Aetna Countersues Bogus Device Promoters

Stephen Barrett, M.D.

Aetna has filed suit against a device manufacturer who made the mistake of filing a lawsuit accusing Aetna of improperly classifying the Cavitat device as "investigational and experimental." Aetna's Clinical Policy Bulletins (CPBs), which cover hundreds of topics, provide the basis for its claims determinations to members and providers of many health benefit plans. In 2002, Aetna issued a CPB which explained why Aetna would not cover diagnostic or treatment procedures related to use of the device. The original suit was filed in 2004 by Cavitat Medical Technologies and its president Robert J. Jones., who accused Aetna of publication of injurious falsehoods, unlawful restraint of trade, and racketeering. However, Aetna had done none of these things, and the plaintiffs did not allege a single instance of illegal conduct to support their false charges. The racketeering charge and nearly all of the others have been dismissed, but Aetna has not let the matter drop. The countersuit states:

- The Cavitat, an ultrasound device, is claimed to help dentists diagnose neuralgia-inducing cavitational osteonecrosis (NICO), a condition that lacks scientific recognition.
- Cavitat proponents advocate very aggressive treatments that include tooth extractions and invasive jawbone operations. Many of these practitioners also prescribe other dubious treatments that can cost thousands of dollars
- The original lawsuit was generated and financed by Cavitat users and others who apparently hoped that it would intimidate Aetna and other insurance companies into paying for practices associated with use of the device.
- Many of the organizers "conspired to accomplish their objectives through unlawful acts . . . insurance fraud; illegal and unauthorized research activities; the unauthorized practice of medicine and dentistry; misrepresenting that the Cavitat device was exempt from FDA regulations; misrepresenting that the Cavitat device was approved by the FDA and, specifically, approved by the FDA for detecting diseased bone; obstruction of justice; witness tampering; and barratry."
- To fund the suit, Cavitat solicited funds from third parties who had invested in the company, some of whom had a monetary stake in its survival, as well as others whose livelihoods derived from the use of the Cavitat device. In exchange, each of these individuals was promised a share of the anticipated recovery.

Aetna is seeking recovery of its legal costs plus punitive damages that could amount to millions of dollars. <u>See Quackwatch for additional information about "NICO."</u>

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLORADO

Civil Action No. 04-CV-1849-MSK-OES

CAVITAT MEDICAL TECHNOLOGIES, INC., Plaintiff and Counterclaim-Defendant, AND ROBERT J. JONES, Counterclaim-Defendant,

v.

AETNA, INC., Defendant and Counterclaim-Plaintiff.

DEFENDANT AETNA INC.'S ORIGINAL COUNTERCLAIM

Defendant Aetna Inc. ("Aetna") asserts this Counterclaim against Plaintiffs Cavitat Medical Technologies, Inc. ("Cavitat") and Robert J. Jones ("Jones") as follows:

INTRODUCTION

1. Cavitat manufactures and promotes the use of a purported ultrasound imaging system (the "Cavitat device") invented by Jones. Aetna brings this counterclaim against Cavitat and Jones to answer in damages for their role in wrongfully orchestrating, aiding, and abetting efforts by providers of lion-covered dental and medical services to defraud Aetna by misrepresenting, concealing or otherwise mischaracterizing the services rendered to patients for the purpose of obtaining payment for non-covered services. In connection with these illegal efforts, Cavitat and Jones have also misrepresented and exaggerated the capabilities of the Cavitat device, thereby assisting providers in their efforts to market questionable, often dangerous and potentially disfiguring, non-covered dental and medical services to Aetna's insureds. These wrongful activities have been undertaken with the financial assistance of certain providers and other third parties. In conspiracy with these agents and associates, Cavitat and Jones have wrongfully interfered with and induced others to interfere with Aetna's existing contracts. Some of the conspirators have a direct and substantial financial interest in claims asserted by Cavitat and Jones in the First Amended Complaint, including the racketeering claims and other claims which were asserted in bad faith and without substantial justification in conjunction with the aforesaid efforts to wrongfully obtain payment for non-covered dental and medical services. Others conspirators named, and others yet unknown, share a common interest and economic motivation to perpetuate an ongoing scheme to obtain direct and indirect reimbursement from Aetna for themselves and others by disquising improper billings or through other means. These persons also perpetuate an ongoing scheme to induce, counsel or assist others to bill or seek reimbursement for services they know or should have known that Aetna does not recognize or consider eligible for coverage or reimbursement.

JURISDICTION AND PARTIES

2. This Court has jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1332 or 1367. The action is between citizens of different states and the matter in controversy exceeds the value of \$75,000, exclusive of interest and costs.

3. Aetna is a Pennsylvania corporation with a principal place of business at 980 Jolly Road, Blue Bell, Pennsylvania 19422.

4. Cavitat is a corporation incorporated in Colorado and was at one time based in Colorado, but is now based in Texas, at 150 CR 1558, Suite C, Alba, Texas 7541 0.

5. Counterclaim-Defendant Jones is an individual resident of Texas, whose business address is 150 CR 1558, Suite C, Alba, Texas 75410. At all times material hereto, Jones personally directed the activities of Cavitat complained of herein. All of Jones' individual claims have already been dismissed although he remains a party and an officer of Cavitat. Jones can be served with service of process at 150 CR 1558, Suite C, Alba, Texas 74510.

BACKGROUND FACTS

6. Neuralgia-inducing cavitational osteonecrosis ("NICO") or NICO-like conditions which the Cavitat device purports to detect have been theoretically described over the years by a profusion of names including Roberts bone cavities, Ratner bone cavities, alveolar cavitational osteopathosis, maxillofacial osteonecrosis and cavitations. Proponents of NICO and the use of the Cavitat device speculate that NICO may be present and totally without symptoms and, at other times, NICO has been alleged to be the cause of chronic, sometimes intense, pain in the upper and lower jaw or face causing necrosis of alveolar bone and, ultimately, the formation of supposedly characteristic alveolar bone cavities. However, the proposed cause-andeffect relationship between NICO cavitations and facial pain has not been established by evidence-based scientific criteria. Even NICO's advocates agree that the scientific and diagnostic status of NICO has not been definitively established nor has its alleged cause been determined. The mainstream scientific medical and dental communities do not recognize the clinical significance of a NICO diagnosis utilizing the Cavitat device. The clinical effectiveness of the Cavitat device has not been conclusively or sufficiently demonstrated in the evidence-based medical community or supported with appropriately-controlled studies, including follow-up studies, published in peer-reviewed medical journals.

7. Among NICO's most vocal advocates are a minority of dentists and dental surgeons sometimes called biological dentists who believe, among other things, that systemic diseases spread from focal infection points in the mouth such as periodontal infections, viable teeth with amalgam fillings, NICO lesions and "dead" or root-canal treated teeth. Advocates of the focal point theory (or theory of focal sepsis) have from time to time linked purportedly septic foci to cancer, MLS syndrome, arthritis, diseases of the kidney, heart, nervous, gastrointestinal, endocrine and other systems, atherosclerosis, coronary thrombosis, ischemic heart disease and other disease processes. Like NICO itself, these theories are controversial at best and have not been accepted by the mainstream science or evidence-based dental and medical communities. Indeed, troubling is the fact that many NICO patients may be easy prey for unscrupulous dentists and oral surgeons who use NICO as a springboard for promoting other unconventional theories, products, services, and related therapies,

some of which are equally controversial, untested, unproven, and even unethical and harmful.

8. Aetna is a managed care company that provides various claims administrative services to benefit plans that are regulated by federal law although various state laws also affect or regulate certain aspects of plan administration. These benefit plans are established or maintained by employers for the purpose of providing health care coverage and other benefits to employees. Indeed, the vast majority of Americans with health care coverage receive their health benefits from such benefit plans. These benefit plans can be funded through the purchase of insurance or otherwise. Other benefit plans are self-funded such that the employer and employee directly or indirectly fund the available benefits. In all instances, the plan has a process for employees to submit claims for benefits pursuant to the terms of the various benefit plans. Aetna provides various claims administrative services to thousands of plans in the country and has millions of Aetna members nationwide who receive their health care coverage from Aetna or its affiliates.

9. Aetna typically serves as the claims administrator for the health benefit plans. In connection with this role, Aetna usually has fiduciary duties to the benefit plans, including determining which claims submitted by members are eligible for reimbursement or payment under the terms of the health benefit plan. In connection with this role, Aetna must follow federal and state statutes and regulations addressing plan administration which require it to provide a written basis for its benefit and coverage decisions in connection with claims for benefits submitted by its members or their health care providers.

10. While not all benefit plans are identical, typically the terms of the benefit plans to which Aetna provides administrative services contain an experimental or investigational exclusion. This exclusion typically defines a drug, device, procedure or treatment as investigational or experimental if there are insufficient outcomes data available from controlled scientific trials published in peer-reviewed literature to substantiate its safety or effectiveness for the disease or injury involved, or where a recognized national medical or dental society or regulatory agency has determined that it is investigational or experimental.

11. Existing and prospective health care providers and Aetna members have an interest in knowing in advance of contemplated surgery whether a procedure or device is or is not a covered benefit under the terms of the relevant insurance plan. One way in which Aetna provides the basis for its claims determinations to members and their health care providers is the development and publishing of Clinical Policy Bulletins ("CPBs"). Aetna has hundreds of CPBs. Generally, CPBs provide information to Aetna's members, prospective members and their respective health care providers and others regarding various medical conditions and treatments. Additionally, the CPBs provide Aetna's coverage position and the basis for its coverage position. In this fashion, Aetna members and health care providers are supplied information (often in advance of a contemplated surgery or treatment) as to whether a procedure or device is covered or not under the terms of their employee benefit plan. This is one way in which Aetna fulfills its duties to the employee benefit plans to which it provides services.

12. CPB 642 advises members and their health care providers that Aetna considers treatment by the Cavitat device to detect NICO in jawbones to be experimental and

investigational because there is no adequate scientific evidence to support its clinical value. Additionally, CPB 642 advises members and their health care providers that surgery for NICO, including the scraping of "infected cavities" and removal of vital or root-canal treated teeth, is considered experimental and investigational because the clinical significance of NICO is in question. The basis for Aetna's coverage determination regarding the Cavitat device and NICO surgery being investigational and experimental is contained in CPB 642, which is reviewed periodically, and updated in the event that additional information regarding the subject matter is obtained, provided or discovered.

13. As a matter of law and public policy, the value of CPBs and other statements regarding coverage such as Explanations of Benefits ("EOBs") are of such a value to members, providers and the public that they are privileged from claims of disparagement. Aetna is privileged to publish CPBs for the protection of the interests of third persons and the public, in addition to its own interests. Aetna is also privileged to share coverage information with others having a common interest in the subject matter of the CPBs.

14. There is no doubt that a review of CPB 642 provides Aetna's members and their health care providers notice that NICO-related treatment is not covered under health plans to which Aetna provides claims administrative services. Nonetheless, aided and abetted by Cavitat and Jones, certain providers have utilized various means to defraud Aetna by misrepresenting, concealing or otherwise mischaracterizing the services rendered to patients for the purpose of obtaining payment for non-covered services.

ORIGIN OF CAVITAT'S AND JONES' SCHEME TO DEFRAUD

15. Cavitat is a business which has been unsuccessfully attempting for years to establish a market in mainstream dentistry for the Cavitat device.

16. Jones is believed to be an individual with an undergraduate degree in civil engineering, but having no medical background, no training in medicine, dentistry or any medical-related field and no license to practice any form of medicine. Jones nevertheless claims lie can diagnose that ordinary root canals and fillings in the teeth create a pathway for toxins and infections to enter the body and that this medical condition is evidenced by holes, cavitations or lesions in the jaw bone.

17. Jones also claims that through his own research, he discovered that healthy genes in the human body are adversely affected by such toxins and thereby mutated, causing a host of medical problems throughout the body, not just in the jaw or mouth. Although he lacks any recognized form of medical, dental or scientific training or licensures, Jones claims to have discovered that the presence of such cavitations is a precursor to cancer, multiple sclerosis, heart attacks, stroke, Alzheimer's, autism and other diseases.

18. Jones and other supporters of the Cavitat device claim that through the use of sound waves, the Cavitat device is capable of precisely detecting these purportedly diseased cavitations or lesions in the jaw that are alleged to be the by-product, inter alia, of root canal therapy and amalgam filings. The alleged condition purportedly reflected by the presence of these cavitations or lesions is often generally referred to by these individuals as NICO.

19. Jones, the owner of Cavitat, admits that mainstream evidence-based science and organizations such as the American Dental Association ("ADA") have not endorsed the efficacy of the Cavitat device to detect NICO or otherwise. In this respect, Jones has claimed that the ADA is engaging in a cover-up and an intentional campaign to misinform the public. The lawsuit against Aetna is another collateral attempt by Cavitat, Jones and other associated persons to strike at mainstream evidence-based medicine that views NICO and the Cavitat device as unproven.

20. A fringe but very vocal element of so-called biological dentists and holistic medical practitioners adhere to the same claims as Jones. They promote the existence of NICO even though they readily acknowledge that NICO is not a condition that is recognized by evidence-based, mainstream medicine or dentistry.

21. Jones or his son, Robert Y. Jones (who is also bereft of medical training or licensure), purportedly train dentists or health care providers on how to use the Cavitat device to produce computer-generated, color-coded images. They also tell dentists how to diagnose pathologies and interpret such images to diagnose the presence of NICO. Neither Jones nor his son is believed to have any formal or informal training in the use of modern diagnostic medical devices, nuclear medicine, diagnostic radiology or the computer-based diagnosis of any illness.

22. The proponents of the Cavitat device not only contend that it can detect NICO, but they also advocate very aggressive and inconsistent forms of treatments including colonic therapy when this alleged malady is detected. If such a cavitation or lesion is claimed to be found near teeth, many of these proponents of the Cavitat device advise patients that complete removal of these often vital teeth is necessary, even if the teeth are asymptomatic. Furthermore, they recommend that the gum tissue at the site be surgically opened and that the patient's jaw bone be exposed and the bone scraped and portions removed to eliminate the alleged lesion. Sometimes, bone or other reconstructive material needs to be grafted onto the surgical site to repair the damage from the NICO surgery and promote healing, and dental implants or prostheses (at additional cost to the patients) are used to replace the teeth removed.

23. Furthermore, many of these practitioners also prescribe vitamins, supplements and other treatments (such as injectable minerals), homeopathic remedies and drugs, and other treatments of dubious origin and effectiveness leading to the harm or potential harm to their patients as well as the billing of these patients of thousands and thousands of dollars.

24. Cavitat, Jones and others who claim the existence of NICO promote the sale and use of the Cavitat device by organizing their own seminars to convince dentists and other providers what NICO is, how to use the Cavitat device, how to convince patients of the need for surgery and also how to perform the recommended surgery, related procedures and related services. For example, a proponent of the Cavitat device, Dr. Wesley Shankland, II ("Dr. Shankland"), whose practice is based in Ohio, provides instructional lectures at Cavitat-sponsored seminars on how to perform such surgery. Dr. Shankland has provided such instruction to dentists in other states and in other countries. Dr. Shankland also conducts his own profit-making seminars with providers steered to him by Cavitat and Jones.

25. On information and belief, some practitioners attending Cavitat-sponsored seminars have little or no experience with advanced or high risk oral surgery, but are provided with materials recommending what surgical tools to use, how to make incisions, what to do in case of complications during surgery (such as in the event of arterial lacerations and nerve damage, or perforation of a sinus cavity) and recommendations on post-operative procedures.

26. The individuals who provide presentations at these Cavitat-sponsored lectures, such as Dr. Shankland, Dr. Jerry Bouquot ("Dr. Bouquot") and Dr. Boyd Haley ("Dr. Haley"), have their business expenses paid by Cavitat. At least in Dr. Shankland's case, Cavitat has also provided him with free upgrades to his Cavitat device in exchange for his services at these lectures. Cavitat and Dr. Shankland promote the Cavitat device as a centerpiece of a highly profitable practice and have boasted that a provider's income can be substantially increased by using the Cavitat device.

27. These promotional lectures, organized and sponsored by Cavitat, sometimes featured a presentation made by Jones in which he describes how he discovered genes that are mutated by "toxins" introduced via root canal therapy that, in turn, purportedly create systemic health problems in an individual. During such presentations, Jones has claimed that his research was funded with money from Dr. William Glaros ("Dr. Glaros"), one of the earliest and most prolific users of the Cavitat device. Through efforts such as these promotional lectures, and through contacts established via the Internet and by other means, Cavitat has continued to funnel business to favored individuals such as Dr. Bouquot, Dr. Shankland, Dr. Michael Margolis ("Dr. Margolis"), Dr. Haley and others, who in turn committed themselves to try to promote the Cavitat device and develop and publish research to support Cavitat's claims.

28. Central also to Cavitat and the conspirators' schemes is their interlinking of various worldwide Internet sites which promote their services for the diagnosis, care and treatment of NICO and the use of the Cavitat device.

29. One of those sites is called Dentalhelp.org. Although intentionally disguised as a non-associated entity, it is in fact owned and operated by Cavitat and Robert Jones. The site not only purports to serve as a worldwide listing of holistic and biological dentists and physicians, but also provides advertising and referrals to Cavitat device owners and other members of the conspiracy and publishes the array of suggested procedural codes which Cavitat, Jones and the other conspirators use as part of the ongoing scheme.

30. Cavitat also promotes the sale and use of the Cavitat device by publicizing how its use can greatly increase a practitioner's revenue by increasing the number of diagnostic, laboratory and related surgical procedures performed. Cavitat makes recommendations as to the amounts that its customers or providers should bill for use of its device, related surgeries and pathologies services and states that a dentist can earn 100x their initial investment in the first year alone by using the Cavitat device.

31. Also at these seminars, Cavitat teaches attendees how to thwart potential and ongoing investigations and disciplinary actions by state dental boards and governmental investigators.

32. Cavitat also provides its customers and attendees with a laundry list of American Medical Association ("AMA") Current Procedure Terminology ("CPT") codes and ADA codes and teaches attendees how to use the codes when billing insurance companies for the diagnosis and treatment of NICO or NICO-related conditions. Many of these codes, when submitted to an insurance company or claims administrator, are designed to conceal or misrepresent the fact that the treatment rendered was Cavitat device- or NICO-related. In this way, reimbursement is often obtained.

33. Nowhere in the AMA or ADA CPT Codes is there a descriptive term or procedure for the treatment of NICO.

34. The World Health Organization has not recognized NICO as a pathologic condition in its publication, International Classification of Diseases, Ninth Revision ("ICD-9"), which serves as the generally-accepted standard for describing recognized diseases and illnesses. Some providers who bill for the treatment of NICO disguise the diagnosis by submitting claims with codes that are recognized with the ICD-9.

35. Cavitat claims that it began producing and selling its devices in the 1990s. It claims to have used a prototype at New Mexico Institute of Mining and Technology in 1995 and 1996. A different version of the device was used at the Air Force Academy in 1997. Yet another version of the device was tested nationwide in 1998. Cavitat began "beta testing" the Cavitat device at six separate sites in 1999. On information and belief, various versions of the Cavitat devices were marketed and sold prior to FDA clearance and before any application was made by Cavitat to the FDA to clear the device for marketing.

36. When Cavitat began marketing its device, however, it misrepresented to potential customers that it had received approval from the FDA to sell the device for its promoted uses.

37. Cavitat also represented to potential customers that an Investigational Review Board ("IRB") had been established in conjunction with West Virginia University to monitor clinical trials involving the Cavitat device. This was represented to have been arranged through an oral pathologist that once worked at the West Virginia University School of Dentistry, Dr. Bouquot. An IRB must be established pursuant to federal regulations when a device such as the Cavitat is undergoing clinical trials on human subjects or when human tissue is being collected from patients in connection with the medical services being rendered. Oversight by an IRB helps ensure that the clinical trial is being conducted in a proper scientific and safe manner, that only qualified individuals are participating in the clinical trial, that patients are fully informed as to the experimental nature of the procedures involved, and that tissue samples collected from them are being used for research purposes. Despite requests, Cavitat has failed to provide evidence that the requirements and protocol required of all IRBs were met in this instance.

38. During this time, users of the Cavitat device were encouraged to perform surgical procedures, to collect human tissue samples from patients allegedly suffering from NICO, and to send all after-the-fact biopsy samples of human bone and tissue to certain pre-selected laboratories for analysis. 39. Primarily, Cavitat directed these biopsy samples to be sent for analysis to a for-profit laboratory owned by Dr. Bouquot in West Virginia known as Head & Neck Diagnostics of America. Almost without fail, Dr. Bouquet's pathology reports confirm the questionable clinical

diagnosis of the practitioner. Practitioners then use the pathology report as an afterthe-fact justification for the already completed surgery and the bills submitted for payment in connection with the treatment.

40. Dr. Bouquot coined the terms NICO and maxillofacial osteonecrosis. He is sympathetic to the efforts of Cavitat to gain mainstream acceptance for treating these purported conditions by invasive surgical intervention. He also has a monetary interest in Cavitat's success in that endeavor. The biopsy business directed to him by Cavitat helped his laboratory to become one of the largest of its kind in the nation and Dr. Bouquot profited significantly from his association with Cavitat in this regard.

41. Also associated in this scheme is Dr. Haley and his laboratory, Alt Inc., which promotes and interlinks, as described above, its oral toxicity testing products and services with promotion of the Cavitat device. Dr. Haley, like Dr. Bouquot, uses these promotions and interlinks to profit from, justify, defend or otherwise obscure the true nature of the procedures and alleged conditions being treated by owners of the Cavitat device. Dr. Haley uniformly diagnoses or confirms the existence of toxins or other pathologies to support his care, diagnosis and treatment of this unrecognized condition.

42. Cavitat customers knew or should have known that claims for NICO and NICOrelated services submitted to Aetna were considered investigational and experimental and, therefore, not covered or eligible for reimbursement. Nevertheless, Cavitat and others affiliated with Cavitat coached its customers on how to use general codes when submitting claims which would hide the true nature of the services at issue.

43. Also, Cavitat encouraged its owners to use incentives such as bonuses and sales commissions for their office staff to sell patients on the purported value of the Cavitat services.

44. Another tactic used by Cavitat to popularize the use of its device was to offer financial incentives in the form of sales commissions to healthcare providers themselves, and others, for effecting a sale of a machine. Cavitat frequently offered a commission on such sales. Cavitat had such an arrangement, for example, with Dr. John Tate in South Carolina.

CAVITAT'S PATTERN OF THREATS - FIRST THE FDA

45. To try to further its efforts to be accepted by mainstream dentistry, Cavitat tried to use the results of the skewed "research" it generated in an unsuccessful effort to have the Food and Drug Administration ("FDA") agree that the Cavitat device could be marketed as a device that was capable of detecting NICO.

46. To raise capital for this effort, Cavitat also retained investment banking firms and business sale consultants. Cavitat's investment banking firms concluded that NICO was a controversial condition, that its acceptance was clouded by the current practitioners, and that any wider support for Cavitat or the existence of NICO would take many years, if ever, to develop. Additionally, the investment banking firms and consultants concluded that Cavitat's patents were suspect and limited to diagnosing NICO, and other purported applications of the Cavitat device technology were specifically limited by the patents of others. In other words, the Cavitat device was

limited to searching for a purported condition the clinical significance of which has not been accepted by the mainstream, evidence-based medical and dental communities. As evidence of its malicious intent toward Aetna, Cavitat did not disclose this information to the public, but instead continued its attacks on mainstream medicine, including this suit against Aetna.

47. To assist this effort, Cavitat also mobilized the few medical professionals economically allied with it who supported the use of the Cavitat device and who claim to believe in the existence of NICO (and who had profited greatly over time from that perspective). These persons included Dr. Bouquot, as well as Dr. Shankland and Dr. Margolis. Additionally, they were designated as members of Cavitat's Scientific Board of Advisors and used to make presentations and to offer testimonials to potential investors concerning the effectiveness of the Cavitat device, as well as to compile research for presentation to the FDA. The members of Cavitat's Scientific Board of Advisors presented the results of their alleged research to the FDA and argued in Cavitat's favor for approval of its application. When the FDA began to question the validity of the research submitted, and whether the Cavitat device could really detect diseased bone, Cavitat made specious threats of litigation against the FDA.

48. Despite the research and documentation submitted by Cavitat in connection with its application, the FDA expressly rejected Cavitat's request to label and market its device as capable of diagnosing NICO or of distinguishing between normal and diseased bone. In disapproving Cavitat's proposed labeling for the device, the FDA included a specific statement to the effect that the device had not been proven capable of distinguishing diseased bone from normal bone: "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." Moreover, the FDA also rejected Cavitat's attempt to have the Cavitat device marketed as a stand-alone diagnostic tool, but instead noted that the device was only effective as an adjunct to standard radiographic evaluation (x-rays) and clinical diagnostic procedures.

49. The FDA's decision not to approve Cavitat's intended marketing strategy was a blow to both Cavitat's effort to attract investment dollars and its scheme to promote acceptance of the Cavitat device among mainstream practitioners. Cavitat misinformed its investors that the FDA's decision was improperly engineered by FDA personnel with political agendas. Cavitat also stated that the FDA's decision had forced Cavitat to focus its marketing efforts to foreign countries, falsely stating that it had enforceable contracts to sell the Cavitat device in Spain, Portugal, Italy, India, New Zealand and Australia.

CAVITAT'S PATTERN OF THREATS - NEXT THE ADA

50. Despite its failed efforts with the FDA, Cavitat continued to misrepresent to potential customers that the Cavitat device was capable of detecting specific pathology and NICO contrary to the limited clearance of the FDA. Cavitat and its associates, including members of the Cavitat Scientific Advisory Committee, frequently misrepresented that the device was unrestricted and FDA-approved. Cavitat and persons affiliated with Cavitat presented these statements in their marketing efforts in such a manner as to falsely state and suggest that the FDA had

approved the device as capable of detecting disease conditions and diseased bone, when in fact the FDA had concluded just the opposite.

51. Despite Cavitat's unsuccessful experience with the FDA, it continued its efforts to obtain the acceptance of evidenced-based mainstream dentistry, and did so by applying to the ADA for that organization's "seal of approval." Once again, Cavitat attempted to use the economic self-promotional and flawed research it had helped individuals such as Dr. Bouquot and Dr. Shankland compile. Cavitat even had Dr. Bouquot contact the ADA directly to vouch for the effectiveness of the device.

52. The ADA, however, also questioned NICO as a recognized scientific malady, and questioned the documentation compiled by Drs. Bouquot, Shankland, et al. which supposedly supported the clinical effectiveness of the Cavitat device in detecting NICO. The ADA, after a scientific and thorough analysis of the device and the claims of Cavitat, Jones and its proponents, refused to give its seal of approval to the Cavitat device. Just as it had done with the FDA, Cavitat then directed specious threats of litigation against the ADA for its refusal to approve the device. Cavitat informed its investors that the ADA's refusal to provide the seal of approval for the Cavitat device had destroyed Cavitat's business, and that Cavitat was considering suing the ADA for that reason. Cavitat told its investors that as a result of the ADA's actions, it would have to close its offices in Colorado, move its operations to Texas, and terminate almost all of its remaining employees.

CAVITAT'S PATTERN OF THREATS - NOW AETNA

53. In September of 2004, Cavitat informed its investors that the ADA had refused to provide its seal of approval for the Cavitat device for improper reasons, and alleged that the ADA and its members had conspired to create an illegal boycott against Cavitat. Cavitat falsely informed its investors that it had filed suit against this illegal boycott, and that it had also sued individual state dental boards for participating in the illegal boycott. Cavitat's internal documents, now discovered in this case, provided no mention that Aetna was in any way responsible for its problems.

54. To fund this baseless litigation, Cavitat solicited funds from third parties who had invested in the company, some of whom had a monetary stake in its survival, as well as others whose livelihoods derived from the use of the Cavitat device, and created the Cavitat Legal Fund. In exchange for money to fund the litigation, Cavitat promised each of these individuals a share of the anticipated recovery in this case, effectively selling stakes in the litigation, to individuals who had no standing to maintain it.

55. The individuals who contributed money to this improper and frivolous litigation effort included Darrel and Patricia Hershey of Parker, Colorado, Dr. Margolis of Mesa, Arizona, Dr. Glaros of Houston, Texas, Dr. William Medlock of West Palm Beach, Florida and Drs. John Tate and Robert Jones of Spartanburg, South Carolina.

56. In exchange for unspecified "information," Cavitat also promised a percentage of the anticipated recovery to <u>Timothy Bolen</u> ("Bolen"), who portrays himself on the Internet as a 'Crisis Management Consultant." Bolen, acting with his wife, Jan, and their company "JuriMed," have been attempting to promote the business of Cavitat for some time. As Cavitat's agent, Bolen, his wife, and company have engaged in a venal and systematic campaign to attack Aetna and persons whom Cavitat alleges

are associated with Aetna, all for the purpose of his making money for himself and the others he has acted in concert with in advancing the baseless claims asserted against Aetna in this lawsuit. Bolen has a history of advocating for the sale of holistic and alternative medical products and concepts and of attacking evidence-based mainstream medicine. He has been "hired," "retained" or "consulted" in the past by attorneys and for individuals accused of medical fraud, malpractice and quackery. He also has provided crisis management services for medical practitioners accused of unethical conduct. Indeed, Cavitat and Jones rewarded Bolen for his actions in connection with "public relations" provided to Cavitat and for his "consulting contributions to the partnership" between Cavitat, Jones, Bolen and others. It is clear that these services were intended by Jones and Cavitat to include the ongoing and orchestrated personal attacks and intimidation of witnesses in this action as well as continuing to abuse the Courts and Aetna for their mutual economic profit and ambitions.

57. Even a cursory effort at ascertaining the past activities of Bolen would have revealed to Cavitat and its representatives the disreputable tactics engaged in by Bolen on behalf of his "clients." Bolen has been in frequent and collusive contact with Jones, his attorneys and others for the improper purpose of advancing the meritless claims against Aetna. This has included public meetings in Dallas, Texas in March 2005 where Jones, his agents and Bolen falsely stated that Aetna was involved in a "conspiracy" to harm Cavitat and biological or homeopathic dentists.

58. Additionally, Cavitat, Jones, Bolen and others have engaged in a campaign to intimidate and obstruct testimony of witnesses under subpoena in this case by various means including the posting of false representations on the Internet and physical stalking of witnesses in this case. Aetna incorporates by reference its Response to Plaintiffs' Motion for Protective Order or To Quash Subpoenas filed in this case and attached as Exhibit 1 to this Counterclaim.

59. Cavitat and Jones, while admitting that they were in contact with Bolen, attempted to hide from Aetna and the Court the fact that Bolen was a participant in the Cavitat Legal Fund and had a known and demonstrable economic self-interest in improperly influencing this litigation until the Court ordered production of documents reflecting this fact. Although Cavitat and its agents also concealed Bolen's ongoing role as agent provocateur, which discovery has now revealed to be covertly described as "public relations services." In open Court, Cavitat and Jones described Bolen as a "loose cannon" and described his accusations as often false and wrong, and yet failed to admit that Bolen was agent-in-fact for the Cavitat Legal Fund, Cavitat and Jones. Such conduct is direct evidence of the fact that Cavitat and Jones lacked substantial justification to bring suit against Aetna.

COUNT I: FRAUDULENT MISREPRESENTATION

60. Aetna hereby incorporates the allegations of paragraphs 1 through 59 as if fully set forth herein at length.

61. Cavitat and Jones, in the course of their business dealings and transactions, knowingly and intentionally made false statements of material fact concerning the capabilities of the Cavitat device, and the FDA's approval of the Cavitat device, in the course of marketing and promoting the device.

62. Cavitat and Jones also made and continue to make intentionally false representations to dentists regarding the proper manner and form in which dentists could lawfully submit bills to Aetna to obtain payment for services involving the Cavitat, and NICO-related surgeries. Cavitat and Jones made such false representations to these third parties with the intent of having these third parties rely thereon, and knowing that by doing so, providers would submit bills for payment to Aetna in such a manner as to disguise the fact that the bill was a request for payment for services which were experimental and otherwise a non-covered benefit. 63. As a direct and proximate result, Aetna suffered damages, both general and special, as alleged hereafter.

COUNT II: NEGLIGENT MISREPRESENTATION

64. Aetna hereby incorporates the allegations of paragraphs 1 through 64 as if fully set forth herein at length.

65, Even if the misrepresentations made by Cavitat and Jones were not intentionally false, such misrepresentations were still false and material, and Cavitat and Jones supplied that false information in the course of its business dealings and transactions.

66. Cavitat and Jones failed to exercise reasonable care in making these false statements.

67. The providers to whom these false statements were communicated reasonably relied upon them, and Cavitat and Jones knew or should have known that as a consequence, bills would be submitted to Aetna for payment by these providers, in a form and manner which obscured the fact that the services reflected in the bills were actually experimental in nature, and not otherwise considered by Aetna to be covered services.

68. As a direct and proximate result, Aetna suffered damages, both general and special, as alleged hereafter.

COUNT III: CONSPIRACY

69. Aetna hereby incorporates the allegations of paragraphs 1 through 69 as if fully set forth herein at length.

70. Cavitat and Jones, along with other persons such as Sarah Jones, Robert Y. Jones, Dr. Bouquot, Dr. Shankland, Dr. Margolis, Dr. Haley, Bolen and others, had a meeting of the minds to work together jointly to profit, legitimize or otherwise disguise the use of the Cavitat device; gain the approval of mainstream dentistry for the use of the Cavitat device in the diagnosis and treatment of NICO; and, have the condition known as NICO accepted by mainstream medicine and dentistry.

71. Cavitat, Jones and those with whom they had a meeting of the minds, conspired to accomplish their objectives through unlawful acts, including by committing, or causing to be committed, the unlawful acts described herein, including: insurance fraud; illegal and unauthorized research activities; the unauthorized practice of medicine and dentistry; misrepresenting that the Cavitat device was exempt from

FDA regulations; misrepresenting that the Cavitat device was approved by the FDA and, specifically, approved by the FDA for detecting diseased bone; obstruction of justice; witness tampering; and barratry.

72. As a direct and proximate result, Aetna suffered damages, both general and special, as alleged hereafter.

COUNT IV: ATTORNEYS' FEES UNDER COLORADO LAW

73. Aetna hereby incorporates the allegations of paragraphs 1 through 73 as if fully set forth herein at length.

74. The claims against Aetna lacked substantial justification, were interposed for delay and harassment, or have unnecessarily expanded this proceeding by improper conduct.

75. Additionally, all of Jones' claims against Aetna, and all the racketeering claims and other of Cavitat's claims against Aetna, have now been dismissed.

76. Aetna is, therefore, entitled to its reasonable attorneys' fees under COL. REV. STAT. ANN. §§ 13-17-103 & 201 (West 2005).

DAMAGES

77. Aetna hereby incorporates the allegations of paragraphs 1 through 77 as if set out in full.

78. As a direct and proximate result of that conduct, Aetna has suffered both general and special damages within the jurisdictional limits of this Court. Without limitation, Aetna is entitled to recover and seeks recovery for: claims improperly submitted and paid as a result of that conduct; other expenses incurred as a result of that conduct, including but not limited to costs of court, and litigation expenses; and attorneys' fees and pre- and post-judgment interest in the maximum amount allowed by law.

EXEMPLARY DAMAGES

79. Aetna hereby incorporates the allegations of paragraphs 1 through 79 as if set out in full.

80. The conduct of Jones and Cavitat as well as Bolen and their other agents was intentional, willful, wanton, malicious, reckless, grossly negligent and deserving of punishment.

81. Aetna is therefore entitled to exemplary or punitive damages in the maximum amount allowed by law to punish Jones and Cavitat and to deter other similarly-situated persons from engaging in like conduct.

PRAYER

WHEREFORE, Aetna respectfully prays that Cavitat take nothing by its claims, that Aetna be granted judgment against Jones and Cavitat, and for such other and further relief to which Aetna shall show itself entitled.

DATED this the 24th day of June, 2005.

Respectfully submitted.

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ATTORNEYS FOR DEFENDANT AND COUNTERCLAIM-PLAINTIFF AETNA INC.

CERTIFICATION OF SERVICE

I hereby certify that on June 24, 2005, I electronically filed the foregoing with the Clerk of Court using the CMIECF system which will send notification of such filing to the following e-mail addresses:

areid@waltergerash.com

John B. Shely Attorney for Defendant Andrews Kurth LLP 600 Travis, Suite 4200 Houston, Texas 77002 (713) 220-4105 This article was posted on June 30, 2005.