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DISTRICT COURT, CITY & COUNTY OF DENVER

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**CAVITAT MEDICAL TECHNOLOGIES, INC.,
and
ROBERT J. JONES,**

Plaintiffs,

v.

AETNA, INC.,

Defendant.

Δ COURT USE ONLY Δ

Case Number:

Div.:

Ctrl.:

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ATTORNEYS FOR PLAINTIFFS

COMPLAINT AND DEMAND FOR JURY TRIAL

COME NOW, the Plaintiffs, CAVITAT MEDICAL TECHNOLOGIES, INC., and ROBERT J. JONES, by and through their counsel, the WALTER L. GERASH LAW FIRM, P.C., and for their Complaint against the Defendant AETNA, INC. state as follows:

GENERAL ALLEGATIONS

1. Plaintiff CAVITAT Medical Technologies, Inc. ("CAVITAT, Inc.") is a corporation organized under the laws of the State of Colorado and has its principle place of business in the state of Colorado 80014. CAVITAT, Inc. is engaged in the business of manufacturing the CAVITAT, a sonar bone imaging instrument, in Colorado and markets the tool and the technology in Colorado, the United States and internationally.

2. Plaintiff Robert J. Jones is a resident of the state of Colorado. Mr. Jones is the co-inventor of the CAVITAT and the founder of CAVITAT, Inc. Mr. Jones is the President and CEO of, and a major shareholder in, CAVITAT, Inc.

3. Defendant Aetna, Inc. ("Aetna") is a Pennsylvania corporation which directly and through its subsidiaries is engaged in the business of providing medical and dental insurance in all 50 states of the United States, including the state of Colorado and the County of Denver.

4. Quackwatch (aka "Quackwatch, Inc.") is a Pennsylvania corporation engaged in the activity of disseminating and publishing information regarding what it purports to be "health-related frauds, myths, fads, and fallacies." Such information is disseminated and published in nationally and internationally to the public, including Aetna, among others. Quackwatch is funded by, among other sources, Stephen Barrett ("Barrett"), individual contributions, and profits from the sales of its publications. Barrett is the founder and an officer and chairman of the board of Quackwatch and operator of its website. Barrett with Robert S. Baratz ("Baratz"), John Dodes ("Dodes"), and Marvin Schissel ("Schissel") are jointly engaged in Dental Watch, a project of Quackwatch.

5. National Council Against Heath Fraud ("NCAHF") is a California corporation engaged in the activity of disseminating and publishing information regarding what it purports to be "health misinformation, fraud, and quackery." Such information is disseminated and published in nationally and internationally to the public, including Aetna., among others. NCAHF is funded by, among other sources, individual contributions and membership dues. Barrett and Baratz are officers of NCAHF and Dodes is an officer of the NCAHF New York chapter..

6. John E. Dodes is the co-author with Marvin Schissel of "Cavitational Osteopathosis, NICO, and 'Biological Dentistry'" ("Dodes & Schissel Paper"). The Paper was not peer reviewed.

7. Working with experts in the field of maxillofacial surgery, in the early 1990's Mr. Jones invented the CAVITAT, a sonar imaging system that uses ultrasound technology to create a computer image of bones. The present focus of application is upon detection of jawbone pathology, however the technology has wide application for other bones in the body.

8. When the CAVITAT is used, sound waves are sent through the bone via a very small transducer, which is pressed against the outside of the cheek. The ultrasound waves sent through the bone and picked up by the sensor on the opposite side of the bone can locate areas of bone loss or destruction. Once the signal data is acquired, it is sent to a computer, which converts it to a digital perspective 3-D color image.

9. The CAVITAT is completely safe as applied to the human body. It produces no ionizing radiation. The CAVITAT is intended to be used in conjunction with other diagnostic tools, such as x-rays, by a healthcare provider.

10. In March of 2001, Plaintiffs applied for FDA 510(k) approval to market CAVITAT. Thereafter, Plaintiffs began marketing, production, and sales of the CAVITAT in Colorado, nationally, and internationally under their 501(k) application. Plaintiffs received final FDA clearance on February 15, 2002.

11. In February, 1998, and January, 2001, Mr. Jones applied for his United State patents for the CAVITAT technology. The patents were awarded on February 29, 2000, and March 2, 2004, respectively. Mr. Jones has 21 claims on the first patent and 17 claims on a second patent regarding the CAVITAT and its technology.

12. After Plaintiffs applied for FDA approval in 2001, and at all times hence to the present day, Quackwatch, NCAHF, Barrett, Baratz, Dodes, and Schissel disseminated and published on the internet and in other media to the public, including Aetna., among others, the Dodes & Schissel Paper and other information regarding the use and efficacy of diagnostic tools, such as the CAVITAT, in the detection of infected cavities within jaw bones, a condition termed neuralgia inducing cavitational osteonecrosis ("NICO").

13. Specifically, said these entities and persons asserted that there is no scientific evidence to support the existence of NICO as a medical condition or the diagnostic methods used to identify the medical condition. They asserted that dental practice which engages the diagnosis of NICO is fraudulent and that the submission of insurance claims for such practice is insurance fraud and is a violation of dental licensing requirements. These assertions were false and misleading and defamatory.

14. After receiving this information from these entities and persons, Aetna adopted and published and disseminated to its insureds, medical and dental health service providers, the medical and dental and insurance industries, and the public, a clinical policy which categorically denied insurance coverage for the diagnosis and treatment of NICO and specifically denied insurance coverage for use of the CAVITAT ultrasonograph. In its policy publication and dissemination, Aetna cited extensively to the Dodes and Schissel Paper and asserted that the CAVITAT is experimental and investigational and that there is no scientific evidence to support its clinical value. Aetna further asserted therein that the effectiveness of the CAVITAT had not been sufficiently demonstrated before the FDA and had not undergone an appropriate peer review on the abstracts concerning the CAVITAT. A true copy of said

Aetna policy publication and dissemination is attached hereto and fully incorporated herein as Exhibit 1.

15. These assertions which Aetna knowingly and purposefully published were made available to millions of persons and entities over the internet worldwide, including but not limited to persons in the County of Denver and the state of Colorado, and to federal and state governmental agencies, to the dentistry and medical professions, to dentistry and medical licensing boards, to dentistry and medical associations, and to insurance claims examiners and companies, among others,

16. These assertions which Aetna knowingly and purposefully published and disseminated were and are false and misleading and defamatory.

17. At the time these assertions were published and disseminated, Aetna knew or should have known that the assertions were false and misleading and defamatory.

18. At the time of the aforesaid acts by Aetna, Plaintiff CAVITAT, Inc. had existing contracts and prospective contracts for the purchase and use of the CAVITAT and associated technology.

19. Following the commission of the aforesaid acts by Aetna, the sales of the CAVITAT by CAVITAT, Inc., and the profits therefrom, were decimated as the current and potential purchasers and users of the CAVITAT could not be assured of insurance coverage and were put in fear of criminal or civil sanctions, including malpractice, and the loss of or restrictions on their licenses to practice dentistry or medicine.

20. As a direct and proximate result of the aforesaid acts of Aetna, Plaintiff CAVITAT, Inc. and its product and technology, the CAVITAT, suffered and continues to suffer severe injury to the reputation and marketability of each and a great loss in profits. The acts of Aetna discouraged existing and potential purchasers and users and investors and caused and continues to cause CAVITAT, Inc. great pecuniary loss.

21. As a direct and proximate result of the aforesaid acts of Aetna, Plaintiff Robert J. Jones suffered and continues to suffer severe injury to his reputation as the inventor of the CAVITAT and its technology, as the founder of CAVITAT, Inc., and as their primary spokesperson. Plaintiff Jones further suffered and continues to suffer substantial pecuniary injury in the loss of the value of his shares and interests in CAVITAT, Inc., and in the loss of his investment in CAVITAT, Inc., the CAVITAT, and the technology. Plaintiff Jones has also suffered and continues to suffer injury for emotional distress.

**FIRST CLAIM FOR RELIEF
(Publication of Injurious Falsehood)**

22. Plaintiffs reallege Paragraphs 1 through 21 above as though set forth in full herein.

23. Aetna failed to conduct appropriate due diligence to determine the truthfulness of its assertions in regard to NICO and diagnostic procedures and technology, particularly the CAVITAT.

24. The aforesaid acts of Aetna were done with malicious intent to injure the Plaintiffs.

25. The circumstances under which Aetna's publications were made were such as to make reliance on the publication by prospective CAVITAT purchasers and users, and their patients, and the current and prospective investors in CAVITAT, Inc., and its technology, reasonably foreseeable.

26. Prospective CAVITAT purchasers and users, and their patients, and the current and prospective investors in CAVITAT, Inc., and its technology, would understand the injurious nature of Aetna's publications.

27. Prospective CAVITAT purchasers and users, and their patients, and the current and prospective investors in CAVITAT, Inc., and its technology, would associate the injurious publications of Aetna with CAVITAT, Inc.

28. Aetna's relationship with CAVITAT, Inc. is competitive in nature in that CAVITAT usage to assist patients and their healthcare providers would contractually compel Aetna to pay for CAVITAT usage through its insurance policies.

29. Aetna intentionally published defamatory statements, which was known to be false and misleading, for the purpose of injuring the plaintiff and obtaining a competitive advantage.

30. As a direct and proximate result of the aforesaid acts of the Defendant, Plaintiffs suffered the injuries set forth in Paragraphs 20 and 21 above.

SECOND CLAIM FOR RELIEF
(Tortious Interference with a Prospective Business Advantage)

31. Plaintiffs reallege Paragraphs 1 through 30 above as though set forth in full herein.

32. Plaintiffs had a prospective business relationship with third parties independent of Aetna, namely dentists, dental surgeons, and physicians who were potential CAVITAT purchasers throughout the state of Colorado, the United States, Canada, Mexico, South America, Europe, and other parts of the world.

33. Plaintiffs had a reasonable expectancy of economic gain resulting from these prospective relationships.

34. Aetna engaged in conduct alleged above that had an adverse effect on these relationships.

35. Aetna intended to cause the destruction of or harm to these relationships.

36. Aetna's conduct was a proximate cause of the destruction of or harm to these relationships.

37. As a direct and proximate result of the aforesaid acts of Defendant, Plaintiffs suffered the injuries set forth in Paragraphs 20 and 21 above.

THIRD CLAIM FOR RELIEF
(Negligent Interference with a Prospective Business Advantage)

38. Plaintiffs reallege Paragraphs 1 through 37 above as though set forth in full herein.

39. Aetna possessed a duty not to interfere with the Plaintiffs' prospective relationships.

40. Aetna negligently engaged in conduct alleged above that had an adverse effect on the relationship.

41. Aetna's conduct was a proximate cause of the destruction of or harm to the relationship.

42. As a direct and proximate result of the aforesaid acts by Aetna, Plaintiffs suffered the injuries set forth in Paragraphs 20 and 21 above.

FOURTH CLAIM FOR RELIEF
(Interference With Contract Or Prospective Contractual Relation)

43. Plaintiffs reallege Paragraphs 1 through 42 above as though set forth in full herein.

44. Aetna, by the aforesaid acts, wrongfully interfered with existing and prospective contracts between CAVITAT Inc. and CAVITAT purchasers.

45. Aetna, by the aforesaid acts, employed wrongful means to interfere with CAVITAT Inc.'s contracts.

46. Aetna, by the aforesaid acts, created or continued an unlawful restraint of trade.

47. Aetna's purpose is at least in part to advance its interest in saving its own costs on insuring its clients.

48. Aetna's acts set forth above have interfered with and negatively impacted the social interests of promoting new technologies to diagnose debilitating illnesses and of allowing qualified dental surgeons to decide how best to diagnose their patients.

49. Prospective and existing CAVITAT purchase contracts between dentists and dental surgeons and CAVITAT Inc. were broken in close temporal proximity to Aetna's aforesaid interference.

50. As a direct and proximate result of the aforesaid acts of the Defendant, Plaintiffs have suffered the injuries set forth in Paragraphs 20 and 21 above.

FIFTH CLAIM FOR RELIEF
(Federal and State RICO [18 U.S.C.A. §§ 1961 et seq. and C.R.S. §18-17-104])

51. Plaintiffs reallege Paragraphs 1 through 50 above as though set forth in full herein.

52. Aetna, Quackwatch, NCAHF, Barrett, Baratz, Dodes, and Schissel, at all relevant times herein were and are each "persons" as defined by 18 U.S.C. §1961(3) and C.R.S. §18-17-103(4).

53. Aetna, Quackwatch, NCAHF, Barrett, Baratz, Dodes, and Schissel, at all relevant times herein, were and are each engaged in an "enterprise" within the meaning of 18 U.S.C. §1961(4) and C.R.S. §18-17-103(2).

54. Aetna, Quackwatch, NCAHF, Barrett, Baratz, Dodes, and Schissel, at all relevant times herein, were and are each engaged in joint conduct in the intentional and purposeful transmittal by mail and by wire in interstate or foreign commerce false or fraudulent writings regarding the methods and tools used to diagnose NICO, including the CAVITAT. Aetna and said persons and entities were and are associated in fact for a common joint purpose, and collectively constitute an "enterprise" within the meaning of 18 U.S.C. §1961(4) and C.R.S. §18-17-103(2).

55. Aetna, Quackwatch, NCAHF, Barrett, Baratz, Dodes, and Schissel, at all relevant times herein, were and are each employed or associated with an enterprise, and participated and participates in the conduct of the enterprise affairs through a pattern of racketeering activity in violation of 18 U.S.C. §1962(c) and C.R.S. §18-17-104(3). Said pattern of racketeering activity included and includes, but was and is not limited to, the preparation, publication, dissemination, and transmittal of information by U.S. Mail and by wire through internet web sites by wire and other media, which falsely represented the Plaintiffs' product and technology, constituting a violation of 18 U.S.C. §§ 1341, 1343, 1347, and 1349, and C.R.S. §18-17-103(5)(a); and

56. As a direct and proximate result of the conduct of Aetna as set forth above, the Plaintiffs suffered the injuries set forth in Paragraphs 20 and 21 above.

WHEREFORE, Plaintiffs pray for judgment against Defendant Aetna, Inc. as follows:

General damages in an amount to be determined by a jury as compensation for injuries to Plaintiff CAVITAT Inc., including but not limited to, its business reputation and good will, its market value, its profits and business, and its future profits and investments;

General damages in an amount to be determined by a jury as compensation for injuries to Plaintiff Robert Jones, including but not limited to, his emotional suffering and injuries to his business and personal reputations, the value and profits from his shares in CAVITAT Inc., and the value and profits in the sale and marketing of the CAVITAT and associated technology;

Special damages in an amount to be determined by a jury are further requested by Plaintiff CAVITAT Inc. as compensation for the loss of specific business transactions;

Pre- and post- judgment interest; and


Costs and such other relief as this Court may deem proper.

**PLAINTIFFS DEMAND A TRIAL TO A JURY OF SIX (6) PERSONS
ON ALL ISSUES SO TRIABLE.**

Respectfully submitted this 12th day of August, 2004.

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Clinical Policy Bulletins

Number: 0642

Subject: Neuralgia Inducing Cavitational Osteonecrosis (NICO) and Cavitat Ultrasonography

Important Note

This Clinical Policy Bulletin expresses Aetna's determination of whether certain services or supplies are medically necessary. Aetna has reached these conclusions based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). Aetna expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. **Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusions or other benefit limitations applicable to this service or supply.** The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Aetna) for a particular member. The member's benefit plan determines coverage. Some plans exclude coverage for services or supplies that Aetna considers medically necessary. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Issues Manual can be found on the following website:
<http://cms.hhs.gov/manuals/pub06pdf/pub06pdf.asp>.

Policy

- I. Aetna considers surgery (including scraping of "infected cavities" and removal of root-canal-treated teeth) and/or any other therapies (e.g., rinsing the "cavity" with colloidal silver and administering chelation therapy and intravenous vitamin C) and bone graft replacement for the treatment of NICO related diagnoses to be experimental and investigational because the clinical significance of this syndrome is in question.
- II. Aetna considers the Cavitat Ultrasonograph, an ultrasonograph bone densitometer that has primarily been used to detect neuralgia inducing cavitational osteonecrosis (NICO) in the jawbones, experimental and investigational because there is no scientific evidence to support its clinical value.

Background

The clinical significance of "neuralgia inducing cavitational osteonecrosis" (NICO), or cavitational osteopathosis, has been called into question. Dodes and Schissel (2000) reviewed the history of this syndrome. They explained that the American Academy of Biological Dentistry and other proponents of NICO claim that facial pain is caused by infected "cavities" within the jawbones. In addition, some proponents claim they can cure such conditions as arthritis, heart disease, and pain throughout the body by removing these infected cavities from the patient's jawbones. Unlike abscesses, cysts, or

periapical lesions, these cavities are not apparent on x-ray films, but are only detectable with a Cavitat Ultrasonograph.

Proponents claim that these infected cavities are not treatable with antibiotics, but the infection must be cured by surgically scraping them out. Some practitioners have advocated rinsing the "cavity" with colloidal silver and administering chelation therapy and intravenous vitamin C. Some proponents of biological dentistry have claimed that root-canal-treated teeth cause NICO as well as a host of other chronic systemic diseases. These proponents remove all root-canal-treated teeth and most of the vital teeth close to the area where they say an infection exists. As a result, patients have had healthy teeth removed without any improvement in their diseases.

Dodes and Schissel concluded, however, that there is no scientific evidence to support these assertions or the diagnostic and treatment methods based on them. NICO's prime promoter is J.E. Bouquot, D.D.S., M.S.D., a West Virginia oral pathologist who coined the term in the 1980s. Dodes and Schissel reported that several oral pathologists who blindly reviewed the same tissue blocks that Dr. Bouquot had diagnosed as having NICO judged the tissue to be entirely normal.

The Cavitat Ultrasonograph (Cavitat Medical Technologies, Aurora, CO) provides an ultrasound-based, three-dimensional image of the alveolar processes of the maxilla and mandible. The Cavitat Ultrasonograph was cleared for marketing by the FDA based on a 510(k) application. Thus, the manufacturer was not required to supply the evidence of effectiveness that would be required to support a pre-market approval application (PMA). The FDA-approved labeling states that the clinical significance of the Cavitat ultrasound images is unknown. The indications section of the product labeling contains the following statement:

The clinical significance and correlation of the CAVITAT (Ultrasonograph) images, including column height and color grading, has not been established for specific osseous pathology, or normal bone. Positive images represent alveolar regions that attenuate ultrasound signals.

According to the manufacturer, the Cavitat ultrasonograph detects and precisely images porosity of the bone to aid medical professionals in diagnosing bone marrow edema syndrome, neuralgia inducing cavitation osteonecrosis (NICO), osteomyelitis and periodontal pockets of the buccal bone. However, there are no articles on the effectiveness of the Cavitat published in peer-reviewed medical journals. The manufacturer cites a number of abstracts in support of the effectiveness of the Cavitat. However, abstracts do not undergo the detailed peer review that is required for publication of an article in a quality peer-reviewed medical journal. Furthermore, the abstracts provide insufficient description of study methodology to allow one to draw conclusions about the validity of the results. For example, the abstracts fail to provide sufficient detail about how subjects for study were selected, inadequate description of the gold standard, whether the investigators were blinded to results of competing studies, and whether the results of the ultrasonography improved outcomes.

In fact, the FDA labeling states that "The clinical significance and correlation of the CAVITAT (Ultrasonograph) images, including column height and color grading, has not been established for specific osseous pathology, or normal bone....."

The above policy is based on the following references:

1. Bouquot J, Martin W, Wroblewski G. Computer-based thru-transmission sonography (CTS) imaging of ischemic osteonecrosis of the jaws -- a preliminary investigation of 6 cadaver jaws and 15 pain patients [abstract]. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2001;92:550. Available at: <http://www.cavitatmedtech.homesitead.com/Publication1.html>. Accessed July 8, 2002.
2. Bouquot JE, Shankland WE II, Margolis M. Through-transmission alveolar ultrasonography (TAU) -- new technology for evaluation of bone density and desiccation. Comparison with radiology of 170 biopsied alveolar sites of osteoporotic and ischemic disease [abstract]. Oral Surg Oral Med

- Oral Pathol Oral Radiol Endod. 2002;93: In press. Available at:
<http://www.cavitatmedtech.homestead.com/Publication2.html>. Accessed July 8, 2002.
3. Bouquot JE, Margolis M, Shankland WE II. Through-transmission alveolar sonography (TTAS) -- a new technology for evaluation of medullary diseases. Correlation with histopathology of 285 scanned alveolar sites [abstract]. Proceedings, annual meeting, American Academy of Oral & Maxillofacial Pathology, New Orleans, April 2002. Available at:
<http://www.cavitatmedtech.homestead.com/Publication3.html>. Accessed July 8, 2002.
 4. Bouquot JE, Shankland WE II, Margolis M, Glaros W. Through-transmission alveolar ultrasonography (TAU) -- new technology for detection of low bone density of the jaws. Comparison with radiology for 92 osteoporotic alveolar sites with histopathologic confirmation. Proceedings, annual meeting, American Academy of Oral & Maxillofacial Pathology, New Orleans, LA, April 2002. Available at:
<http://www.cavitatmedtech.homestead.com/Publication4.html>. Accessed July 8, 2002.
 5. Cavitat Medical Technologies, Inc. [Website]: Available at:
<http://www.cavitatmedtech.homestead.com/index.html>. Accessed July 8, 2002.
 6. Dodes JE, Schissel M. Cavitational osteopathosis, NICO, and 'biological dentistry'. Allentown, PA: Quackwatch; July 14, 2000. Available at:
<http://www.quackwatch.com/01QuackeryRelatedTopics/cavitation.html>. Accessed July 8, 2002.
 7. U.S. Food and Drug Administration, Center for Devices and Radiologic Health. Cavitat Ultrasound Bone Densitometer ("Cavitat"). 510(k) No. K011147. Rockville, MD: FDA; February 15, 2002. Available at: <http://www.fda.gov/cdrh/pdf/k011147.pdf>. Accessed July 8, 2002.
 8. Shankland WE 2nd. Medullary and odontogenic disease in the painful jaw: Clinicopathologic review of 500 consecutive lesions. *Cranio*. 2002;20(4):295-303.
 9. US Food and Drug Administration. 510(k)s Final Decisions Rendered for February 2002. Available at: <http://www.fda.gov/cdrh/510k/sumfeb02.html>. Accessed February 2003.

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