

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

KAITLIN DEFOREST, individually and on  
behalf of all others similarly situated,

Plaintiff,

v.

PHILIPS NORTH AMERICA, LLC AND  
PHILIPS HOLDING USA INC.,

Defendants.

CASE NO. \_\_\_\_\_

**CLASS ACTION**

**COMPLAINT**

**JURY TRIAL DEMANDED**

Plaintiff Kaitlin Deforest (“Plaintiff”), by her undersigned counsel, brings this class action complaint against Defendants Philips North America, LLC and Philips Holding USA Inc. (collectively, “Defendants”), 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 ACTION**

1. This is a consumer protection class action arising out of Defendants’ false and misleading advertising of their pacifiers featuring the prominent misrepresentation that they are “orthodontic,” which is deceptive and misleading to reasonable consumers.<sup>1</sup>

2. The reasonable consumer understands “orthodontic” to mean that the pacifiers promote oral development, but as more fully described herein, no pacifier is capable of promoting oral development, and worse, prolonged pacifier use can cause significant harm by interfering with the proper development of teeth and orofacial structures. Children who use pacifiers to continue

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<sup>1</sup> Subject to further discovery, such pacifiers include all pacifiers in the following collections: AVENT® Ultra Air Pacifiers and AVENT® Ultra Soft Pacifiers (hereinafter “Orthodontic Pacifier(s)”).

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 chewing, swallowing, speech and jaw development and function. Dental malocclusions and teeth misalignment may also have a significant adverse effect on psychosocial development, self-image and social well-being. Therefore, calling a pacifier “orthodontic” is misleading to the reasonable consumer.

3. Defendants manufacture, market, distribute and sell the Orthodontic Pacifiers throughout New York and nationwide. Defendants’ Orthodontic Pacifiers come in a variety of styles, colors and sizes.

4. “Orthodontics” is the branch of dentistry that corrects improperly positioned teeth and jaws. Through their marketing, advertising statements and misleading use of the term “orthodontic,” Defendants affirmatively represent to reasonable consumers that their Orthodontic Pacifiers promote healthy oral development or improve oral outcomes.

5. Defendants’ advertisement and prominent use of the term “orthodontic” is misleading to a reasonable consumer and is an affirmative representation that their Orthodontic Pacifiers promote healthy oral development or improve oral outcomes. Defendants’ use of the term “orthodontic” is designed to induce consumers to pay a premium price and buy the Orthodontic Pacifiers that do not perform as promised for their children. Defendants’ Orthodontic Pacifiers cannot, and do not, support healthy oral and orofacial development of children.

6. On the Orthodontic Pacifiers’ packaging and in their uniform 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. More fundamentally, Defendants' false claim that their pacifiers are "orthodontic" falsely suggests that the Orthodontic Pacifiers are somehow better for a child's oral health than a generic pacifier—they are not.

8. Through their advertising statements, Defendants induced Plaintiff to purchase their Orthodontic Pacifiers. Plaintiff reasonably believed that Defendants' Orthodontic Pacifiers would promote healthy oral development or improve oral outcomes for her children. 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/or disclosed material information concerning the non-orthodontic nature of the Orthodontic Pacifiers.

9. Through false, misleading and deceptive advertisements, Defendants violated New York law by representing that their Orthodontic Pacifiers promote healthy oral development or improve oral outcomes. Specifically, Plaintiff asserts claims for relief and restitution under New York's Consumer Protection from Deceptive Acts and Practices statutes, N.Y. Gen. Bus. Law §§ 349 and 350 ("New York Consumer Protection Act"), as well as similar consumer protection statutes of other included states, claims of unjust enrichment, breach of warranties and negligent misrepresentation.

10. Plaintiff brings this action on behalf of herself and a Class of similarly situated consumers who purchased Orthodontic Pacifiers manufactured by Defendants nationwide, and in other states with similar consumer protection statutes. Plaintiff also seeks to represent a New York State Class.

11. Plaintiff seeks to halt Defendants' dissemination of false and misleading representations, to correct the false and misleading perception that Defendants' representations

created in the minds of reasonable consumers and to obtain redress for those who purchased Defendants' Orthodontic Pacifiers in the form of actual and statutory damages, costs of suit and reasonable attorneys' fees.

### **JURISDICTION AND VENUE**

12. 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 \$5,000,000.00 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.

13. This Court has personal jurisdiction over Defendants because Defendants conduct business in New York. Defendants marketed, promoted, distributed and sold the Orthodontic Pacifiers at issue in New York, rendering exercise of jurisdiction by New York courts permissible.

14. 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**

#### ***Plaintiff Kaitlin DeForest***

15. Plaintiff Kaitlin DeForest is a citizen of New York and, at all relevant times to this action, resided in Staten Island, New York.

16. In approximately March 2024, Plaintiff purchased two (2) packs of Defendants' Orthodontic Pacifiers—Philips Avent Ultra Soft Pacifiers—for her child from Amazon.com, for approximately \$13.89. Prior to that purchase, Plaintiff purchased Defendants' Orthodontic Pacifiers from a Target store located in Staten Island, New York, for approximately \$6.99 (Philips Avent Ultra Soft Pacifier). Plaintiff purchased the Orthodontic Pacifiers for her two children, most

recently for her child who was approximately nine (9) months old at the time of purchase. Plaintiff saw and relied on Defendants' representation that the pacifiers were "orthodontic." Defendants failed to disclose clearly and conspicuously the material facts that, contrary to Defendants' advertising and marketing statements, the Orthodontic Pacifiers were not capable of promoting healthy oral development or improving oral outcomes. Plaintiff would have paid less for the Orthodontic Pacifiers for use by her children or would not have bought them at all, but for Defendants' misrepresentations and omissions of material fact. By purchasing the falsely advertised Orthodontic Pacifiers without any warning about risks associated with the use of pacifiers, Plaintiff suffered an injury-in-fact and lost money.

17. Prior to her purchases in 2023 and 2024, Plaintiff purchased the Orthodontic Pacifiers periodically over a period of approximately three (3) years for her two children. Plaintiff's children used the Orthodontic Pacifiers on a daily basis.

18. Shortly after her purchase of the Orthodontic Pacifiers in March 2024, Plaintiff discovered that the Orthodontic Pacifiers were not capable of promoting healthy oral development or improving oral outcomes for her children. Upon this discovery, Plaintiff ceased use of Defendants' Orthodontic Pacifiers.

19. The Orthodontic Pacifiers Plaintiff purchased, like all of Defendants' Orthodontic Pacifiers at issue, are not capable of promoting healthy oral development or improving oral outcomes. Plaintiff purchased the Orthodontic Pacifiers because she believed, based on the representations made by Defendants, that the Orthodontic Pacifiers 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 Orthodontic Pacifiers or would not have purchased them.

***Defendants Philips North America, LLC and Philips Holding USA Inc.***

20. Defendant Philips North America, LLC is a Delaware limited liability company with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips North America, LLC is the owner, manufacturer and/or distributor of the Orthodontic Pacifiers.

21. Defendant Philips Holding USA Inc. is a Delaware corporation with its principal place of business at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips Holding USA, Inc. is a holding company that manages the operations of Philips North America, LLC's various lines of business.<sup>2</sup> Philips North America, LLC is managed by Philips Holding USA Inc.

22. Defendants Philips North America, LLC and Philips Holdings USA Inc. have marketed, advertised and sold pacifiers, including the Orthodontic Pacifiers in the United States, New York and this District.

**FACTUAL ALLEGATIONS**

**I. Defendants' Orthodontic Pacifiers**

23. Defendants manufacture, market, distribute and sell a line of "orthodontic" pacifiers. The Orthodontic Pacifiers are sold at various brick-and-mortar retail and grocery stores. Defendants' Orthodontic Pacifiers are also sold online through the websites of the same retailers, as well as on Amazon.com, other online retailers and Defendants' own website.

24. Defendants' Orthodontic Pacifiers are sold under the AVENT<sup>®</sup> brand name and include the following products for all age ranges:

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<sup>2</sup> Corporate Disclosure Statement in *Newsome, Jr. v. Philips North America LLC*, No. 4:22-cv-04101-HSG (N.D. Cal. July 13, 2022), ECF No. 2 ("Philips Holdings USA Inc. is the member/manager of the Philips North America, LLC.").

- AVENT® Ultra Air Pacifiers; and
- AVENT® Ultra Soft Pacifiers.

## II. Defendants' False and Deceptive Advertising

25. Defendants, through their advertisements—including on the Orthodontic Pacifier packaging and labeling—consistently conveyed to consumers in New York and throughout the United States that their Orthodontic Pacifiers promote healthy oral development or improve oral outcomes for children of all ages.

26. Throughout the class period, the Orthodontic Pacifiers have consistently and uniformly been advertised with on-label “orthodontic” representations:



27. Defendants' use of the word “orthodontic” conveys to reasonable consumers that the Orthodontic Pacifiers are capable of promoting healthy oral development or improving oral



outcomes. This representation is false and misleading because the Orthodontic Pacifiers do not promote healthy oral development or improve oral outcomes in this manner.

28. Defendants' website confirms that Defendants intend for consumers to understand "orthodontic" to mean that their pacifiers will assist in healthy oral development.<sup>3</sup> The webpages for Defendants' Orthodontic Pacifiers, include the following additional "orthodontic" representations:

- "Designed for natural oral development;"
- "Natural Oral Development;" and
- "Our orthodontic, symmetrical silicone nipples are designed for natural oral development."<sup>4</sup>

29. Similarly, on their website Defendants present the following in their Frequently Asked Questions section:

Are Philips Avent pacifiers orthodontically safe? Yes, all Philips Avent pacifiers are safe. Our pacifiers are soft, and the small nipple flattens easily. It adapts to the baby's tongue and palate. The shape of the pacifier spreads the pressure evenly on the baby's jaw, teeth, and gums."<sup>5</sup>

30. This website marketing confirms Defendants' intent to mislead reasonable consumers regarding the "orthodontic" nature of the Orthodontic Pacifiers.

31. 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

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<sup>3</sup> See Philips Avent, *Pacifiers*, <https://www.usa.philips.com/c-m-mo/pacifiers> (last accessed: Feb. 10, 2025).

<sup>4</sup> See e.g., Philips Avent, *Ultra Soft*, [https://www.usa.philips.com/c-p/SCF091\\_05/pacifier-ultra-air-pacifier#see-all-benefits](https://www.usa.philips.com/c-p/SCF091_05/pacifier-ultra-air-pacifier#see-all-benefits) (last accessed: Mar. 11, 2025); Philips Avent, *Ultra Air*, [https://www.usa.philips.com/c-p/SCF085\\_54/pacifier-ultra-air-pacifier#see-all-benefits](https://www.usa.philips.com/c-p/SCF085_54/pacifier-ultra-air-pacifier#see-all-benefits) (last accessed: Mar. 11, 2025).

<sup>5</sup> Philips Avent, *Philips Support* (Sept. 16, 2024), <https://www.usa.philips.com/c-f/XC000003051/are-philips-avent-pacifiers-orthodontically-safe> (last accessed Feb. 10, 2025).



clearly market and label their products as Orthodontic Pacifiers, Defendants mislead reasonable consumers by labeling the Orthodontic Pacifiers as “orthodontic” and by failing to prominently and conspicuously disclose these risks on their Orthodontic Pacifier packaging and advertising materials.

32. Based on these representations and omissions, it is clear that Defendants intend to induce in consumers a common belief that Defendants’ Orthodontic Pacifiers do not pose any risk to the oral or orofacial health of children and, further, that the Orthodontic Pacifiers promote healthy oral development or improve oral outcomes.

### **III. Scientific Studies Confirm That Defendants’ Representations Are False, Deceptive and Misleading Because no Pacifier is “Orthodontic”**

33. 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.”<sup>6</sup>

34. In fact, there is little to no measurable difference between traditional and “orthodontic” pacifiers, yet Defendants market their Orthodontic Pacifiers as promoting an added benefit over traditional pacifiers. “The articles selected . . . agree that there are occlusal and

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<sup>6</sup> 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).

orofacial implications to the structures in the two types of nozzles, but with no statistical differences between them.”<sup>7</sup> 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.<sup>8</sup> This reality is reflected in academic literature which advises ending infant pacifier use before ten (10) months of age<sup>9</sup> and in the guidance materials from the American Academy of Pediatric Dentistry, which does not differentiate between conventional and “orthodontic” pacifiers.<sup>10</sup>

35. The scientific literature identified and discussed below illustrates the well-documented risks of pacifier usage 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 herein, Defendants knew, or should have known, that their 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

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<sup>7</sup> Corrêa, C. D. C., et al. (2016), *Interferência dos bicos ortodônticos e convencionais no sistema estomatognático: revisão sistemática*, Cotas 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 8.

<sup>8</sup> Medeiros et al., *supra* note 8 at 294.

<sup>9</sup> Sexton S, N. R. (2009), *Risks and Benefits of Pacifiers*, Am Fam Physician 79(8), 681-85, 684.

<sup>10</sup> American Academy of Pediatric Dentistry (2022) *Policy on Pacifiers*, available at [https://www.aapd.org/research/oral-health-policies--recommendations/p\\_pacifiers.pdf/](https://www.aapd.org/research/oral-health-policies--recommendations/p_pacifiers.pdf/) (last accessed: Feb. 10, 2025); American Academy of Pediatric Dentistry, *Management of the Developing Dentition and Occlusion in Pediatric Dentistry*, The Reference Manual of Pediatric Dentistry 408 (2021).

of developing various forms of dental malocclusions, they were omitting material facts that would alter any reasonable consumer's decision to purchase Orthodontic Pacifiers.

***Dental and Orthodontic Literature and Studies***

36. 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 1950's when the first orthodontic pacifier was introduced in the United States and marketed to the public.<sup>11</sup>

37. 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."<sup>12</sup> 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.*

38. Studies dating back to as early as the 1870's have consistently demonstrated the link between non-nutritive sucking habits and abnormalities in dental development and occlusion.<sup>13</sup> By the time the first "functional/orthodontic" pacifier was introduced in the 1950's, it

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<sup>11</sup> 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).

<sup>12</sup> 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).

<sup>13</sup> 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 (footnote continued)

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).

39. Since the 1960’s, hundreds of studies 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.<sup>14</sup>

***“Orthodontic” Versus Conventional Pacifiers***

40. 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 13. 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).

41. 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

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(1878).

<sup>14</sup> *See* Schmid et al., *supra* note 9.

found for mean overjet, mean openbite, occurrence of openbite, or occurrence of posterior crossbite.” *Id.*<sup>15</sup>

42. 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 14. “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.

43. 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.<sup>16</sup>

44. 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.<sup>17</sup> The study found that: “prolonged pacifier use was associated with various types of

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<sup>15</sup> Adair et al. refer to “orthodontic” pacifiers as “functional exercisers,” in reference to the original branding from the first line of orthodontic pacifiers.

<sup>16</sup> 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.

<sup>17</sup> A. Lima et al., *Effects of Conventional and Orthodontic Pacifiers on the Dental Occlusion* (footnote continued)

[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.

45. Consistent with the Adair, Zardetto and Lima studies described above, nearly every clinical study examining the effects of the prolonged use of “orthodontic” pacifiers 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 8.

46. 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: “[i]n children between 6-60 months, is there a difference in the occurrence of malocclusion between the types of the pacifiers (conventional or orthodontic) used?” *Id.* at 288.

47. 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.

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*of Children Aged 24-36 Months Old*, 27:2 Int. J. Paediatr. Dent. 108 (2016).

48. 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.

***Impact of Prolonged Pacifier Use on Oral Development***

49. 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 8; Schmid et al., *supra* note 9.

50. 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.



### Anterior Open Bite

51. 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*<sup>18</sup>

52. 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 13, 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.

53. 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 14, at 556. Additionally, “[w]ith respect to degree of open bite in millimeters . . . there was no significant difference between

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<sup>18</sup> 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).

children who used the conventional pacifier and those who used the physiological one.” *Id.* at 556-57.

54. 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 19, at 5.

55. 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 9, at 3.

56. In addition to the above research, the 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.<sup>19</sup>

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<sup>19</sup> 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 13; 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*, (footnote continued)

### Posterior Crossbite

57. 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 Crossbite<sup>20</sup>

58. 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 14, at 556; Adair et al., *supra* note 13, at 441.

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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 8.

<sup>20</sup> Warren and Bishara, *supra* note 21, at 354.

59. 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 21, at 351.

60. "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.* at 351. 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.

61. 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 9, 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.*<sup>21</sup>

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<sup>21</sup> Scavone et al., *Prevalence of Posterior Crossbite Among Pacifier Users: a Study in the Deciduous Dentition*, Braz. J. Oral Res. 153 (2007); 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 21; 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*, (footnote continued)

### Excessive Overjet

62. 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*

63. 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 13, at 439. Between children who used conventional pacifiers and those who used “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

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

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 14, at 556.

64. 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 19, 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.

65. 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 9, 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.*<sup>22</sup>

### **Class II Canine Relationship**

66. 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:

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<sup>22</sup> See also Adair, Melson, Warren, Zardetto, Zimmer, Dimberg, Lima *supra* note 21; 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*

67. 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 13, 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. Dimberg, et al, *supra* note 21.<sup>23</sup>

#### **Dental Arch Alterations**

68. 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.<sup>24</sup>

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<sup>23</sup> *See also* Farsi, Zardetto, Lima, Melson, *supra* note 21; Ravn, *supra* note 24; Schmid et al., *supra* note 9.

<sup>24</sup> *See, e.g.,* Adair, Warren and Bishara, Zardetto, Ogaard, Larsson, *supra* note 23; Bowden, (footnote continued)





*Figure 5 – Narrowed Palate*

69. 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 9, at 8; *see also* Warren and Bishara, *supra* note 21, at 350-51.

70. 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.

71. 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

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*supra* note 24; 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).

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 14, at 559.

### **Other Conditions and Psychosocial Development**

72. 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.<sup>25</sup> 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.

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



*Figure 6 – Diastema*<sup>26</sup>

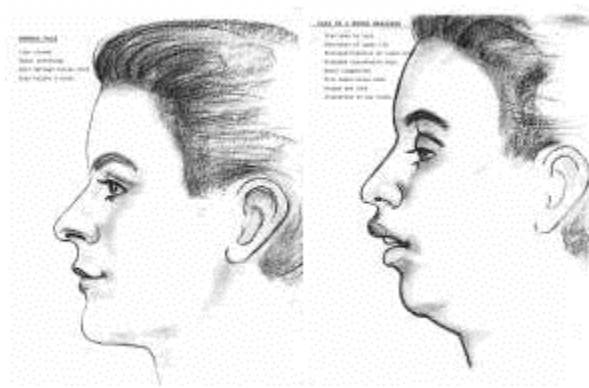
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<sup>25</sup> See, e.g., Zardetto, *supra* note 14; Bowden, *supra* note 24; B. Black et al., *Harmful Oral Habits*, 23 *Ortodon.* 40 (1990); S. Adair, *Nonnutritive Sucking Habits in Infants and Preschool Children: a Review and Recommendations for 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 9.

<sup>26</sup> See also Figure 2.

74. Lima et al. and others have demonstrated a link between prolonged pacifier use and the development of increased spacing between the teeth.<sup>27</sup> 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.

75. Oral myofunctional alterations can also develop from prolonged pacifier usage (see, e.g., Zardetto et al., *supra* note 14) 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:



*Figure 7 – Lip Incompetence (right)*

76. 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.<sup>28</sup> "[D]entofacial esthetics plays an important role in social interaction and psychological well-being.

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<sup>27</sup> See, e.g., Kohler and Holst, *supra* note 21.

<sup>28</sup> 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).

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 examined dissatisfaction with dental appearance and negative psychosocial impacts made similar conclusions.<sup>29</sup>

77. 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.”<sup>30</sup> 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

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<sup>29</sup> 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 (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).

<sup>30</sup> 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).

secondary psychosocial effects that can impact a child's self-image and social well-being throughout his or her life.

### **IMPACT OF DEFENDANTS' WRONGFUL CONDUCT**

78. Despite ample dental and orthodontic studies and literature demonstrating the contrary, Defendants consistently convey to reasonable consumers, through their advertising statements and labeling, that their Orthodontic Pacifiers promote healthy oral development or improve oral outcomes. Defendants' misleading use of the term "orthodontic" on their Orthodontic Pacifiers' packaging constitutes illegal conduct. As a result of Defendants' wrongful and misleading advertising statements, Plaintiff and Class Members were injured at the time of purchase.

79. As prominent, longtime and iconic manufacturers and distributors of baby products—including pacifiers—Defendants possess specialized knowledge regarding the safety and efficacy of their Orthodontic Pacifiers, 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 concomitant duty to disclose potential risks of product use.

80. 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 their Orthodontic Pacifiers do not promote healthy oral development or improve oral outcomes for children, nor do they prevent teeth misalignment.

81. Defendants knew, or should have known, that their Orthodontic Pacifiers do not promote healthy oral development or improve oral outcomes for children.

82. Defendants' material misrepresentations and omissions, set forth in this Complaint, were disseminated uniformly to Plaintiff and all Class Members through the Orthodontic Pacifiers' 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.

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

84. Plaintiff would have paid less, or would not have purchased Defendants' Orthodontic Pacifiers had Defendants made truthful advertising statements concerning their Orthodontic Pacifiers' impact on oral and orofacial health of her children.

85. 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 have paid less or would not have paid had Defendants truthfully advertised their Orthodontic Pacifiers.

86. Plaintiff and Class Members are reasonable consumers who were injured by purchasing Defendants' Orthodontic Pacifiers. Because of Defendants' material misrepresentations and omissions in their statements and advertisements concerning their Orthodontic Pacifiers—including on the Orthodontic Pacifiers' packaging and labeling—Plaintiff and Class Members were harmed at the time of purchase.

87. Defendants' misrepresentations and omissions were material factors in influencing Plaintiff's and Class Members' decision to purchase the Orthodontic Pacifiers.

88. Defendants' conduct has injured Plaintiff and Class Members because Defendants' Orthodontic Pacifiers do not promote healthy oral development or improve oral outcomes. Rather, Defendants' Orthodontic Pacifiers have known and substantial risks that Defendants failed to conspicuously disclose to Plaintiff and Class Members.

**FED. R. CIV. P. 9(b) ALLEGATIONS**  
*(Affirmative and By Omission)*

89. Although Defendants are in the best position to know what content they placed on their Orthodontic Pacifier packaging, their website(s) and in marketing materials during the relevant timeframe, and the knowledge they had regarding the Orthodontic Pacifiers' incapability to promote healthy oral development or improve oral outcomes and their failure to disclose those facts to consumers, to the extent necessary, Plaintiff satisfies the requirements of Rule 9(b) by alleging the following facts with particularity:

90. **WHO:** Defendants made material misrepresentations and/or omissions of fact through their Orthodontic Pacifier packaging, their website(s) and in marketing materials regarding the Orthodontic Pacifiers capability to promote healthy oral development or improve oral outcomes, and omitted material information regarding the Orthodontic Pacifiers' incapability to promote healthy oral development or improve oral outcomes.

91. **WHAT:** Defendants' conduct was, and continues to be, fraudulent because they omitted and concealed that the Orthodontic Pacifiers do not promote healthy oral and orofacial development, a fact that Defendants knew, or should have known, to be true, but nonetheless marketed, and continue to market, the Orthodontic Pacifiers as promoting healthy oral and orofacial development. Thus, Defendants' conduct deceived Plaintiff and Class Members into



believing that the Orthodontic Pacifiers are capable of promoting healthy oral development or improving oral outcomes. Defendants knew, or should have known, this information is material to reasonable consumers—including Plaintiff and Class Members—in making their purchasing decisions, yet they continued to pervasively market and label their Orthodontic Pacifiers as promoting healthy oral and orofacial development.

92. **WHEN:** Defendants made material misrepresentations and/or omissions during the putative class periods and at the time Plaintiff and Class Members purchased the Orthodontic Pacifiers, prior to and at the time Plaintiff and Class Members made claims after realizing the Orthodontic Pacifiers' incapability to promote healthy oral development or improve oral outcomes, and continuously throughout the applicable class periods.

93. **WHERE:** Defendants' marketing message was uniform and pervasive, carried through material misrepresentations and/or omissions on the labeling of their packaging, their website(s) and through marketing materials.

94. **HOW:** Defendants made material misrepresentations and/or failed to disclose material facts regarding the Orthodontic Pacifiers, including, but not limited to, the Orthodontic Pacifiers' incapability to promote healthy oral development or improve oral outcomes.

95. **WHY:** Defendants made the material misrepresentations and/or omissions detailed herein for the express purpose of inducing Plaintiff, Class Members and all reasonable consumers to purchase and/or pay a price premium for the Orthodontic Pacifiers, the effect of which was Defendants profited by selling the Orthodontic Pacifiers to many thousands of consumers.

96. **INJURY:** Plaintiff and Class Members purchased, paid a premium or otherwise paid more for the Orthodontic Pacifiers when they otherwise would not have absent Defendants' misrepresentations and/or omissions.

### **CLASS DEFINITIONS AND ALLEGATIONS**

97. Pursuant to Federal Rule of Civil Procedure 23(b)(2) and (b)(3), Plaintiff brings this action on behalf of herself and the proposed Nationwide Class:<sup>31</sup>

All persons who purchased in the United States any of the AVENT® branded Ultra Air or Ultra Soft Pacifiers, within the applicable statute of limitations, until the date notice is disseminated.

98. Pursuant to Federal Rule of Civil Procedure 23(b)(2) and (b)(3), Plaintiff brings this action on behalf of herself and the proposed Multi-State Consumer Protection Class:

All persons who purchased in the state of New York or any state with similar laws<sup>32</sup> any of the AVENT® branded Ultra Air or Ultra Soft Pacifiers, within the applicable statute of limitations, until the date notice is disseminated.

99. Pursuant to Federal Rule of Civil Procedure 23(b)(2) and (b)(3), Plaintiff brings this action on behalf of herself and the proposed New York Class:

All persons who purchased in the State of New York any of the AVENT® branded Ultra Air or Ultra Soft Pacifiers, within the applicable statute of limitations, until the date notice is disseminated.

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<sup>31</sup> Unless otherwise specified, all references in this Complaint to “Classes” or the “Class” refer collectively to the Nationwide Class, Multi-State Consumer Protection Class and New York Class.

<sup>32</sup> While discovery may alter the following, Plaintiff asserts that the other states with similar consumer fraud laws under the facts of this case include, but are not limited to: Alaska (AS § 45.50.471, *et seq.*), Arkansas (Ark. Code § 4-88-101, *et seq.*), California (Cal. Bus. & Prof. Code § 17200, *et seq.*), Connecticut (Conn. Gen. Stat. § 42-110, *et seq.*), Delaware (Del. Code tit. 6, § 2511, *et seq.*), District of Columbia (D.C. Code § 28-3901, *et seq.*), Florida (Fla. Stat. § 501.201, *et seq.*), Hawaii (Haw. Rev. Stat. § 480-1, *et seq.*), Illinois (815 ICLS § 501/1, *et seq.*), Massachusetts (Mass. Gen. Laws Ch. 93A, *et seq.*), Michigan (Mich. Comp. Law § 445.901, *et seq.*), Minnesota (Minn. Stat. § 325F.67, *et seq.*), Missouri (Mo. Rev. Stat. § 407.010, *et seq.*), New Jersey (N.J. Stat. § 56:8-1, *et seq.*), New York (N.Y. Gen. Bus. Law. § 394, *et seq.*), Rhode Island (R.I. Gen. Laws § 6-13.1-1, *et seq.*), Vermont (Vt. Stat. tit. 9, § 2451, *et seq.*), Washington (Wash. Rev. Code § 19.86.010, *et seq.*), and Wisconsin (Wis. Stat. § 100.18, *et seq.*). *See Langan v. Johnson & Johnson Consumer Companies, Inc.*, 897 F.3d 88, 96 (2d Cir. 2018); *Mancuso v. RFA Brands, LLC*, 454 F. Supp. 3d 197, 201, 204 (W.D.N.Y. 2020); *see also Benson v. Newell Brands, Inc.*, No. 19 C 6836, 2021 WL 5321510, \*9-10 (N.D. Ill. Nov. 16, 2021) (certifying a similar multi-state consumer protection class).

100. 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 Classes; and (v) the Judge and staff to whom this case is assigned, and any member of the Judge's immediate family.

101. Plaintiff reserves the right to modify the Class definitions, if necessary, to include additional Orthodontic Pacifiers, but bearing different brand name, or otherwise.

102. Certification of Plaintiff's claims for class-wide treatment is appropriate because Plaintiff can prove the elements of her 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.

103. **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.

104. **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" representations amount to materially deceptive statements; (4) whether Defendant's Orthodontic Pacifiers are "orthodontic;" (5) whether Defendants' conduct violates the consumer fraud statutes, including the New York Consumer Fraud Statutes; (6) whether Defendants' conduct was unjust and in violation of principles of justice, equity and good conscience; (7) whether Defendants breached the express and implied warranties made to Plaintiff and Class Members; (8) whether Defendants' conduct satisfies the elements of fraud; (9) whether Defendants' conduct satisfies the elements of negligent misrepresentation; (10) whether Plaintiff and Class Members conferred financial benefits on Defendants by purchasing Defendants' Orthodontic Pacifiers; (11) whether Defendants' profits resulting from Plaintiff's and Class Members' purchases and/or 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 Classes and predominate over individual issues. Further, the issues of fact and law applicable to the Classes are identical to the issues of fact and law applicable to each individual Member of the proposed Classes.

105. **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 herein. 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 the Orthodontic Pacifiers. By advancing her 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.

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

Plaintiff is an adequate representative of the Classes because Plaintiff has no interest adverse to the interests of the Members of the proposed Classes 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.

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

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

**108. 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**

#### **BREACH OF IMPLIED WARRANTY**

*(On Behalf of Plaintiff DeForest and the Nationwide Class and, in the alternative, the New York Class)*

109. Plaintiff hereby adopts and incorporates by reference the allegations contained in paragraphs 1 through 108 as though fully set forth herein.

110. Defendants are merchants and were at all relevant times involved in the manufacturing, distributing, warranting and/or selling of the Orthodontic Pacifiers.

111. The Orthodontic Pacifiers are goods within the relevant laws and Defendants knew, or had reason to know, of the specific use for which the Orthodontic Pacifiers, as goods, were purchased.

112. The implied warranty of merchantability included with the sale of each Orthodontic Pacifier means Defendants warranted that the Orthodontic Pacifiers would be fit for the ordinary purposes for which the Orthodontic Pacifiers were used and sold, and were not otherwise injurious to consumers, that the Orthodontic Pacifiers would pass without objection in the trade, be of fair and average quality and conform to the promises and affirmations of fact made by Defendants. This implied warranty of merchantability is part of the basis for the benefit-of-the-bargain between Defendants on one hand, and Plaintiff and Class Members on the other.

113. Defendants breached the implied warranty of merchantability because the

Orthodontic Pacifiers are not fit for their ordinary purpose of promoting healthy oral development or improving oral outcomes for consumers' children, *inter alia*, the Orthodontic Pacifiers are incapable of promoting healthy oral development or improving oral outcomes, and therefore could not be reasonably characterized as "orthodontic."

114. The aforementioned problems associated with the Orthodontic Pacifiers constitute products that are not "orthodontic" by nature and fail to promote healthy oral development or improve oral outcomes for consumers' children, and therefore, Defendants have breached the implied warranty of merchantability.

115. Defendants' warranty expressly applies to the original purchaser and any succeeding owner of the Orthodontic Pacifiers, creating privity between Defendants on the one hand, and Plaintiff and Class Members on the other.

116. Nonetheless, privity is not required because Plaintiff and Class Members are the intended beneficiaries of Defendants' warranties and their sale of the Orthodontic Pacifiers through retailers. Defendants' retailers were not intended to be the ultimate consumers of the Orthodontic Pacifiers and have no rights under the warranty agreements. Defendants' warranties were designed for, and intended to, benefit the consumers only and Plaintiff and Class Members were the intended beneficiaries.

117. More specifically, Defendants' intention that their warranties apply to Plaintiff and Class Members as third-party beneficiaries is evident from the statements contained in the product literature, including their warranties. Likewise, it was reasonably foreseeable that Plaintiff and Class Members would be the intended beneficiaries of the Orthodontic Pacifiers and warranties.

118. Defendants impliedly warranted that the Orthodontic Pacifiers were of merchantable quality and fit for such use. These implied warranties included, among other things:



(i) a warranty that the Orthodontic Pacifiers manufactured, supplied, distributed and/or sold by Defendants promote healthy oral development or improved oral outcomes for consumers' children; and (ii) a warranty that the Orthodontic Pacifiers are fit for their intended use by consumers' children.

119. Contrary to the applicable implied warranties, the Orthodontic Pacifiers, at the time of sale and thereafter, are not fit for their ordinary and intended purpose of providing Plaintiff and Class Members with Orthodontic Pacifiers that promoted healthy oral development or improved oral outcomes for their children. Instead, the Orthodontic Pacifiers are incapable of promoting healthy oral development or improving oral outcomes, as alleged herein.

120. Defendants' failure to adequately repair or replace the Orthodontic Pacifiers caused the warranty to fail in its essential purpose.

121. Defendants breached the implied warranties because the Orthodontic Pacifiers were sold as incapable of promoting healthy oral development or improving oral outcomes for consumers' children, which substantially reduced and/or prevented the Orthodontic Pacifiers from being "orthodontic."

122. As a direct and proximate result of the foregoing, Plaintiff and Class Members suffered, and continue to suffer, financial damage and injury, and are entitled to all damages, in addition to costs, interest and fees, including attorneys' fees, as allowed by law.

## **SECOND CAUSE OF ACTION**

### **BREACH OF EXPRESS WARRANTY**

***(On Behalf of Plaintiff DeForest and the Nationwide Class and, in the alternative, the New York Class)***

123. Plaintiff hereby adopts and incorporates by reference the allegations contained in paragraphs 1 through 108 as though fully set forth herein.

124. Plaintiff and Class Members purchased the Orthodontic Pacifiers either directly from Defendants or through retailers, such as Target, Walmart and Amazon.com.

125. Defendants are, and were at all relevant times, “merchants” under U.C.C. § 2-313, and related State U.C.C. provisions.

126. In connection with their sale of the Orthodontic Pacifiers, Defendants, as the designer, manufacturer, marketer, distributor and/or seller, expressly warranted that the Orthodontic Pacifiers promote healthy oral development or improve oral outcomes for consumers’ children, most prominently by classifying the pacifiers as “orthodontic.”

127. Defendants’ warranty representations consist of the categorization of the Orthodontic Pacifiers as “orthodontic” and the pervasive marketing campaign, including the representations described herein that are made online and on the Orthodontic Pacifiers’ packaging.

128. The express written warranties covering the Orthodontic Pacifiers were a material part of the bargain between Defendants on one hand and Plaintiff, the Class and consumers on the other. At the time Defendants made these express warranties, Defendants knew reasonable consumers were purchasing the Orthodontic Pacifiers because they believed them to be as labeled and marketed.

129. Each of the Orthodontic Pacifiers have an identical or substantially identical product representation(s) as they each contain the product classification “orthodontic.”

130. Defendants breached their express warranties by selling the Orthodontic Pacifiers that were, in actuality, incapable of promoting healthy oral development or improving oral outcomes for consumers’ children, as promised in their labeling and marketing. Defendants breached the warranties because they sold the Orthodontic Pacifiers with the classification of “orthodontic,” despite the Orthodontic Pacifiers’ incapability to promote healthy oral development

or improve oral outcomes for consumers' children, which was known to Defendants and unknown to consumers at the time of sale/purchase. Defendants further breached the warranties because they improperly and unlawfully deny valid warranty claims, and they have failed or refused to adequately repair or replace the Orthodontic Pacifiers with products that are actually as represented.

131. Defendants breached their express warranties to adequately repair or replace the Orthodontic Pacifiers despite their knowledge of the Orthodontic Pacifiers' incapability to promote healthy oral development or improve oral outcomes for consumers' children, and/or despite their knowledge of alternative formulations, designs, materials and/or options for manufacturing and/or marketing and labeling of the Orthodontic Pacifiers.

132. Defendants further breached their express written warranties to Plaintiff and Class Members in that the Orthodontic Pacifiers are incapable of promoting healthy oral development or improving oral outcomes for consumers' children at the time they leave the manufacturing plant, and on the first day of purchase, and by failing to disclose and actively concealing the risks from consumers.

133. The Orthodontic Pacifiers that Plaintiff and Class Members purchased are incapable of promoting healthy oral development or improving oral outcomes for consumers' children, resulting in loss of the product, loss of use of the product and loss of the benefit of their bargain. Defendants' warranties expressly apply to the original purchaser and any succeeding owner of the Orthodontic Pacifiers for products purchased within the USA, creating privity between Defendants on the one hand, and Plaintiff and Class Members on the other.

134. Likewise, it was reasonably foreseeable that Plaintiff and Class Members would be the intended beneficiaries of the Orthodontic Pacifiers and warranties, creating privity or an

exception to any privity requirement. Plaintiff and each of the Class Members are the intended beneficiaries of Defendants' warranties and their sale of the Orthodontic Pacifiers through retailers. The retailers were not intended to be the ultimate consumers of the Orthodontic Pacifiers and have no rights under the warranty agreements provided by Defendants. Defendants' warranties were designed for, and intended to benefit, the consumer only and Plaintiff and Class Members were the intended beneficiaries of the Orthodontic Pacifiers.

135. Defendants have been provided sufficient notice of their breaches of the express warranties associated with the Orthodontic Pacifiers.

136. Upon information and belief, Defendants received further notice, and have been on notice, of their breach of warranties through their sale of Orthodontic Pacifiers and of their breaches of warranties through customer warranty claims reporting problems with Defendants, consumer complaints at various sources and their own internal and external testing.

137. As a direct and proximate result of Defendants' breach of their express written warranties, Plaintiff and Class Members suffered damages, did not receive the benefit of the bargain and are entitled to recover compensatory damages, including, but not limited to, the cost of inspection, repair and diminution in value. Plaintiff and Class Members suffered damages at the point-of-sale stemming from their purchase or overpayment for the Orthodontic Pacifiers, in addition to loss of the product and its intended benefits.

### **THIRD CAUSE OF ACTION**

#### **NEGLIGENT MISREPRESENTATION**

***(On Behalf of Plaintiff DeForest and the Nationwide Class and, in the alternative, the New York Class)***

138. Plaintiff re-alleges paragraphs 1 through 108 above as if set forth fully in this Count.

139. Pursuant to New York law, Plaintiff must prove the following for a negligent

misrepresentation claim: (1) a false statement of a material fact; (2) Defendants' knowledge that the statement was false; (3) Defendants' intent that the statement induce Plaintiff to act; (4) Plaintiff's reliance upon the truth of the statement; and (5) Plaintiff's damages resulting from reliance on the statement.

140. As sellers of the Orthodontic Pacifiers and merchants, Defendants had a duty to give correct, true and accurate information to Plaintiff and Class Members regarding the nature and capability of the Orthodontic Pacifiers. Defendants had sole possession and control of this information and had a duty to disclose it correctly, truthfully and accurately to Plaintiff and Class Members.

141. Defendants represented that the Orthodontic Pacifiers promote healthy oral development or improve oral outcomes for consumers' children, when in reality, the Orthodontic Pacifiers are incapable of doing so. Defendants knew, or should have known, that the Orthodontic Pacifiers were incapable of promoting healthy oral development or improving oral outcomes for consumers' children.

142. Defendants supplied information—that the Orthodontic Pacifiers promote healthy oral development or improve oral outcomes for consumers' children—that was known by Defendants to be desired by Plaintiff and Class Members and to induce them to purchase the Orthodontic Pacifiers. Defendants knew that making these representations would induce consumers to purchase their Orthodontic Pacifiers.

143. Plaintiff and Class Members relied upon Defendants' representations that the Orthodontic Pacifiers promote healthy oral development or improve oral outcomes for consumers' children when purchasing the Orthodontic Pacifiers. Further, Plaintiff's and Class Members' reliance was in-fact to their detriment because the Plaintiff and Class Members purchased, at a

price premium, the Orthodontic Pacifiers that were incapable of promoting healthy oral development or improving oral outcomes for their children.

144. Plaintiff and Class Members are entitled to all relief the Court finds proper as a result of Defendants' actions described herein.

#### **FOURTH CAUSE OF ACTION**

##### **FRAUD**

***(On Behalf of Plaintiff DeForest and the Nationwide Class and, in the alternative, the New York Class)***

145. Plaintiff re-alleges paragraphs 1 through 108 above as if set forth fully in this Count.

146. Defendants knew, or should have known, that the Orthodontic Pacifiers were incapable of promoting healthy oral development or improving oral outcomes for consumers' children.

147. Defendants provided Plaintiff and Class Members with false or misleading material information and failed to disclose material facts about the true nature of the Orthodontic Pacifiers, including the fact that the Orthodontic Pacifiers were incapable of promoting healthy oral development or improving oral outcomes for their children.

148. Defendants had exclusive knowledge of the capability and/or incapability of the Orthodontic Pacifiers to promote healthy oral development or improve oral outcomes for consumers' children, at the time of sale and at all other relevant times. Neither Plaintiff nor Class Members, in the exercise of reasonable diligence, could have independently discovered the true nature of the Orthodontic Pacifiers prior to purchase.

149. Defendants had the capacity to, and did, deceive Plaintiff and Class Members, into believing they were purchasing "orthodontic" pacifiers that would promote healthy oral development or improve oral outcomes for their children.

150. Defendants undertook active and ongoing steps to conceal the true nature of the Orthodontic Pacifiers. Plaintiff is not aware of anything in Defendants' packaging, labeling, advertising, publicity or marketing materials that disclosed the truth about the Orthodontic Pacifiers, despite Defendants' awareness of the problem.

151. The facts concealed and/or not disclosed by Defendants to Plaintiff and Class Members are material facts in that a reasonable person would have considered them important in deciding whether to purchase (or pay the same price for) the Orthodontic Pacifiers.

152. Defendants intentionally concealed and/or failed to disclose material facts for the purpose of inducing Plaintiff and Class Members to act thereon.

153. Plaintiff and Class Members justifiably acted, or relied upon, the concealed and/or nondisclosed facts to their detriment, as evidenced by their purchase of, or overpayment for, the Orthodontic Pacifiers.

154. Plaintiff and Class Members suffered a loss of money in an amount to be proven at trial as a result of Defendants' fraudulent concealment and nondisclosure because they would not have purchased the Orthodontic Pacifiers, or would not have purchased the Orthodontic Pacifiers for the price they did, if the true facts concerning the Orthodontic Pacifiers had been known.

155. Plaintiff and Class Members are entitled to all relief the Court finds proper as a result of Defendants' actions described herein.

#### **FIFTH CAUSE OF ACTION**

#### **VIOLATION OF NEW YORK'S DECEPTIVE PRACTICES ACT**

**N.Y. Gen. Bus. Law §§ 349, *et seq.***

***(On Behalf of Plaintiff DeForest and the New York Class)***

156. Plaintiff re-alleges paragraphs 1 through 108 above as if set forth fully in this Count.



157. 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).

158. The practices alleged herein—namely, deceiving customers into believing that the Orthodontic Pacifiers promote healthy oral development or improve oral outcomes—are unfair, deceptive and misleading in violation of GBL § 349.

159. The foregoing deceptive acts and practices were directed at Plaintiff and Members of the New York Class.

160. Defendants’ misrepresentations, including the 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 promote healthy oral development or improve oral outcomes. A reasonable consumer attaches importance to such representations and is induced to act thereon in making purchasing decisions.

161. Plaintiff and Members of the New York Class were injured as a direct and proximate result of Defendants’ unlawful acts as they would not have purchased or would have paid less for Defendants’ Orthodontic Pacifiers, but-for Defendants’ material misrepresentations regarding the Orthodontic Pacifiers’ capability to promote healthy oral development or improve oral outcomes for their children, as described in this Complaint.

162. As a result of Defendants’ unlawful actions, Plaintiff and Members of the New York Class seek to enjoin Defendants’ deceptive and unlawful acts and practices described herein; to recover the greater of their actual damages or fifty dollars (\$50.00) per violation; and to recover treble damages, reasonable attorneys’ fees and all other remedies this Court deems proper.

**SIXTH CAUSE OF ACTION**

**VIOLATION OF NEW YORK’S DECEPTIVE PRACTICES ACT**

**N.Y. Gen. Bus. Law §§ 350, *et seq.***

***(On Behalf of Plaintiff DeForest and the New York Class)***

163. Plaintiff re-alleges paragraphs 1 through 108 above as if set forth fully in this Count.

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

165. 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.

166. Defendants’ claims that the Orthodontic Pacifiers promote healthy oral development or improve oral outcomes, including the prominent labeling with the misleading “orthodontic” descriptor, are untrue, materially misleading and deceive consumers into believing the Orthodontic Pacifiers possess traits which they cannot.

167. Defendants’ misrepresentations regarding the Orthodontic Pacifiers are material to a reasonable consumer because they relate to their essential purpose, *i.e.*, the ability to promote healthy oral development or improve oral outcomes. A reasonable consumer attaches importance to such representations and is induced to act thereon in making purchase decisions.

168. Plaintiff and Members of the New York Class were induced to purchase the Orthodontic Pacifiers by Defendants’ misrepresentations on the Orthodontic Pacifiers’ labels.

169. Plaintiff and Members of the New York Class were injured as a direct and proximate result of Defendants’ unlawful acts as they would not have purchased or would have

paid less for Defendants' Orthodontic Pacifiers, but-for Defendants' material misrepresentations regarding the Orthodontic Pacifiers' capability to promote healthy oral development or improve oral outcomes for their children, as described in this Complaint.

170. As a result of Defendants' unlawful actions, Plaintiff and Members of the New York 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 (\$500.00) per violation; and to recover treble damages, reasonable attorneys' fees and all other remedies this Court deems proper.

### **SEVENTH CAUSE OF ACTION**

#### **VIOLATION OF STATE CONSUMER PROTECTION STATUTES (*On Behalf of Plaintiff DeForest and the Multi-State Consumer Protection Class*)**

171. Plaintiff re-alleges paragraphs 1 through 108 above as if set forth fully in this Count.

172. Plaintiff and Class Members have been injured as a result of Defendants' violations of the state consumer protection statutes listed above in paragraph 98 and footnote 32, which provide redress to Plaintiff and Class Members based on Defendants' fraudulent, deceptive, unfair and unconscionable acts, practices and conduct.

173. 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 Protection Class.

174. Defendants violated the Multi-State Consumer Protection Class's states' unfair and deceptive acts and practices laws by representing that the Orthodontic Pacifiers promote healthy oral development or improve oral outcomes.

175. Defendants' misrepresentations were material to Plaintiff's and Class Members' decisions to purchase the Orthodontic Pacifiers, and/or pay a premium for the Orthodontic

Pacifiers.

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

177. As a result of Defendants' violations of the aforementioned states' unfair and deceptive practices laws, Plaintiff and Class Members paid a premium for the Orthodontic Pacifiers.

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

179. Pursuant to the aforementioned states' unfair and deceptive practices laws, Plaintiff 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.

### **EIGHTH CAUSE OF ACTION**

#### **UNJUST ENRICHMENT/QUASI-CONTRACT**

***(On Behalf of Plaintiff DeForest and the Nationwide Class and, in the alternative, the New York Class)***

180. Plaintiff re-alleges paragraphs 1 through 108 above as if set forth fully in this Count.

181. 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 New York, as there is no societal benefit from false advertising, only harm. While Plaintiff and Class Members were harmed at the time of purchase, Defendants were unjustly enriched by their misrepresentations and omissions.

182. Plaintiff and Class Members were harmed when purchasing Defendants'

Orthodontic Pacifiers as a result of Defendants' material representations and omissions, as described in this Complaint. Plaintiff and Class Members purchased Defendants' Orthodontic Pacifiers. Plaintiff and Class Members have suffered injury in-fact and lost money as a result of paying a premium price for the Orthodontic Pacifiers, and as a result of Defendants' unlawful, unfair and fraudulent business practices.

183. Defendants' conduct allows them to knowingly realize substantial revenue from selling the Orthodontic Pacifiers at the expense of, and to the detriment of, Plaintiff and Class Members and to Defendants' benefit and enrichment. Defendants' retention of these benefits violates fundamental principles of justice, equity, good conscience and is in contradiction to the established public policy of New York.

184. Plaintiff and Class Members conferred significant financial benefits and paid substantial compensation to Defendants for their Orthodontic Pacifiers, which are not as Defendants represent them to be.

185. Under common law principles of unjust enrichment and quasi-contract, it is inequitable for Defendants to retain the benefits conferred by Plaintiff's and Class Members' purchases or overpayments.

186. Plaintiff and Class Members seek disgorgement of all profits resulting from such purchases or overpayments and establishment of a constructive trust from which Plaintiff and Class Members may seek restitution.

### **JURY DEMAND**

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

**REQUEST FOR RELIEF**

WHEREFORE, Plaintiff, individually and on behalf of Members of the proposed Classes, 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 Classes 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 injunctive relief as permitted by law or equity, including enjoining Defendants from continuing the unlawful practices as set forth herein, and order Defendants to engage in a corrective advertising campaign;

E. Ordering Defendants to pay attorneys' fees and litigation costs to Plaintiff and Members of the Classes;

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

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

Dated: May 21, 2025

Respectfully submitted,

/s/ Laurie Rubinow  
James C. Shah  
Laurie Rubinow (Bar No. LR-6637)  
Anna K. D'Agostino (Bar No. AKD-5913900)  
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*Attorneys for Plaintiff and Putative Classes*

*\*Pro Hac Vice forthcoming*

## CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

**I. (a) PLAINTIFFS**

KAITLIN DEFOREST, individually and on behalf of all others similarly situated

(b) County of Residence of First Listed Plaintiff Staten Island, NY  
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Miller Shah LLP, 225 Broadway, Suite 1830, New York, NY 10007; (866) 540-5505

**DEFENDANTS**

Philips North America, LLC and Philips Holding USA Inc.

County of Residence of First Listed Defendant Middlesex County, MA  
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

**II. BASIS OF JURISDICTION** (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

**III. CITIZENSHIP OF PRINCIPAL PARTIES** (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- |   | PTF                                   | DEF                        |   | PTF                        | DEF                                   |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State                   | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State     | <input type="checkbox"/> 4 | <input type="checkbox"/> 4            |
| Citizen of Another State                | <input type="checkbox"/> 2            | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3            | <input type="checkbox"/> 3 | Foreign Nation  | <input type="checkbox"/> 6 | <input type="checkbox"/> 6            |

**IV. NATURE OF SUIT** (Place an "X" in One Box Only)

Click here for: [Nature of Suit Code Descriptions.](#)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input checked="" type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice <b>PERSONAL INJURY</b> <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other <b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act <b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>INTELLECTUAL PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark <input type="checkbox"/> 880 Defend Trade Secrets Act of 2016 <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit (15 USC 1681 or 1692) <input type="checkbox"/> 485 Telephone Consumer Protection Act <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education <b>PRISONER PETITIONS</b> <b>Habeas Corpus:</b> <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <b>Other:</b> <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

**V. ORIGIN** (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District (specify) ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

**VI. CAUSE OF ACTION**

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

28 U.S.C. §§ 1332(d)(2)

Brief description of cause:

Consumer protection class action

**VII. REQUESTED IN COMPLAINT:**

☒ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$

\$5,00,000.00+

CHECK YES only if demanded in complaint:

JURY DEMAND:

☒ Yes ☐ No

**VIII. RELATED CASE(S) IF ANY**

(See instructions):

JUDGE

DOCKET NUMBER

DATE

05/21/2025

SIGNATURE OF ATTORNEY OF RECORD

/s/ Laurie Rubinow

*Laurie Rubinow*

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE



**CERTIFICATION OF ARBITRATION ELIGIBILITY**

Local Arbitration Rule 83.7 provides that with certain exceptions, actions seeking money damages only in an amount not in excess of \$150,000, exclusive of interest and costs, are eligible for compulsory arbitration. The amount of damages is presumed to be below the threshold amount unless a certification to the contrary is filed.

Case is Eligible for Arbitration ☐

I, Laurie Rubinow, counsel for Plaintiffs, do hereby certify that the above captioned civil action is ineligible for compulsory arbitration for the following reason(s):

- ☒ monetary damages sought are in excess of \$150,000.00 exclusive of interest and costs,
- ☒ the complaint seeks injunctive relief, or
- ☐ the matter is otherwise ineligible for the following reason:

**DISCLOSURE STATEMENT - FEDERAL RULES CIVIL PROCEDURE 7.1**

Identify any parent corporation and any publicly held corporation that owns 10% or more of its stocks. Add an additional page if needed.

**RELATED CASE STATEMENT (Section VIII on the Front of this Form)**

Please list all cases that are arguably related pursuant to Division of Business Rule 3 in Section VIII on the front of this form. Rule 3(a) provides that "A civil case is "related" to another civil case for purposes of this guideline when, because of the similarity of facts and legal issues or because the cases arise from the same transactions or events, a substantial saving of judicial resources is likely to result from assigning both cases to the same judge and magistrate judge." Rule 3(a) provides that "A civil case shall not be deemed "related" to another civil case merely because the civil case involves identical legal issues, or the same parties." Rule 3 further provides that "Presumptively, and subject to the power of a judge to determine otherwise pursuant to paragraph (b), civil cases shall not be deemed to be "related" unless both cases are still pending before the court."

**NEW YORK EASTERN DISTRICT DIVISION OF BUSINESS RULE 1(d)(3)**

*If you answer "Yes" to any of the questions below, this case will be designated as a Central Islip case and you must select Office Code 2.*

1. Is the action being removed from a state court that is located in Nassau or Suffolk County? ☐ Yes ☒ No
2. Is the action—not involving real property—being brought against United States, its officers or its employees AND the majority of the plaintiffs reside in Nassau or Suffolk County? ☐ Yes ☒ No
3. If you answered "No" to all parts of Questions 1 and 2:
  - a. Did a substantial part of the events or omissions giving rise to claim or claims occur in Nassau or Suffolk County? ☐ Yes ☒ No
  - b. Do the majority of defendants reside in Nassau or Suffolk County? ☐ Yes ☒ No
  - c. Is a substantial amount of any property at issue located in Nassau or Suffolk County? ☐ Yes ☒ No
4. If this is a Fair Debt Collection Practice Act case, was the offending communication received in either Nassau or Suffolk County? ☐ Yes ☒ No

*(Note, a natural person is considered to reside in the county in which that person is domiciled; an entity is considered a resident of the county that is either its principal place of business or headquarters, of if there is no such county in the Eastern District, the county within the District with which it has the most significant contacts).*

**BAR ADMISSION**

I am currently admitted in the Eastern District of New York and currently a member in good standing of the bar of this court.



Yes



No

Are you currently the subject of any disciplinary action (s) in this or any other state or federal court?



Yes (If yes, please explain)



No

I certify the accuracy of all information provided above.

Signature: Laurie Rubinow