

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK**

NAOMI HARRIS, individually and on behalf
of all others similarly situated,

Plaintiff,

v.

NEWELL BRANDS INC. and
GRACO CHILDREN'S PRODUCTS, INC.,

Defendants.

CASE NO. 1: 23-cv-0784 (AMN/CFH)

CLASS ACTION

COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Naomi Harris ("Plaintiff"), by her undersigned counsel, brings this class action complaint against Defendants Newell Brands Inc. and Graco Children's Products, Inc. (collectively, "Defendants" or "NUK"), individually and on behalf of all others similarly situated, and alleges upon personal knowledge as to her acts and experiences, and as to all other matters, upon information and belief, including the investigation conducted by Plaintiff's attorneys.

NATURE OF THIS ACTION

1. This is a consumer protection class action arising out of Defendants' false and misleading advertising of its pacifiers, which feature the prominent misrepresentation that they are "orthodontic," which is deceptive and misleading to reasonable consumers.

2. As more fully described below, as no pacifier is capable of promoting oral development and prolonged pacifier use by children can cause significant harm by interfering with the proper development of their teeth and orofacial structures, calling a pacifier "orthodontic" is misleading to the reasonable consumer. Children who use pacifiers to continue non-nutritive sucking habits 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 New York. Defendants' "orthodontic" pacifiers come in a variety of styles, colors, and sizes.

4. "Orthodontics" is the branch of dentistry that corrects teeth and jaws that are positioned improperly. Through its 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.

5. Defendants' advertisement and use of the term "orthodontic" pacifier is misleading to a reasonable consumer and is an affirmative representation that its products promote healthy oral and orofacial development in children. 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. 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 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 and do not support or improve children's oral or orofacial health and development.

8. Through their advertising statements, Defendants induced Plaintiff to purchase NUK "orthodontic" pacifiers for use by her children. Plaintiff reasonably believed that Defendants' "orthodontic" pacifiers would promote oral development for her children or prevent teeth misalignment. Plaintiff and putative class members were injured at the time of purchase because they would not have paid a premium price for Defendants' "orthodontic" pacifiers had Defendants made truthful advertising statements and disclosed material information concerning the non-orthodontic nature of the pacifiers.

9. Through false, misleading, and deceptive advertisements, Defendants have violated New York's consumer protection statute by representing that their "orthodontic" pacifiers promote healthy oral and orofacial development in children.

10. Plaintiff asserts claims for relief and restitution arising from Defendants' false, misleading, and deceptive advertising. Plaintiff alleges violations of New York's Consumer Protection from Deceptive Acts and Practices statute, N.Y. Gen. Bus. Law §§ 349 and 350 ("New York Consumer Protection Act").

11. Plaintiff brings this action on behalf of herself and a Class of similarly situated consumers who purchased an "orthodontic" pacifier manufactured by Defendants in New York State.

12. Plaintiff, for herself and for the Class, brings 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, and to obtain redress for those who have purchased Defendants' "orthodontic" pacifiers.

13. Plaintiff, for herself and for the Class, seeks actual and statutory damages, and costs of suit and reasonable attorneys' fees.

JURISDICTION AND VENUE

14. 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.

15. This Court has personal jurisdiction over Defendants because Defendants conduct business in New York. Defendants have marketed, promoted, distributed, and sold the "orthodontic" pacifiers at issue in New York, rendering exercise of jurisdiction by New York courts permissible.

16. 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 Plaintiff's claims occurred in this district.

PARTIES

17. Plaintiff Naomi Harris is a citizen of New York and, at all relevant times to this action, resided in Troy, New York.

18. In approximately March 2021, Plaintiff purchased one of Defendants' "orthodontic" pacifiers for her child at the Walmart located in Troy, New York, for approximately

\$8.99. Plaintiff purchased the pacifier for her child who was approximately 19 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. Plaintiff would have paid less for the "orthodontic" pacifier for use by her child 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, Plaintiff suffered an injury-in-fact and lost money.

19. Prior to her purchase in March 2021, Plaintiff had been purchasing NUK branded "orthodontic" pacifiers periodically over a period of approximately ten (10) years for her four children.

20. Plaintiff's children used the NUK "orthodontic" pacifier on a daily basis, as her children used other NUK "orthodontic" pacifiers that Plaintiff purchased before and since March 2021.

21. The NUK "orthodontic" pacifier Plaintiff purchased, like all of Defendants' pacifiers at issue, is not an orthodontic product. Plaintiff 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 known the truth about Defendants' misrepresentations and omissions at the time of purchase, Plaintiff 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 Graco Children's Products, Inc. purchased NUK USA LLC, at the time a wholly owned subsidiary of Newell Brands Inc., in December 2017. The principal place of business of Graco Children's Products, Inc. is located at 6655 Peachtree Dunwoody Road, Atlanta, Georgia 30328. Defendant Graco Children's Products, Inc. is a distributor of NUK pacifiers in the United States, including in New York and this district.

24. Defendants Newell Brands Inc. and Graco Children's Products, Inc. have marketed, advertised, and sold NUK pacifiers, including NUK "orthodontic" pacifiers in the United States, including in New York and this district.

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 New York and throughout the United States that their Orthodontic Pacifiers 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. In addition to the misleading "orthodontic" claim, the packaging for some of NUK's Orthodontic Pacifiers at issue here include the following statements:

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

30. The product packaging for all of NUK's Orthodontic Pacifiers refers consumers to Defendants' website, <https://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, includes the following statement: "NUK Orthodontic Pacifiers . . . feature a unique, improved asymmetrical nipple that naturally fits baby's palate to allow more room for a natural sucking motion, reduces pressure on teeth and jaws, and helps prevent teeth misalignment." See https://www.nuk-usa.com/pacifiers-oral-care/shop-by-age/0-6-months/nuk-classic-orthodontic-pacifiers-0-6-months/SAP_2073312.html.

31. In addition, on its website NUK claims that it makes an "Orthodontic Pacifier" which "is flatter to allow more room for a natural sucking motion, slimmer to reduce pressure on the jaw and teeth, and narrower to prevent teeth misalignment." See <https://www.nuk-usa.com/pacifiers-oral-care/pacifier-collections/classic-orthodontic/>.

32. And lastly, the Frequently Asked Questions on Defendant'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/on/demandware.store/Sites-nuk-Site/default/Support-Show?cfid=pacifiers-faq>.

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

34. 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 products as Orthodontic Pacifiers, 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."

35. 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 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 Because "Orthodontic" Pacifiers Do Not Exist

36. Despite Defendants' statements and representations, their Orthodontic Pacifiers pose significant health risks to children and do not provide orthodontic benefits to children. 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

37. In fact, there is little to no measurable difference between traditional and "orthodontic" pacifiers. "The articles selected . . . agree that there are occlusal and orofacial implications to the structures in the two types of nozzles, but with no statistical differences between them."² As a result, children who use a pacifier, regardless of the pacifier's shape, will have higher

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 Corrêa, C. D. C., et al. (2016), *Interferência dos bicos ortodônticos e convencionais no sistema* (footnote continued)

rates of, and an increased risk for, malocclusion traits and other oral-health related issues than children with no pacifier sucking habits.³ This reality is reflected in academic literature which advises ending infant pacifier use before ten (10) months of age⁴ and in the guidance materials from the American Academy of Pediatric Dentistry, which does not differentiate between conventional and “orthodontic” pacifiers.⁵

38. The scientific literature identified and discussed below illustrates the well-documented risks of pacifier usage by children and establishes the misleading nature of Defendants’ advertising statements—specifically Defendants’ use of the term “orthodontic.” Defendants’ advertising statements are false and misleading against the backdrop of this expansive body of scientific literature. Given the literature and studies below, 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, 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.

DENTAL AND ORTHODONTIC LITERATURE AND STUDIES

A. Early Studies Linking Pacifier Usage to Dental Malocclusions

estomatognático: revisão sistemática, *Codas* 28(2): 182-189, 188; *see also*, K. Schmid et al., *The Effect of Pacifier Sucking on Orofacial Structures: a Systematic Literature Review*, 19:8 *Prog. Orthod.* 1 (2018); Medeiros et al., *supra* note 1.

³ Medeiros et al., *supra* note 1 at 294.

⁴ Sexton S, N. R. (2009), *Risks and Benefits of Pacifiers*, *Am Fam Physician* 79(8), 681-685, 684.

⁵ American Academy of Pediatric Dentistry (2022) *Policy on Pacifiers*. Retrieved June 21, 2023, from https://www.aapd.org/research/oral-health-policies--recommendations/p_pacifiers.pdf/; American Academy of Pediatric Dentistry, *Management of the Developing Dentition and Occlusion in Pediatric Dentistry*, *The Reference Manual of Pediatric Dentistry* 408 (2021).

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.⁶

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."⁷ 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 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.⁸ 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,

⁶ 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).

⁷ 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).

⁸ 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).

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.⁹

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 6. 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 habits. *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 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

⁹ *See* Schmid et al., *supra* note 2.

found for mean overjet, mean openbite, occurrence of openbite, or occurrence of posterior crossbite.” *Id.*¹⁰

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 7. “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 559.¹¹

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.¹² The study found that: “prolonged pacifier use was associated with various types of

¹⁰ Adair et al. refer to “orthodontic” pacifiers as “functional exercisers,” in reference to the original Nuk™ branding from the first line of orthodontic pacifiers.

¹¹ Zardetto and many dental and orthodontic researchers advocate that a more appropriate term for “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.

¹² 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).

[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.

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 et al., *supra* note 2.

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 Bite*¹³

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 6, 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 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 7, 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.

¹³ 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).

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 12, 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 2, at 3.

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.¹⁴

¹⁴ 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. 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 6; 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* (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:



Figure 2 – Posterior Crossbite¹⁵

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 7, at 556; Adair et al., *supra* note 6, 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

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.

¹⁵ Warren and Bishara, *supra* note 14, at 354.

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 14, at 351.

63. “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.* 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.

64. 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 2, 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).¹⁶

¹⁶ 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 14; 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. (footnote continued)

3. Excessive Overjet

65. 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

66. 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 6, 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

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

the conventional pacifier and those who sucked the orthodontic ones.” Zardetto et al., *supra* note 7, at 556.

67. 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 12, 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.

68. 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 2, 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.*¹⁷

4. Class II Canine Relationship

69. 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:

¹⁷ See also Adair, Melsen, Warren, Zardetto, Zimmer, Dimberg, Lima *supra* note 14; 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

70. 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 6, 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 14.¹⁸

5. Dental Arch Alterations

71. 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.¹⁹

¹⁸ *See also* Farsi, Zardetto, Lima, Melsen, *supra* note 14; Ravn, *supra* note 17; Schmid et al., *supra* note 2.

¹⁹ *See, e.g.*, Adair, Warren and Bishara, Zardetto, Ogaard, Larsson, *supra* note 16; Bowden, *supra* (footnote continued)



Figure 5 – Narrowed Palate

72. 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 2, at 8; see also Warren and Bishara, *supra* note 14, at 350-51.

73. Specifically, Warren and Bishara found “pacifier 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.

74. 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

note 17; 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).

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 7, at 559.

6. Other Conditions and Psychosocial Development

75. 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.²⁰ 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.

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

²⁰ See, e.g., Zardetto, *supra* note 7; Bowden, *supra* note 17; 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 2.



Figure 6 – Diastema²¹

77. Lima et al. and others have demonstrated a link between prolonged pacifier use and the development of increased spacing between the teeth.²² 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.

78. Oral myofunctional alterations can also develop from prolonged pacifier usage (see, e.g., Zardetto et al., *supra* note 7) 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:

²¹ See also Figure 2.

²² See, e.g., Lima, and Kohler and Holst, *supra* note 14.



Figure 7 – Lip Incompetence (right)

79. 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.²³ “[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.²⁴

²³ 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).

²⁴ 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)

80. 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.”²⁵ 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

81. Despite ample dental and orthodontic studies and literature demonstrating the contrary, Defendants consistently convey to reasonable consumers, through their advertising statements, that their Orthodontic Pacifiers promote healthy oral and orofacial development. Defendants’ misleading use of the term “orthodontic” on their product packaging constitutes illegal conduct. As a result of Defendants’ wrongful and misleading advertising statements, Plaintiff and class members are injured at the time of purchase.

82. 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

(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).

²⁵ 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).

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 concomitant duty to disclose potential risks of product use.

83. 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 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, and that those products do not promote the healthy oral and orofacial development of children, nor do they prevent or correct teeth misalignment.

84. 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.

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

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

87. Plaintiff would have paid less for Defendants' Orthodontic Pacifiers had Defendants made truthful advertising statements concerning the impact on oral and orofacial health of "orthodontic" pacifiers.

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

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

90. Defendants' misrepresentations and omissions were a material factor in influencing Plaintiff's and Class members' decision to purchase Orthodontic Pacifiers.

91. Defendants' conduct has injured Plaintiff and Class members because Defendants' Orthodontic Pacifiers do not promote healthy oral and orofacial development and do not prevent or correct teeth misalignment. Rather, Defendants' Orthodontic Pacifiers have known, substantial risks, and Defendants failed to conspicuously disclose those risks to Plaintiff and Class members.

CLASS DEFINITION AND ALLEGATIONS

92. Pursuant to Federal Rule of Civil Procedure 23(b)(3), Plaintiff brings this action on behalf of herself and the proposed class (the "Class"):

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

93. Excluded from the Class 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.

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

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

96. **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 Class are: (1) whether Defendants' representations regarding their Orthodontic Pacifiers are misleading and deceptive; (2) whether Defendants' representations and omissions concerning their Orthodontic Pacifiers involved representations and omissions of material facts; (3) whether Defendants' Orthodontic Pacifiers promote or benefit the oral and orofacial health of children of any age; (4) whether Defendants' conduct, as set forth in this Complaint, violates the New York Consumer Protection Act; and (5) 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.

97. **Typicality – Federal Rule of Civil Procedure 23(a)(3).** Plaintiff's 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. Plaintiff 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, Plaintiff 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.

98. **Adequacy of Representation – Federal Rule of Civil Procedure 23(a)(4).** Plaintiff is an adequate representative of the Class because Plaintiff has no interest adverse to the interests of the members of the proposed Class and Plaintiff has retained counsel competent and experienced in complex commercial and consumer class action litigation. Plaintiff intends to prosecute this action vigorously. The interests of the Class members will be fairly and adequately protected by Plaintiff and her counsel.

99. **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 Class individually controlling the prosecution of separate actions. The damages or other financial detriment suffered by Plaintiff 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 New York 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 NEW YORK'S DECEPTIVE PRACTICES ACT
N.Y. Gen. Bus. Law §§ 349, *et seq.*
(On Behalf of Plaintiff Harris and the Class)**

100. Plaintiff Harris, individually and on behalf of the Class, brings this cause of action and hereby adopts and incorporates the preceding paragraphs as if fully set forth herein.

101. The New York General Business Law (“GBL”) § 349, prohibits “[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state” GBL § 349(a).

102. The practices alleged herein—namely, deceiving customers into believing that the Orthodontic Pacifiers possess orthodontic traits that improve oral health—are unfair, deceptive, and misleading in violation of GBL § 349.

103. The foregoing deceptive acts and practices were directed at Plaintiff Harris and other members of the Class.

104. Defendants' misrepresentations, including its prominent labeling of the Orthodontic Pacifiers with the misleading "orthodontic" claim, are material to a reasonable consumer because they relate to the Orthodontic Pacifiers' essential purpose, *i.e.*, the ability to improve oral health. A reasonable consumer attaches importance to such representations and is induced to act thereon in making purchasing decisions.

105. Plaintiff Harris and members of the Class have been injured as a direct and proximate result of Defendants' unlawful acts as they would have paid less for Defendants' Orthodontic Pacifiers but for Defendants' material misrepresentations regarding the Orthodontic Pacifiers' ability to improve oral health, as described in this Complaint.

106. As a result of Defendants' unlawful actions, Plaintiff Harris and members of the Class seek to enjoin Defendants' deceptive and unlawful acts and practices described herein; to recover the greater of their actual damages or fifty dollars per violation; and to recover treble damages, reasonable attorneys' fees, and all other remedies this Court deems proper.

SECOND CAUSE OF ACTION
VIOLATION OF NEW YORK'S DECEPTIVE PRACTICES ACT
N.Y. Gen. Bus. Law §§ 350, *et seq.*
(On Behalf of Plaintiff Harris and the New York Class)

107. Plaintiff Harris, individually and on behalf of the Class, brings this cause of action and hereby adopts and incorporates the preceding paragraphs as if fully set forth herein.

108. GBL § 350 provides in relevant part: "False advertising in the conduct of any business, trade or commerce . . . in this state is hereby declared unlawful."

109. In turn, GBL § 350-a defines false advertising as:

advertising, including labeling, of a commodity...if such advertising is misleading in a material respect. In determining whether any advertising is misleading, there shall be taken into account (among other things) not only representations made by statement, word, design, device, sound or any combination thereof, but also the extent to which the advertising fails to reveal facts material in the light of such representations with respect to the commodity...to which the advertising relates

under the conditions prescribed in said advertisement, or under such conditions as are customary or usual.

110. Defendants' claim that the Orthodontic Pacifiers can improve oral health, including its prominent labeling of them with the misleading "orthodontic" descriptor, are untrue and materially misleading and deceive consumers into believing the Orthodontic Pacifiers can improve oral health, which they cannot.

111. Defendants' misrepresentations regarding the Orthodontic Pacifiers are material to a reasonable consumer because they relate to the products' essential purpose, *i.e.*, oral health. A reasonable consumer attaches importance to such representations and is induced to act thereon in making purchase decisions.

112. Plaintiff Harris and the Class Members were induced to purchase the Orthodontic Pacifiers by Defendants' misrepresentations on the Orthodontic Pacifiers' labels.

113. Plaintiff Harris and members of the Class have been injured as a direct and proximate result of Defendants' unlawful acts as they would have paid less for Defendants' Orthodontic Pacifiers but for Defendants' material misrepresentations regarding the Orthodontic Pacifiers' ability to improve oral health, as described in this Complaint.

114. As a result of Defendants' unlawful actions, Plaintiff Harris and members of the Class seek to enjoin Defendants' misleading and unlawful acts and practices described herein; to recover the greater of their actual damages or five hundred dollars per violation; and to recover treble damages, reasonable attorneys' fees, and all other remedies this Court deems proper.

JURY DEMAND

115. Plaintiff demands a trial by jury of all claims in this Complaint so triable.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of other members of the proposed Class, respectfully requests that the Court enter judgment in Plaintiff's favor and against Defendants as follows:

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

B. Ordering payment of actual and punitive damages;

C. Ordering payment of statutory damages pursuant to N.Y. Gen. Bus. Law §§ 349(h) and 350-d(1);

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

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: June 28, 2023

Respectfully submitted,

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**Pro Hac Vice Forthcoming*

ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: [NUK 'Orthodontic' Pacifiers Do Not Support Children's Dental Development as Advertised, Class Action Says](#)
