UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
TERRE HAUTE DIVISION

MICHAEL HAILE, and MELANIE PAPPALARDI Plaintiffs, vs. STEVE GALELLA, D.D.S., ORTHOMATRIX CORP., INC., also d/b/a FACIAL BEAUTY INSTITUTE, and d/b/a ORTHOLOGIC, and JOHN'S DENTAL LABORATORY, INC., Defendants.	)	Case No.:

PLAINTIFFS' COMPLAINT

Plaintiffs Michael Haile and Melanie Papplardi, by and through their undersigned counsel, by way of Complaint against Steve Gallella, D.D.S., OrthoMatrix Corp, Inc., also d/b/a as Facial Beauty Institute ("FBI") and OrthoLogic, and John's Dental Laboratory, Inc. ("John's Dental"), hereby allege as follows:

PARTIES

1. Plaintiff Michael Haile is an individual and citizen of Virginia, residing at 6649 Medinah Lane Alexandria, VA 22312. At all times relevant to the case, he was and is an adult. His claims arise from the laws of Indiana.

2. Plaintiff Melanie Papplardi is an individual and citizen of New York, with an address at 131 S Highland Avenue, APT A5, Ossining, NY 10562. At all times relevant to the case, she was and is an adult. Her claims arise from the laws of Indiana.

3. At all times relevant, defendant John's Dental was an Indiana Corporation and citizen of Indiana with a principal place of business at 423 South 13th Street in Terre Haute, Indiana, 47807.

4. At all relevant times, defendant Steve Galella, D.D.S. ("Dr. Galella) was an individual and a citizen of Tennessee residing at 997 Eastwood Terrace, Collierville, Tennessee, 38017.

5. At all relevant times, defendant OrthoMatrix Corp., Inc. ("OrthoMatrix"), d/b/a Facial Beauty Institute ("FBI") and d/b/a OrthoLogic, was a foreign corporation organized under the laws of the State of Tennessee, and a citizen of Tennessee, with a principal place of business at 875 West Poplar Avenue, Suite 16, Collierville, Tennessee, 38017. FBI is a wholly owned division and/or tradename of defendant OrthoMatrix.

JURISDICTION

6. This Court's jurisdiction is based upon diversity of citizenship as set forth in 28 U.S.C. Section 1332 in that all of the plaintiffs are citizens of different states than each of the defendants.

7. The amount in controversy with respect to each plaintiff is in excess of Seventy-Five Thousand Dollars, exclusive of interest and costs.

8. This Court has personal jurisdiction over John's Dental because John's Dental is an Indiana Corporation.

9. This Court has personal jurisdiction over the remaining defendants because they regularly conducted business in Indiana with specific connection to the manufacturing, marketing and sale of the device and/or type of device at issue in this Complaint and the claims of plaintiffs. In particular, defendants Galella and OrthoMatrix receive and have received payments from defendant John's Dental related to the manufacture and/or sale of the type of device at issue in this

Complaint, including of the exact devices at issue in this Complaint. In addition, defendant Galella in his position as an officer, employee and/or agent of defendant OrthoMatrix, has, through an agreement with defendant John's Dental, approved each of the subject devices for sale and consulted or was available for consulting in regard to each such device manufactured and sold in Indiana.

VENUE

10. Pursuant to 28 U.S.C. 1391, venue is properly laid in this district because a substantial part of the transactions and issues giving rise to plaintiffs' claims occurred in this judicial district.

FACTUAL ALLEGATIONS COMMON TO ALL COUNTS

NATURE OF THE ACTION

11. This is an action for money damages for personal injury suffered by the plaintiffs as the result of the installation of a dental appliance which defendants designed, manufactured and marketed despite no scientific or clinical basis to prove it was either safe or effective.

12. The appliance, known as an "Anterior Growth Guidance Appliance" ("AGGA") was manufactured, designed, and marketed as a proven means of correcting dental, facial and airway abnormalities in lieu of complex jaw surgery for adult patients.

13. Defendants promoted AGGA, taught dentists how it allegedly functioned, and prepared AGGA treatment plans for dentists, claiming that AGGA causes three-dimensional changes in the nasomaxillary complex of adults, including growing/advancing/remodeling the maxilla to move forward horizontally over time by as much as or more than 10 mm, through a process of mechanical force and new bone deposition resulting from stimulation of a nerve in the palate, and that it was a reasonable alternative to jaw surgery.

14. Plaintiffs allege that these claims are false, and are contrary to medical science; that instead AGGA works in adults, inter alia, to push the upper teeth out of their housing in the alveolar bone, that it causes no new bone growth or dimensional changes in the nasomaxillary complex of adults (whose nasomaxillary complex, unlike those of children, have stopped growing naturally), that it is not a reasonable alternative to jaw surgery for adults, and that it presents a risk of serious and permanent harm for adults.

15. As a result of the fact that, for adults, AGGA as negligently designed and manufactured was not reasonably safe and was unreasonably dangerous, the promotion and teaching of AGGA involving false representations to dentists including plaintiffs' dentists, the creation of a treatment plan utilizing a product that is unreasonably dangerous to adults, the failure to warn plaintiffs and/or their dentists about the actual risks of AGGA to adults, and the installation of AGGA in plaintiffs have caused plaintiffs to sustain significant and permanent damage to their teeth and face, economic loss, disfigurement, embarrassment, loss of enjoyment of life, and physical and mental pain and suffering.

FACTS ALLEGED

HISTORY OF AGGA

16. At all times relevant to the case, Dr. Galella was a general dentist duly licensed by the State of Tennessee and a diplomate of an organization called the International Board of Orthodontics.

17. Prior to January 2010, Dr. Galella designed the dental appliances called AGGA and the Controlled Arch system of brackets and wires ("CAB").

18. Prior to 2010, Dr. Galella founded FBI, and at all times relevant to the Complaint Dr. Galella and FBI shared office space in Tennessee, along with OrthoMatrix.

19. Prior to 2010, FBI became an unincorporated division and/or trade name of OrthoMatrix.

20. At all times relevant to the Complaint, Dr. Galella was an officer of, employed by and working in furtherance of the business of, and/or acted as agent of, FBI and, therefore of OrthoMatrix.

21. At all times relevant to the Complaint, OrthoMatrix, through its division FBI, and Dr. Galella, offered and taught courses to dentists on the use and alleged safety and efficacy of AGGA and CAB.

22. At all times relevant to the Complaint, OrthoMatrix, through its unincorporated division or trade name FBI and/or through another unincorporated division or tradename of OrthoMatrix called OrthoLogic, maintained a program that purported to analyze patients' dental/cranio maxillofacial condition using "radiologists" and "experts" to determine whether said patients were appropriate candidates for AGGA/CAB treatment, and prepare AGGA and CAB treatment plans for such patients with comprehensive instructions that were alleged to be specific and customized for each patient ("the program").

23. At all times relevant to the Complaint, Dr. Galella, and OrthoMatrix made certain representations ("the representations") to dentists throughout the world, including the dentists who treated the plaintiffs, that:

a. AGGA is a device that causes three-dimensional changes in the nasomaxillary complex of adults, including growing/advancing/remodeling the maxilla to move forward horizontally over time by as much or more than 10 mm;

b. AGGA causes these nasomaxillary changes in adults through a process of mechanical force and new bone deposition resulting from stimulation of a nerve in the palate;

c. as the maxilla moves forward, upper teeth move with it, including in adults;

d. by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward, including in adults;

e. the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face, including in adults;

f. AGGA is reasonably safe for installation into dental patients' mouths, including in adults;

g. AGGA can be utilized as a substitute for jaw surgery, including in adults.

24. At all times relevant to the Complaint, Dr. Galella, and OrthoMatrix, made additional representations to dentist throughout the world, including to dentists treating plaintiffs, that, once AGGA causes the desired maxilla and mandible position to be obtained, and AGGA was then removed, CAB could be used to make relatively minor adjustments in order to guide all teeth to their proper positions, as well as to widen the dental arches, including in adults;

25. The representations, made at all times relevant to the Complaint by Dr. Galella, and OrthoMatrix, were made for the purpose of, *inter alia*, causing dentists to promote AGGA and CAB to consumers, including adult consumers in New York, Virginia, Connecticut, Pennsylvania and Indiana.

26. Neither AGGA nor CAB have ever been submitted to the Federal Drug Administration, or any other government agency, for approval, and they have never been approved by any governmental agency for use in the United States.

27. Dr. Galella and OrthoMatrix, knew or should have known that, while the representations may have been true in regard to the use of AGGA by children (who are still growing naturally), the representations as to adults were unproven, not supported by medical knowledge or science, and were false and materially misleading, and that:

a. in adults, AGGA is not a device that can cause changes in the nasomaxillary complex of adults;

b. AGGA is not a device that mechanically causes the maxilla of an adult to move forward horizontally over time as much or more than 10 mm;

c. AGGA does not stimulate new bone growth resulting in changes to the nasomaxillary complex of an adult;

d. AGGA does not move the maxilla in an adult; instead, it pushes certain of the upper teeth forward over time within the alveolar bone which is attached to the maxilla;

e. in adults, as AGGA pushes the upper teeth forward, the teeth are pushed out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

f. AGGA does not open an adult user's airway;

g. AGGA is unreasonably dangerous to adult patients in whom it is installed, and is not reasonably safe for use by such patients; and,

h. AGGA is not a substitute for jaw surgery for adults.

28. At all times relevant to the Complaint, John's Dental was in the business of, *inter alia*, manufacturing, selling and putting into the stream of commerce, dental appliances including but not limited to AGGA and CAB, and was bound to anticipate that their products would be,

through dental professionals, presented to the general public for their use, including but not limited to use by consumers within each state of the United States, as well as throughout the world.

29. At all times relevant to the Complaint, John's Dental paid a royalty and/or other fee to both OrthoMatrix and to Galella, or an entity controlled by Galella, for every AGGA device manufactured and sold by John's Dental. As part of the royalty agreement, Galella, as officer, employee and/or agent of OrthoMatrix, was required to reject or approve every AGGA device and was available at request of John's Dental for evaluation of the propriety of any prescription for an AGGA device.

PLAINTIFF MICHAEL HAILE

30. Prior to May 2019, dentist Dr. Leonard Kundel ("Dr. Kundel") of Connecticut , was provided instruction by Dr. Galella in the use, safety and efficacy of AGGA ("the course").

31. On information and belief, Dr. Kundel paid OrthoMatrix for the course.

32. During the teaching of the courses Dr. Galella made various representations about the safety and efficacy of AGGA, which representations included those set forth above and which were unproven, not supported by medical knowledge or science, untested by any clinical trial, unsupported by peer-reviewed literature, and which were false and materially misleading.

33. On information and belief, the course, which lasted approximately 2.5 days, largely comprised the extent of Dr. Kundel's training concerning AGGA and CAB.

34. Prior to May 2019, Mr. Haile sought treatment from Dr. Kundel for, *inter alia*, difficulties with his airway and an open bite; Dr. Kundel then prescribed and installed an AGGA device ("AGGA 1") as treatment for those conditions/symptoms. On February 10, 2021, Dr. Michael Chung ("Dr. Chung") removed the AGGA device and installed a second AGGA device ("AGGA 2"). (Collectively, AGGA 1 and AGGA 2 referred to as "the AGGA's").

35. At no time did Dr. Galella or OrthoMatrix ever warn Dr. Kundel, Dr. Chung or Mr. Haile that, in regard to adult users, when used for the purpose of making changes in the nasomaxillary complex, AGGA was unproven, was not supported by scientific or medical knowledge, was not reasonably safe, was unreasonably dangerous, was not efficacious, and presented a risk of serious and permanent injury to consumers.

36. Prior to May 2019, Dr. Kundel consulted with OrthoMatrix, through Dr. Galella and others, in regard to whether Mr. Haile was an appropriate candidate for AGGA and CAB, and for the purpose of establishing an AGGA and CAB treatment plan.

37. More specifically, prior to May 2019, on information and belief, Dr. Kundel submitted a questionnaire and dental records concerning Mr. Haile to OrthoMatrix's Total Diagnostics internet portal, and thereafter and as a result, OrthoMatrix, through Dr. Galella and others, produced an AGGA/CAB treatment plan for Mr. Haile ("the Haile treatment plan") and otherwise represented to Dr. Kundel and to Mr. Haile that AGGA and CAB were appropriate treatments for Mr. Haile.

38. Prior to May 2019, Dr. Kundel, on information and belief in reliance on advice, instruction and guidance provided by OrthoMatrix, and Dr. Galella submitted information and/or specifications to John's Dental concerning Mr. Haile and did place an order for an AGGA appliance to be manufactured by John's Dental for the specific use by Mr. Haile.

39. Prior to February 2021, on information and belief, Dr. Chung consulted with OrthoMatrix, through Dr. Galella and others, in regard to whether Mr. Haile was an appropriate candidate for a second AGGA and CAB, and for the purpose of establishing an AGGA and CAB treatment plan.

40. More specifically, prior to February 2021, on information and belief, Dr. Chung submitted a questionnaire and dental records concerning Mr. Haile to OrthoMatrix's Total Diagnostics internet portal, and thereafter and as a result, OrthoMatrix, through Dr. Galella and others, produced an AGGA/CAB treatment plan for Mr. Haile ("the 2nd Haile treatment plan") and otherwise represented to Dr. Chung and to Mr. Haile that AGGA and CAB were appropriate treatments for Mr. Haile.

41. Prior to February 2021, Dr. Chung, on information and belief in reliance on advice, instruction and guidance provided by OrthoMatrix, and Dr. Galella submitted information and/or specifications to John's Dental concerning Mr. Haile and did place an order for an AGGA appliance to be manufactured by John's Dental for the specific use by Mr. Haile.

42. Prior to May 2019, John's Dental did manufacture AGGA 1 for use by Dr. Kundel for installation in Mr. Haile's mouth, did place it in the stream of commerce and did sell that appliance to Dr. Kundel, who was then within Connecticut, and John's Dental knew at the time it was placed into the stream of commerce that it would be installed in a member of the public, and specifically that Dr. Kundel would install it in Mr. Haile.

43. Prior to February 10, 2021, John's Dental did manufacture AGGA 2 for use by Dr. Chung for installation in Mr. Haile's mouth, did place it in the stream of commerce and did sell that appliance to Dr. Chung, who was then within Virginia, and John's Dental knew at the time it was placed into the stream of commerce that it would be installed in a member of the public, and specifically that Dr. Chung would install it in Mr. Haile.

44. At the time of sales of the AGGA's to Drs. Kundel and Chung, John's Dental impliedly warranted and represented that the AGGA's were fit, capable and suitable for the ordinary purposes for which they were intended, that they were fit for the specific purpose for

which they were sold to Drs. Kundel and Chung, that they had no design defects, that they were of merchantable quality, and that they were safe and not unreasonably dangerous.

45. Mr. Haile reasonably relied upon the implied warranties of John's Dental, as well as on its skill and judgment.

46. Prior to the AGGA's being placed into the stream of commerce and sold to Drs. Kundel and Chung for use on Mr. Haile, Dr. Galella did inspect and examine photographs of those AGGA's and of molds of Mr. Haile teeth, knew or should have known that the AGGA's were for an adult's teeth, and pronounced the AGGA's fit to be used on Mr. Haile.

47. At the time of sale of the AGGA's to Drs. Kundel and Chung, the AGGA's were inherently defective by virtue of their design, were not fit for their intended purpose nor for the specific purpose for which they were sold for installation in Mr. Haile's mouth; they were not of merchantable quality, were not reasonably safe, were unreasonably dangerous and defective, all at the time each left the possession, custody and control of John's Dental, for reasons that include but are not limited to:

a. AGGA as designed, manufactured and sold was not based on valid scientific principles, and in an adult does not change the nasomaxillary complex in three, or any, dimensions, does not stimulate new bone growth, does not move the maxilla forward horizontally by as much or more than 10 mm, does not open a user's airway, is in no way a substitute for jaw surgery in an adult;

b. AGGA is unreasonably dangerous in that, rather than move the maxilla or make any three-dimensional changes in the adult nasomaxillary complex, it pushes the upper teeth forward and, after moving more than a limited amount, out of their safe

position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

c. While AGGA may have additional utility for children, the utility of AGGA in an adult is in its moving teeth a limited amount within the bone (a function that can be performed by other, standard orthodontic appliances), is far outweighed by the risks AGGA creates;

d. John's Dental failed to warn Drs. Kundel and Chung or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

48. At the time that John's Dental manufactured, placed into the stream of commerce and sold to Drs. Kundel and Chung each of the AGGA's for Mr. Haile, those appliances were not reasonably safe for use on adults, were not minimally safe for their expected purpose, and were dangerous to the extent beyond which would be contemplated by the ordinary dentist or consumer who purchases or uses them, with the ordinary knowledge common to such dentists or users.

49. At all times relevant to the Complaint, had Mr. Haile been warned of the defects and deficiencies of each AGGA as described above, he would not have embarked on any course of treatment using AGGA.

50. At all times relevant to the Complaint, had Drs. Kundel and Chung been warned by any of the defendants of the defects and deficiencies of AGGA as described above on information and belief, neither would not have embarked on any course of treatment of Mr. Haile using AGGA.

51. At all times relevant to the Complaint, Mr. Haile would not by exercise of ordinary and reasonable care have discovered the defects and deficiencies of AGGA as described above nor perceived its danger.

52. Sometime after February, 2020, Mr. Haile suspected that the AGGA 1 device was causing him damage, but he was assured by his provider that this was a normal part of the treatment. By August 2021, after AGGA 2 had been installed, he became aware that the AGGA's had caused him severe and permanent injury, and he had the AGGA 2 device removed.

53. At all times relevant to the Complaint, Dr. Galella, and OrthoMatrix, engaged in consumer-related conduct that was materially misleading in that: 1) each of them made material

misrepresentations to dentists through the course and other courses, and through website marketing to both dentists and consumers, to the effect that AGGA was safe and efficacious for adults and was a reasonable and functionally effective alternative to jaw surgery for adults that would create three-dimensional changes in the adult nasomaxillary complex including movement of the maxilla; 2) such material misrepresentations were made with the knowledge and expectation that those dentists would advertise and otherwise offer AGGA as a safe and efficacious treatment alternative to adult consumers, including but not limited to adult consumers in Connecticut, Indiana and Virginia including Mr. Haile; and, 3) such material misrepresentations were made with the knowledge and expectation that members of the general public would ask dentists for AGGA and/or otherwise accept AGGA as a safe and efficacious treatment alternative to jaw surgery, consumers, including but not limited to consumers in Connecticut, Indiana and Virginia including Mr. Haile.

54. As a result of the installation and use of the AGGA appliances, Mr. Haile has been caused to suffer significant and permanent injury and damage, including but not limited to: loose anterior maxillary teeth; pain; flaring of the front teeth; gum recession; probably root resorption and alveolar bone loss; economic loss related to the cost of said worthless and harmful AGGA treatment and the cost of attempted remediation; prolonged suffering from the conditions for which he originally sought treatment; embarrassment; disfigurement; and other injuries and damages.

55. Mr. Haile at all times relevant to the Complaint acted reasonably, and nothing he reasonably did or failed to do caused or contributed to cause his injuries.

COUNT I:

Product Liability-Negligence Against Defendant Dr. Galella

56. Plaintiff Michael Haile reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

57. Defendant Dr. Galella was negligent in that, *inter alia,* he negligently designed the AGGA's that were installed in Mr. Haile, an adult, when he knew or should have known that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to Galella's education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by plaintiff, all as aforesaid.

58. Dr. Galella acted with reckless disregard for the safety of others, including Mr. Haile.

59. As a direct and proximate result of the negligence of Dr. Galella, and his reckless disregard for the safety of others including Mr. Haile, Mr. Haile has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Michael Haile demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Steve Galella, D.D.S., plus interest and costs.

COUNT II:

Negligence Against Defendant OrthoMatrix and Defendant Galella

60. Plaintiff Michael Haile reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

61. OrthoMatrix was negligent in that, *inter alia,* it, either directly or by or through its division or trade name FBI and/or OrthoLogic, and/or through its officer Galella :

a. taught the course to Dr. Kundel, informing him and others that the AGGA device was safe and efficacious for use by adults, when it knew or should have known that the theory behind AGGA regarding its use on adults and its alleged function of making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, was contrary to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, that it had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Haile, all as aforesaid;

b. negligently produced the Haile treatment plan and the 2nd Haile treatment plan for Mr. Haile's dentists for the installation of the AGGA's in Mr. Haile, when it knew or should have known that said device, when used for the purpose of making changes in the nasomaxillary complex, was unproven for use by adults, it was neither safe nor efficacious for adults, the principles upon which it allegedly functioned for adults were not supported by and were in contravention of medical knowledge and science, it was unreasonably

dangerous for adults and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Haile; ,

c. through its officer Galella, approved AGGA's for use by Mr. Haile, when Galella knew or should have known by the mold and photographs of Mr. Haile's teeth as aforesaid that he was an adult, and/or he failed to inquire as to whether Mr. Haile was indeed an adult; and Galella knew or should have known that said devices, when used for the purpose of making changes in the nasomaxillary complex, was unproven for use by adults, they were neither safe nor efficacious for adults, the principles upon which they allegedly functioned for adults were not supported by and were in contravention of medical knowledge and science, they were unreasonably dangerous for adults and that they could and foreseeably would cause the type of injury and damage suffered by Mr. Haile;

d. marketed AGGA to Dr. Kundel, Dr. Chung, to Mr. Haile and to dentists and consumers throughout the world, as a product that was safe and efficacious for adults when it knew or should have known that claims made about AGGA making three- dimensional changes in the nasomaxillary complex of adults were contrary to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Haile, all as aforesaid; and,

e. failed to warn purchasers of AGGA and dentists to whom it taught the course including Dr. Kundel and other similar courses, or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including, inter alia, causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

62. OrthoMatrix and Galella acted with reckless disregard for the safety of others, including Mr. Haile.

63. As a direct and proximate result of the negligence of OrthoMatrix and Galella, and their reckless disregard for the safety of others including Mr. Haile, Mr. Haile has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Michael Haile demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Orthomatrix Corp., Inc. and defendant Steve Galella, D.D.S., plus interest and costs.

COUNT III:

Product Liability-Breach of Warranties Against Defendant John's Dental

64. Plaintiff Michael Haile reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

65. At the time that the AGGA's sold to Mr. Haile's dentists as aforesaid last left the possession, custody or control of John's Dental, the devices were inherently defective by virtue of their design, were not fit for their intended purpose nor for the specific purpose for which they were sold for installation in Mr. Haile's mouth, were not of merchantable quality, were not reasonably or minimally safe, and were unreasonably dangerous and defective, all at the time each left the possession, custody and control of John's Dental, for reasons that were described above, in regard to its use by adults.

66. The defective nature of the subject AGGA's includes their lack of warnings, at the time each last left the possession, custody and control of defendant John's Dental, in that they failed to warn purchasers of AGGA, or anyone else:

a. of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

b. that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla;

c. that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth.

d. that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

e. if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

67. When used for the purpose for which it was intended, AGGA has limited utility for adults and presents a risk of serious and permanent injury to adults when used as intended by the designer, manufacturer and seller to make dimensional changes in the nasomaxillary complex, all as aforesaid.

68. As a result of the foregoing, John's Dental was in breach of the implied warranties of merchantability and fitness for a particular purpose in regard to the aforesaid AGGA's sold to Mr. Haile's dentists and installed in him as aforesaid.

69. Mr. Haile relied on the aforementioned implied warranties in agreeing to the installation of the AGGA's.

70. As a direct and proximate result of those breaches of implied warranties, separately and together, Mt. Haile has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Michael Haile demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT IV:

Indiana Product Liabilty Act Against Defendant John's Dental

71. Plaintiff Michael Haile reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

72. At the time the subject AGGA's were sold by John's Dental to Mr. Haile's dentists, the devices were not reasonably safe, were defectively designed and in a condition not reasonably contemplated by Mr. Haile, the ultimate user, including for the reasons that the function for which they were designed was not possible to achieve in adults, and was in contravention of principles of physiology and anatomy, and carried substantial risk of serious injury for adults, and that they lacked necessary warnings as above.

73. At the time the subject AGGA's were sold by John's Dental to Mr. Haile's dentists as aforesaid, the products posed a substantial likelihood of harm to Mr. Haile or any other adult user and were unreasonably dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases them with the ordinary knowledge common to consumers, including because the products' tendency, rather than to move the maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare

out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to Mr. Haile as a result of the use of the products.

74. No reasonable person who knew the risk of harm of using AGGA at the time of manufacture would conclude that the benefit of the product outweighed the risk to adult users.

75. The defective design of the AGGA devices installed in Mr. Haile's mouth was the sole and/or substantial cause and/or factor in bringing about his injuries or damages.

WHEREFORE, plaintiff Michael Haile demands Judgment in an amount of in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT V:

Product Liability- Negligence Against Defendant John's Dental

76. Plaintiff Michael Haile reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

77. At the time the subject AGGA's were sold by John's to Mr. Haile's dentists as aforesaid, John's Dental knew or should have known that the devices, for use in adults, were not reasonably safe, were negligently designed and in a condition not reasonably contemplated by Mr. Haile, the ultimate user, including for the reasons that the function for which they were designed was not possible to achieve and was in contravention of principles of physiology and anatomy, and the devices carried substantial risk of serious injury for adults, and that they lacked necessary warnings as above.

78. At the time the AGGA's were sold by John's Dental to Mr. Haile's dentists as aforesaid, the products posed a substantial likelihood of harm to Mr. Haile or any other adult user and were unreasonably dangerous to an extent beyond that which would be contemplated by the

ordinary consumer who purchases them with the ordinary knowledge common to consumers, including because the products' tendency when used in adults, rather than to move the maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to Mr. Haile as a result of the use of the products.

79. No reasonable person who knew the risk of harm of using AGGA at the time of manufacture would conclude that the benefit of the product outweighed the risk to adult users.

80. The negligent and defective design of the AGGA's installed in Mr. Haile's mouth was the sole and/or substantial cause and/or factor in bringing about his injuries or damages.

WHEREFORE, plaintiff Michael Haile demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT VI:

Indiana Deceptive Consumer Sales Act ("IDCSA") Against Defendant John's Dental

81. Plaintiff Michael Haile reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

82. Indiana Deceptive Consumer Sales Act ("IDCSA"), Indiana Code Sections 24-5-0.5 et seq makes unlawful any deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in Indiana.

83. John's Dental has engaged in consumer-oriented conduct that is materially misleading, in that it has, in the course of marketing AGGA to consumers (including Indiana consumers) directly, and to dentists (including Indiana dentists) for the purpose of enticing consumers (including Indiana consumers) to use AGGA, represented falsely that:

a. AGGA is a device that causes three-dimensional changes in the nasomaxillary complex of adults, including growing/advancing/remodeling the maxilla to move forward horizontally over time by as much or more than 10 mm;

b. AGGA causes these nasomaxillary changes in adults through a process of mechanical force and new bone deposition resulting from stimulation of a nerve in the palate;

c. as the maxilla moves forward, upper teeth move with it, including in adults;

d. by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward, including in adults;

e. the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face, including in adults;

f. AGGA is reasonably safe for installation into dental patients' mouths, including in adults;

g. AGGA can be utilized as a substitute for jaw surgery, including in adults.

84. These false representations are material in that they go to the essence of the function of AGGA as claimed by John's Dental, and their falsity means that the product is essentially useless for adults.

85. AGGA is unreasonably dangerous as designed and manufactured, and can cause substantial and permanent damage, as set forth above.

86. As a direct and proximate result of the material misrepresentations, Mr. Haile allowed AGGA's to be installed in his mouth, and as a result suffered serious and permanent injury as described above.

87. This conduct of John's Dental has affected and will continue to affect not just Mr. Haile but also adult consumers at large within the State of Indiana who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

88. This conduct of John's Dental has also affected and will continue to affect Indiana dentists who, based on those misrepresentations, will utilize AGGA on adult Indiana consumers and thereby visit substantial and permanent injury on such consumers who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

89. John's Dental, through its material misrepresentations, has violated IDCSA, thereby causing Mr. Hailesevere and permanent injury and damage as described above.

WHEREFORE, plaintiff Michael Haile demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus treble damages, attorney's fees interest and costs.

PLAINTIFF MELANIE PAPPALARDI

90. Prior to August 2020, dentist Dr. Michael Kun, of Pennsylvania, "Dr. Kun") was provided instruction by Dr. Galella in the use, safety and efficacy of AGGA.

91. On information and belief, Dr. Kun paid OrthoMatrix for the instruction by Dr. Galella.

92. During the teaching of the courses, Dr. Galella made representations not supported by medical knowledge or science, untested by any clinical trial, unsupported by peer-reviewed literature, and which were false and materially misleading

93. On information and belief, the courses, each of which lasted approximately 2.5 days, largely or completely comprised the extent of Dr. Kun's training concerning AGGA and CAB.

94. Prior to August 2020, Ms. Pappalardi sought treatment from Dr. Kun for, *inter alia*, temporomandibular joint disease, and Dr. Kun prescribed an AGGA device for the purpose of resolving or alleviating that condition, improving her airway, reducing pain and improving her appearance, by making three-dimensional changes in her nasomaxillary complex.

95. At no time did Dr. Galella, or OrthoMatrix ever warn Dr. Kun or Ms. Pappalardi that, in regard to adult users, when used for the purpose of making changes in the nasomaxillary complex, AGGA was unproven, was not supported by scientific or medical knowledge, was not reasonably safe, was unreasonably dangerous, was not efficacious, and presented a risk of serious and permanent injury to consumers.

96. Prior to December 2018, Dr. Kun consulted with OrthoMatrix, through Dr. Galella and others, in regard to whether Ms. Pappalardi was an appropriate candidate for AGGA and CAB, and for the purpose of establishing an AGGA and CAB treatment plan.

97. More specifically, prior to August 2020, on information and belief, Dr. Kun submitted a questionnaire and dental records concerning Ms. Pappalardi to OrthoMatrix's Total Diagnostics internet portal, and thereafter and as a result, OrthoMatrix, through Dr. Galella and others, produced an AGGA/CAB treatment plan for Ms. Pappalardi ("the Pappalardi treatment plan") and otherwise represented to Dr. Kun and to Ms. Pappalardi that AGGA and CAB were appropriate treatments for Ms. Pappalardi.

98. Prior to August 2020, Dr. Kun, on information and belief in reliance on advice, instruction and guidance provided by OrthoMatrix, and Dr. Galella submitted information and/or

specifications to John's Dental concerning Ms. Pappalardi and did place an order for an AGGA appliance to be manufactured by John's Dental for the specific use by Ms. Pappalardi.

99. Prior to August 2020, John's Dental did manufacture an AGGA appliance for use by Dr. Kun for installation in Ms. Pappalardi's mouth, did place it in the stream of commerce and did sell that appliance to Dr. Kun, who was then within Pennsylvania; John's Dental knew at the time it was placed into the stream of commerce that it would be installed in a member of the public, and specifically that Dr. Kun would install it in Ms. Pappalardi.

100. At the time of sale of the AGGA to Dr. Kun, John's Dental impliedly warranted and represented that the AGGA was fit, capable and suitable for the ordinary purposes for which it was intended, that it was fit for the specific purpose for which it was sold to Dr. Kun, that it had no design defects, that it was of merchantable quality, and that it was safe and not unreasonably dangerous.

101. Ms. Pappalardi reasonably relied upon the implied warranties of John's Dental, as well as on its skill and judgment.

102. Prior to the AGGA being placed into the stream of commerce and sold to Dr. Kun for use on Ms. Pappalardi, Dr. Galella did inspect and examine photographs of that AGGA device and of a mold of Ms. Pappalardi's teeth, knew or should have known that the AGGA device was for an adult's teeth, and pronounced the AGGA fit to be used for Ms. Pappalardi.

103. At the time of the sale of the AGGA to Dr. Kun, the AGGA was inherently defective by virtue of its design, was not fit for its intended purpose nor for the specific purpose for which it was sold for installation in Ms. Pappalardi's mouth; it was not of merchantable quality, was not reasonably safe, was unreasonably dangerous and defective, all at the time it left the possession, custody and control of John's Dental, for reasons that include but are not limited to:

a. AGGA as designed, manufactured and sold was not based on valid scientific principles, and in an adult does not change the nasomaxillary complex in three, or any, dimensions, does not stimulate new bone growth, does not move the maxilla forward horizontally by as much or more than 10 mm, does not open a user's airway, is in no way a substitute for jaw surgery in an adult;

b. AGGA is unreasonably dangerous in that, rather than move the maxilla or make any three-dimensional changes in the adult nasomaxillary complex, it pushes the upper teeth forward and, after moving more than a limited amount, out of their safe position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

c. While AGGA may have additional utility for children, the utility of AGGA in an adult is in its moving teeth a limited amount within the bone (a function that can be performed by other, standard orthodontic appliances), is far outweighed by the risks AGGA creates;

d. John's Dental failed to warn Dr. Kun or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

104. At the time that John's Dental manufactured, placed into the stream of commerce and sold to Dr. Kun the AGGA appliance for Ms. Pappalardi, that appliance was not reasonably safe for use on adults, was not minimally safe for its expected purpose, and was dangerous to the extent beyond which would be contemplated by the ordinary dentist or consumer who purchases or uses it, with the ordinary knowledge common to such dentists or users.

105. At all times relevant to the Complaint, had Ms. Pappalardi been warned of the defects and deficiencies of AGGA as described above, she would not have embarked on any course of treatment using AGGA.

106. At all times relevant to the Complaint, had Dr. Kun been warned by any of the defendants of the defects and deficiencies of AGGA as described above then, on information and belief, he would not have embarked on any course of treatment of Ms. Pappalardi using AGGA.

107. At all times relevant to the Complaint, Ms. Pappalardi would not by exercise of ordinary and reasonable care have discovered the defects and deficiencies of AGGA as described above nor perceived its danger.

108. By some point in 2021, Ms. Pappalardi became concerned about tooth sensitivity and loosening of teeth that were apparently being caused by use of the AGGA; she had it removed in August 2021.

109. At all times relevant to the Complaint, Dr. Galella, and OrthoMatrix, engaged in consumer-related conduct that was materially misleading in that: 1) each of them made material misrepresentations to dentists through the course and other courses, and through website marketing to both dentists and consumers, to the effect that AGGA was safe and efficacious for adults and was a reasonable and functionally effective alternative to jaw surgery for adults that would create three-dimensional changes in the adult nasomaxillary complex including movement of the maxilla; 2) such material misrepresentations were made with the knowledge and expectation that those dentists would advertise and otherwise offer AGGA as a safe and efficacious treatment alternative to adult consumers, including but not limited to consumers in Pennsylvania and Indiana; and, 3) such material misrepresentations were made with the knowledge and expectation that adult members of the general public would ask dentists for AGGA and/or otherwise accept AGGA as a safe and efficacious treatment alternative to jaw surgery, consumers, including but not limited to adult consumers in Pennsylvania and Indiana.

110. As a result of the installation and use of the AGGA appliances, Ms. Pappalardi has been caused to suffer significant and permanent injury and damage, including but not limited to: front upper teeth pushed out of the alveolar bone; nerve damage; extreme tooth sensitivity; probably loss of teeth; economic loss related to the cost of said worthless and harmful AGGA

treatment and the cost of attempted remediation; prolonged suffering from the conditions for which she originally sought treatment; embarrassment; disfigurement; and other injuries and damages.

111. Ms. Pappalardi at all times relevant to the Complaint acted reasonably, and nothing she did or failed to do caused or contributed to cause her injuries.

COUNT VII:

Product Liability-Negligence Against Defendant Dr. Galella

112. Plaintiff Melanie Pappalardi reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

113. Defendant Dr. Galella was negligent in that, *inter alia,* he negligently designed the AGGA device that was installed in Ms. Pappalardi, an adult, when he knew or should have known that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to Galella's education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by plaintiff, all as aforesaid.

114. Dr. Galella acted with reckless disregard for the safety of others, including Ms. Pappalardi.

115. As a direct and proximate result of the negligence of Dr. Galella, and his reckless disregard for the safety of others including Ms. Pappalardi, Ms. Pappalardi has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Melanie Pappalardi demands Judgment in an amount in excess of One Hundred Thousand Dollars against defendant Steve Galella, D.D.S., plus interest and costs.

COUNT VIII:

Negligence Against Defendant Orthomatrix And Defendant Galella

116. Plaintiff Melanie Pappalardi reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

117. OrthoMatrix was negligent in that, *inter alia,* it, either directly or by or through its division or trade name FBI and/or OrthoLogic, and/or through its officer Galella:

a. taught the course to Dr. Kun, informing him and others that the AGGA device was safe and efficacious for use by adults, when it knew or should have known that the theory behind AGGA regarding its use on adults and its alleged function of making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, were contrary to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, that it had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Pappalardi, all as aforesaid;

b. marketed AGGA to Dr. Kun, to Ms. Pappalardi, and to dentists and consumers throughout the world, as a product that was safe and efficacious for adults when it knew or should have known that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, had limited utility for adults, that it was unreasonably dangerous and that it

could and foreseeably would cause the type of injury and damage suffered by Ms. Pappalardi, all as aforesaid; and,

c. failed to warn purchasers of AGGA and dentists to whom it taught the course including Dr. Kun and other similar courses, or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including, inter alia, causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

d. negligently produced the Pappalardi treatment plan for Ms. Pappalardi's dentist for the installation of an AGGA device on Ms. Pappalardi, when it knew or should have known that said device, when used for the purpose of making changes in the nasomaxillary complex, was unproven for use by adults, it was neither safe nor efficacious for adults, the principles upon which it allegedly functioned for adults were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous for adults and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Pappalardi; and,

e. through its officer Galella, approved an AGGA device for use by Ms. Pappalardi, when Galella knew or should have known by the mold and photographs of Ms. Pappalardi's teeth as aforesaid that she was an adult, and/or he failed to inquire as to whether Ms. Pappalardi was indeed an adult; and Galella knew or should have known that said device, when used for the purpose of making changes in the nasomaxillary complex, was unproven for use by adults, it was neither safe nor efficacious for adults, the principles upon which it allegedly functioned for adults were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous for adults and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Pappalardi.

118. OrthoMatrix and Galella acted with reckless disregard for the safety of others, including Ms. Pappalardi.

119. As a direct and proximate result of the negligence of OrthoMatrix and Dr. Galella, and their reckless disregard for the safety of others including Ms. Pappalardi, Ms. Pappalardi has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Melanie Pappalardi demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Orthomatrix Corp., Inc., and defendant Steve Galella, D.D.S., plus interest and costs.

COUNT IX:

Product Liability-Breach Of Warranties Against Defendant John's Dental

120. Plaintiff Melanie Pappalardi reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

121. At the time that the AGGA device that was sold to Ms. Pappalardi's dentist last left the possession, custody or control of John's Dental, the device was inherently defective by virtue of its design, was not fit for their intended purpose nor for the specific purpose for which it was sold for installation in Ms. Pappalardi's mouth, was not of merchantable quality, was not reasonably or minimally safe, was unreasonably dangerous and defective, and the utility of the device in moving teeth through adult bone as done by orthodontic appliances was outweighed by the risk of substantial risk of harm, all at the time it left the possession, custody and control of John's Dental, for reasons that were described above, in regard to its use by adults.

122. The defective nature of the subject AGGA device includes its lack of warnings, at the time it last left the possession, custody and control of defendant John's Dental, in that it failed to warn purchasers of AGGA, or anyone else:

a. of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

b. that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla;

c. that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth.

d. that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

e. if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

123. When used for the purpose for which it was intended, AGGA has limited utility for adults and presents a risk of serious and permanent injury to adults when used as intended by the designer, manufacturer and seller to make dimensional changes in the nasomaxillary complex, all as aforesaid.

124. As a result of the foregoing, John's Dental was in breach of the implied warranties of merchantability and fitness for a particular purpose in regard to the aforesaid AGGA device sold to Ms. Pappalardi's dentist and installed in Ms. Pappalardi's mouth.

125. Ms. Pappalardi relied on the aforementioned implied warranties in agreeing to the installation of the AGGA devices.

126. As a direct and proximate result of those breaches of implied warranties, separately and together, Ms. Pappalardi has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Melanie Pappalardi demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT X:

Indiana Product Liabilty Act Against Defendant John's Dental

127. Plaintiff Melanie Pappalardi reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

128. At the time the subject AGGA device was sold by John's Dental to Ms. Pappalardi's dentist, the device was not reasonably safe, was defectively designed and in a condition not reasonably contemplated by Ms. Pappalardi, the ultimate user, including for the reasons that the function for which it was designed was not possible to achieve in adults, and was in contravention of principles of physiology and anatomy, and carried substantial risk of serious injury for adults, and that it lacked necessary warnings as above.

129. At the time the subject AGGA device was sold by John's Dental to Ms. Pappalardi's dentist, the product posed a substantial likelihood of harm to Ms. Pappalardi or any other adult user and was unreasonably dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to consumers, including because the product's tendency, rather than to move the maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare

out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to Ms. Pappalardi as a result of the use of the product.

130. No reasonable person who knew the risk of harm of using AGGA at the time of manufacture would conclude that the benefit of the product outweighed the risk to adult users.

131. The defective design of the AGGA devices installed in Ms. Pappalardi's mouth was the sole and/or substantial cause and/or factor in bringing about his injuries or damages.

WHEREFORE, plaintiff Melanie Pappalardi demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT XI

Product Liability- Negligence Against Defendant John's Dental

132. Plaintiff Melanie Pappalardi reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

133. At the time the subject AGGA device was sold by John's Dental to Ms. Pappalardi's dentist, John's Dental knew or should have known that the device, for use in adults, was not reasonably safe, was negligently designed and in a condition not reasonably contemplated by Ms. Pappalardi, the ultimate user, including for the reasons that the function for which it was designed was not possible to achieve and was in contravention of principles of physiology and anatomy, and the devices carried substantial risk of serious injury for adults, and that it lacked necessary warnings as above.

134. At the time the AGGA device was sold by John's Dental to Ms. Pappalardi's dentist, the product posed a substantial likelihood of harm to Ms. Pappalardi or any other adult user and was unreasonably dangerous to an extent beyond that which would be contemplated by

the ordinary consumer who purchases it with the ordinary knowledge common to consumers, including because the product's tendency when used in adults, rather than to move the maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to Ms. Pappalardi as a result of the use of the product.

135. No reasonable person who knew the risk of harm of using AGGA at the time of manufacture would conclude that the benefit of the product outweighed the risk to adult users.

136. The negligent and defective design of the AGGA devices installed in Ms. Pappalardi's mouth was the sole and/or substantial cause and/or factor in bringing about her injuries or damages.

WHEREFORE, plaintiff Melanie Pappalardi demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT XII:

Indiana Deceptive Consumer Sales Act ("IDCSA")
Against Defendant John's Dental

137. Plaintiff Melanie Pappalardi reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

138. Indiana Deceptive Consumer Sales Act ("IDCSA"), Indiana Code Sections 24-5-0.5 et seq makes unlawful any deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in Indiana.

139. John's Dental has engaged in consumer-oriented conduct that is materially misleading, in that it has, in the course of marketing AGGA to consumers (including Indiana

consumers) directly, and to dentists (including Indiana dentists) for the purpose of enticing consumers (including Indiana consumers) to use AGGA, represented falsely that:

a. AGGA is a device that causes three-dimensional changes in the nasomaxillary complex of adults, including growing/advancing/remodeling the maxilla to move forward horizontally over time by as much or more than 10 mm;

b. AGGA causes these nasomaxillary changes in adults through a process of mechanical force and new bone deposition resulting from stimulation of a nerve in the palate;

c. as the maxilla moves forward, upper teeth move with it, including in adults;

d. by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward, including in adults;

e. the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face, including in adults;

f. AGGA is reasonably safe for installation into dental patients' mouths, including in adults;

g. AGGA can be utilized as a substitute for jaw surgery, including in adults.

140. These false representations are material in that they go to the essence of the function of AGGA as claimed by John's Dental, and their falsity means that the product is essentially useless for adults.

141. AGGA is unreasonably dangerous as designed and manufactured, and can cause substantial and permanent damage, as set forth above.

142. As a direct and proximate result of the material misrepresentations, Ms. Pappalardi allowed AGGA to be installed in her mouth, and as a result suffered serious and permanent injury as described above.

143. This conduct of John's Dental has affected and will continue to affect not just Ms. Pappalardi but also adult consumers at large within the State of Indiana who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

144. This conduct of John's Dental has also affected and will continue to affect Indiana dentists who, based on those misrepresentations, will utilize AGGA on adult Indiana consumers and thereby visit substantial and permanent injury on such consumers who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

145. John's Dental, through its material misrepresentations, has violated IDCSA, thereby causing Ms. Pappalardi severe and permanent injury and damage as described above.

WHEREFORE, plaintiff Melanie Pappalardi demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus treble damages, attorney's fees interest and costs.

JURY TRIAL DEMAND

Plaintiffs hereby demand a trial by jury on all Counts so triable.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, as follows:

1. For compensatory damages in excess of $100,000.00;

2. For punitive damages in an amount to be proven at trial;

3. For attorney's fees and costs of suit incurred herein;

4. For pre-judgment and post-judgment interest as allowed by law; and

5. For such other and further relief as is appropriate under the circumstances.

Respectfully submitted,

s/Alan C. Milstein
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Dated: **March 2, 2022**