotes the natural development of jaw and teeth.” *See* <https://www.nuk-usa.com/orthodontic-pacifier/orthodontic-pacifier.html>.

33. And lastly, the Frequently Asked Questions on Defendant NUK USA LLC’s website further claims that the “orthodontic nipple is asymmetrical to promote healthy oral development,” and that “NUK® pacifiers also promote the natural development of baby’s teeth and jaw through integrated channels on the orthodontic nipple that reduce jaw and palate pressure.” *See* <https://www.nuk-usa.com/faq.html>.

34. This website marketing confirms Defendants’ intent to mislead reasonable consumers regarding the orthodontic nature of the pacifiers.

35. In their product advertising statements, Defendants fail to disclose—on the product

packaging and labeling of Orthodontic Pacifiers, on their website, or elsewhere—the well-documented risks associated with prolonged pacifier use by children over the age of 24 months.

36. Defendants are well aware of the risks of prolonged pacifier use to children’s oral and orofacial health, most notably the risk of various dental malocclusions. Given that Defendants clearly market and label their Orthodontic Pacifiers for children over the age of 24 months, Defendants mislead reasonable consumers by failing to prominently and conspicuously disclose these risks on their Orthodontic Pacifier product packaging and advertising materials that would otherwise not be known to reasonable consumers given Defendants’ labeling and marketing of the Orthodontic Pacifiers as “orthodontic.”

37. Based on these representations, it is clear that Defendants intend to induce in consumers a common belief that NUK’s Orthodontic Pacifiers do not pose any risk to the oral or orofacial health of children over the age of 24 months and, further, that the Orthodontic Pacifiers enhance children’s oral and orofacial health and development.

III. Scientific Studies Confirm That Defendants’ Representations Are False, Deceptive, and Misleading.

38. Despite Defendants’ statements and representations, its Orthodontic Pacifiers pose significant health risks to children over the age of 24 months and do not provide orthodontic benefits to children even under the age of 24 months. Decades of research studies have established the relationship between prolonged non-nutritive oral habits like pacifier sucking and the development of malocclusion traits as well as alterations to oral myofunctional structures. More significant, however, are the numerous studies that consistently demonstrate that there is no scientific evidence “to support the concept that the usage of orthodontic pacifiers is able to prevent

malocclusion traits when compared to the usage of conventional pacifiers.”¹ As a result, children who use a pacifier, regardless of the pacifier’s shape, will have higher rates of, and an increased risk for, malocclusion traits and other oral-health related issues than children with no pacifier sucking habits. *Id.* at 294.

DENTAL AND ORTHODONTIC LITERATURE AND STUDIES

A. Early Studies Linking Pacifier Usage to Dental Malocclusions

39. The use of objects to satisfy infants’ natural sucking instincts is a historically well-established practice, but the modern pacifier, in particular the so-called “orthodontic” pacifier, is a fairly recent innovation, dating back to the late 1950s when the first orthodontic pacifier was introduced in the United States and marketed to the public: the Nuk™ Functional Orthodontic Nursing Nipple and Orthodontic Pacifier/Exerciser.²

40. Pacifiers are useful for infants during the first three months of life when their sucking needs are greatest because, if their natural “sucking urge is not completely satisfied by breast or bottle feeding, the infant will have a surplus of sucking urge which may lead either to frustration or to satisfaction.”³ However, “[a]t approximately the seventh month, [the sucking urge] decreases and can be considered unnecessary in the neurophysiological perspective. This occurs because the neuromuscular structures at this stage are being matured and prepared for coordinated eating and drinking activities. Thus, from this age onwards, sucking must gradually be substituted

¹ R. Medeiros et al., *Malocclusion Prevention Through the Usage of an Orthodontic Pacifier Compared to a Conventional Pacifier: a Systematic Review*, 19:5 *Eur. Arch. Paediatr. Dent.* 287, 287 (2018).

² S. Adair et al., *Effects of Current and Former Pacifier Use on the Dentition of 24- to 59-Month Old Children*, 17:7 *Pediatr. Dent.* 437, 437 (1995).

³ C. Zardetto et al., *Effects of Different Pacifiers on the Primary Dentition and Oral Myofunctional Structures of Preschool Children*, 24 *Pediatr. Dent.* 552, 552-53 (2002).

(footnote continued)

by mastication.” *Id.*

41. Studies dating back to as early as the 1870s have consistently demonstrated the link between non-nutritive sucking habits and abnormalities in dental development and occlusion.⁴ By the time the first “functional/orthodontic” pacifier was introduced in the 1950s, it was well understood that non-nutritive sucking “leads to reduced overbite, as well as increased overjet, protrusion of the maxillary incisors and a narrowing of maxillary posterior arch width.” *Id.* (internal citation omitted).

42. Since the 1960s, hundreds of studies have evaluated the effects of prolonged pacifier usage on children’s oral development, affirming the findings of earlier research, and establishing the link between prolonged non-nutritive sucking in the form of pacifier usage and the development of malocclusions and impaired development of orofacial structures.⁵

B. “Orthodontic” Versus Conventional Pacifiers

43. Adair et al. were among the first to conduct clinical studies directly examining the effects of using an “orthodontic” pacifier as compared to using a conventional pacifier. *See* Adair, *supra* note 2. Adair’s 1995 study evaluated the occlusions of 24- to 59-month-old current and former pacifier users and compared them to children of the same age with no non-nutritive sucking habit. *Id.* The study confirmed the findings of previous studies that, when compared to habit-free children, “children with a history of pacifier use have a significantly higher occurrence of increased overjet, a greater mean overjet, [] reduced overbite . . . [and] the prevalences [sic] of posterior

⁴ *See* J. Warren et al., *Effects of Oral Habits’ Duration on Dental Characteristics in the Primary Dentition*, 132:12 J. Am. Dent. Assoc. 1685, 1685 (2001) *citing* Campbell M., *Fruitless Sucking*, 13 Brit. J. Dent. Sci. 371 (1870), Chandler TH, *Thumb-Sucking*, 20 Dent. Cosmos 440 (1878).

⁵ *See* K. Schmid et al., *The Effect of Pacifier Sucking on Orofacial Structures: a Systematic Literature Review*, 19:8 Prog. Orthod. 1 (2018).

crossbites and openbites were also higher.” *Id.* at 442 (internal citations omitted).

44. With respect to whether there were any differences in the occurrence of dental malocclusions between children who used an “orthodontic” pacifier versus a conventional pacifier, Adair et al. found that “[c]omparison of the two pacifier groups does not support the purported advantages of functional exercisers over conventional pacifiers. No significant differences were found for mean overjet, mean openbite, occurrence of openbite, or occurrence of posterior crossbite.” *Id.*⁶

45. In 2002, Zardetto et al. conducted a study to evaluate and compare dental arch characteristics and oral myofunctional structures of 36 to 60-month-old children who: (1) exclusively used an “orthodontic” pacifier; (2) exclusively used a conventional pacifier; or (3) were habit free. *See Zardetto et al., supra* note 3. “In agreement with many studies performed earlier, children with a pacifier sucking habit in this study showed greater alterations on primary occlusion, such as anterior open bite, posterior crossbite, Class II primary canine relationship, decrease of upper intercanine width, [] increased overjet . . . [and] alterations on the shape of hard palate and tonicity of lips and tongue” when compared to habit-free children. *Id.* at 558.

46. Zardetto, like Adair, found no substantial differences in the occurrence of dental malocclusions between children who used an “orthodontic” pacifier versus a conventional pacifier. “Children who were pacifier users (physiological and conventional) were significantly more likely to show open bite, posterior crossbite, increased overjet, and alteration in cheek mobility than habit free children.” *Id.* at 559.⁷

⁶ Adair et al. refer to “orthodontic” pacifiers as “functional exercisers,” in reference to the original Nuk™ branding from the first line of orthodontic pacifiers.

⁷ Zardetto and many dental and orthodontic researchers advocate that a more appropriate term for (footnote continued)

47. More recently, in 2016, Lima et al. examined the effects of conventional and “orthodontic” pacifiers on the dental occlusions of children between the ages of 24 and 36 months.⁸ The study found that: “prolonged pacifier use was associated with various types of [malocclusion] in the primary dentition, corroborating results of previous studies. The most prevalent types of [malocclusion] in the primary dentition were [anterior overjet], [anterior overbite], and [posterior crossbite]. The prevalence and intensity of [malocclusion] were much lower among the children who did not use pacifiers, which confirms the results of previous studies.” *Id.* at 8-9 (internal citations omitted). These outcomes were observed regardless of the type of pacifier used. *Id.* at 10-11.

48. Consistent with the Adair, Zardetto, and Lima studies described above, nearly every clinical study examining the effects of the prolonged use of orthodontic pacifiers has found that there is no advantage or benefit to using an orthodontic pacifier over a conventional pacifier, and that prolonged use of an “orthodontic” pacifier results in the same risks and harms as would occur with a prolonged non-nutritive sucking habit. *See* Medeiros et al., *supra* note 1.

49. In their 2018 systematic literature review, Medeiros et al. reviewed currently available studies that examined and compared the effects of using conventional or “orthodontic” pacifiers, seeking to answer the following: “In children between 6-60 months, is there a difference in the occurrence of malocclusion between the types of the pacifiers (conventional or orthodontic) used?” Medeiros et al., *supra* note 1, at 288.

“orthodontic” pacifiers is “physiological” pacifiers, due to their shape, and argue that “the terminology ‘orthodontic’ is misleading, since it implies that this type of pacifier may perform some type of dental correction.” *Id.* at 555.

⁸ A. Lima et al., *Effects of Conventional and Orthodontic Pacifiers on the Dental Occlusion of Children Aged 24-36 Months Old*, 27:2 *Int. J. Paediatr. Dent.* 108 (2016).

50. Medeiros et al. concluded that there is no difference in the occurrence of malocclusion between users of “orthodontic” and conventional pacifiers, and further, that there is no evidence “to support the concept that the usage of orthodontic pacifiers is able to prevent malocclusion traits when compared to the usage of conventional pacifiers.” *Id.* at 287, 294.

51. Medeiros et al. also concluded that “factors such as duration and frequency of use of any type of pacifier shape were more associated with the development of malocclusion” and “the anatomy of the pacifiers is not a determinate to protect the occlusion compared to frequency and duration.” *Id.* at 293-94.

C. Impact of Prolonged Pacifier Use on Oral Development

52. As described above, the prolonged use of “orthodontic” pacifiers, including the Orthodontic Pacifiers at issue here, results in the same risks as would occur with the use of conventional pacifiers. These risks include development of the following conditions and dental malocclusions:

- Anterior open bite;
- Posterior crossbite;
- Class II malocclusion;
- Excessive overjet;
- Decreased upper intercanine width;
- Increased mandibular canine arch width;
- Diastema;
- Oral myofunctional alterations; and,
- Negative impacts on psychosocial development.

See Medeiros et al., *supra* note 1; Schmid, *supra* note 5.

53. Each of these conditions is a serious disturbance to a child's oral and/or orofacial development. And each may result in the need for interceptive treatments, such as orthodontic appliances, and in some cases surgical intervention.

1. Anterior Open Bite

54. An anterior open bite ("AOB") is a condition where the front teeth fail to touch, and there is no overlap between the upper and lower incisors, as depicted in the image below:



Figure 1 – Pacifier-Induced Anterior Open Bite⁹

55. Adair et al. found that a “significantly higher percentage of children with a history of pacifier use had openbites, compared with those with no habit.” Adair et al., *supra* note 2, at 440. For children who developed open bites, “the mean pacifier use time in months was significantly higher” than for children who did not develop open bites, with an average mean of 26.8 months. *Id.* at 440-41. This led Adair et al. to conclude that “[l]onger pacifier use time in months was associated with anterior openbite.” *Id.* at 443.

56. Affirming Adair's findings, Zardetto et al. found that “[a]nterior open bite was

⁹ A.X. Graciano Parra et al., *Two-Phase Treatment of Anterior Open Bite*, 51:12 J. Clin. Orthod. 801, 802 (2017) (overviewing diagnoses of malocclusions in a five-year old child with pacifier habit, and treatment required for correction).

present only in children with pacifier sucking habits, and no statistically significant difference was found between the 2 pacifier-sucking groups.” Zardetto et al., *supra* note 3, at 556. Additionally, “[w]ith respect to degree of open bite in millimeters . . . there was no significant difference between children who used the conventional pacifier and those who used the physiological one.” *Id.* at 556-57.

57. Lima et al. found that “[u]se of either conventional or orthodontic pacifiers was a risk factor for AOB” and that a “strong positive correlation was detected between habit duration and AOB ($R = 0.782$; $P < 0.01$); 61.6% of the AOB size was determined based on the duration of pacifier use.” Lima et al., *supra* note 8, at 5.

58. In their 2018 meta-analysis, Schmid et al. found that “[f]ifteen out of the reviewed 17 articles showed a strong association between AOB and the use of a pacifier when compared with the [sic] children not using a pacifier,” and duration of pacifier use played an “important role.” Schmid et al., *supra* note 5, at 3. Indeed, “[t]wo studies showed that children who used a pacifier for more than 2 years were more likely to develop an AOB than children who used it for less than 2 years.” *Id.*

59. In addition to the above research, a wealth of other studies performed over the years reflect the same finding that prolonged use of a pacifier results in a greater likelihood and prevalence of AOB.¹⁰

¹⁰ See, e.g., L. Kohler and K. Holst, *Malocclusion and Sucking Habits of Four-Year-Old Children*, 62 Acta. Paediat. Scand. 373 (1973); E. Larsson, *Dummy- and Finger-Sucking Habits in 4-Year-Olds*, 68:2 Swed. Dent. J. 219 (1975); B. Melson et al., *Sucking Habits and Their Influence on Swallowing Pattern and Prevalence of Malocclusion*, 1:4 Eur. J. Orthod. 271 (1979); S. Adair et al., *Evaluation of the Effects of Orthodontic Pacifiers on the Primary Dentitions of 24- to 59-Month-Old Children: Preliminary Study*, 14 Pediatr. Dent. 13 (1992); P. Paunio et al., *The Finnish Family Competence Study: The Effects of Living Conditions on Sucking Habits in 3-Years-Old Finnish Children and the Association Between These Habits and Dental Occlusion*, 51 Acta. (footnote continued)

2. Posterior Crossbite

60. Posterior crossbite (“PCB”) is a condition where the posterior top teeth are inside the posterior bottom teeth when touching, as depicted below:

Odontol. Scand. 23 (1993); E. Larsson, *Artificial Sucking Habits: Etiology, Prevalence, and Effect on Occlusion*, 20 Int. J. Orofac. Myol. 10 (1994); Adair, *supra* note 2; N. Farsi et al., *Sucking Habits in Saudi Children: Prevalence, Contributing Factors, and Effects on the Primary Dentition*, 19 *Pediatr. Dent.* 28 (1997); J. Warren and S. Bishara, *Duration of Nonnutritive Sucking Behaviors and Their Effects on the Dental Arches in the Primary Dentition*, 121:4 *Am. J. Ortho. Dentofac. Orthop.* 347 (2002); C. Zardetto et al., *Effects of Different Pacifiers on the Primary Dentition and Oral Myofunctional Structures of Preschool Children*, 24 *Pediatr. Dent.* 552 (2002); C. Katz et al., *Nonnutritive Sucking Habits and Anterior Open Bite in Brazilian Children: a Longitudinal Study*, 27:5 *Pediatr. Dent.* 369 (2005); K. Duncan et al., *Sucking Habits in Childhood and the Effects on the Primary Dentition: Findings of the Avon Longitudinal Study of Pregnancy and Childhood*, 18:3 *Int. J. Paediatr. Dent.* 178 (2008); S. Faccioli Hebling et al., *Relationship Between Malocclusion and Behavioral, Demographic and Socioeconomic Variables: a Cross-Sectional Study of 5-Year-Olds*, 33 *J. Clin. Pediatr. Dent.* 75 (2008); E. Oliveira Góis et al., *Influence of Nonnutritive Sucking Habits, Breathing Pattern and Adenoid Size on the Development of Malocclusion*, 78:4 *Angle Orthod.* 647 (2008); L. Dimberg et al., *Prevalence of Malocclusion Traits and Sucking Habits Among 3-Year-Old Children*, 34 *Swed. Dent. J.* 35 (2010); S. Zimmer et al., *Efficacy of a Novel Pacifier in the Prevention of Anterior Open Bite*, 33 *Pediatr. Dent.* 52 (2011); C. Tibolla et al., *Association Between Anterior Open Bite and Pacifier Sucking Habit in Schoolchildren in a City of Southern Brazil*, 17 *Dent. Press J. Orthod.* 89 (2012); R. de Sousa et al., *Prevalence and Associated Factors for the Development of Anterior Open Bite and Posterior Crossbite in the Primary Dentition*, 4:25 *Braz. Dent. J.* 336 (2014); S. Moimaz et al., *Longitudinal Study of Habits Leading to Malocclusion Development in Childhood*, 14 *BMC Oral Health* 96 (2014); S. Zimmer et al., *Anterior Open Bite in 27 Months Old Children After Use of Novel Pacifier – a Cohort Study*, 40:4 *J. Clin. Pediatr. Dent.* 28 (2016); A. Germa et al., *Early Risk Factors for Posterior Crossbite and Anterior Open Bite in the Primary Dentition*, 86:5 *Angle Orthod.* 832 (2016); A. Lima et al., *Effects of Conventional and Orthodontic Pacifiers on the Dental Occlusion of Children Aged 24-36 Months Old*, 27:2 *Int. J. Paediatr. Dent.* 108 (2016); C. Cardozo Amaral et al., *Perinatal Health and Malocclusions in Preschool Children: Findings from a Cohort of Adolescent Mothers in Southern Brazil*, 152:5 *Am. J. Orthod. Dentofac. Orthop.* 613 (2017); Medeiros, *supra* note 1.

(footnote continued)



Figure 2 – Posterior Crossbite¹¹

61. Both Adair et al. and Zardetto et al. found increased rates of posterior crossbites among children with pacifier sucking habits. See Zardetto et al., *supra* note 3, at 556; Adair et al., *supra* note 2, at 441. Notably, with respect to duration of pacifier use, Adair et al. found that pacifier users, of either conventional or “orthodontic” pacifiers, had “a significantly higher percentage of posterior crossbites (26.1 months[]) . . . compared with those whose habits ended [less than] 15.5 months.” Adair et al., *supra* note 2, at 441.

62. Warren and Bishara’s 2002 study on the duration of pacifier sucking habits and their effect on primary dentition found that, “[p]rolonged pacifier habits resulted in significant changes to dental arch parameters and occlusal traits (e.g., increased mandibular arch width and greater prevalence of posterior crossbite and anterior open bite)” and that “pacifier habits were strongly associated with the development of posterior crossbite.” Warren and Bishara, *supra* note 11, at 351. Specifically, the study found that “there was a statistically significant increase in the prevalence of posterior crossbite with pacifier habits longer than 24 months.” *Id.* at 349.

63. The study also accounted for differences between children who sucked on a digit, as opposed to a pacifier, and found that “children with pacifier habits of 24 to 36 months and 48 months or longer had significantly ($P=.034$ and $.044$ respectively, chi-square) higher prevalence of posterior crossbite than did children with the same duration of digit habits.” *Id.* at 350-51.

¹¹ Warren and Bishara, *supra* note 10, at 354.

64. “The increase in the prevalence of posterior crossbites with pacifier habits is the result of the combination of a significant increase in mandibular arch width. Some of these changes persisted well beyond the cessation of the pacifier habits.” *Id.* “Perhaps more importantly, the study found that pacifiers habits 24 to 36 months long resulted in an increased prevalence of posterior crossbite at age 5 compared with shorter pacifier habits or no nonnutritive sucking.” *Id.* Consequently, Warren and Bishara concluded that “even though nonnutritive sucking fulfills physiological needs during infancy and may comfort toddlers, persistence of these habits beyond 2 or 3 years of age significantly increases the probability of developing undesirable dental arch and occlusal traits at the end of the primary dentition stage.” *Id.* at 355.

65. According to the 2018 meta-analysis of Schmid et al., no less than nine studies concluded that pacifier use can lead to posterior crossbite. Schmid et al., *supra* note 5, at 3. And, notably, one study that considered the duration of pacifier use found that “children who discontinued pacifier sucking by 2 years of age presented a lower prevalence of posterior crossbite (17.2%) than the ones that continued the pacifier sucking until 4 to 6 years of age (27.3%).” *Id.*; Scavone et al., *Prevalence of Posterior Crossbite Among Pacifier Users: a Study in the Deciduous Dentition*, *Braz. J. Oral Res.* 21:2 Oral Res. 153 (2007).¹²

¹² See also Kohler and Holst, Larsson, Melsen, Paunio, Adair, Warren, Zardetto, Duncan, Faccioli Hebling, Oliveira Góis, Zimmer, Dimberg, de Sousa, Moimaz, Germa, Lima, and Cardozo Amaral, *supra* note 10; T. Modéer et al., *Sucking Habits and Their Relation to Posterior Cross-Bite in 4-Year-Old Children*, 90 *Scand. J. Dent. Res.* 323 (1982); B. Ogaard et al., *The Effect of Sucking Habits, Cohort, Sex, Inter canine Arch Widths, and Breast or Bottle Feeding on Posterior Crossbite in Norwegian and Swedish 3-Year-Old Children*, 106:2 *Am. J. Orthod. Dentofac. Orthop.* 161 (1994); E. Larsson, *Sucking, Chewing, and Feeding Habits and the Development of Crossbite: a Longitudinal Study of Girls From Birth to 3 Years of Age*, 71:2 *Angle Orthod.* 116 (2001); S. Bishara et al., *Changes in the Prevalence of Nonnutritive Sucking Patterns in the First 8 Years of Life*, 130:1 *Am. J. Orthod. Dentofac. Orthop.* 31 (2006); H. Scavone et al., *Prevalence of Posterior Crossbite Among Pacifier Users: a Study in the Deciduous Dentition*, 21:2 *Braz. Oral Res.* 153 (2007); S. Melink et al., *Posterior Crossbite in the Deciduous Dentition Period, its Relation* (footnote continued)

3. Excessive Overjet

66. Overjet refers to the horizontal extension of the upper front teeth over the lower front teeth. Excessive overjet is another form of malocclusion that is more prevalent in children who use pacifiers, and is a condition where the upper front teeth are significantly further forward than the lower front teeth, as depicted below:



Figure 3 – Excessive Overjet

67. Adair et al. found that children “with a history of pacifier use had a mean overjet that was significantly greater than that of habit-free children.” Adair et al., *supra* note 2, at 439. Between children who used conventional pacifiers and those who use orthodontic pacifiers, Adair et al. found “[t]here was no difference in mean overjet, nor in the percentage of children in each group with overjets [greater than] 4 mm.” *Id.* at 440. Similarly, Zardetto et al. found, with respect to the amount of overjet, that “a statistically significant difference was found among those who had no sucking habits (control group) and those who sucked pacifiers, be they conventional or physiological ones. There was no difference in mean overjet (mm) among the children who sucked the conventional pacifier and those who sucked the orthodontic ones.” Zardetto et al., *supra* note 3, at 556.

with Sucking Habits, Irregular Orofacial Functions, and Otolaryngological Findings, 138:1 Am. J. Orthod. Dentofac. Orthop. 32 (2010).

68. Lima et al. found that “[p]acifier use is significantly associated with [accentuated overjet] and mainly with AOB, the prevalence rates of which were 96.3% among the pacifier users and just 3.7% in the [control group].” Lima et al., *supra* note 8, at 116. Lima et al. also found that “habit duration is a relevant factor in the determination of the size of AOB and [accentuated overjet]. In this study, duration exhibited positive correlations with both [accentuated overjet and AOB],” leading Lima to conclude that “habit duration was a strong predictor of MO occurrence and severity.” *Id.* at 118.

69. In their meta-analysis, Schmid et al. noted that numerous studies have shown “that the prevalence of overjet is increased in children using a pacifier when compared with children who do not use a pacifier.” Schmid et al., *supra* note 5, at 7. Moreover, with respect to duration, a “higher prevalence of overjet was associated with a pacifier sucking habit at 12, 18, and 30 months after birth.” *Id.*¹³

4. Class II Canine Relationship

70. A class II canine relationship or class II malocclusion refers to a common orthodontic classification of a distal molar and canine relationship, in other words, a misalignment of the upper and lower molars, as depicted below:

¹³ See also Adair, Melsen, Warren, Zardetto, Zimmer, Dimberg, Lima *supra* note 10; J. Ravn, *Sucking Habits and Occlusion in 3-Year-Old Children*, 84 *Scan. J. Dent. Rev.* 204 (1976); B. Bowden, *The Effects of Digital and Dummy Sucking on Arch Widths, Overbite, and Overjet: a Longitudinal Study*, 11 *Aust. Dent. J.* 396 (1966).



Figure 4 – Class II Malocclusion

71. Adair et al. found that “[c]lass II primary canine relationships on one or both sides were significantly more common among the pacifier group,” regardless of pacifier type, as compared to habit-free children. Adair et al., *supra* note 2, at 439. Among users of “orthodontic” pacifiers, Adair found that the “occurrences of Class II primary canines and distal step molars were statistically significantly greater among the users of functional exercisers.” *Id.* at 440. Dimberg et al. similarly showed that there was a statistically significant higher rate of Class II malocclusions in pacifier users. *Supra*, note 10.¹⁴

5. Dental Arch Alterations

72. Dental arches are the two arches of teeth, one on each jaw, that together constitute the dentition. Prolonged pacifier usage has been demonstrated to lead to a significant increase in mandibular arch width and decrease of upper intercanine width, resulting in a narrowed and constricted palate that reduces the spacing needed for adult teeth to erupt (*see* Figure 5 below), among other harmful changes to dental arch parameters and oral development.¹⁵

¹⁴ *See also* Farsi, Zardetto, Lima, Melsen, *supra* note 10; Ravn, *supra* note 13; Schmid et al., *supra* note 5.

¹⁵ *See, e.g.*, Adair, Warren and Bishara, Zardetto, Ogaard, Larsson, *supra* note 12; Bowden, *supra* (footnote continued)



Figure 5 – Narrowed Palate

73. Warren and Bishara’s examination of the effect of the duration of pacifier use on different aspects of dental arch “found a statistically significant increased mandibular canine arch width and a statistically significant decrease in palatal depths” among prolonged pacifier users. See Schmid et al., *supra* note 5, at 8; see also Warren and Bishara, *supra* note 10, at 350-51.

74. Specifically, Warren and Bishara found “children with pacifier habits of 36 to 48 months duration had significantly greater mandibular arch widths.” Warren and Bishara, *supra* note 10, at 349. Compared to children with digit-sucking habits of the same duration: “Children with pacifier habits of 36 to 48 months had significantly ($P=.013$, t test) greater mandibular arch widths than did children with digit habits of the same length” *Id.* at 350. “[P]acifier habits were strongly associated with the development of posterior crossbite, increased mandibular arch widths, and shallower palatal depths.” *Id.* at 351. Prolonged pacifier usage results in “a significant increase in mandibular arch width and a tendency for a decrease in maxillary arch width” which results in an “increase in the prevalence of posterior crossbites.” *Id.* at 351.

note 13; S. Bishara et al., *Influence of Feeding and Non-Nutritive Sucking Methods on the Development of the Dental Arches: Longitudinal Study of the First 18 Months of Life*, 9 *Pediatr. Dent.* 13 (1987).

75. Zardetto et al. also found that “there is an association between a narrow and high hard palate and children with sucking habits,” which “can be explained by the fact that the tongue is forced and remains in an inferior position when the child is sucking a pacifier. Furthermore, the pacifier nipple is pressed against the hard palate by the tongue and the upper teeth in the canine and the molar area lack palatal support from the tongue during sucking exercise, decreasing arch width. It is clear that the shape of the hard palate depends on the width of the upper arch. Therefore, if this width decreases, the hard palate becomes narrower and there is less space for the tongue. When the child inserts the nipple of a pacifier into his or her mouth, it occupies the functional space of the mouth, displaces the tongue to a lower position, and separates the lips.” *See Zardetto et al., supra* note 3, at 559.

6. Other Conditions and Psychosocial Development

76. In addition to the above conditions, prolonged pacifier usage is also associated with a range of other secondary conditions, including diastema, increased oral myofunctional alterations, such as lip incompetence, lip entrapment, and a decrease in muscular tonicity of the tongue and lips.¹⁶ While the impact of these conditions on a child’s physiological oral development varies, studies have confirmed that the development of abnormal oral conditions such as these can have a severe impact on a child’s psychosocial development, self-image, and social well-being.

77. For example, diastema is a condition marked by increased spacing between the teeth, as depicted below:

¹⁶ *See, e.g., Zardetto, supra* note 3; Bowden, *supra* note 13; B. Black et al., *Harmful Oral Habits*, 23 *Ortodon.* 40 (1990); S. Adair, *Nonnutritive Sucking Habits in Infants and Preschool Children: a Review and Recommendations for Anticipatory Guidance*, 4 *Master Clin. Pediatr. Dent.* 14 (1996); M. Camargo et al., *Rational use of the Pacifier*, 1 *J. Bras. Odontopediatr. Odontol. Bebe* 44 (1998); Schmid et al., *supra* note 5.



*Figure 6 – Diastema*¹⁷

78. Lima et al. and others have demonstrated a link between prolonged pacifier use and the development of increased spacing between the teeth.¹⁸ While diastema by itself is typically considered more of a cosmetic issue, as discussed below, the impact of dental aesthetics on subjective self-perception can have considerable and lasting effects into adolescence and adulthood.

79. Oral myofunctional alterations can also develop from prolonged pacifier usage (*see, e.g., Zardetto et al., supra* note 3) and, in addition to impacting oral development and oral health, can also impact a child's psychosocial development. Lip incompetence, for example, is a condition marked by the inability of the lips to stay together when the mouth is in a closed posture, as depicted the comparative image below:

¹⁷ *See also* Figure 2.

¹⁸ *See, e.g.,* Lima, and Kohler and Holst, *supra* note 10.

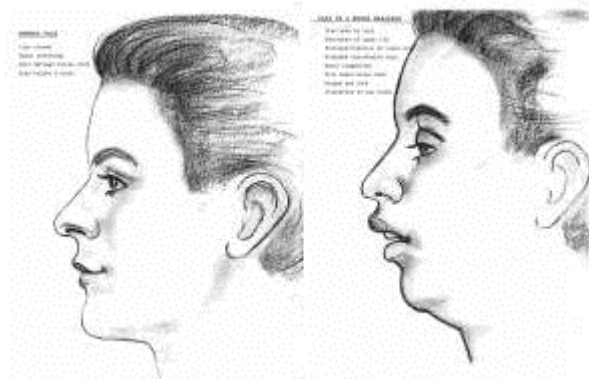


Figure 7 – Lip Incompetence (right)

80. Paula et al. evaluated adolescent’s self-perception of dental aesthetics and found that severity of malocclusion and oral health directly correlated to quality of life and body-image.¹⁹ “[D]entofacial esthetics plays an important role in social interaction and psychological well-being. The impact of oral health conditions on quality of life, especially in items of satisfaction with appearance, may result in feelings of shame in social contacts and those who are psycho-socially disadvantaged.” *Id.* at 1192. Numerous studies that have examined dissatisfaction with dental appearance and negative psychosocial impacts have made similar conclusions.²⁰

¹⁹ Paula et al., *Psychosocial Impact of Dental Esthetics on Quality of Life in Adolescents: Association with Malocclusion, Self-Image, and Oral Health-Related Issues*, 79:6 *Angle Orthod.* 1188 (2009).

²⁰ See, e.g., N.A. Mandall et al., *Perceived Aesthetic Impact of Malocclusion Andoral Self-Perceptions in 14- to 15-Year-Old Asian and Caucasian Children in Greater Manchester*, 21 *Eur. J. Orthod.* 175 (1999); M. Al-Sarheed et al., *Orthodontic Treatment Need and Self-Perception of 11- to 16-Year-Old Saudi Arabian Children with a Sensory Impairment Attending Special Schools*, 30 *J. Orthod.* 39 (2003); I. Grzywacz, *The Value of the Aesthetic Component of the Index of Orthodontic Treatment Need in the Assessment of Subjective Orthodontic Treatment Need*, 25 *Eur. J. Orthod* 57 (2003); U. Klages et al., *Dental Aesthetics, Self-Awareness, and Oral Health-Related Quality of Life in Young Adults*, 26 *Eur. J. Orthod.* 507 (2004); E. Bernabe and C. Flores-Mir, *Orthodontic Treatment Need in Peruvian Young Adults Evaluated through Dental Aesthetic Index*, 76 *Angle Orthod.* 417 (2006); L.S. Marques et al., *Malocclusion: Esthetic Impact and Quality of Life among Brazilian School Children*, 129 *Am J. Orthod. Dentofacial Orthop.* 424 (2006); P. Van Der Geld et al., *Smile Attractiveness: Self-Perception and Influence on Personality*, 77 *Angle Orthod.* 759 (2007); P.M. Kenealy et al., *The Cardiff Dental Study: a 20-Year Critical Evaluation of the Psychological Health Gain from Orthodontic Treatment*, 13 *Br. J. Health Psychol.* 17 (footnote continued)

81. Negative self-perception resulting from malocclusions and dental appearance can also last into adulthood. In a longitudinal fifteen-year study, Helm et al. “concluded that certain malocclusions, especially conspicuous occlusal and space anomalies, may adversely affect body image and self-concept, not only at adolescence but also in adulthood.”²¹ Thus while the physiological effects of prolonged pacifier usage have a demonstrable and often visible impact on a child’s oral development, as discussed above, prolonged pacifier usage also can result in secondary psychosocial effects that can impact a child’s self-image and social well-being throughout his or her life.

IV. Impact of Defendants’ Wrongful Conduct

82. Despite ample dental and orthodontic studies and literature demonstrating the contrary, Defendants consistently convey to reasonable consumers, through their advertising statements and omissions, that their Orthodontic Pacifiers are safe for use by children 24 months and older, and that their Orthodontic Pacifiers promote healthy oral and orofacial development.

83. As prominent, longtime, and iconic manufacturers and distributors of baby products, including pacifiers, Defendants possess specialized knowledge regarding the safety and efficacy of their products, and they are in a superior position to know the risks associated with their use. Indeed, any company in the baby product industry is well aware of the need for hyperawareness of product safety—from a legal, regulatory, and ethical standpoint—and the

(2007); E.S. Traebert and M.A. Peres, *Do Malocclusion Affect the Individual’s Oral Health Related to Quality of Life?*, 5 *Oral Health Prev. Dent.* 3 (2007); U. Klages et al., *Perception of Occlusion, Psychological Impact of Dental Esthetics, History of Orthodontic Treatment and Their Relation to Oral Health in Naval Recruits*, 77 *Angle Orthod.* 675 (2007); X. Dahong et al., *Effect of Incisor Position on the Self-Perceived Psychosocial Impacts of Malocclusion Among Chinese Young Adults*, 83:4 *Angle Orthod.* 617 (2013).

²¹ S. Helm et al., *Psychosocial Implications of Malocclusion: A 15-year Follow-Up Study in 30-Year-Old Danes*, 87:2 *Am. J. Orthod.* 110 (1985).

concomitant duty to disclose potential risks of product use.

84. Defendants knew or should have known, but failed to disclose, that children who use pacifiers, including Defendants' Orthodontic Pacifiers, to continue non-nutritive sucking habits past the age of 24 months have an increased risk of various forms of dental malocclusions. Defendants also knew or should have known, but failed to disclose, that their Orthodontic Pacifiers pose risks to children over the age of 24 months, and that those products do not promote the healthy oral and orofacial development of children, nor do they prevent or correct teeth misalignment.

85. Defendants knew or should have known that their Orthodontic Pacifiers do not promote healthy dental occlusion or provide orthodontic benefit for children of any age (including those under the age of 24 months).

86. Defendants' material misrepresentations and omissions set forth in this Complaint were disseminated uniformly to Plaintiffs and all Class members through product packaging and labeling, exposing Plaintiffs and all Class members to Defendants' false, deceptive, and misleading advertising and unfair, unlawful, and fraudulent business practices that deceived Plaintiffs and are likely to deceive reasonable consumers, including Plaintiffs and Class members.

87. When purchasing Defendants' Orthodontic Pacifiers, Plaintiffs relied upon Defendants' misrepresentations and omissions, including Defendants' failure to disclose the material fact that prolonged pacifier use by children over the age of 24 months increases the risk of developing various dental malocclusions.

88. Plaintiffs would not have paid a premium price or purchased the Orthodontic Pacifiers marketed for use by children over the age of 24 months had Defendants made truthful advertising statements and disclosed material information concerning risks associated with prolonged pacifier use.

89. Plaintiffs would not have purchased, or would have paid less for, Defendants' Orthodontic Pacifiers marketed for use by children 24 months or younger had Defendants made truthful advertising statements concerning the impact on oral and orofacial health of "orthodontic" pacifiers.

90. Defendants' material misrepresentations and omissions set forth in this Complaint induced Plaintiffs to purchase Defendants' Orthodontic Pacifiers and resulted in the payment of money by Plaintiffs to or for the benefit of Defendants that Plaintiffs would not have paid had Defendants truthfully advertised its pacifiers.

91. Plaintiffs and Class members have been and will continue to be deceived or misled by Defendants' false and misleading misrepresentations and omissions concerning Defendants' Orthodontic Pacifiers.

92. Plaintiffs and Class members are reasonable consumers who have been injured by purchasing Defendants' Orthodontic Pacifiers. Because of Defendants' material misrepresentations and omissions in their statements and advertisements concerning their Orthodontic Pacifiers, including on product packaging and labeling, Plaintiffs and Class members were harmed at the time of purchase.

93. Defendants' misrepresentations and omissions were a material factor in influencing Plaintiffs' and Class members' decision to purchase Orthodontic Pacifiers.

94. Defendants' conduct has injured Plaintiffs and Class members because Defendants' Orthodontic Pacifiers are not safe for use by children over the age of 24 months, do not promote healthy oral and orofacial development, and do not prevent or correct teeth misalignment. Rather, Defendants' Orthodontic Pacifiers have known, substantial risks when used by children over the age of 24 months, and Defendants failed to conspicuously disclose those risks to Plaintiffs and

Class members.

95. Defendants continue to engage in the unlawful acts and practices set forth in this Complaint.

96. Unless enjoined, Defendants' unlawful acts and practices described in this Complaint will continue.

CLASS DEFINITION AND ALLEGATIONS

97. Pursuant to Federal Rules of Civil Procedure 23(b)(2) and 23(b)(3), Plaintiffs bring this action on behalf of themselves and the proposed Classes²²: Plaintiffs bring this action on behalf of themselves and the proposed Nationwide Class:

All persons who purchased in the United States any of the NUK® branded Orthodontic Pacifiers, within the applicable statute of limitations, until the date notice is disseminated.

98. Pursuant to Federal Rules of Civil Procedure 23(b)(2) and 23(b)(3), Plaintiffs bring this action on behalf of themselves and the proposed Nationwide Subclass:

All persons who purchased in the United States any of the NUK® branded Orthodontic Pacifiers, within the applicable statute of limitations, for use by a child 24 months or older until the date notice is disseminated.

99. Pursuant to Federal Rules of Civil Procedure 23(b)(2) and 23(b)(3), Plaintiffs bring this action on behalf of themselves and the proposed Multi-State Consumer Protection Class:

All persons who purchased in the State of Illinois or any state with similar laws²³

²² Unless otherwise specified, all references in this Complaint to "Classes" or the "Class" refer collectively to the Nationwide Class, the Nationwide Subclass, the Multi-State Consumer Protection Class, the Multi-State Consumer Protection Subclass, the Illinois Class, and the Illinois Subclass.

²³ While discovery may alter the following, Plaintiffs assert that the other states with similar consumer fraud laws under the facts of this case include, but are not limited to: Arkansas (Ark. Code § 4-88-101, et seq.); Colorado (Colo. Rev. Stat. § 6-1-101, et seq.); Connecticut (Conn. Gen. Stat. § 42-110, et seq.); Delaware (Del. Code tit. 6, § 2511, et seq.); District of Columbia (D.C. (footnote continued))

any of the NUK® branded Orthodontic Pacifiers, within the applicable statute of limitations, until the date notice is disseminated.

100. Pursuant to Federal Rules of Civil Procedure 23(b)(2) and 23(b)(3), Plaintiffs bring this action on behalf of themselves and the proposed Multi-State Consumer Protection Subclass:

All persons who purchased in the State of Illinois or any state with similar laws²⁴ any of the NUK® branded Orthodontic Pacifiers, within the applicable statute of limitations, for use by a child 24 months or older until the date notice is disseminated.

101. Pursuant to Federal Rules of Civil Procedure 23(b)(2) and 23(b)(3), Plaintiffs bring this action on behalf of themselves and the proposed Illinois Class:

All persons who purchased in the State of Illinois any of the NUK® branded Orthodontic Pacifiers, within the applicable statute of limitations, until the date notice is disseminated.

102. Pursuant to Federal Rules of Civil Procedure 23(b)(2) and 23(b)(3), Plaintiffs bring this action on behalf of themselves and the proposed Illinois Subclass:

All persons who purchased in the State of Illinois any of the NUK® branded Orthodontic Pacifiers, within the applicable statute of limitations, for use by a child 24 months or older until the date notice is disseminated.

Code § 28-3901, et seq.); Florida (Fla. Stat. § 501.201, et seq.); Hawaii (Haw. Rev. Stat. § 480-1, et seq.); Idaho (Idaho Code § 48-601, et seq.); Illinois (815 ICLS § 505/1, et seq.); Maine (Me. Rev. Stat. tit. 5 § 205-A, et seq.); Massachusetts (Mass. Gen. Laws Ch. 93A, et seq.); Michigan (Mich. Comp. Laws § 445.901, et seq.); Minnesota (Minn. Stat. § 325F.67, et seq.); Missouri (Mo. Rev. Stat. § 407.010, et seq.); Montana (Mo. Code. § 30-14-101, et seq.); Nebraska (Neb. Rev. Stat. § 59 1601, et seq.); Nevada (Nev. Rev. Stat. § 598.0915, et seq.); New Hampshire (N.H. Rev. Stat. § 358-A:1, et seq.); New Jersey (N.J. Stat. § 56:8-1, et seq.); New Mexico (N.M. Stat. § 57-12-1, et seq.); New York (N.Y. Gen. Bus. Law § 349, et seq.); North Dakota (N.D. Cent. Code § 51-15-01, et seq.); Oklahoma (Okla. Stat. tit. 15, § 751, et seq.); Oregon (Or. Rev. Stat. § 646.605, et seq.); Rhode Island (R.I. Gen. Laws § 6-13.1-1, et seq.); South Dakota (S.D. Code Laws § 37-24-1, et seq.); Texas (Tex. Bus. & Com. Code § 17.41, et seq.); Virginia (VA Code § 59.1-196, et seq.); Vermont (Vt. Stat. tit. 9, § 2451, et seq.); Washington (Wash. Rev. Code § 19.86.010, et seq.); West Virginia (W. Va. Code § 46A-6- 101, et seq.); and Wisconsin (Wis. Stat. § 100.18, et seq.). *See Mullins v. Direct Digital, LLC*, No. 13-cv-1829, 2014 WL 5461903 (N.D. Ill. Sept. 30, 2014), *aff'd*, 795 F.3d 654 (7th Cir. 2015).

²⁴ *Id.*, *supra* note 23.

103. Excluded from the Classes are: (i) Defendants, any entity in which any Defendant has a controlling interest or which has a controlling interest in any Defendant, and Defendants' legal representatives, predecessors, successors and assigns; (ii) governmental entities; (iii) Defendants' employees, officers, directors, agents, and representatives and their family members; (iv) all persons who make a timely election to be excluded from the class; and (v) the Judge and staff to whom this case is assigned, and any member of the Judge's immediate family.

104. Certification of Plaintiffs' claims for class-wide treatment is appropriate because Plaintiffs can prove the elements of their claims on a class-wide basis using the same evidence as would be used to prove those elements in individual actions alleging the same claims.

105. **Numerosity – Federal Rule of Civil Procedure 23(a)(1).** Members of the proposed Classes are so numerous that the individual joinder of all absent Class members is impracticable. While the exact number of Class members is unknown to Plaintiffs at this time and is in the exclusive control of Defendants, it is ascertainable by appropriate discovery. Plaintiffs are informed and believe, based upon the nature of the trade and commerce involved, that the proposed Classes includes many thousands of Class members who are geographically diverse so that joinder of all Class members is impracticable.

106. **Commonality and Predominance – Federal Rule of Civil Procedure 23(a)(2) and 23(b)(3).** This action involves common questions of law and fact, which predominate over any questions affecting individual Class members. Among the questions of law or fact common to the proposed Classes are: (1) whether Defendants' representations regarding their Orthodontic Pacifiers are misleading and deceptive; (2) whether Defendants failed to disclose material information concerning risks associated with prolonged pacifier use by children over the age of 24 months; (3) whether Defendants' representations and omissions concerning their Orthodontic

Pacifiers involved representations and omissions of material facts; (4) whether Defendants' Orthodontic Pacifiers promote or benefit the oral and orofacial health of children of any age, including those 24 months and under; (5) whether Defendants' Orthodontic Pacifiers are safe for use in children over 24 months; (6) whether Defendants' conduct, as set forth in this Complaint, violates the Illinois Consumer Fraud Act; (7) whether Defendants should be enjoined from continuing to make false, deceptive, and misleading statements regarding their Orthodontic Pacifiers; (8) whether Defendants' conduct was unjust and in violation of principles of justice, equity, and good conscience; (9) whether Plaintiffs and Class members confer financial benefits on Defendants by purchasing Defendants' Orthodontic Pacifiers; (10) whether it is unjust for Defendants to retain the benefits conferred by Plaintiffs' and Class members' overpayments for Orthodontic Pacifiers; (11) whether Defendants' profits resulting from Plaintiffs' and Class members' overpayments are subject to equitable disgorgement; and (12) whether Defendants should pay damages or restitution, and in what amount. These questions and others are common to the class and predominate over individual issues. Further, the issues of fact and law applicable to the Class are identical to the issues of fact and law applicable to each individual member of the proposed Class.

107. **Typicality – Federal Rule of Civil Procedure 23(a)(3).** Plaintiffs' claims are typical of the other Class members' claims because, among other things, all Class members were comparably injured through the uniform, prohibited conduct described above. Plaintiffs and Class members all suffered the same harm as a result of Defendants' common, false, deceptive, and misleading acts and practices in the sale of their Orthodontic Pacifiers. By advancing their claims, Plaintiffs will also advance the claims of all Class members because Defendants' unlawful conduct caused and continues to cause all Class members to suffer similar harm.

108. Adequacy of Representation – Federal Rule of Civil Procedure 23(a)(4).

Plaintiffs are adequate representatives of the Classes because Plaintiffs have no interest adverse to the interests of the members of the proposed Classes, and Plaintiffs have retained counsel competent and experienced in complex commercial and consumer class action litigation. And Plaintiffs intend to prosecute this action vigorously. The interests of the Class members will be fairly and adequately protected by Plaintiffs and their counsel.

109. Declaratory and Injunctive Relief – Federal Rule of Civil Procedure 23(b)(2).

Defendants have acted or refused to act on grounds generally applicable to Plaintiffs and the other Class members, thereby making appropriate final injunctive relief and declaratory relief, as described below, with respect to the Class as a whole.

110. Superiority – Federal Rule of Civil Procedure 23(b)(3). A class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. There is no special interest in the members of the Classes individually controlling the prosecution of separate actions. The damages or other financial detriment suffered by Plaintiffs and the other Class members are relatively small compared to the burden and expense that would be required to individually litigate their claims against Defendants, so it would be impracticable for Class members to individually seek redress for Defendants' wrongful conduct. Even if Class members could afford individual litigation, the court system could not. Class treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the duplication of effort and expense that numerous individual actions would entail. Individualized litigation creates a potential for inconsistent or contradictory judgments and increases the delay and expense to all parties and the court system.

By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court. Furthermore, Defendants transact substantial business in Illinois, and will not be prejudiced or inconvenienced by the maintenance of this class action in this forum.

CLAIMS ALLEGED

**FIRST CAUSE OF ACTION
VIOLATION OF THE ILLINOIS
CONSUMER FRAUD AND DECEPTIVE TRADE PRACTICES ACT
(On Behalf of the Illinois Class and Subclass)**

111. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

112. Plaintiffs bring this action individually and on behalf of the Illinois Class and Subclass.

113. In Illinois, the Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505/1, *et seq.*, prohibits “unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact or the use or employment of any practice described in Section 2 of the ‘Uniform Deceptive Trade Practices Act’”

114. Plaintiffs and the Class members were injured by Defendants’ deceptive misrepresentations, concealments and omissions and these misrepresentations, concealments and omissions were material and deceived Plaintiffs and the Class.

115. Defendants do business in Illinois, sell and distribute their Orthodontic Pacifiers in Illinois, and engaged in deceptive acts and practices in connection with the sale of Orthodontic Pacifiers in Illinois and elsewhere in the United States.

116. The Orthodontic Pacifiers purchased by Plaintiffs and the Class members were “consumer items” as that term is defined under the Illinois Consumer Fraud Act.

117. Defendants engaged in unfair and deceptive acts in violation of 815 Ill. Comp. Stat. 505/2 when they misrepresented and deceptively concealed, suppressed and/or omitted the material information known to Defendants as set forth above concerning their Orthodontic Pacifiers, which has caused damage and injury to Plaintiffs and the Class members.

118. Defendants represented, directly or indirectly, that their Orthodontic Pacifiers promote healthy oral development and prevent teeth and jaw misalignment, when, in reality, they result in worse outcomes for children of any age than not using a pacifier and result in oral and orofacial health outcomes that are no better than the use of conventional pacifiers.

119. Defendants represented, directly or indirectly, that their Orthodontic Pacifiers are beneficial to the oral and orofacial health of children over the age of 24 months when, in reality, Defendants’ Orthodontic Pacifiers are harmful to children over the age of 24 months and in no way contribute to their healthy oral and orofacial development.

120. Defendants failed to disclose in their advertising statements the material fact that prolonged pacifier use by children over the age of 24 months significantly increases the risk of developing various dental malocclusions.

121. Defendants knew or should have known that their health representations were false and misleading, and that by omitting and failing to disclose in their advertising the risks associated with prolonged pacifier use by children over the age of 24 months, most notably the risk of developing various forms of dental malocclusions, they were omitting material facts that would alter any reasonable consumer’s decision to purchase Orthodontic Pacifiers for children over the age of 24 months.

122. Defendants' deceptive acts occurred in a course of conduct involving trade and commerce in Illinois and throughout the United States.

123. Defendants intended Plaintiffs and all Class members to rely on their deceptive acts.

124. Defendants' deceptive acts proximately caused actual injury and damage to Plaintiffs and the Class members.

125. Plaintiffs and Class members would not have purchased, or would have paid less for, Defendants' Orthodontic Pacifiers marketed for use by children under 24 months but for Defendants' material misrepresentations as described in this Complaint.

**SECOND CAUSE OF ACTION
VIOLATION OF THE ILLINOIS
UNIFORM DECEPTIVE TRADE PRACTICES ACT
(On Behalf of the Illinois Class and Subclass)**

126. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

127. Plaintiffs bring this action individually and on behalf of the Illinois Class and Illinois Subclass.

128. The Illinois Deceptive Trade Practices Act ("UDTPA"), 815 Ill. Comp. Stat. 510/2, *et seq.*, prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact."

129. 815 ILCS 510/2 provides in pertinent part that a "person engages in a deceptive trade practice when, in the course of his or her business, vocation, or occupation," the person does any of the following: "(5) represents that goods or services have . . . uses, benefits or quantities that they do not have . . . ; (7) represents that goods or services are of a particular standard, quality,

or grade or that goods are a particular style or model, if they are of another; . . . [or] (12) engages in any other conduct which similarly creates a likelihood of confusion or misunderstanding.”

130. Defendants engaged in unfair and deceptive acts in violation of 815 Ill. Comp. Stat. 510/2 when they misrepresented and deceptively concealed, suppressed and/or omitted the material information known to Defendants as set forth above concerning their Orthodontic Pacifiers, which has caused damage and injury to Plaintiffs and the Class members.

131. Defendants represented, directly or indirectly, that their Orthodontic Pacifiers promote healthy oral development and prevent teeth and jaw misalignment, when, in reality, they result in worse outcomes for children of any age than not using a pacifier and result in oral and orofacial health outcomes that are no better than the use of conventional pacifiers.

132. Defendants represented, directly or indirectly, that their Orthodontic Pacifiers are beneficial to the oral and orofacial health of children over the age of 24 months when, in reality, Defendants’ Orthodontic Pacifiers are harmful to children over the age of 24 months and in no way contribute to their healthy oral and orofacial development.

133. Defendants failed to disclose in their advertising statements the material fact that prolonged pacifier use by children over the age of 24 months significantly increases the risk of developing various dental malocclusions.

134. Defendants knew or should have known that their health representations were false and misleading, and that by omitting and failing to disclose in its advertising the risks associated with prolonged pacifier use by children over the age of 24 months, most notably the risk of developing various forms of dental malocclusions, they were omitting material facts that would alter any reasonable consumer’s decision to purchase Orthodontic Pacifiers for children over the age of 24 months.

135. Defendants' deceptive acts occurred in a course of conduct involving trade and commerce in Illinois and throughout the United States.

136. Defendants' deceptive acts proximately caused actual injury and damage to Plaintiffs and the Class members.

137. Plaintiffs and Class members would not have purchased, or would have paid less for, Defendants' Orthodontic Pacifiers marketed for use by children under 24 months but for Defendants' material misrepresentations as described in this Complaint.

138. Defendants intended Plaintiffs and all Class members to rely on their deceptive acts.

THIRD CAUSE OF ACTION
VIOLATION OF STATE CONSUMER PROTECTION STATUTES
(On Behalf of Plaintiffs and the Multi-State Consumer Class and Subclass)

139. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

140. Plaintiffs and Class members have been injured as a result of Defendants' violations of the state consumer protection statutes listed above in paragraph 99 and footnote 23, which also provide a basis for redress to Plaintiffs and Class members based on Defendants' fraudulent, deceptive, unfair and unconscionable acts, practices and conduct.

141. Defendants' conduct as alleged herein violates the consumer protection, unfair trade practices and deceptive acts laws of each of the jurisdictions encompassing the Multi-State Consumer Class and Subclass.

142. Defendants violated the Multi-State Consumer Class and Subclass' states' unfair and deceptive acts and practices laws by representing that their Orthodontic Pacifiers promote healthy oral development and prevent teeth and jaw misalignment, when, in reality, they result in worse outcomes for children of any age than not using a pacifier and result in oral and orofacial health outcomes that are no better than the use of conventional pacifiers.

143. Defendants further represented, directly or indirectly, that their Orthodontic Pacifiers are beneficial to the oral and orofacial health of children over the age of 24 months when, in reality, Defendants' Orthodontic Pacifiers are harmful to children over the age of 24 months and in no way contribute to their healthy oral and orofacial development.

144. Defendants' misrepresentations were material to Plaintiffs' and Class members' decision to purchase the Orthodontic Pacifiers or pay a premium for the Orthodontic Pacifiers.

145. Defendants made their untrue and/or misleading statements and representations willfully, wantonly, and with reckless disregard for the truth.

146. As a result of Defendants' violations of the aforementioned states' unfair and deceptive practices laws, Plaintiffs and Class members paid a premium for the Orthodontic Pacifiers.

147. As a result of Defendants' violations, Defendants have been unjustly enriched.

148. Pursuant to the aforementioned states' unfair and deceptive practices laws, Plaintiffs and Class members are entitled to recover compensatory damages, restitution, punitive and special damages including but not limited to treble damages, reasonable attorneys' fees and costs and other injunctive or declaratory relief as deemed appropriate or permitted pursuant to the relevant law.

FOURTH CAUSE OF ACTION
UNJUST ENRICHMENT/QUASI-CONTRACT
(On Behalf of the Nationwide Class and Subclass)

149. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

150. Plaintiffs bring this action individually and on behalf of the Nationwide Class and Subclass.

151. Defendants' unfair and unlawful contract includes, among other things, making false and misleading representations and omissions of material fact, as set forth in this Complaint.

Defendants' acts and business practices offend the established public policy of Illinois, as there is no societal benefit from false advertising, only harm. While Plaintiffs and Class members were harmed, Defendants were unjustly enriched by their misrepresentations and omissions.

152. Plaintiffs and Class members were harmed as a result of Defendants' material representations and omissions, as described in this Complaint. Each Plaintiff and Class member purchased Defendant's Orthodontic Pacifiers. Plaintiffs and Class members have suffered injury in fact and lost money as a result of paying a premium price for the Orthodontic Pacifiers and by purchasing the Orthodontic Pacifiers at all for use by children 24 months or older, and as a result of Defendants' unlawful, unfair, and fraudulent business practices.

153. Defendants' conduct allows Defendants to knowingly realize substantial revenues from selling their Orthodontic Pacifiers at the expense of, and to the detriment of, Plaintiffs and Class members, and to Defendants' benefit and enrichment. Defendants' retention of these benefits violates fundamental principles of justice, equity, and good conscience.

154. Plaintiffs and Class members confer significant financial benefits and pay substantial compensation to Defendants for their Orthodontic Pacifiers, which are not as Defendants represent them to be.

155. Under common law principles of unjust enrichment and quasi-contract, it is inequitable for Defendants to retain the benefits conferred by Plaintiffs' and Class members' overpayments.

156. Plaintiffs and Class members seek disgorgement of all profits resulting from such overpayments and establishment of a constructive trust from which Plaintiffs and Class members may seek restitution.

JURY DEMAND

Plaintiffs demand a trial by jury of all claims in this Complaint so triable.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of other members of the proposed Classes, respectfully request that the Court enter judgment in Plaintiffs' favor and against Defendants as follows:

A. Declaring that this action is a proper class action, certifying the Classes as requested herein, designating Plaintiffs as Class Representatives and appointing the undersigned counsel as Class Counsel;

B. Ordering payment of actual and punitive damages, restitution and disgorgement of all profits and unjust enrichment that Defendants obtained from Plaintiffs and the Class members as a result of Defendants' unlawful, unfair and fraudulent business practices;

C. Ordering injunctive relief as permitted by law or equity, including enjoining Defendants from continuing the unlawful practices as set forth herein, and ordering Defendants to engage in a corrective advertising campaign;

D. Ordering Defendants to pay attorneys' fees and litigation costs to Plaintiffs and the other members of the Classes;

E. Ordering Defendants to pay both pre- and post-judgment interest on any amounts awarded; and

F. Ordering such other and further relief as may be just and proper.

Dated: October 16, 2019

Respectfully submitted,

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*Application for *Pro Hac Vice* Forthcoming