UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
TERRE HAUTE DIVISION

MICHELLE BARKER, Plaintiff, vs. STEVE GALELLA, D.D.S. and, ORTHOMATRIX CORP., INC., d/b/a FACIAL BEAUTY INSTITUTE and d/b/a ORTHOLOGIC, Defendants.	)	Case No.:

PLAINTIFF'S COMPLAINT

Plaintiff Michelle Barker, by and through his undersigned counsel, by way of Complaint against Steve Galella, D.D.S. and OrthoMatrix Corp, Inc., allege as follows:

PARTIES

1. Plaintiff Michelle Barker is an individual and citizen of Arizona with an address of 5108 W. Fawn Drive, Laveen, Arizona 85339. At all times relevant to the case, she was and is an adult. Her claims arise from the laws of Indiana.

2. 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.

3. 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.

JURISDICTION

4. This Court's jurisdiction is based upon diversity of citizenship as set forth in 28 U.S.C. § 1332 in that plaintiff is a citizen of a different state or country than each of the defendants.

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

6. This Court has personal jurisdiction over the 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 plaintiff. In particular, defendants Galella and OrthoMatrix receive and have received payments from an Indiana corporation based in Indiana (John's Dental Laboratory, Inc., or "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 said 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

7. 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 plaintiff's claims occurred in this judicial district.

FACTUAL ALLEGATIONS COMMON TO ALL COUNTS

NATURE OF THE ACTION

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

9. 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.

10. Defendant Dr. Galella is the designer of the AGGA appliance.

11. Both defendants created product inserts that accompanied the AGGA appliances when delivered to the dentist who installed it on plaintiff; both defendants approved the fit of the subject AGGA appliance on plaintiff; defendant Dr. Galella, as part of his duties as an officer of Defendant OrthoMatrix, was available to answer questions concerning the use of AGGA on this plaintiff; both defendants received, directly or indirectly, royalty payments from the sale of AGGA devices; both defendants promoted AGGA, and taught dentists or caused dentists to be taught, including dentists practicing in Arizona, how it allegedly functioned, and in so doing claimed 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.

12. Plaintiff alleges that these claims of AGGA's efficacy 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, that defendants failed to warn about these deficiencies in AGGA, and that it presents a risk of serious and permanent harm for adults.

13. As a result of the fact, for adults - that AGGA was negligently designed and manufactured; that it was not reasonably safe and was unreasonably dangerous; that the promotion and teaching of AGGA involving false representations to dentists including plaintiff's dentist; that neither plaintiff nor her dentist were warned about the actual risks of AGGA to adults; and that the product was specifically approved for use on plaintiff - the installation of AGGA in plaintiff has caused plaintiff to sustain significant and permanent damage to her teeth and face, economic loss, disfigurement, embarrassment, loss of enjoyment of life, and physical and mental pain and suffering.

FACTS ALLEGED

14. 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.

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

16. Prior to 2010, Dr. Galella founded Facial Beauty Institute ("FBI") and OrthoLogic, wholly owned divisions and/or tradenames of OrthoMatrix, and at all times relevant to the Complaint Dr. Galella and FBI shared office space in Tennessee, along with OrthoMatrix.

17. 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.

18. At all times relevant to the Complaint, other than when he initially designed AGGA, Dr. Galella was an officer of, employed by and working in furtherance of the business of, and/or acting as agent of, OrthoMatrix.

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

20. Prior to February 6, 2018, Dr. Galella agreed to allow instructors at LVI Global, LLC ("LVI") in Las Vegas, Nevada, to teach a course to dentists (the "F20 course") which was primarily if not completely comprised of his representations about the alleged safety and efficacy of AGGA and CAB.

21. Prior to February 6, 2018, dentist Dr. John Garza ("Dr. Garza") of Gilbert, Arizona took the F20 course at LVI's campus in Las Vegas, Nevada.

22. At all times relevant to the Complaint, Dr. Galella, and OrthoMatrix made certain representations ("the AGGA representations") to dentists throughout the world 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.

23. At all times relevant to the Complaint, Dr. Galella, and OrthoMatrix, made additional representations to dentist throughout the world, 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 ("the CAB representations").

24. The AGGA representations and CAB 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 Arizona.

25. These same AGGA and CAB representations referenced above were made to dentists taking the aforementioned F20 course at LVI, including Dr. Garza.

26. Neither AGGA nor CAB have ever been listed with the Food & Drug Administration ("FDA") as required by law, or to any other government agency, for approval, and they have never been approved by any governmental agency for use in the United States.

27. AGGA is not touted to be an orthodontic device by defendants.

28. Had AGGA been submitted to the FDA to determine its proper classification under federal regulations, it would have been classified as a Class II device, requiring pre-market approval by the FDA prior to being sold for installation into human beings, including plaintiff.

29. AGGA is neither safe nor efficacious, and would not have been approved by the FDA for sale to consumers, had it been submitted to the FDA as required by law.

30. Dr. Galella and OrthoMatrix, knew or should have known that, while their 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.

31. At all times relevant to the Complaint, John's Dental manufactured, sold and put 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 Arizona and Germany.

32. 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.

33. During the teaching of the F20 course taken by Dr. Garza, the AGGA and CAB representations -which originated with defendants as aforesaid and were taught by LVI by agreement with defendants- were made, and same 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.

34. On information and belief, the course, which lasted approximately 2.5 days, largely or completely comprised the extent of Dr. Garza' training concerning AGGA and CAB.

35. At no time during the F20 course, consistent with the information supplied by defendants for that course, was Dr. Garza ever warned that, in regard to adult users, AGGA was unproven, was not supported by scientific or medical knowledge, was not reasonably safe, was unreasonably dangerous, was not efficacious, presented a risk of serious and permanent injury to consumers; nor were Dr. Garza or plaintiff ever so warned by defendants.

36. On or about February 6, 2018, Ms. Barker sought treatment from Dr. Garza at his practice in Gilbert, Arizona for Temporomandibular Disorder (TMD) symptoms. Dr. Garza informed Ms. Barker that she was "midface deficient" and, prior to April 30, 2018, he prescribed treatment with an AGGA device for the purpose of expanding her upper jaw and, as described by Dr. Garza, the space would fill in with bone. Dr. Garza also indicated that AGGA would address her migraines, headaches and unstable bite.

37. Prior to April 30, 2018, John's Dental did manufacture an AGGA appliance for use by Dr. Garza for installation in Ms. Barker's mouth, did place it in the stream of commerce and did sell that appliance to Dr. Garza, who was then within the State of Arizona; 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. Garza would install it in Ms. Barker.

38. Prior to April 30, 2018, defendants produced the product insert that accompanied the AGGA device upon its sale to Dr. Garza, and such insert repeated material and false representations about AGGA made in the F20 course and by defendants as aforesaid; and said insert failed to warn:

(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 the maxilla;

(c) that using AGGA for the purpose of attempting to make three-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.

39. Pursuant to an agreement between John's Dental and defendants, John's Dental was the exclusive manufacturer of AGGA, and, further pursuant to that agreement, no dentist including Dr. Garza would have been permitted to prescribe an AGGA for any patient including plaintiff unless the dentist had taken either the F20 course or another course on AGGA taught directly by defendants.

40. Prior to the AGGA being placed into the stream of commerce and sold to Dr. Garza for use on plaintiff, defendants did inspect and examine photographs of that AGGA device and of a mold of plaintiff'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 on plaintiff.

41. Defendants are "manufacturers" and "sellers" of the AGGA device installed in the plaintiff, under the Indiana Product liability Act ("the Act"). More specifically:

a. Dr. Galella is a "manufacturer" by virtue of the fact that he designed the product, pursuant to §34-6-2-77(a) of the Act;

b. OrthoMatrix is a "manufacturer" pursuant to § 34-6-2-77(a), as it otherwise prepared the product for sale,

c. OrthoMatrix is a "seller" because it engaged in the business of selling a product by collecting a per-sale royalty from John's Dental, pursuant to § 34-6-2-13677(a);

d. Additionally, as a "seller", OrthoMatrix is by extension a "manufacturer" under § 34-6-2-77(a)(2), as it exercises significant control over product specifications.

42. Defendants knew at the time it was placed into the stream of commerce that the aforementioned AGGA appliance would be installed in a member of the public, and specifically that Dr. Garza would install it in plaintiff.

43. At the time that the AGGA device was manufactured, placed into the stream of commerce and sold to Dr. Garza for plaintiff, 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.

44. At the time of sale of the AGGA to Dr. Garza, defendants 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. Garza, that it had no design defects, that it was of merchantable quality, and that it was safe and not unreasonably dangerous.

45. Plaintiff reasonably relied upon the aforementioned implied warranties, as well as on defendants' skill and judgment.

46. At all times relevant to the Complaint, had plaintiff or Dr. Garza been warned of the defects and deficiencies of AGGA as described above, neither would have embarked on any course of treatment using AGGA.

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

48. In September 2018, Dr. Garza removed AGGA from Ms. Barker, and the next day installed CAB or similar orthodontic braces in her, which braces she wore until 2023.

49. On information and belief, on or about December 21, 2021, Dr. Garza received an email from Dr. William Dickerson of Las Vegas Institute, informing him and others, in effect, that AGGA did not work to achieve maxillary advancement or growth in adults. Dr. Garza did not inform Ms. Barker of that fact.

50. On May 1, 2023, Ms. Barker was examined by an orthodontist who told her that her back teeth were not touching and that she had short roots; he stated he could potentially provide treatment in the future.

51. Thereafter, on May 9, 2023, Ms. Barker met with another dentist who informed her that he could not treat her due to her short roots and potential loss of her front teeth; he referred her to another dentist with more experience in complex cases.

52. On May 23, 2023, Ms. Barker was examined by another orthodontist who explained to her that AGGA would never work.

53. On May 30, 2023, Dr. Garza's office called Ms. Barker to advise that her braces were in; Ms. Barker was confused as it was her understanding that she would be receiving a retainer or Invisalign to further correct her bite, not braces. Dr. Garza got on the phone and explained that it would take over forty trays to fix her bite and they had agreed to braces as the next step, which was not Ms. Barker's recollection. At that time, Ms. Barker became worried that the AGGA that had been installed in her was causing injury.

54. 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 Arizona including plaintiff; 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 Arizona including plaintiff.

55. As a result of the installation and use of the AGGA appliance, Ms. Barker has been caused to suffer significant and permanent injury and damage, including but not limited to: gum damage, bone loss, shortened roots, tipped molars, loose and sensitive teeth, and other injury and damage including physical, mental and emotional pain and suffering as we as economic loss.

56. Ms. Barker 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 I:

Product Liability-Negligence Against Defendant Dr. Galella

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

58. Defendant Dr. Galella was negligent in that, *inter alia,* he negligently designed the AGGA devices that was installed in plaintiff, 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.

59. Dr. Galella acted with reckless disregard for the safety of others, including plaintiff.

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

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

COUNT II:

Negligence Against Defendants OrthoMatrix and Galella

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

62. Defendants were negligent in that, *inter alia,* they:

a. approved an AGGA device for use by plaintiff, when they knew or should have known that she was an adult, and/or they failed to inquire as to whether plaintiff was indeed an adult; and defendants 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 plaintiff;

b. produced a product insert to accompany the AGGA sold to plaintiff's dentist as aforesaid, which insert made material misstatements about the safety and efficacy of AGGA, and failed to warn as aforesaid;

c. made representations to LVI or its instructors teaching the F20 course to Dr. Garza about the safety and efficacy of AGGA as aforesaid, when they knew or should have known that such representations were false, that they would be transmitted to dentists such as Dr. Garza, and would be relied upon to install AGGA on patients sch as plaintiff.

63. OrthoMatrix and Galella acted with reckless disregard for the safety of others, including plaintiff.

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

WHEREFORE, plaintiff Michelle Barker demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant OrthoMatrix Corp., Inc., d/b/a Facial Beauty Institute and d/b/a Orthologic and defendant Steve Galella, D.D.S., plus interest and costs.

COUNT III:

Violation of Indiana Product Liability Act Against Defendants Dr. Galella and OrthoMatrix

65. Plaintiff Michelle Barker reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

66. The Indiana Product Liability Act ("IPLA", or, "the Act") governs product liability actions in Indiana against manufacturers and sellers of products.

67. Under the Act, "a person who sells, leases or otherwise puts into the stream of commerce any product in a defective condition unreasonably dangerous to any user or consumer…is subject to liability for physical harm caused by that product."

68. Dr. Galella, as the person who designed the subject AGGA product, is a manufacturer under the Act.

69. Dr. Galella and OrthoMatrix are manufacturers under the Act in that they approved the AGGA product for use on plaintiff; drafted a product insert with warnings and instructions that was sold with the AGGA product; received royalties from the sale of the subject AGGA device; prepared the AGGA product for sale, including but not limited to its approval of the device for use on Plaintiff and/or its providing specifications for manufacture of the AGGA device; all as aforesaid.

70. OrthoMatrix and Dr. Galella are sellers under the Act as each received a royalty as aforesaid and were thus engaged in the business of selling the subject AGGA.

71. Defendants Dr. Galella and OrthoMatrix, as manufacturers and sellers of the subject AGGA device, failed to warn plaintiff and Dr. Garza, as aforesaid, that in regard to adult users, 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.

72. This failure to warn rendered the device defective, and the device was thereby also defective in design.

73. Plaintiff was a consumer of the product and was in a class of persons defendants should have reasonably expected to be subject to the harm caused by the defective condition.

74. The product was expected to and did reach plaintiff without substantial alteration of the condition in which the product was manufactured, designed and sold.

75. The defective condition of defendants' AGGA product was a direct and proximate cause of physical harm and other injury and damage including economic damage to plaintiff as aforesaid.

WHEREFORE, Plaintiff Michelle Barker demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against Defendants Steve Galella, D.D.S and OrthoMatrix Corp., Inc., d/b/a Facial Beauty Institute and d/b/a Orthologic, plus interest and costs.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays 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.

JURY TRIAL DEMAND

Plaintiff hereby demands a trial by jury on all Counts so triable.

Respectfully submitted,

s/Alan C. Milstein
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