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December 10, 1984

Bryant D. Paris, Jr.  
Executive Secretary  
Board of Medical Examiners  
State of North Carolina  
Suite 214, 222 North Person Street  
Raleigh, NC 27601

Re: Board Hearing/Submittal

Dear Mr. Paris:

Enclosed is a memorandum regarding chelation therapy which is being submitted on behalf of the American Academy of Medical Preventics in connection with the Board's hearings relating to the following physicians:

1. Theodore C. Rozema, M.D.;
2. John L. Laird, M.D.;
3. Jeffrey D. Stillson, M.D.; and
4. Logan T. Robertson, M.D.

Hearings concerning all four (4) physicians have been scheduled for March 15, 1985 at 1:00 p.m. before the Board.

Our local counsel in this matter is Howard E. Manning, Jr., Esq. of Manning, Fulton & Skinner, and I have provided him with a copy of the Memorandum, as well as forwarding a copy to Mike Weddington, attorney for the Board.

I would ask that the Board consider the material submitted in connection with the charges and allegations made, and further, respond to the previously submitted request to set forth the specific basis of the charges.

**SEELEY, SAVIDGE & AUSSEM**

A LEGAL PROFESSIONAL ASSOCIATION

I thank you for your attention to this matter, and should you or Mr. Weddington have questions or wish to discuss the matter further, do not hesitate to call.

Very truly yours,



Thomas M. Carolin

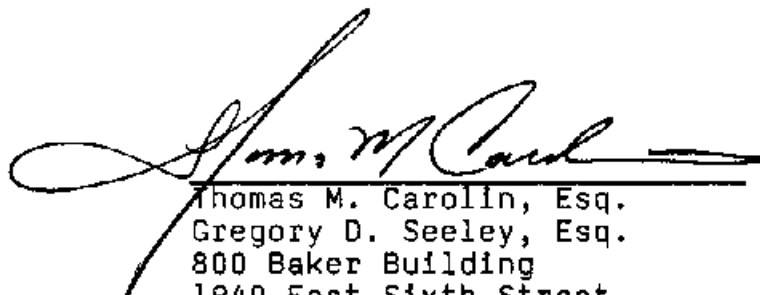
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Enclosure

cc: Mike Weddington, Esq.  
Howard E. Manning, Jr., Esq.  
Theodore C. Rozema, M.D.  
John L. Laird, M.D.  
Jeffrey D. Stillson, M.D.  
Logan T. Robertson, M.D.

BEFORE THE BOARD OF MEDICAL EXAMINERS  
OF THE  
STATE OF NORTH CAROLINA

In re: Chelation Therapy            )  
  )  
  )  
  )  
  )

Now comes the American Academy of Medical Preventics, by and through its counsel, and herein submits a memorandum calling for the Board of Medical Examiners of the State of North Carolina to refrain from impeding, restricting, or interfering with the use of chelation therapy by North Carolina physicians.



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Pro Hoc Vice

OF COUNSEL;  
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## I. PRELIMINARY STATEMENT

The American Academy of Medical Preventics, hereinafter referred to as "AAMP", is a not-for-profit corporation composed of over 400 licensed physicians who are engaged in the practice of, or research in, occlusive vascular disease and its related fields. Member physicians use alternative cardiovascular therapies that involve, inter alia, the early detection and identification of risk factors of the patient and intensive education in modifying the patient's life style to alter these risk factors. Chelation therapy may be employed to correct the course of the patient's disease process before it reaches crisis proportions. Among the purposes of AAMP is to advance support for and to assist the research in and application of chelation therapy to occlusive vascular disease and other degenerative diseases associated with aging. Member physicians' fields of interest include, but are not limited to, preventive; holistic; metabolic; orthomolecular; and nutritional medicine.

It has come to the attention of AAMP that the Board of Medical Examiners of the State of North Carolina (hereinafter "the Board") may shortly take a position against the use of chelation therapy, asserting that as used in cases of circulatory disorder, coronary or other arterial arteriosclerosis, chelation therapy may constitute a treatment that is in violation of North Carolina law relative to the practice of medicine, and a cause for the Board to cancel, revoke, or suspend the license of any practitioner of medicine who utilizes chelation therapy . In particular, AAMP

has been apprised that charges and allegations have been preferred against various physicians, with the Board contending that prescribing the use of ethylene-diaminetetraacetic acid (EDTA) for treatment and alleviation of vascular ailments constitutes grounds, pursuant to N.C.G.S. Secs. 90-14(a)(6), (8) and (12) for the suspension or revocation of the license to practice medicine.

It is respectfully submitted that were the Board to examine the relevant law, as well as the practice of EDTA chelation therapy, it will find that restricting, interfering with or impeding with the growth of chelation therapy as practiced by qualified physicians in the State of North Carolina is unwarranted. On behalf of those physicians who engage in the practice of chelation therapy, AAMP posits that the characterization of their treatment as unprofessional, fraudulent or exploitive, is unconscionable. As more fully explained in the discussion which ensues, chelation therapy is a valid and proper course of treatment, based upon scientific rationale, and consistent with sound medical practice. The adoption by the Board of a position restrictive to its use is an invalid restraint upon the practice of medicine which would adversely affect the standard of medical care available to the citizenry, contrary to law, and a disservice to the public.

## II. THERAPEUTIC HISTORY OF CHELATION THERAPY

The discussion of chelation therapy in relation to the laws of North Carolina perhaps best begins with a definition of terms. North Carolina law requires that a physician utilize full methods

diagnosis and treatment, they are expected to utilize the most comprehensive methods of treatment available.

In determining that EDTA chelation therapy is necessary for a specific patient, those engaged in the practice of medicine are utilizing the type of treatment envisioned by the law, which calls upon the practitioner utilize treatments designed to alleviate the disease or ailment diagnosed. It is the treating, clinical physician who is best acquainted with the patient's medical history, examination results, condition and needs. It is this physician, who is in attendance, who is in a superior position of assessing the condition (socioeconomical, psychological and medical) of the patient, and what would constitute the best treatment for that particular patient.

Derived from the Greek "chele" meaning "claw", the word "chelation" etymologically describes the chelate substance's characteristic of a pincerlike binding to bivalent metal or other minerals. Ethylene diamine tetraacetic acid, (EDTA) is a synthetic amino acid, first used in the 1940's for treatment of heavy metal poisoning. It is still 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 was considered possibly effective in the treatment of occlusive vascular disorders as arteriosclerosis, and prior to 1970, EDTA was used in the treatment of scleroderma.

EDTA chelation therapy has been determined by many licensed physicians in North America to be an effective treatment for occlusive vascular diseases, as it improves blood flow and relieves symptoms associated with the disease. It performs this function by chelating; i.e., removing excess calcium deposits on arterial walls, thereby removing obstructions and increasing blood flow. Arterial flexibility improves secondarily, permitting further increased blood flow. EDTA, in binding ionic metal catalysts and making them chemically inert, reduces the production of free radicals - promiscuously reactive molecules and molecular fragments which react aggressively with other molecules, See, E. M. Cranton, J. P. Frackelton, "Treatment of Free Radical Pathology In Chronic Degenerative Diseases With EDTA Chelation Therapy" Journal of Holistic Medicine. Vol. 6, No. 1, Spring/Summer, 1984. Appendix I appended hereto contains a compendium of papers outlining the current status of chelation therapy in its bibliography, as do the publications submitted herewith. A review of these papers evinces the fact that physicians utilizing chelation therapy are very concerned with both the healing art and the remedies for disease; and further that the use of EDTA is indeed curative, i.e., used in the cure of disease.

Chelation therapy is considered by the licensed physicians who utilize it to be an alternative to surgical treatment for chronic occlusive vascular disease. In September, 1978 the Office of Technology Assessment (OTA) published a report entitled "Assessing the Efficacy and Safety of Medical Technologies" and in one

portion of that report discussed the efficacy and safety of surgery for coronary artery disease, and concluded as follows:

Coronary artery bypass surgery is based on a scientific rationale and may be of measureable 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, Emphasis supplied. (The full text of the case study relating to Surgery for Coronary Artery disease is attached as Appendix XV). The importance of this study is twofold, in that: 1) it demonstrates that although over 70,000 operations were performed in 1977, the benefits of such surgery were never clearly demonstrated (Id., at 43); and 2) chelation therapy, like bypass surgery is based upon a scientific rationale and is of measurable benefit to patients. There is no reason why bypass surgery should be condoned, while chelation therapy should be condemned. A recent article in the New England Journal of Medicine (March 22, 1984) reports upon myocardial infarction and mortality in the coronary artery surgery study (CASS) randomized trial, and as stated in the Abstract:

ABSTRACT: The long-term benefit of coronary bypass surgery in terms of longevity and prevention of major ischemic events in patients who have mild angina is not well defined. The randomized Coronary Artery Surgery Study (CASS) was designed to evaluate this issue; it consists of 780 patients who were considered operable and who had mild stable angina pectoris or who were free of angina after infarction. As a result of the randomization process there were no significant differences in base-line variables between patients randomly assigned to medical and to surgical therapy.

The full text of the Article is appended as Appendix XV(A).

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. (A copy of the pre-publication draft is attached as Appendix XVI). 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 nutrition, nutritional supplementation, physical exercise and moderation of health-destroying habits all have common therapeutic mechanisms which reduce free radical causes of age-related degenerative diseases.

As is also noted therein, published studies describe beneficial results of utilization of chelation therapy. Id., at page 2. The beneficial results are reiterated in a letter from Dr. G. A. Poda which appeared in the November 18, 1983, issue of American Medical News. (Appendix XVII). Dr. Poda is not alone in his request that a useful drug not be arbitrarily taken away, and the Association urges the Board not to accomplish such a result.

The necessity of heart surgery, and the scheduling of such surgery has undergone criticism, and is still being questioned by many in the medical community. As noted in the Wall Street Journal, November 5, 1981 (Appendix XVIII) a Harvard School of Public Health study found that many patients thought to need bypass surgery could survive just as well with judicious use of new drugs and a diet and exercise program. It is also interesting to note that in 1981, an estimated 110,000 patients underwent bypass surgery.

### III. PHYSICIANS IN THE STATE OF NORTH CAROLINA

As earlier noted in this discussion, physicians who utilize chelation therapy are treating disease by a system of medical practice, and given the provisions of North Carolina law, that law should not be construed so as to discriminate against their particular system of medical practice, nor should this Board, in exercising the authority granted to it under the law, effect such a discriminatory result. In adopting a position opposed to the use of chelation therapy, the Board is accomplishing such a result, and acting contrary to the powers conferred upon it.

When a physician becomes licensed in the State of North Carolina, the physician is recognized by the State as capable of exercising acceptable clinical judgment. Such a licensed physician has the right, and indeed, the duty, to treat a patient as he or she thinks best, within the parameters of his or her professional judgment. To require that acceptance of co-practitioners be obtained in order that the physician practice medicine would unduly infringe upon the right to practice medicine. Whether or not a particular therapy should be undertaken is a decision which should be made by the treating physician, who is in a far better position to determine whether EDTA chelation therapy is indicated for a particular patient. Given the fact that the requirements of learning, skill and examination provided by the North Carolina law for obtaining a license to practice medicine bear a direct, substantial and reasonable relation to the practice of medicine, it seems somewhat anomalous that having demonstrated the required learning and skill, and having passed the examination and obtained a license, the physician is not permitted to exercise the judgment developed from his experience; but instead, must bow to the dictates of those unfamiliar with the peculiar facts and circumstances of the case calling for that judgment.

Merely because a particular method of treatment is not the method which is "prevailing", the Board cannot hold that the method is unprofessional or dishonorable: practitioners immoral. The Board would do well to look to the opinion of Acting Chief Judge Boyer in Rogers v. State Board of Medical Examiners, 371 So. 2d 1037 (Fla. App. 1979) aff'd 387 So. 2d 937 (Fla. S. Ct. 1980). In discussing the right of the State Board of Medical Examiners to prohibit a physician from administering chelation therapy, Judge Boyer noted that provisions of the Constitution grant a person certain inalienable rights, among which must be numbered 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. Certainly, this Board is not bound by the pronouncements of Judge Boyer, nor, for that matter, is it bound by the laws of the State of Florida. However, the reasoning which led to the result in Rogers remains as true in North Carolina as in Florida: utilization of a therapy which is different is not unprofessional or dishonorable.

It is respectfully submitted that the Board refrain from depriving patients of the opportunity to utilize alternative means of treatment for their chronic occlusive vascular disease. The right of a patient to make an informed choice should be held inviolate by the Board, which having licensed the physician,

should allow the physician to practice medicine. That the practice departs from the "prevailing" practice should be of no consequence, for as has been time and time again demonstrated, especially in the field of medicine, 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 impede progress in those and other fields of science and the healing arts.

Id., at 1041.

In determining that EDTA chelation therapy is necessary for a specific patient, those engaged in the practice of medicine are utilizing the type of treatment envisioned by the law, which calls upon the practitioner utilize treatments designed to alleviate the disease or ailment diagnosed. It is the treating, clinical physician who is best acquainted with the patient's medical history, examination results, condition and needs. It is this

physician, who is in attendance, who is in a superior position of assessing the condition (socioeconomical, psychological and medical) of the patient, and what would constitute the best treatment for that particular patient.

EDTA chelation therapy has been recognized by physicians as an acceptable method of treatment, provided that it is administered properly and adherence to the accepted standard of practice is had. In the case of DeHart v. State Board of Registration in Podiatry, 97 Mich. App. 307 (1980) the Michigan Court noted that an accepted standard of practice in medicine for the administration of chelation therapy and for the administration of intravenous therapy in general exists, and includes the following:

1. An adequate history and physical examination of the patient must be taken prior to administration.
2. An adequate check of vital signs, i.e., blood pressure, pulse rate and respiration, prior to administration, monitoring thereof during administration and checking after administration are required.
3. Blood testing, urine testing, and kidney function testing prior to administration are required.

Id., at 316. This acceptable standard of practice regarding chelation therapy should not be disregarded by the Board, for it is an acceptable standard of practice acknowledged by physicians licensed to practice medicine in the State of Michigan, its Board of Registration, and the Courts. The results in Michigan should be persuasive in North Carolina.

There is 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 by-pass surgery and to other treatments, as demonstrated by the results from independent studies relating to blood flow. Set out in the Appendix are numerous articles wherein the results of these studies are discussed. In addition to the studies documenting the improvement in circulation of the blood following chelation therapy, there is abundant anecdotal evidence that chelation therapy is a viable alternative to bypass surgery. Writing in the July 1984 issue of Prevention, Dr. James P. Carter, chairman of the Department of Nutrition, Tulane University School of Public Health and Tropical Medicine and a professor of pediatrics at Tulane University School of Medicine, made the following observation:

we think an awful lot of coronary bypass surgery is being done, and studies have shown that some of it may have been done unnecessarily. The only real indications for bypass surgery are for relief of symptoms or when the left anterior descending coronary artery is the only one blocked. The most recent studies indicate that coronary bypass surgery does not reduce the chances of subsequent heart attack, nor does it prolong life. On the other hand, if relief of the symptoms is a primary objective, there is plenty of anecdotal evidence to suggest that EDTA chelation therapy usually does this. Chelation therapy might be viable, less expensive, less invasive adjunct and/or alternative.

Prevention, Vol. 36, No. 7 page 78.

EDTA chelation therapy has been frequently criticized for the reason that the American Medical Association has refused its endorsement as an acceptable alternative treatment for coronary or other arterial atherosclerotic diseases. However, since only one-third of all practicing physicians in the United States belong to the American Medical Association, it can hardly be said that the A.M.A. represents a majority opinion of the medical profession. With all due respect to the American Medical Association, it is unfair and unreasonable to rely solely upon its opinion when that opinion represents only a minority of the physicians licensed to practice medicine. Controlled studies conducted by licensed physicians must be respected and relied upon in a pioneering area of treatment, especially when these physicians are qualified and familiar with the treatment.

It is understandable that hostility to the treatment is voiced by vascular surgeons and other vascular specialists who have a vested interest in maintaining the status quo and whose income is derived from the existing situation. Concern with the impediment produced by those with a vested interest in maintaining the status quo was discussed in a Federal Trade Commission action involving the AMA, with the Administrative Law Judge noting such actions to be a:

formidable impediment to competition in the delivery of health care services by physicians in this country. That barrier has served to deprive consumers of the free flow of information about the availability of health care services, to deter the offering of innovative forms of health care and to

stifle the rise of almost every type of health care delivery that could potentially pose a threat to the income of free-for-service physicians in private practice. The costs to the public in terms of less expensive or even, perhaps, more improved forms of medical services are great.

Docket No. 9064, November 13, 1978. An individual's health and welfare is more vital than the vested concerns, and to best service the citizens of the State of North Carolina, physicians must be permitted to utilize EDTA chelation therapy.

In addition to economics, a lack of understanding may contribute to the disdain shown by orthodox medicine to chelation therapy. That the therapy deviates from the "accepted" treatment should not be a cause to have the therapy deemed illegal. In 1820, Robert Gibbon Johnson ate a tomato on the steps of a courthouse in Salem, New Jersey. That he didn't die was a matter of interest to both the local citizenry and the medical world; for at that time, everyone in North America knowing the tomato to be from the solanaceae family, knew the tomato to be poisonous. To eat one was to commit suicide. Writing of North America's avulsion to the tomato, Drs. James and Jean Goodwin, in JAMA "Special Communication" (May 11, 1984; Vol. 251, No. 18) analogized, to the tomato, the rejection of many efficacious treatment "which do not make sense in the light of accepted theories...". As stated in the article:

...three issues...matter in picking a therapy: Does it help? How toxic is it? How much does it cost?...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.

The Tomato Effect: Rejection of Highly Efficacious Therapy, Id.

The evidence relating to chelation therapy shows the therapy to be helpful, non-toxic and relatively inexpensive.

IV. RESTRICTION TO FDA PACKAGE INSERT GUIDELINES  
IS INAPPROPRIATE

In examining chelation therapy, or any drug therapy, a state medical board will invariably examine the Food and Drug Administration's position respecting the drug. EDTA was originally approved by the FDA in July of 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, 645 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 the drug has not been approved. Id., at 1048. A distinct statement of the Act's policy of non-interference 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 of 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 education value derives from the fact that it is 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 wherewithall 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.

United States v. Evers, 453 R. Supp. 1149-50, aff'd. 643 F. 2d 1043 supra. The latter observation is particularly true with regard to EDTA in that patents on the chelation drug expired in 1968 (see patent attached as Appendix II). Because of expiration, compliance to prove effectiveness under the new guidelines of Federal Regulations would be extremely expensive to drug companies who could not protect their investment. For example, Abbott Laboratories considers Endrate (disodium edetate injection) to be effective for uses not indicated in the package insert, but has decided not to spend the eight million dollars estimated as the cost to substantiate clinical effectiveness for such indications. See, March 8, 1974 Bureau of Quality Assurance Memorandum. Diphenylhydantoin (DPH) has approval for only epilepsy, but has been used for numerous other conditions. As to the propriety of such other uses, the Drefus Medical Foundation stated the following:

The only FDA approved indication for use of DPH is for epilepsy. It is a function of the FDA to respond to applications for use of a new drug or for new uses for an old drug. It has not been the function of the FDA to discover new uses for old drugs. If no application for indication of new uses has been submitted to the FDA approves nor disapproves such uses. To the best of our knowledge

the only submission for new use of DPH has been in cardiology, presently being reviewed.

\* \* \*

Patents on DPH expired in 1963. No company has exclusive rights to sell it. It is inexpensive. One of the incentives for a drug company to apply to the FDA for approval of indication for a new use for an old drug is the exclusive right to sell it..

S. Bogoch, M.D., Ph.D. and J. Dreyfus, B.A., LL.D. (Hon.) DPH, 1975, Appendix p. 95.

The drug-package insert only sets up guidelines, not parameters, for the use of medication. As is the case with DPH, many other 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.

Recently the FDA reaffirmed the appropriateness of prescribing approved drugs for uses not included in their official labeling. In a recent FDA Drug Bulletin, the following statement appears:

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. Such "unapproved" or, more precise, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature. (emphasis added).

of a second physician in a decision to perform an abortion was void as without rational connection to the patient's needs and undue infringement on the physician's right to practice. Doe v. Bolton, 410 U.S. 179, 200-01 (1973); See also, Beal v. Doe, 432 U.S. 438 (1977).

Recently the Florida Supreme Court 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. 2d 937 (Fla. S. Ct. 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 not persuasive. The Court observed:

Entrusted with the enforcement of the appropriate standards for the practice of medicine, the Board, in restricting Dr. Roger's professional activities, was acting under the State's police power and pursuant to Sections 458.1201(1)(m) and 458.1201(1)(p). 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 for 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. Cf. Golden v. McCardy, 337 So. 2d 388 (Fla. 1976). Furthermore, the evidence demonstrates that no fraud or deception was exercised by Dr. Rogers upon his patients who were fully informed of the nature of the procedures and the possibility of no improvement. Sanctions were imposed against Dr. Rogers because he utilized a modality not accepted by the Board as having been proven effective, not that Dr. Rogers had defrauded his patients into believing the chelation treatment was secure for their conditions. 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 (The full text of the Rogers opinion is attached as Appendix III).

Fear of reprisal for utilizing a modality not accepted by the department or appropriate board places the North Carolina physician in a difficult position. Limiting the use of chelation therapy to only heavy metal poisoning or research work calls upon the physician to balance jeopardy of his license and the needs of his patient. Surely, the use of a therapy which the physician, in his independent, clinical judgment, has determined to be beneficial to his patient should not bring into force the provisions of Sections 90-14 so as to deprive the patient of beneficial treatment as the result of such treatment departing from the "accepted" uses of

EDTA chelation therapy. The objective of the law is not served by the labeling of those who have demonstrated their character, schooling, training and professional conduct to be such as to obtain a license, as quacks because they now use their character, schooling, and training in the treatment of patients.

It is generally accepted that every physician owes a "duty of reasonable disclosure of available choices with respect to proposed therapy and the dangers inherent and intentionally involved in each" to his patient. Cobbs v. Grant, 8 Cal. 3d 229, 502 P. 2d 1 (Cal. Sp. Ct., 1972). Should a doctor or hospital fail to deliver the best treatment available to a patient, medical malpractice may result. In fact, in California in Peoples v. Monticino, 66 Cal. App. 2d 85, 152 P. 2d 5 (1944) it was suggested that a doctor is potentially subject to criminal liability if he fails to administer a curative substance and the death or injury of a patient results. In other words, the failure to suggest chelation therapy in the appropriate situation may subject a physician to a criminal or civil liability. In Harnish v. Children's Hosp. Med. Center, 387 Mass. 152 (1982) the Supreme Judicial Court of Massachusetts held that the failure of a physician to divulge alternative methods of treatment constitutes professional misconduct and malpractice. As noted by Justice Cardoza:

Any human being of adult years and sound mind has the right to determine what should be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, [sic] for which he is liable for damages. This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained.

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

Adoption of a position limiting the use of EDTA chelation therapy to only certain situations creates the foundation for the suggestion voiced in Peoples, supra, in that it forecloses resort to alternative, viable methods of treatment. A patient has the right to be informed that methods other than surgery exist relating to the treatment of his illness. The failure to inform the patient of the alternative can result in liability; the removal of the choice by restriction and limitations as to the use of the therapy benefits Hobson rather than Hippocrates.

In recent years, the trend of the law is toward recognition thta the patient's right to a choice of treatment is a fundamental right of privacy. Roe v. Wade; Doe v. Bolton, supra. In Planned Parenthood of Central Missouri v. Danforth, 428 U.S. 52 (1976) the Supreme Court held a state law prohibiting the use of a particular technique of abortion invalid as an unreasonable regulation of the patient's right to an abortion. See also, Wolfe v. Schroering, 388 F. Supp. 631 (W. D. Ky. 1974); Rutherford v. United States, 399 F. Supp. 1208 (W. D. Okla. 1975) aff'd 542 F. 2d 1137 (10th Cir. 1976). Considerable deference is accorded the patient's



(Appendix V) The letter's enclosures confirm the right of a physician to practice medicine unfettered by dictates of governmental agencies. That is not to say or suggest that the practice is or should be unregulated. Certainly, the practice should be confined to those who are qualified to administer it. However, medical care is an evolving science and regulations which restrict those able to perform can too often stifle creativity, innovation and medical advancements.

Reference is also made to another A.M.A. letter which encourages use of therapies deemed best by a patient's doctor. (Appendix VI). The FDA itself recognizes that a drug may be used by doctors for an indication not in the labeling approval. (See Dr. J. Richard Crout, Director, Bureau of Drugs letter April 16, 1974, Appendix VII). As earlier noted, it is in the best interest of the patient to allow the treating physician to determine the course of treatment.

This Board is empowered to discipline the unauthorized practice of medicine based upon certain criteria vested in it by the legislature. In so doing, the Board is acting in a quasi judicial capacity. It is therefore improper for this Board to predetermine the guilt, or create a presumption of guilt, without knowing the particular circumstances surrounding each individual case; i.e. the needs of patients and medical environment. Nothing in the enabling statutes specifically empowers the Board to take the action it is taking. The instant position is an attempt to

invade a subject which is the exclusive prerogative of the legislature. It is through its police power that the state has the power to enact comprehensive, detailed and rigid regulations concerning the practice of medicine. Garcia v. Texas State Bd. of Med. Examiners, 384 F. Supp. 434 (D.C., 1974). In conjunction with this power flows the duty to exercise that power in a fair and impartial manner. The physician's license is a valuable property right: the law allowing the Board to deprive a physician of that right is penal in nature: it is to be strictly construed, and construed in favor of the physician. Such a construction does not nor should it permit a finding that use of chelation therapy is unprofessional or fraudulent conduct. Furthermore, as practiced by the physicians of North Carolina, there is little likelihood that defrauding or deceiving the public will take place, for these physicians take the time to fully inform their patients concerning the treatment.

This Board is in the process of adopting the position that use of chelation therapy is a violation of North Carolina law, and equates the use of such therapy to "...unprofessional conduct". Section 90-14 (a)(6). It is being asserted by this Board that physicians who utilize chelation therapy are unable to practice medicine with reasonable skill or safety. It is respectfully submitted that use of the therapy does not call into issue the skill of the physician, and further, that the safety of the patient does not seem to be a paramount concern to this Board.

Utilization of the therapy is a far cry from the type of activities normally held to be unprofessional or incompetent. See, In Re Kincheloe, 272 N.C. 116 (1967).

Surely, the physician who utilizes chelation therapy differs vastly from Kincheloe, who caused his patient to remove all of her clothing without any medical reason or necessity, examined various parts of her nude body while no other person was present, administered a hypodermic which rendered her unconscious; and while in that condition he acted in an unprofessional capacity and engaged in sexual intercourse with her. Just as Kincheloe should have been censured, chelating physicians should not.

#### VII. CONCLUSION

Accordingly, for the foregoing reasons, it is respectfully requested that the practice of EDTA chelation therapy not be hindered, and that those physicians, licensed by the State to practice utilizes such therapy, not be condemned by this Board as charlatans -- dishonorable or unprofessional. The request is made not only for the medical profession -- but more importantly, for those individuals who suffer from chronic occlusive vascular disease.

Surely, this Board has the experience, competence and common-sense to realize that chelation therapy, as utilized by trained and licensed physicians, poses no threat to the health and welfare of the citizens of the State of North Carolina. Surely,

this Board is cognizant of the fact that it cannot dictate to physicians as to how they shall practice medicine; nor to the populace or the type of medical treatment they can obtain. This Board knows now, what it took the State Board of Osteopathic Medical Examiners in Florida four (4) years of administrative and court proceedings to determine -- activities aimed at restricting a physician's use of chelation therapy unreasonably interfere with the right to practice medicine.

For the foregoing reasons, it is respectfully requested that the Board of Medical Examiners of the State of North Carolina refrain from restricting, interfering with or impeding the growth of chelation therapy as practiced by qualified physicians in the State of North Carolina.

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