UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
TERRE HAUTE DIVISION

ANTOINE PENTREATH, Plaintiff, v. STEVE GALELLA, D.D.S., ORTHOMATRIX CORP., INC., d/b/a FACIAL BEAUTY INSTITUTE and d/b/a ORTHOLOGIC and JOHN'S DENTAL LABORATORY, INC., Defendants.	Case No. _____ **COMPLAINT AND JURY TRIAL DEMAND**

Plaintiff Antoine Pentreath ("Plaintiff"), by way of Complaint against Defendants Steve Galella, D.D.S., OrthoMatrix Corp., Inc. d/b/a Facial Beauty Institute and d/b/a OrthoLogic and John's Dental Laboratory, Inc. (collectively, "Defendants"), hereby says, states, and avers as follows:

PARTIES

1. Plaintiff Antoine Pentreath is an individual and citizen of California with an address of 17438 Horace Street, Granada Hills, California 91344. At all times relevant to this matter, Plaintiff was and is an adult. Plaintiff's 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. FBI is a wholly owned division and/or tradename of Defendant OrthoMatrix.

4. At all times relevant, Defendant John's Dental Laboratory, Inc. ("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.

5. Defendants Dr. Galella, John's Dental and OrthoMatrix were involved in manufacturing, designing, and marketing the appliance, known as "Anterior Growth Guidance Appliance" ("AGGA") as a proven means of correcting dental, facial and airway abnormalities in lieu of complex jaw surgery for adult patients. The aforementioned Defendants will collectively be referred to as the "AGGA Defendants."

JURISDICTION

6. 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.

7. The amount in controversy 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 Plaintiff.

In particular, Defendants Dr. Galella and OrthoMatrix receive and have received payments from 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, Dr. 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

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 Plaintiff's 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 Plaintiff as the result of the installation of a dental appliance which the AGGA Defendants designed, manufactured and marketed despite no scientific or clinical basis to prove it was either safe or effective.

12. The AGGA 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.

13. Plaintiff alleges 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.

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

HISTORY OF AGGA

15. 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.

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

17. 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.

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

19. FBI, and therefore OrthoMatrix, and Dr. Galella, offered and taught courses to dentists on the use and alleged safety and efficacy of AGGA and CAB.

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, FBI and therefore OrthoMatrix made certain representations ("the representations") to dentists throughout the world, including the dentists who treated Plaintiff, 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, FBI and therefore OrthoMatrix made additional representations to dentists throughout the world, including to the dentist treating Plaintiff, 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, FBI and therefore OrthoMatrix, were made for the purpose of, *inter alia*, causing dentists to promote AGGA and CAB to consumers, including adult consumers in Croatia.

26. Neither AGGA nor CAB have ever been submitted to the Federal Drug Administration ("FDA"), or 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 the AGGA 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 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.

31. 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 within Croatia.

32. At all times relevant to the Complaint, John's Dental paid a royalty and/or other fee to both OrthoMatrix and to Dr. Galella or an entity controlled by Dr. Galella, for every AGGA device manufactured and sold by John's Dental.

PLAINTIFF ANTOINE PENTREATH

33. A notation by Dr. Carson in Plaintiff's medical records indicates that, on or about December 12, 2018, Dr. Galella consulted on Plaintiff's treatment.

34. Prior to February 2019, Dr. Galella agreed to allow instructors at LVI Global, LLC ("LVI") in Las Vegas, Nevada, to teach a course to dentists (the "F20 courts") which had as its subject matter primarily AGGA and CAB.

35. Prior to February 2019, Dr. Kathleen Carson ("Dr. Carson") of Integrative Dental Arts took the F20 course at LVI's campus in Las Vegas, Nevada.

36. During the teaching of the F20 course taken by Dr. Carson, the representations about AGGA were made 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.

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

38. In or about mid-February 2019, Plaintiff sought treatment from Dr. Carson at her practice in Agoura Hills, California for facial aesthetics and facial symmetry, at which time Dr. Carson informed Plaintiff that AGGA treatment would make his face more symmetrical and more aesthetically pleasing, as well as provide better overall functionality of teeth and oral condition; she then prescribed treatment with an AGGA device for the purpose of stimulating growth of the upper arch, which would thereby allegedly improve the symmetry and aesthetics of his face.

39. Dr. Carson further informed Plaintiff that the AGGA device would correct his facial asymmetry by growing the upper jaw 6-8 mm, with corresponding movement of the mandible.

40. This representation concerning the allegedly anticipated maxillary growth was consistent with the treatment plan.

41. At no time prior to February 2019 was Dr. Carson or Plaintiff 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, and presented a risk of serious and permanent injury to consumers.

42. Prior to February 2019, Dr. Carson consulted with OrthoMatrix, through Dr. Galella and others, in regard to whether Plaintiff was an appropriate candidate for AGGA and CAB, and for the purpose of establishing an AGGA and CAB treatment plan.

43. More specifically, prior to February 2019, on information and belief, Dr. Carson submitted a questionnaire and dental records concerning Plaintiff 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 Plaintiff ("the treatment plan") and otherwise represented to Dr. Carson and to Plaintiff that AGGA and CAB were appropriate treatments for Plaintiff.

44. Prior to February 2019, Dr. Carson, 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 Plaintiff and did place an order for an AGGA appliance to be manufactured by John's Dental for the specific use by Plaintiff.

45. At no time during the F20 course, consistent with the information supplied by Dr. Galella and OrthoMatrix for that course, was Dr. Carson 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. Carson or Plaintiff ever so warned by Defendants Dr. Galella and OrthoMatrix.

46. Prior to February 2019, the AGGA Defendants produced the product insert that accompanied the AGGA device upon its sale to Dr. Carson, and such insert repeated material and false representations about AGGA made in the F20 course and by Dr. Galella and OrthoMatrix as aforesaid; and said insert failed to warn:

(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 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;

(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.

47. Prior to February 2019, John's Dental did manufacture in Indiana an AGGA appliance for use by Dr. Carson for installation in Plaintiff's mouth, did place it in the stream of commerce and did sell that appliance to Dr. Carson, who was then within California; 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. Carson would install it in Plaintiff.

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

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

50. Prior to the AGGA being placed into the stream of commerce and sold to Dr. Carson for use on Plaintiff, Dr. Galella 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 for Plaintiff.

51. At the time of the sale of the AGGA to Dr. Carson, 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 Plaintiff'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. Carson 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 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.

52. At the time that John's Dental manufactured, placed into the stream of commerce and sold to Dr. Carson the AGGA appliance 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.

53. 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.

54. The AGGA device was removed by Dr. Carson in October 2019, and Controlled Arch Brace ("CAB") was installed by her in November 2019.

55. Dr. Carson removed CAB in February 2022.

56. Any concerns voiced by Plaintiff to Dr. Carson from time to time during her treatment, including those of flared teeth or insufficient correction of the jaw, were consistently downplayed by her, up to and beyond May 24, 2022, as either intended sequelae of the treatment, issues that were correctable after treatment, or the maximum improvement that could be achieved.

57. At some time after March 2023, Plaintiff saw a piece on television about the fact that AGGA does not work as claimed, that it does not grow the jaw, and that it can cause significant harm to patients.

58. As a result of his use of the AGGA appliance, plaintiff has suffered and continues to suffer loose teeth, damage to his gums, tooth root resorption, bone loss and headaches.

59. To date, Plaintiff has not found a dentist or other dental professional to remedy the damage caused by AGGA.

60. 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 California 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 California including Plaintiff.

61. As a result of the installation and use of the AGGA appliances, Plaintiff has been caused to suffer significant and permanent injury and damage.

62. Plaintiff, at all times relevant to the Complaint acted reasonably, and nothing she did or failed to do caused or contributed to cause his injuries.

COUNT I:

NEGLIGENCE AGAINST DEFENDANTS ORTHOMATRIX AND DR. GALELLA

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

64. Defendants OrthoMatrix and Dr. Galella were negligent in that, *inter alia,* they:

a. negligently produced the treatment plan for Plaintiff's dentist for the installation of an AGGA device on Plaintiff, when they 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. approved an AGGA device for use by Plaintiff, when they knew or should have known that he was an adult, and/or he failed to inquire as to whether Plaintiff was indeed an adult; and Dr. 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 Plaintiff;

c. 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;

d. made representations to LVI or its instructors teaching the F20 course to Dr. Carson 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. Carson, and would be relied upon to install AGGA on patients sch as Plaintiff.

65. OrthoMatrix and Dr. Galella acted with reckless disregard for the safety of others, including Plaintiff.

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

COUNT II:

VIOLATION OF INDIANA PRODUCT LIABILITY ACT AGAINST DEFENDANTS DR. GALELLA, ORTHOMATRIX AND JOHN'S DENTAL

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

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

61. 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."

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

63. Dr. Galella and OrthoMatrix are manufacturers under the Act in that they created the treatment plan for Plaintiff, approved the AGGA product for use on Plaintiff, purported to analyze Plaintiff's dental/cranio maxillofacial condition to prepare for AGGA treatment, and received royalties from the sale of the subject AGGA device, all as aforesaid.

64. OrthoMatrix is also a manufacturer under the Act as it is an entity who otherwise 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.

65. 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.

66. John's Dental is both a manufacturer and a seller under the Act, as it both manufactured and sold the subject AGGA device, and put it into the stream of commerce.

67. Defendants Dr. Galella, OrthoMatrix and John's Dental, as manufacturers and sellers of the subject AGGA device, failed to warn Plaintiff and Dr. Carson, 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.

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

69. 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.

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

71. 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 Antoine Pentreath demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against Defendants OrthoMatrix Corp., Inc.

d/b/a Facial Beauty Institute, Steve Galella, D.D.S. and John's Dental Laboratory, Inc., 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.

Respectfully submitted,

Date: May 3, 2024

s/Alan C. Milstein

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JURY TRIAL DEMAND

Please take notice that the Plaintiff demands a trial by jury as to all issues in the above matter.

Date: May 3, 2024

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