

LEGAL STATUS OF CHELATION THERAPY

From American College for Advancement in Medicine Paper on EDTA Chelation Therapy

PRELIMINARY STATEMENT

This Position Paper addresses and elaborates on questions pertaining to physician administration of EDTA chelation therapy in accordance with ACAM's protocol. Chelation therapy has been safely and effectively utilized by physicians throughout the nation and over a million patients have received demonstrable benefit from it.

I. INTRODUCTION

The American College for Advancement in Medicine ("ACAM") was founded in 1973 as a non-profit corporation and is presently comprised of approximately 750 licensed physicians, many of whom are engaged in the treatment of, or research in, occlusive vascular disease and its related fields. Member physicians study and use innovative and advanced cardiovascular therapies that involve, inter alia, the early detection and identification of risk factors in patients and intensive education in modifying the individual patient's lifestyle to alter such risk factors. Among the purposes of ACAM are to advance support for and to further research in the application of EDTA chelation therapy and other sound innovative therapies for occlusive vascular disease and degenerative diseases associated with aging. As a professional organization, ACAM presents biannual educational seminars to its membership.

It is ACAM's position, as more fully explained in the discussion that ensues, that chelation therapy is a valid and proper course of treatment, based upon scientific rationale, supported by many [published clinical studies](#), and consistent with sound medical practice. Restricting its use by qualified physicians would amount to a wholly unneeded restraint upon the practice of medicine that would adversely affect the standard of medical care available to patients. Such restriction would be contrary to law and a disservice to the public.

II. THERAPEUTIC HISTORY OF CHELATION THERAPY

Ethylenediaminetetraacetic acid ("EDTA") is a man-made amino acid first used in the 1940's for treatment of heavy metal poisoning. EDTA chelation therapy is widely recognized as effective for that use as well as certain others, including emergency treatment of hypercalcemia and the control of ventricular arrhythmias associated with digitalis toxicity. Studies by the National Academy of Sciences/National Research Council in the late 1960's indicated that EDTA chelation therapy was considered possibly effective in the treatment of occlusive vascular disorders caused by arteriosclerosis.

Clinical experience with EDTA chelation therapy has convinced substantial numbers of licensed physicians in North America that it is a safe and effective treatment for atherosclerotic vascular disease, as it consistently improves blood flow and relieves symptoms associated with the disease in greater than 80% of the patients treated. As members of the medical profession are generally aware, the pathogenesis of atherosclerotic disease is extraordinarily complex. The scientific principles underlying the efficacy of EDTA chelation therapy in impeding each step of the disease process are beyond the scope of this position paper, but they are elaborated upon in the [many published clinical studies](#) and research papers available.

In its simplest terms, the rationale for its efficacy is that EDTA chelation therapy, in binding ionic metal catalysts and removing them from the body, reduces subsequent abnormal production of oxygen free radical reactive molecules and molecular fragments which react destructively with other molecules. See, [E. M. Cranton](#), J. P. Frackelton, Free Radical Pathology in Age-Associated Diseases: Treatment with EDTA Chelation, [Nutrition](#), and Antioxidants, Journal of Advancement in Medicine, Vol. 2, Nos. 1, 2, Spring/Summer, 1989. (1)

There is now widespread agreement that EDTA chelation therapy removes metallic catalysts which cause excessive oxygen free radical proliferation, thereby reducing pathological lipid peroxidation of cell membranes, DNA, enzyme systems and lipoproteins and allowing the body's natural healing mechanisms to halt and often reverse the disease process.

Steinberg, et al., state in the April 6, 1989, *New England Journal of Medicine*, 1989; 320(14):915-924, concerning Modifications of Low-density Lipoprotein That Increase Its Atherogenicity through free radical peroxidation, "oxidative modification is absolutely dependent on low concentrations of copper or iron in the medium and is therefore completely inhibited by ethylenediaminetetraacetic acid (EDTA)." (2)

Chelation therapy is considered by the licensed physicians who utilize it to be an effective first step [alternative](#) to surgical treatment for atherosclerotic vascular disease in most cases. In the instances where a licensed physician believes that bypass surgery or the interventional cardiac catheterization techniques of thrombolysis and balloon angioplasty are more appropriate, he or she will refer those patients out. These alternatives to chelation therapy though are not without their respective detractors and attendant risks.

In September 1978 the Office of Technology Assessment ("OTA"), a branch of the United States Congress, aided by an advisory board composed of leading medical and university school faculty, published a report entitled "Assessing the Efficacy and Safety of Medical Technologies". One portion of that report discussed the efficacy and safety of surgery for coronary artery disease, concluding as follows:

Coronary artery bypass surgery is based on a scientific rationale and may be of measurable benefit to some patients. It is usually performed for angina pectoris and appears to give substantial relief from symptoms, but the extent to which this relief is an effect of surgery is not known. Limited studies suggest that coronary bypass surgery improves life expectancy significantly for only a small number of patients, with a particular type of coronary artery disease. Controlled studies have shown no improvement in life expectancy for patients studied. *Id.* at page 44. (3)

The importance of this analysis is its recognition, though over 70,000 operations were performed in 1977, that the benefits of such surgery have yet to be demonstrated. (4)

A more recent article in the *New England Journal of Medicine* (March 22, 1984) reported upon myocardial infarction and mortality in the coronary artery surgery study (CASS) randomized trial, and summarized as follows in the Abstract:

ABSTRACT: There were no statistically significant differences in the survival rate or in the myocardial infarction rate between subgroups of patients randomly assigned to medical and to surgical therapy when they were analyzed according to initial group assignment, number of diseased vessels, or ejection fraction. Therefore, as compared with medical therapy, coronary bypass surgery appears neither to prolong life nor to prevent myocardial infarction in patients who have mild angina or who are asymptomatic after infarction in the five-year period after coronary angiography. (5)

The necessity of heart surgery and the scheduling of such surgery has undergone substantial criticism of late by many in the medical community. Despite this criticism, in 1981 an estimated 110,000 patients underwent bypass surgery. By 1983 the annual number of operations had increased to 191,000, and by 1989 the number had soared to over 368,000. (6)

As stated by Dr. Thomas A. Preston, professor of cardiology at the University of Washington School of Medicine and chief of cardiology at Pacific Medical Center:

[Coronary-bypass surgery] is heralded by the popular press, aggrandized by our profession, and actively sought by the consuming public. It is the epitome of modern medical technology. Yet, as it is now practiced, its net effect on the nation's health is probably negative. The operation does not cure patients, it is scandalously overused, and its high cost drains resources from other important areas of need.

Fully half of the bypass operations performed in the United States are unnecessary. A decade of scientific study has shown that except in certain well-defined situations, bypass surgery does not save lives or even prevent heart attacks: Among patients who suffer from coronary-artery disease, those who are treated without surgery enjoy the same survival rates as those who undergo open-heart surgery. (Preston TA: Marketing an operation: Coronary artery bypass surgery. *J Holistic Med* 1985;7(1):8-15., *MD Magazine*, Feb. 1995.)

In an article entitled "The Appropriateness of Performing Coronary Artery By-Pass Surgery", published by the American Medical Association in JAMA 1988, 260:505-509, the authors report the results of a randomized study conducted to determine the level of judiciousness currently being applied by physicians in performing coronary artery bypass surgery. The authors report that only fifty-six percent (56%) of the surgeries were performed for appropriate reasons. As stated in the abstract to this article, "eliminating the performance of [such] inappropriate procedures may lead to reductions in health care expenditures or to improved patient outcomes."

Balloon angioplasty is an alternative to venous grafting which is enjoying increased popularity among vascular surgeons. Experience with this technique, though, has shown that serious complications, including permanent renal failure, occur in up to 8% of cases and that technical failure rates for iliac and femoral angioplasties occur in up to 50% of cases.(7) Moreover, it must be remembered that both this technique and venous grafting are very point specific, in distinct contrast to chelation therapy, which benefits the entire vascular system. Furthermore, the costs associated with the various treatment modalities are widely disparate. A typical bypass surgery costs the patient in excess of \$30,000.00, the usual balloon angioplasty over \$12,000.00, and an average course of chelation treatments \$3,000.00 to \$5,000.00, including ancillary costs.

The scientific rationale of chelation therapy is demonstrated in the before noted article of E. M. Cranton, M.D. and J. P. Frackelton, M.D. As stated in the Abstract:

ABSTRACT: Recent discoveries in the field of free radical pathology provide a coherent, unifying scientific basis to explain the many and diverse benefits reported from treatment with EDTA chelation therapy. The free radical concept provides a scientific basis for treatment and prevention of the major causes of disability and death, including arteriosclerosis, dementia, cancer, arthritis and numerous other diseases. EDTA chelation therapy, nutritional supplementation, physical exercise and moderation of health destroying habits all have common therapeutic mechanisms which reduce free radical causes of age-related diseases.

Chelation therapy, like bypass surgery and angioplasty, is based upon a scientific rationale and is of measurable benefit to patients. There is no reason why surgery should be condoned, while chelation therapy is often condemned simply because it has not heretofore undergone large-scale, double-blind, placebo-controlled trials.

As elaborated upon in the OTA report, only 10 to 20 percent of all procedures currently used in medical practices have been shown to be efficacious by controlled trial.(8)

The efficacy of chelation therapy has been clinically demonstrated to thousands of doctors through positive results in over a million cases where this treatment was utilized. One pilot double blind study on chelation therapy has already been completed with strongly favorable results.(9)

The safety of chelation therapy, when properly administered, is not an issue. It is estimated that over a million patients nationally have been safely treated with chelation therapy by physicians utilizing the protocol developed by the American College for Advancement in Medicine.(10) No reported fatalities have occurred in the United States when the ACAM protocol has been followed. Whenever chelation therapy is used in its widely-accepted role to combat lead poisoning, the dosages given even to children are administered much more rapidly than those administered to adults under this protocol. The risks associated with surgical procedures are far greater by comparison. The Food and Drug Administration determined that EDTA chelation therapy was safe prior to approving the Investigational New Drug protocol for the ongoing double-blind placebo-controlled studies.

It is the treating, clinical physician who is best acquainted with the patient's medical history, examination results, condition and needs. It is the attending physician who is in the best position to assess the condition (medical, socioeconomic, and psychological) of the patient as well as what constitutes the best treatment for the patient. Despite criticism in the form of opinions from physicians who characteristically have never utilized the treatment modality, not a single valid study has ever been shown to support or warrant such distraction.

III. PHYSICIAN USE OF INNOVATIVE THERAPIES

As noted earlier in this Position Paper, physicians who utilize chelation therapy are treating atherosclerotic vascular disease in

accordance with sound scientific principles, and they should not be discriminated against for using safe and efficacious innovative therapies.

When a physician becomes licensed by the state, the physician is recognized by the state as capable of the diagnosis and treatment of any human disease, pain, injury, deformity or other physical or mental condition.

Such a licensed physician has the right, and indeed, the ethical duty, to treat a patient as he or she thinks best, within the parameters of his or her professional judgment and with the highest regard for the health and welfare of the public.

It has long been held that deference must be given to the state of advancement of the profession at the time of treatment. Whether or not a particular therapy should be undertaken is a decision which should be made by the treating physician, who is in the best position to determine whether EDTA chelation therapy is indicated for a particular patient.

In *Stuart v. Wilson*, 211 F. Supp. 700 (D.C. 1963), *aff'd*, 371 U.S. 576, it was noted that "the requirements of learning, skill and examination provided by the Texas Medical Practices Act for obtaining a license to practice medicine bear a direct, substantial and reasonable relation to the practice of medicine." It seems incongruous that having demonstrated the required learning and skill, and having passed the examination and obtained a license, a physician should not be permitted to exercise the judgment developed from his experience.

Moreover, as one court has described the healing arts, medicine is an inexact science, and eminently qualified physicians may legitimately diverge in their beliefs as to what constitutes the best treatment. However, such a difference does not amount to unprofessional conduct. See *Fitzgerald v. Manning*, 679 F.2d 341, 347 (4th Cir. 1982).

This does not mean that the State is required to give credence to every peculiar theory or school of medicine. "Without doubt, it is reasonable for the State to outlaw witch doctors, voodoo queens, bee-stingers and various other cults, which no reasonably intelligent man would choose for the treatment of his ills." *England vs. Bd. of Medical Examiners*, 259 F.2d 626, 627 (5th Cir. 1958). Asking rhetorically, "Just where is the dividing line?" The England court held:

Under all of the cases, we think it is that the State cannot deny to any individual the right to exercise a reasonable choice in the method of treatment of his ills, nor the correlative right of practitioners to engage in the practice of a useful profession. *Id.* at 627.

The critical question, therefore, is whether or not EDTA chelation therapy is a reasonable choice of treatment modality. Given the fact alone that ACAM's membership of hundreds of doctors nationwide have successfully treated over a million patients with EDTA chelation therapy, it is difficult to fathom how anyone could assert that this treatment is not a reasonable choice of therapy.

Merely because a particular method of treatment is not the method which is "prevailing" does not support a proposition that the method is ineffective or deceitful. A review of all of the available medical articles discloses that chelation therapy is firmly based upon accepted scientific principles and that both current professional theory and practice have demonstrated the efficacy of this treatment.

An enlightening article entitled "The Tomato Effect--Rejection of Highly Efficacious Therapies" was published by the American Medical Association in *JAMA*, 1984; 251:2387-2390. In this article, Drs. James S. Goodwin and Jean M. Goodwin describe the tomato effect in medicine:

The tomato effect in medicine occurs when an efficacious treatment for a certain disease is ignored or rejected because it does not "make sense" in the light of accepted theories of disease mechanism and drug action. The tomato was largely ignored because it was clearly poisonous; it would have been foolish to eat one. In analogous fashion, there have been many therapies in the history of medicine that, while later proved highly efficacious, were at one time rejected because they did not make sense. ...We contend that the tomato effect is in its own way every bit as influential in shaping modern therapeutics as the placebo effect... Recognition of the reality of the tomato effect, while not preventing future errors, may at least help us better understand our mistakes.

It would seem, ...that modern medicine is particularly vulnerable to the tomato effect. Pharmaceutical companies have increasingly

turned to theoretical over practical arguments for using their drugs... What is lost in such discussions are the only three issues that matter in picking a therapy: Does it help? How toxic is it? How much does it cost? In this atmosphere we are at risk for rejecting a safe, inexpensive, effective therapy in favor of an alternative treatment perhaps less efficacious and more toxic, which is more interesting in terms of our latest views of disease pathogenesis.

In an age when nearly half of the coronary artery bypass surgeries conducted in the United States are recognized as being conducted for inappropriate reasons and the efficacy of such surgery has been frequently called into question, in contrast to the successful experience physicians have had with chelation therapy, it appears that the "tomato effect" has indeed taken place with chelation therapy. The efficacious use of this therapy in treating arteriosclerosis has been demonstrated in patients world-wide. It is only in recent years that the scientific rationale to explain the benefits of chelation therapy has been elucidated in published research on free radical pathology.

In *Rogers v. State Board of Medical Examiners*, 371 So. 2d 1037 (Fla. App. 1979) aff'd, 387 So. 2d 937 (Fla. 1980), the court discussed the right of the State Board of Medical Examiners to prohibit a physician from administering chelation therapy. Acting Chief Judge Boyer noted that provisions of the Constitution grant a person certain inalienable rights, from which derive the right of a patient to receive, pursuant to a voluntary election, chelation therapy, and in the absence of unlawfulness, harm, fraud, coercion or misrepresentation, the Board was without authority to prohibit the physician from administering such therapy. *Id.*, at 1041.

Utilization of a therapy which is different is not unprofessional or unethical conduct. The converse would also hold true. General acceptance of a therapy does not mean that utilization of that therapy is necessarily professional or competent. Many therapies and treatments thought to be "proper" have now been abandoned as barbaric. The use of alternative means of treatment should not arbitrarily be deemed incompetent care.

Time and time again, especially in the field of medicine, experience has taught us that the orthodox view is not necessarily the correct view. As noted by Justice Boyer, and in the concurrence, Justices Melvin and Mills in *Rogers*, *supra*:

History teaches us that virtually all progress in science and medicine has been accomplished as a result of the courageous efforts of those members of the profession willing to pursue their theories in the face of tremendous odds despite the criticism of fellow practitioners. Copernicus was thought to be a heretic when he theorized that the earth was not the center of the universe. Banishment and prison was the reward for discovery that the world was round. Pasteur was ridiculed for his theory that unseen organisms caused infection. Freud met only resistance and derision in pioneering the field of psychiatry. In our own era chiropractic treatment has been slow in receiving the approval of the other professions of the healing arts. We can only wonder what would have been the condition of the world today and the field of medicine in particular had those in the midstream of their profession been permitted to prohibit continued treatment and therapy and impede progress in those and other fields of science and the healing arts. *Id.*, at 1041.

Any restriction on the use of chelation therapy beyond prescribing conformity with the ACAM protocol is entirely unwarranted. EDTA chelation therapy has long been recognized by a substantial, respected minority of physicians as an acceptable method of treatment, provided that it is administered properly and adheres to the accepted standard of practice.

One should not confuse the clear distinction existing between innovative therapy and experimentation. Experimentation has been defined as a procedure with no therapeutic intent, designed to test a hypothesis and/or to develop new knowledge. However, innovative therapy is one which is designed to benefit the individual patient and to manage or solve a particular clinical problem. EDTA chelation therapy has been utilized for nearly 50 years by physicians in this country for various symptoms and ailments. Physicians utilizing EDTA chelation therapy for vascular and other diseases are not intending to generate new knowledge but, rather, to treat the particular needs of the patient with the therapy he or she believes is most appropriate.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, established by Congress in 1974, has identified innovative therapies as those designed solely to enhance the well-being of an individual patient, even if such therapies are not approved by a peer group agency. See, DHEW Pub. No. (05)77-0004, 1977. A significant fear in allowing the use of innovative therapies concerns alleged risks to the patient. This is where the physician's intent comes into play. The intent to treat the individual patient's symptoms and needs, not advance the personal goals of the physician, allows the physician to determine the

risk-benefit ratios involved. It also causes the physician to follow established protocols in the use of the innovative therapy, which will also protect the needs of the patient.

While experimental research involving humans is subject to federal regulations, the use of innovative therapy is not. There is presently no regulation existing which prohibits or restricts the use of innovative therapies. If every innovative therapy needed prior institutional review board approval, an impossible case load would be created and needed therapies would be delayed to the detriment of the patient. It is for the individual physician to determine whether the risks of a certain therapy are too great for the patient. This decision is to be made in light of alternative therapies and upon review of all relevant studies and literature.

There is substantial objective evidence that EDTA chelation therapy is beneficial in the treatment of occlusive arterial disease as well as other diseases. Physicians using EDTA chelation therapy have determined that it is a safe and effective alternative to bypass surgery and other treatments, as demonstrated by the results from independent studies relating to blood flow.

An excellent composite of numerous studies dealing with chelation therapy is "EDTA Chelation Therapy: A Retrospective Study of 2,870 Patients", found in the Text.(11) The authors here chronicle the successful treatment of thousands of patients with chelation therapy. In their conclusion they state "the results of this retrospective analysis suggest that chelation therapy with disodium magnesium EDTA was useful in the therapy of several thousand patients with chronic degenerative, especially cardiovascular, diseases."

Section II of the Text contains a series of clinical studies and analyses of other clinical studies that are original publications or republications, all of which are strongly supportive of chelation therapy.(12) Clinical studies, scientifically conducted by licensed physicians, must naturally be respected and relied upon in a pioneering area of treatment. It is ACAM's position that the efficacy of chelation therapy is supported better by clinical studies than even bypass surgery.

IV. RESTRICTION TO FDA PACKAGE INSERT GUIDELINES IS INAPPROPRIATE

EDTA chelation therapy was originally approved by the FDA in July 1953 under a version of the Federal Food, Drug and Cosmetic Act which required that the drug be shown "safe", i.e., that the benefits outweigh the risks. In 1962, the Act was amended so that any new drugs must be proven both safe and effective before they could be introduced into interstate commerce. The purpose behind the Act is to keep misbranded drugs out of the channels of interstate commerce. *United States v. Evers*, 643 F.2d 1043 (5th Cir. 1981). It was clearly not intended to regulate the practice of medicine and was drafted so that nothing in the statute or the regulations thereunder would prevent a physician from prescribing a drug for a purpose for which it had not been specifically approved. *Id.*, at 1048. An unequivocal statement of the Act's policy of noninterference with the discretion of a treating physician was provided by the FDA itself:

Once [an approved] new drug is in a local pharmacy after interstate shipment, the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the condition for use from those approved in the package insert, without informing or obtaining the approval of the Food and Drug Administration. This interpretation of the Act is consistent with the Congressional intent as indicated in the legislative history of the 1938 Act and the Drug Amendments of 1962. Throughout the debate leading to the enactment, there were repeated statements that Congress did not intend the Food and Drug Administration to interfere with medical practice and references to the understanding that the bill did not purport or regulate the practice of medicine as between the physician and the patient. Congress recognized a patient's right to seek civil damages in the Courts if there should be evidence of malpractice, and declined to provide any legislative restrictions upon the medical profession. *United States v. Evers*, *supra*, 643 F.2d at 1048, quoting 37 Fed. Reg. 16503 (1972).

The Alabama District Court explained a physician's freedom to utilize drugs in a manner not set forth upon the package insert as follows:

It is well-recognized that a package insert may not contain the most up-to-date information about a drug and the physician must be free to use the drug for an indication not in the package insert when such usage is part of the practice of medicine and for the benefit of the patient. Hopefully, the physician would welcome a well-documented package insert because he finds it useful because the information in it is supported by substantial documented evidence. However, the physician can ascertain from medical

literature and from medical meetings new and interesting proposed uses for drugs marketed under package inserts not including the new proposed usages. The package insert's most important educational value derives from the fact that it is a well reviewed, authoritative document. New uses for drugs are often discovered, reported in medical journals and at medical meetings, and subsequently may be widely used by the medical profession. But the Federal Drug Administration does not permit the package insert to be amended to include such uses unless the manufacturer submits convincing evidence to support the change. The manufacturer may not have sufficient commercial interest or financial wherewithal to warrant following the necessary procedures to obtain FDA approval for the additional use of the drug. When physicians go beyond the directions given in the package insert, it does not mean that they are acting illegally or unethically and Congress did not intend to empower the FDA to interfere with medical practice by limiting the ability of physicians to prescribe according to their best judgment.

The drug-package insert only sets up guidelines, not parameters, for the use of medication. Many drugs are commonly used in a way not specifically listed on the drug enclosure. It is the physician, not the insert, that decides upon the method of treatment, for it is the physician and not the FDA who is treating the patient. The inserts are meant to impart information, not restrict the practice of medicine by those qualified to practice.

Dr. John D. Archer of the American Medical Association, in a JAMA editorial, makes a similar observation:

The FDA cannot approve or disapprove of how a legally marketed drug is used by a physician in his practice. The agency approves of what a manufacturer may recommend about uses in its labeling (package insert) and advertising. Failure to recognize this distinction can have various harmful results. The FDA Does Not Approve Uses of Drugs, JAMA, August 24:31, 1984, Vol. 252, No. 8.

Furthermore, the Foreword to the Physicians Desk Reference states in pertinent part as follows:

The FDA has also announced that the FD & C Act "does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling." Thus, the FDA states also that "accepted medical practice" often includes drug use that is not reflected in approved drug labeling. Physicians Desk Reference, 46th Ed., Medical Economics Company, 1992

V. CONSTITUTIONAL CONSIDERATIONS IN RESTRICTING CHOICE IN MEDICAL TREATMENTS

A. The Right of Privacy

Without question, the doctor-patient relationship has evolved in recent history from a state of strong paternalism to the era of self-determination largely existent today. At one time, doctors commanded and decided virtually all treatment options for a patient, with no obligation to consider the patient's values or decisions. The assumption existed that the physician unequivocally knew what was best for his or her patient and that the physician's decisions on the medical benefits or potential harms of a given treatment were dispositive factors in making treatment decisions. In recent history, however, paternalism has given way to an era of patient self-determination as consumers have become aware of treatment alternatives and the fact that different doctors favor different approaches, as well as the potentially profound effects that a treatment decision may involve.

Patients are increasingly asserting their right to be intimately involved in the decision-making process. As stated by J. Cardozo in *Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 105 N.E. 92, 93 (1914), "every human being of adult years and sound mind has a right to determine what shall be done with his own body." Through its adoption of the doctrine of informed consent, the judicial system has embraced the trend towards respecting the personal convictions and values of the individual. This fact was recited as a truism by the Court in *Andrews v. Ballard*, 498 F. Supp. 1038, 1048, which stated:

It is the inalienable nature of the right to decide to obtain or reject medical treatment, which forms the very basis of the requirement, enforced throughout America, that medical practitioners obtain their patients' informed consent prior to administering treatment.

It is now well settled that American law generally protects the patient's right to choose among licensed practitioners to treat illnesses and, correspondingly, the right of licensed practitioners to determine within the scope of their licenses the appropriate treatment. In the early case of *Union Pacific Ry. v. Botsford*, 141 U.S. 250, 251 (1891), the Supreme Court recognized the right of the individual to control his own body in stating:

No right is held more sacred, or is more carefully guarded, by the common law than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.

It has subsequently been held, as a matter not only of state common law but also of Federal constitutional law, that the special nature of the doctor-patient relationship precludes unjustifiable State intrusion with patients' rights to decide independently, with the advice of a physician, to obtain or reject medical treatment. *Roe v. Wade*, 410 U.S. 113 (1973). See also, *Planned Parenthood v. Casey*, 112 S.Ct. 2791, 2806 (1992), which provides:

It is settled now . . . that the Constitution places limits on a State's right to interfere with a person's most basic decisions about family and parenthood, as well as bodily integrity (citations omitted).

This judicial maxim derives from the Due Process Clause of the Fourteenth Amendment, which incorporates most of the Bill of Rights against the States. *Id.* at 2804.

It is firmly established that the First Amendment has a penumbra where privacy is protected from governmental intrusion. *Griswold v. Connecticut*, 381 U.S. 479, 483 (1965). In *Griswold*, the Court held that the right to privacy was "no less important than any other right carefully and particularly reserved to the people" and that "a government purpose to control or prevent activities constitutionally subject to State regulation may not be achieved by means which sweep unnecessarily broadly, and thereby invade the areas of protected freedoms." *Id.* at 485.

In *Andrews v. Ballard*, 498 F. Supp. 1038 (S.D. Tex. 1980), the Court expounded on the right of privacy in dealing specifically within the context of patients' rights to alternative medical treatments. After reviewing the Supreme Court jurisprudence, this court determined that two criteria must be met in order to identify those "decisions which will be recognized as among those that an individual may make without unjustified government interference." *Id.* at 1046. The court explained "first, they must be personal decisions that must primarily involve one's self or one's family. Second, they must be important decisions." *Id.* (citations omitted). In deciding if health care decisions among alternative medical therapies satisfied these criteria, the court elaborated:

The decision to obtain or reject medical treatment, no less than the decision to continue or terminate pregnancy, meets both criteria. First, [such decisions] are, to an extraordinary degree, intrinsically personal. It is the individual making the decision, and no one else, who lives with the pain and the disease. It is the individual making the decision, and no one else, who must undergo or forego the treatment, and it is the individual making the decision, and no one else, who, if he or she survives, must live with the results of that decision. One's health is a uniquely personal possession. The decision of how to treat that possession is of no less personal nature.

Second, it is impossible to discuss the decision to obtain or reject medical treatment without realizing its importance. The decision can either produce or eliminate physical psychological, and emotional ruin. It can destroy one's economic stability. It is, for some, the difference between a life of pain and a life of pleasure. It is, for others, the difference between life and death. *Id.* at 1046-1047.

The Florida Supreme Court has specifically and unanimously upheld chelation therapy as a valid exercise of a physician's right to practice medicine. In *State Board of Medical Examiners of Florida v. Rogers*, 387 So. 2nd 937 (Fla. 1980) *aff'g.*, 371 So. 2d 1037 (Fla. App. 1979), the Court held that the State Board of Medical Examiners was without authority to deprive a licensed physician's patients of the voluntary election to receive chelation therapy, as the State had not shown the therapy to be harmful. The fact that the therapy was not endorsed by the majority of the medical profession was unpersuasive. The Court observed:

Although the State has the power to regulate the practice of Medicine for the benefit of the public health and welfare, this power is not unrestricted. The regulations imposed must be reasonably related to the public health and welfare and must not amount to an arbitrary or unreasonable interference with the right to practice one's profession which is a valuable property right protected by the

due process clause. *Doe v. Bolton*, 410 U.S. 179, 93 S. Ct. 739, 35 L. Ed. 2d 201 (1973); *Dent v. West Virginia*, 129 U.S. 114, 9 S. Ct. 231, 32 L. Ed. 623 (1889).

Under the particular facts of this case, we conclude that the Board's action unreasonably interferes with Dr. Rogers' right to practice medicine by curtailing the exercise of his professional judgment to administer chelation therapy.

The record before us fails to evidence harmfulness as a reasonable basis for the Board's action in restricting use of this treatment... The Board's findings do not support a conclusion of quackery, and the State-imposed limitation on the administration of chelation treatment has not been shown by the evidence to have a reasonable relationship to the protection of the health and welfare of the public. *Id.*, at 939-40. See also, *Clair v. Centre Comm. Hosp.*, 317 Pa. Super. 25, 463 A.2nd 1065 (1983); *Vest v. Cobb*, 76 S.E. 2d 885, 893 (W. Va.).

Some states are taking affirmative legislative steps to explicitly safeguard and provide substantial deference to the treating physician's clinical judgment where patient harm is not an issue. In Alaska Code Annotated, Title 8, Chapter 64, Article 2, at Section 08.64.326, it expressly provides in pertinent part:

The [Medical] board may not base a finding of professional incompetence solely on the basis that a licensee's practice is unconventional or experimental in the absence of demonstrably physical harm to a patient.

Both the House and the Senate of the State of Washington supported a bill proposed by the House Committee on Health Care allowing the use of non-traditional treatment. This bill became law in June 1991. In its House Bill Report, the House Committee stated:

The state medical disciplinary board has discriminated against physicians who practice alternative health care, considered non-traditional medicine. Many patients who receive no satisfaction with traditional medical care have gotten relief from physicians who practice under other theories, including holistic medicine. The Board should not discriminate unreasonably against these physicians as long as no harm is being done. Their patients demand a freedom to choose this health care that they believe is best for them, and this freedom is adversely affected by discrimination and harassment from state disciplinary authorities. HOUSE BILL REPORT, at 2 (1991).

Of note is that the Washington State Medical Association also supported the enactment of this bill.

Similarly, North Carolina amended its medical practice act effective in June 1993 to add the following language:

The Board shall not revoke the license of or deny a license to a person solely because of that person's practice of a therapy that is experimental, non-traditional, or that departs from acceptable and prevailing medical practices unless, by competent evidence, the Board can establish that the treatment has a safety risk greater than the prevailing treatment or that the treatment is generally not effective. N.C. Gen. Stat. Section 90-14(a)(6).

In recent years, the trend in federal constitutional law is clearly toward greater recognition that the patient's right to a choice of treatment is a fundamental right of privacy. *Roe v. Wade*, *supra*; *Doe v. Bolton*, *supra*; *Planned Parenthood v. Casey*, *supra*; and *Andrews v. Ballard*, *supra*. Considerable deference is accorded the patient's determination of what course of treatment to pursue, and there is judicial concern that decisions about personal health care be made by the patient in consultation with his or her physician, free from state regulation.

The developments in both state and federal law recognize a "right to be let alone," i.e., that the final decision among alternative medical treatments -- or between treatment and no treatment -- belongs to the treated. See, *Olmsted v. United States*, 277 U.S. 438, 478 (1928).

B. First Amendment Protection of Commercial Speech

The best test of truth is the power of the thought to get itself accepted in the competition of the market..." *Abrams v. United States*, 250 U.S. 616, 630 (1919) (J. Holmes dissenting). This oft-quoted maxim of First Amendment jurisprudence provides some illumination on the genesis of the First Amendment's application to commercial speech. As stated later by the Supreme Court in the commercial context, "it is the purpose of the First Amendment to preserve an uninhibited marketplace of ideas in which truth will ultimately prevail..." *Red Lion Broadcasting Co. v. F.C.C.*, 395 U.S. 388, 390 (1969); 89 S. Ct. 1794, 1806.

"Commercial speech" is defined as that which proposes a commercial transaction. *Bd. of Trustees of State Univ. of N.Y. v. Fox*, 109 S. Ct. 3028, 3031 (1989). Although the question of whether Justice Holmes' "marketplace of ideas" postulation on free speech extended to the commercial arena was debated for some time, that question was "squarely before" the Court in *Virginia Pharmacy Board v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 760 (1976); 96 S. Ct. 1817, 1825. In concluding that commercial speech was entitled to protection under the First Amendment, the Court began its analysis with a review of several propositions that were already "settled or beyond serious dispute." It was clear that paid advertisement constituted protected speech. Likewise, speech was protected even though it was carried in a form that was "sold" for profit "and even though it may involve a solicitation to purchase or otherwise pay or contribute money." *Id.* at 1825.

In concluding that commercial speech was entitled to First Amendment protection, the Court reasoned that:

As to the particular consumer's interest in the free flow of commercial information, that interest may be as keen, if not keener by far, than his interest in the days most urgent political debate.

So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable and if it is indispensable to the proper allocation of resources in a free enterprise system, it is also indispensable to the formation of intelligent opinions as to how that system ought to be regulated or altered. Therefore, even if the First Amendment were thought to be primarily an instrument to enlighten public decision making in a democracy, we could not say that the free flow of information does not serve that goal *Id.* at 1826-1827.

Subsequent decisions have affirmed these principles. See *Central Hudson Gas v. Public Service Com'n of N.Y.*, 447 US 557, 100 S. Ct. 2343, 2349 (1980) ("commercial expression not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information"); *Discovery Network, Inc. v. City of Cincinnati*, 946 F. 2d 464, 469 (6th Cir. 1991), *aff'd Cincinnati v. Discovery Network, Inc.*, 113 S.Ct. 1505, 123 L.Ed. 2d 99 (1993) ("commercial advertising is essential because it conveys information that permits each person to decide which trades and economic decisions are best for that person... As such, commercial speech also has a high value to the society as well").

It is thus unequivocal that commercial speech is protected under the First Amendment. This protection even applies when the speech communicates only an incomplete version of the relevant facts. "The First Amendment presumes that some accurate information is better than no information at all." *Bates v. State Bar of Arizona*, 433 US 350, 97 S. Ct. 2691, 2704 (1977).

No serious argument can be made that the practice of medicine does not involve commerce, consumers, marketing and money. The medical profession clearly involves numerous commercial transactions. Commercial speech is likewise inherently intertwined in the doctor-patient relationship. So long as such speech is not misleading, any state regulation affecting such speech is subject to judicial scrutiny.

In *Central Hudson Gas v. Public Service Com'n of N.Y.* (1980), 447 US 562, 564; 100 S. Ct. 2343, 2350, the Court held that if a commercial speech communication "is neither misleading nor related to unlawful activity," a government regulation burdening such speech must satisfy the following test:

The State must assert a substantial interest to be achieved by restrictions on commercial speech. Moreover, the regulatory technique must be in proportion to that interest. The limitation on expression must be designed to carefully achieve the State's goal. Compliance with this requirement may be measured by two criteria. First, the restriction must directly advance the state interest involved; the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose. Second,

if the governmental interest could be served as well by a more limited restriction on commercial speech, the excessive restrictions cannot survive.

The Central Hudson Court explained that the careful design requirement on such limitations "recognizes that the First Amendment mandates that speech restrictions be "narrowly drawn." Id. at 2351. The Court also pointed out that speech restrictions that posed no danger to the asserted state interest or merely "conditional and remote eventualities" could not justify suppressive regulation. Id. at 2351, 2353. The Court also noted that regulations completely suppressing commercial speech were reviewed with "special care" and that "in recent years this Court has not approved a blanket ban on commercial speech unless the expression itself was flawed in some way, either because it was deceptive or related to unlawful activity. Id. at 2351, n. 9.

The narrow tailoring requirement of the Central Hudson Test was further elaborated upon by the Supreme Court in *Bd. of Trustees of State Univ. of N.Y. v. Fox* (1989), 109 S. Ct. 3028. In *Fox*, the Court stated that the regulation must not "burden substantially more speech than is necessary to further the government's legitimate interest." Id. at 3034. The Court then explained that:

What our decisions require is a "fit" between the legislature's ends and the means chosen to accomplish those ends - a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is "in proportion to the interest served," that employs not necessarily the least restrictive means but, ... a means narrowly tailored to achieve the desired objective.

We reject the contention that the test we have described is overly permissive. It is far different, of course, from the "rational basis" test used for Fourteenth Amendment equal protection analysis... Here we require the government goal to be substantial, and the cost to be carefully calculated. Moreover, since the state bears the burden of justifying its restrictions, it must affirmatively establish the reasonable fit we require. Id. at 3035.

Thus, while the protection of the public health is concededly a substantial interest, the State bears the burden of demonstrating affirmatively that chelation therapy is inefficacious or unsafe if it intends to burden commercial speech on the matter. It is respectively posited that the State cannot succeed in this endeavor, given the safe and tremendously successful experience physicians have had in utilizing chelation therapy with their patients.

Just as with the doctrine of the right of privacy, the underlying rationale with the commercial speech doctrine is simply a recognition that reasonable people are quite capable of deciding for themselves what is best for them. In responding to the Plaintiff's arguments regarding the need to protect the public, the Supreme Court in *Virginia Pharmacy Board v. Virginia Citizen's Consumer Counsel, Inc.*, 96 S.Ct. 1817, 1829 (1976) summarily stated:

There is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them . . . It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us.

VI. CONCLUSION

As is apparent from the foregoing, it is ACAM's position that a more than sufficient quantum of evidence exists to support the use of EDTA chelation therapy as a safe and efficacious treatment modality and, thus, licensed physicians utilizing chelation therapy should not be impeded in their use of it with their patients.

Under the common law, the State may not deny an individual the right to exercise a reasonable choice in medical care, nor the correlative right of licensed practitioners to provide such care, and the United States Constitution precludes unfair burdening of choice in treatment decisions. Under both the Doctrine of the Right of Privacy and the Commercial Speech Doctrine, substantial deference is given to the individual to make important decisions regarding his own body. As recently reiterated by the Supreme Court, "At the heart of [protected] liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life." *Planned Parenthood v. Casey*, supra, 112 S.Ct. at 2807.



ACAM's position as set forth herein is adopted not only for the medical profession, but more importantly, for the individual patients who can benefit from chelation therapy.

*ACAM gratefully acknowledges the special contribution of its counsel, Gregory D. Seeley, Esq., of Seeley, Savidge & Ausem in developing this position paper.

VII. APPENDIX

TABLE OF LEGAL AUTHORITIES

Abrams v. United States, 250 U.S. 616 (1919)

Andrews v. Ballard, 498 F. Supp. 1038 (S.D. Tex. 1980)

Bates v. State Bar of Arizona, 433 US 350, 97 S. Ct. 2691 (1977)

Bd. of Trustees of State Univ. of N.Y. v. Fox, 109 S. Ct. 3028 (1989)

Central Hudson Gas v. Public Service Com'n of N.Y., 447 US 557, 100 S. Ct. 2343 (1980)

Cincinnati v. Discovery Network, Inc., 113 S.Ct. 1505, 123 L.Ed. 2d 99 (1993)

Clair v. Centre Comm. Hosp., 317 Pa. Super. 25, 463 A.2nd 1065 (1983)

Dent v. West Virginia, 129 U.S. 114, 9 S. Ct. 231, 32 L. Ed. 623 (1889)

Discovery Network, Inc. v. City of Cincinnati, 946 F. 2d 464 (6th Cir. 1991)

Doe v. Bolton, 410 U.S. 179, 93 S. Ct. 739, 35 L. Ed. 2d 201 (1973)

Fitzgerald v. Manning, 679 F. 2d 341 (4th Cir. 1982)

Griswold v. Connecticut, 381 U.S. 479 (1965)

Olmsted v. United States, 277 U.S. 438 (1928)

Planned Parenthood v. Casey, 112 S.Ct. 2791 (1992)

Red Lion Broadcasting Co. v. F.C.C., 395 U.S. 388 (1969)

Roe v. Wade, 410 U.S. 113 (1973)

Rogers v. State Board of Medical Examiners, 371 So. 2d 1037 (Fla. App. 1979)

Schloendorff v. Society of New York Hospital, 211 N.Y. 125, 105 N.E. 92, 93 (1914)

State Board of Medical Examiners of Florida v. Rogers, 387 So. 2nd 937 (Fla. 1980)

Stuart v. Wilson, 211 F. Supp. 700 (D.C. 1963)

Union Pacific Ry. v. Botsford, 141 U.S. 250 (1891)

United States v. Evers, 643 F.2d 1043 (5th Cir. 1981)

Vest v. Cobb, 76 S.E. 2d 885 (W. Va.)

Virginia Pharmacy Board v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976); 96 S. Ct. 1817, 1825

Citations

(1) A copy of this article is contained in the book, "A Textbook on EDTA Chelation Therapy" Journal of Advancement in Medicine, Vol. 2, Nos. 1, 2, Spring/Summer, 1989, pp. 17-54 (hereinafter, this book will be referred to as "Text"). This combined issue is in print and copies are available through Human Sciences Press, Inc., 233 Spring Street, New York, NY 10013-1578.

(2) A free radical is defined as any atom or molecule in a particular state with one unpaired electron in outer orbit. The conversion of molecular oxygen to toxic oxygen radicals occurs by single electron transfer by the mitochondrial or microsomal electron transport chain or through oxidant enzyme systems, such as xanthine oxidase, aldehyde oxidase, flavin dehydrogenase, amine oxidase, cyclooxygenase and lipoxygenase. See R. A. Hinder, J. H. Stein, Oxygen-Derived Free Radicals, Arch Surg 1991; 126:104-105. This article also refers to the implications of oxygen-derived free radicals in atherosclerosis and other diseases.

(3) Hereinafter referred to as "OTA Report at p. 43"

(4) OTA Report at p. 43.

(5) Myocardial Infarction and Mortality in the Coronary Artery Surgery Study (CASS) Randomized Trial, N.Eng.J. Med. 1984, 310, No. 12:750-758.

(6) P. Gundy, Cardiovascular Diseases Remain Nation's Leading Cause of Death, JAMA 1992; 267:335-336.

(7) D. M. Widlus, F.A. Osterman, Evaluation and Percutaneous Management of Atherosclerotic Peripheral Vascular Disease, JAMA 1989; 261:3148-3154.

(8) OTA Report at pp. 60,94.

(9) E. Olszewer, F. Sabbag, J. Carter, A Pilot Double Blind Study of Sodium-Magnesium EDTA in Peripheral Vascular Disease, published in J. of Natl. Med. Assn., March, 1990.

(10) Text, supra. n.1, at pp. 269-305.

(11) See Text, supra n. 3, at pp. 197-211.

(12) Id, at pp. 107-226.