1983-0907-001-055

STATE OF CONNECTICUT

DEPARTMENT OF HEALTH SERVICES

CONNECTICUT BOARD OF MEDICAL EXAMINERS

IN RE:

Robert A. Harris M.D.
12 Gracie Drive
Somers, Connecticut 06071
# 021821

MEMORANDUM OF DECISION

INTRODUCTION

On June 5, 1984, the Connecticut Medical Examining Board (hereinafter "Board") was presented by the Department of Health Services with a Notice of Hearing dated April 5, 1984, and a Three Count Statement of Charges dated April 4, 1984, showing service properly made on Robert A. Harris, M.D. (hereinafter "Respondent").

The Statement of Charges alleged violations of certain provisions of Chapter 370 and 418 of the General Statutes. The Notice of Hearing provided that the hearing would take place on May 1, 1984 at the Department of Health Services, 150 Washington Street, Hartford Connecticut. At the Request of the Respondent's counsel this Hearing date was continued until June 5, 1984.

Respondent was present at this latter time and represented by counsel, which though not admitted to practice in Connecticut was not challenged by the Department of Health Services Counsel. Respondent did not testify or file an answer to the statement of Charges as required by Section 19-2a-17 of the regulations of Connecticut State agencies and his only witness was a non-practicing California physician formerly engaging in the medical practice which is alleged to violate the above statutes. Failing to deny the allegations of the complaint means that pursuant to Section 19-2a-18b of the regulations of the Connecticut State agencies all of the allegations of the complaint "shall be deemed admitted."

Each member of the Board involved in this decision attests that he/she has reviewed the record and that this decision is based entirely on that record.

FINDINGS

1. Respondent was at all pertinent times licensed to practice medicine in Connecticut under License No. 21821.

2. In 1982, the Respondent established, owned and operated a medical treatment facility in Stafford Springs, Connecticut known as the Harris Clinic (hereinafter "clinic").

3. Pursuant to Section 4-182(c) of the General Statutes, the Respondent was provided a full opportunity prior to the institution of agency action to show compliance with all the terms for retention of his license.

4. From on or about April 28, 1982, and continuing until on or about January 1, 1984, the Respondent prescribed or dispensed the legend drug Disotate (Disodium Edetate) to treat his patients for arteriosclerosis (hereinafter "EDTA Chelation Therapy"). Legend drugs ordinarily refer to commonly used drugs for various medical problems.

5. The drug EDTA (ethylenediamine) is a chemical normally dispensed by Pharmacy in a sealed vial in concentrated solution which must be diluted before administering to a patient.

6. The usual mode of administration is to put it into a bottle containing normal saline (salt water); this mixture is then administered intravenously in a slow drip.

7. EDTA Chelation Therapy does not have the approval of the Federal Drug Administration.

8. The Federal Drug Administration allows experimental use of potentially dangerous substances by approved medical practitioners who have submitted an application and detailed protocol.

9. The Respondent did not apply for or receive approval of the Federal Drug Administration for investigational use of EDTA Chelation Therapy during the period April 28, 1982 through January 1, 1984.

10. A well-designed investigational study uses the double-blind method (1/2 the patients receive the drug, 1/2 receive a placebo) and numerous laboratory, technical objective analyses as well as subjective patient questionnaires to measure therapeutic response.

11. The double blind method involves setting up two matched groups of patients, one of which receives the treatment being investigated for a prescribed period of time. The second group receives no treatment. They receive instead a placebo. The mode of therapy is then reversed with the original treated group now receiving the placebo and the previously untreated group receiving the treatment under investigation. The investigating physician never knows which group is which at any time during the investigation.

12. EDTA chelation therapists do not use the double blind method of measuring a patient's therapeutic response to EDTA Chelation Therapy.

13. EDTA chelation therapists instead use each patient as his/her own control.

14. Patients may develop fatal anaphylaxis, and sometimes fatal tetany, and arrhythmia from the administration of EDTA Chelation Therapy.

15. The Respondent did not provide medical equipment at the Clinic needed to treat such medical complications.

DISCUSSION

16. In substance, Counts One and Two allege that the Respondent administered EDTA Chelation Therapy for Arteriosclerosis and that such medical treatment violates the statutory ban against illegal incompetant or negligent conduct and the improper use of legend drugs, under Section 20-13c of the General Statutes, which in pertinent part provides that:

> The board is authorized to restrict, suspend or revoke the license or limit the right to practice of a physician in accordance with section 19a-17, when the board finds that such physician is unable to practice medicine with reasonable skill or safety for any of

> the following reasons: ... 4) illegal incompetent or negligent conduct in the practice of medicine; (5) possession, use, prescription for use, or distribution of controlled substances or legend drugs, except for therapeutic or other medically proper purposes;..."

17. The Respondent, while in the course of his profession between April 28, 1982 and January 1, 1984, administered EDTA Chelation Therapy to his patients.

18. This practice is gravely dangerous and constitutes a medically inappropriate unapproved and improper practice as evinced by the respondent never having received FDA approval or an investigator's license to administer chelation therapy, and uses patients as his/her own control. Standards of professional conduct require medical competance and propriety in applying the healing arts to the public.

19. The administration of EDTA chelation therapy that has received FDA approval is limited to use on persons suffering poisoning by heavy metals such as lead or calcium and is based on the principle in which certain compounds or chelating agents are introduced into the bloodstream to form bonds with the metals.

20. In a person whose bloodstream contains average (normal) amounts of calcium, administration of I.V. EDTA will

decrease the levels of ionized calcium and result in tetany, cardiac arrhythmias, convulsions, and respiratory arrest. It can also cause renal tubular necrosis and renal failure, permanent renal damage, bone marrow depression, and prolongation of the prothrombin time.

21. The use of EDTA Chelation Therapy in persons who have developed arteriosclerotic plaques can be life threatening if loosened material carried by the bloodstream lodges elsewhere, precipitating emboli, strokes or heart attacks.

22. Based on the evidence presented the medical practices of the Respondent in administering EDTA Chelation Therapy to his patients demonstrates that he has violated Section 20-13c of the General Statutes proscribing illegal incompetant negligent or improper medical conduct.

23. Count three alleges that the Respondent promoted and/or advertised the use of EDTA Chelation Therapy for arteriosclerosis in violation of Section 21a-114 of the General Statutes which in pertinent part provides that "the advertisement of a drug or device in representing it to have any effect "...in arteriosclerosis...shall also be deemed to be false..."

24. The Board determined that there was insufficient credible evidence presented to it to the Board to sustain this allegation which therefore is hereby dismissed.

ORDER

25. With respect to Respondent's Motion to Dismiss, it is the unanimous decision of the Board that sufficient reliable and probative evidence was adduced at the June 5, 1984 hearing to enable it to form a reasonable inference that the Respondent was engaged in the medical practice of administering EDTA Chelation Therapy to his patients in violation of Section 20-13c of the General Statutes; therefore the Motion to Dismiss is hereby denied.

26. It is the unanimous decision and order of the Board that the Respondent be hereby placed on probation for five (5) years; that the Respondent no longer practice chelation therapy for the treatment of arteriosclerosis unless and until it

becomes a treatment approved by the Federal Drug Administration; that this prohibition to practice chelation therapy be subject to review upon completion of the probation; that he be fined in the amount of one thousand dollars ($1,000.00) and that he submit a semi-annual affidavit to the Board indicating that he is complying with the conditions of the probation.

27. The Board herewith advises the Department of Health Services of the State of Connecticut of this decision and directs that the registration license of the Respondent be placed on probation or five (5) years in accordance with the conditions set forth herein.

Dated at Hartford Connecticut this 15th day of December

CONNECTICUT BOARD OF
MEDICAL EXAMINERS

By: Henry Kennix MD
Henry Kannix, M.D., Chairman

STATE OF CONNECTICUT

DEPARTMENT OF HEALTH SERVICES

DIVISION OF MEDICAL QUALITY ASSURANCE

| | | |
|---|---|---|
| DEPARTMENT OF HEALTH SERVICES | * | CONNECTICUT MEDICAL EXAMINING BOARD |
| v. | * | |
| | * | 12 OCTOBER 1984 |
| ROBERT A. HARRIS, M.D. | * | |
| LICENSE NO. 21821 | * | |
| CASE NO. 830907-03-055 | * | |

# HEARING BRIEF OF THE DEPARTMENT

## I PRELIMINARY

The Department hereby submits this brief in support of its position that the charges against respondent Harris have been proven. This Memorandum is in four sections: a statement of the facts, a brief review of the case of the Department, a review of the rebuttal case of the respondent and a conclusion. References to the transcript of the hearing are denoted as (Tr.___ ), references to Department Exhibits are (Dept. Ex _____ ), and to Respondent's Exhibits are (Resp. Ex ____ ). Items in the Appendix to this brief are (App ___ ).

Due to the technical nature and the length of the titles of the articles, the exhibits, when referenced, will not be listed by name but will be identified only by the exhibit number or letter. The exhibits will be referenced as indicated in the transcript (Tr. 191 and 192)

## II FACTS

During the winter of 1982-1983, Robert A. Harris established the Harris Clinic in Stafford Springs, Connecticut. On 8 September 1983 an investigator for the Department interviewed Dr. Harris regarding his use of EDTA Chelation Therapy.

Pursuant to §4-182(c) of the General Statutes of Connecticut a compliance conference was scheduled for 2 December 1983. The respondent, through his counsel John Burgess, twice requested continuances of this conference, arguing that Dr. Harris, in response to the 28 October 1983 letter, had closed the Harris Clinic and was in the process of selling his house and moving out of Connecticut. Attorney Burgess did respond to the 6 February 1984 letter (Dept. Ex 1) and a compliance conference by three way telephone call was arranged for 3 p.m. on 17 February 1984. Respondent never called.

In April of 1984 a Statement of Charges issued against respondent and a hearing was scheduled for 1 May 1984. At the request of respondent's prior counsel, the Connecticut Medical Examining Board granted a continuance of the hearing. The hearing was held on 5 June 1984 with respondent and his present counsel in attendance.

III DIRECT CASE OF THE DEPARTMENT

Arnold Katz, M.D., a professor at the University of Connecticut School of Medicine, was the first witness for the Department. Dr. Katz testified that he is head of the Cardiology division at the Medical School and is governor for the State of Connecticut for the American College of Cardiology.

The Department had contacted the American College of Cardiology and the Connecticut State Medical Society to request a spokesperson for the position of each association. Both associations indicated that Arnold Katz was in the best position to testify about Chelation Therapy (Dept. Exhibit 3 and 4).

The position statement of the American College of Cardiology is the best summation of the position of the Department:

"There is insufficient scientific evidence to justify the application of Chelation Therapy for Atherosclerosis on a clinical basis. (emphasis added) At the present time, therefore, Chelation for atherosclerosis should be applied only under on investigational protocol. "(Tr. 21)

Dr. Katz testified that he has since 1964 continuously held grants from the federal government to study calcium and is currently funded at half a million dollars a year to study calcium use in the heart. The record will reflect the position of the Department as to respondent's objection that Dr. Katz is not an expert on EDTA Chelation Therapy for atherosclerosis. Dr. Katz testified to his personal experience with EDTA and other calcium chelators and explained why he would neither use nor endorse this experimental therapy.

This witness first addressed his testimony to the broad principles of scientific research and explained how the proponents of EDTA Chelation Therapy have failed to establish the efficacy or safety of this treatment according to currently accepted standards of medicine:

1. There are no controlled studies or trials of therapy that have been done which meet F.D.A. standards for drug approval.

2. There are no animal trials wherein animals are used as models for human response.[1]

3. Absent controlled studies or animal models a researcher could propose a physiological or anatomical rationale or mechanism to explain positive clinical results. The ability of EDTA to "scavenge" calcium from the body is the main argument of the proponents of EDTA Chelation Therapy.

Under direct exam, Dr. Katz elaborated upon this last rationale for Chelation Therapy which attributes the subjective clinical improvements to removal of calcium from the body. (Dept. Ex 4). For the sake of judicial economy, Dr. Katz's testimony on calcium will be discussed only briefly.

1. An EDTA treatment, given according to Academy of Medical Preventics protocol, provides 10 millimoles of EDTA. The available calcium, essentially the extracellular calcium in the body, totals 33 millimoles. Therefore one treatment will remove one third of the available calcium. This is about one half of the minimum daily dietary requirement for calcium. Therefore one treatment is equivalent to reducing by half the dietary intake of calcium for that day.

2. There is much evidence that the reservoir of bone calcium will be mobilized out of the bone to replace any reduction in serum calcium. This bone calcium can enter the serum at twenty-five times the rate of the EDTA infusion.

3. There is no evidence that EDTA preferentially binds with the calcium in arteriosclerotic plaque. [2] Calcium is only a minor component of atheromas. The real "villian" in arteriosclerotic plaques is cholesterol.

It is for these reasons that Dr. Katz, an expert in cardiology and calcium use in the body, neither uses nor recommends Chelation Therapy for arteriosclerosis. This is the position of every recognized medical society. In the position paper of respondent (Resp. Ex F) and during the cross-exam of Dr. Katz, coronary artery surgery is attacked as unjustified (App. 1). The proponents of Chelation Therapy argue that the proof of efficacy required of EDTA is unreasonable.

This argument is untenable. EDTA Chelation Therapy is being held to the standard of all new drugs or new drug usages as required by F.D.A. To complain that new surgical procedures do not have to be proven to the same standard begs the question. One author did point out that ". . . there is no F.D.A. for the surgeon." (App. 2) Since the function of this brief is not to justify surgical procedures, suffice it to say that the surgeon usually has a physiological or anatomical rationale for the procedures he or she implements.

Christine Van Ness, a medical facilities inspector for the Department of Health Services, testified that she is a member of the Sun Valley Beach Club in Stafford Springs, Connecticut and that she once visited the premises of respondent. Ms. Van Ness bought a book on Chelation Therapy from Dr. Harris. The book was identified by the witness and entered as a full exhibit (Dept. Ex. 5).

Ellen Marmer, M.D. a specialist in pediatric cardiology, also visited the Harris Clinic. Dr. Marmer is a member of the Sun Valley Beach Club and, because of her medical specialty, is familiar with the uses and administration of EDTA as a chelator for lead poisoning in children. Dr. Marmer did not speak with respondent but did have an opportunity to observe the activity in the premises. As Dr. Marmer was not allowed to testify as to the conditions at the clinic, this is the appropriate point in the brief to address respondent's motion to dismiss.

The Department cannot plan its case on the assumption that the respondent will take the stand. The proof of the elements of the charges must be apparent from the direct case of the department. Respondent Harris did not take the stand and respondent's attorney moved to dismiss for failure to establish a prima facie case. The proof of a case in administrative law is not held to the criminal standard in that each and every element of the crime must be proven

beyond a reasonable doubt. Well recognized principles of law require that the Department: (1) prove that respondent was performing Chelation Therapy and (2) prove in what manner this was negligent or incompetent.

In that the Board reserved its decision upon respondent's motion to dismiss and could theoretically decide to issue an order dismissing this case, it is incumbent upon the Department to make an offer of proof as to the testimony of Ellen Marmer. Dr. Marmer testified, to the extent allowed by the Board, as to her knowledge about the performance of Chelation Therapy by respondent.

If allowed, Dr. Marmer would have testified to the conditions of the premises. This is relevant in that the Department advocates the position of the American College of Cardiology that Chelation Therapy should be considered investigational and is not appropriate for clinical treatment. Robert Harris did not take the stand. Only by other, indirect witnesses could the Department establish that respondent was performing Chelation Therapy in a clinical setting.

The testimony of Chris Van Ness and the sale of the book on Chelation Therapy tends to prove that Robert Harris practiced Chelation Therapy in a clinical setting (Tr. 13). Up until the point that respondent's objection was sustained (Tr. 83 and 84), Ellen Marmer's testimony tended to prove that respondent was practicing Chelation Therapy in a clinical setting. The Department's offer of a WFSB videotape of respondent and respondent's ad for Chelation Therapy in the yellow pages were both refused by the Board. Similarly, these exhibits would tend to prove that Robert Harris employed EDTA Chelation Therapy in a clinical setting.

Ellen Marmer was able to testify that she did observe respondent administering I.V. fluids to his clients. The I.V. solutions were dextrose and water, the

bottles did not carry additive labels and the solutions were yellow (Tr. 84). The position of the Food and Drug Administration on Chelation Therapy for arteriosclerosis was delineated in the testimony of Investigator Dan Rowland. This testimony was significant because of the introduction of the F.D.A. press release (Dept. Ex. 6) and for Dan Rowland's testimony that:

1. No IND or new drug application has been filed for EDTA since 1953 (Tr. 115) and
2. The F.D.A. does allow physicians to prescribe approved drugs for unapproved uses.

The Department does not dispute that drugs in the market for one indication are often prescribed for other purposes. Motrin (pre-menstrual syndrome), Inderal (migraine headache) and Clonidine (narcotic addition withdrawal) are all examples of drugs being successfully used for new indications. These new uses for approved drugs are not based on the whim of the practitioner. Alfred Soffer, M.D., who wrote the book on Chelation Therapy [3], agrees with the principle espoused by respondent but states that the prescribing must meet the standard of care in the community (app. 3). The prescribing should be based on reports found in scientific peer review journals, which studies should include the data of carefully designed clinical trials.

## IV DIRECT CASE OF THE RESPONDENT

Garry Gordon, M.D. was the only witness presented by respondent. Dr. Gordon is co-author of the "The Chelation Answer" (Dept. Ex. 5) and is probably the leading proponent of Chelation Therapy in the U.S. (Tr. 117). This witness testified that he had a positive opinion about Chelation Therapy for arteriosclerosis (Tr. 142) and that this opinion was based on:

". . . my personal experience in the treatment of patients that I personally treated and in those patients I, too, was as skeptical about anything that you really aren't familiar with, so the patient's in my practice, it was subjected to before and after measurements. . . " (Tr. 142)

Attorney Seeley used Dr. Gordon's testimony to lay a foundation for the introduction of several articles. This brief will address those articles separately from Garry Gordon's testimony. But first, one final issue as regards respondent's motion to dismiss needs to be addressed.

The Department at this point in the hearing had carried the burden of persuasion on the issue of performance of Chelation Therapy by respondent. Sufficient evidence was presented to make the reasonable person believe Robert Harris was administering EDTA. All Attorney Seeley had to do to rebut the case of the Department on this issue was to put respondent on the stand and ask him "Did you perform EDTA Chelation Therapy?"

Robert Harris did not take the stand. Respondent offered no evidence to refute the evidence of the Department that Dr. Harris was administering EDTA to treat arteriosclerosis. Therefore the Board should conclude that respondent did perform Chelation Therapy for arteriosclerosis.

The second issue the Board must decide concerns the propriety of the treatment. The Board must determine what is the proper protocol, if any, under which EDTA can be used for this purpose. The testimony and exhibits of the Department clearly indicate that EDTA for the treatment of arteriosclerosis should be ". . . applied only under an investigational protocol." (Tr. 21).

No evidence was presented by respondent of any grants or research sponsors for his work. No evidence of any protocol at all was presented. Respondent's only witness testified that Robert Harris was not certified as a specialist by the American Academy of Medical Preventics (Tr. 171)

The Board did hear testimony about the premises in which Robert Harris administered EDTA. The inescapable conclusion is that Dr. Harris was using EDTA in a clinical setting. Since respondent presented no evidence to refute this proof the Board should find for the Department on all counts in the statement of charges.

The testimony of Garry Gordon is useful only insofar as it convinces the Board that the medical establishment is wrong and that EDTA Chelation Therapy may be used in a clinical setting without an investigational protocol.

The issue we are concerned with does not lend itself to resolution by the testimony of any one witness. The Board is being requested, as physicians and as scientists, to judge a therapy. A decision on this issue must be rendered in an objective manner by the method that any scientist would use: a review of the reliable journals and other literature (App. 3).

It is for these reasons that the Department requests that the testimony of Garry Gordon be given only slight weight. No purpose will be served by dissecting Dr. Gordon's testimony but some points do need to be briefly touched on:

1. "Q - Do you know whether or not there have been any type of controlled studies? A - As I indicate, the Academy requires members to test the patients before and after in every instance so that we consider the patient serving as his own control . . ."

Dr. Gordon has let his zeal for this therapy overcome his training: this statement is both an oxymoron and a patent absurdity. "Control" in research means the patient group that does not get the treatment, the experimental group gets the treatment.

2. The purported lack of funding for EDTA research (Tr. 152 and 153) is not an ethical justification for continued experimentation on patients. The witness makes an unsupported assertion that a research study of EDTA will cost "thirty to fifty million dollars" and uses this to create a self-fulfilling prophecy as to why no IND has ever been filed with FDA.

3. Q - "Why do you use the double - lined (sic - should be "double - blind") method? A - Because we have a test that we want the pharmaceutical manufacturer who can make a million dollars a year last year in Tagamet.

   Q - I am not really sure if you are answering my question.

   A - The reason it is there is to keep the foil hidden. We went into too much of an over reaction of the thalidamide (SIC) tragedy. We do not put that requirement on a surgeon who introduces a new procedure.

   Q - So you think double - (blind) is not necessary?

   A - I think double - (blind) has got basic defects in it which we won't have time to get into today." (Tr. 174)

Double blind testing is well accepted as a principle of scientific research (App. 2). This principle was a pillar of the scientific method long before the use of Thalidomide in Europe was found to cause fetal deformity.

Dr. Gordon referred to several journal articles during his testimony. The response in this brief will be confined only to those articles which were introduced as full exhibits.

EXHIBITS OF RESPONDENT

A. "EDTA Chelation Therapy for Arteriosclerosis: History and Mechanisms of Action" Osteopathic Annuals (reprint) February 1976.

An overview, rather than a research report, this article asserts that calcium leaves the arteriosclerotic plaque in response to the uptake of serum calcium by EDTA. There is no cite for this proposition. Previous studies showing a clinical improvement in angina are mentioned but these studies are subjective and anecdotal, without controls or double blind methodology.

The subjective beneficial effects of Chelation Therapy can be attributed solely to the "holistic" treatments that proponents of Chelation Therapy prescribe along with EDTA Chelation. This is both problematic and self-defeating because recognized clinical improvements in symptoms can never properly be attributed to Chelation if all the patients also follow the therapists advice to stop smoking, improve nutrition, increase exercize and begin to practice biofeedback. Persons following all this advice might improve as well with a penny taped to their chests as they would with EDTA Chelation Therapy.

Paradoxically, this article argues that the doctrine of informed consent, which requires that all available therapies be offered to a patient, mandates that Chelation be one of the choices. Yet, the patients who are to receive Chelation are not told that this therapy is (1) an unapproved use of EDTA, (2) experimental, (3) dangerous and (4) you, the patient, are a guinea pig without a purpose because the "experiment" has no controls.

The article recognizes that EDTA preferentially binds with circulating unbound serum calcium, as testified to by Dr. Katz. The article further agrees that the bones can put out calcium at 50 mg/minute, seventy times the rate that Chelation can bind it. All of this is stated to demonstrate how safe EDTA is. This article fully corroborates the testimony of Arnold Katz, M.D.

B. "Abnormal Mitochondrial Oxidative Phosphorylation of Ischemic Myocardium Reversed by $Ca^{+2}$ - Chelating Agents" Peng, et al J. of Molecular and Cellular Cardiology (1971) 9, 897 - 908

The gist of this article is that phosphorylation of ADP to ATP by mitochondria appears to be inhibited by ionic $Ca^{+2}$. The administration of EDTA will counteract or reverse this inhibition. This is a report of a well-designed research trial published in a refereed journal.

There is no mechanism or explanation offered that logically links up this well documented effect of EDTA, the ability of EDTA to facilitate the conversion of ADP to ATP, with any observed clinical symptom improvement. This is the type of research that will be required if Chelation is to ever join the ranks of accepted therapies but it is only one brick - it takes many bricks to make a building.

C. "An evaluation of the Nephrotoxicity of EDTA and DTPA in the Rat" Doolan, et al Toxicology and Applied Pharmacology 10, 481 - 560 (1967).

During his testimony Garry Gordon admitted that EDTA can be harmful to the kidneys: "It can cause a renal tubular necrosis because edetate is clearly more" (Tr. 158). But, Dr. Gordon also contradicts Dr. Marmer's testimony that EDTA is nephrotoxic (Tr. 157). This is the article to which Dr. Gordon was referring in his testimony.

At the risk of oversimplification, the article states:

1) tubular vacuolization is the purported mechanism of EDTA nephrotoxicity
2) kidney function is not impaired by vacuoles because there is no significant elevation of serum creatinine or urea nitrogen, nor is there any impairment in excretion of $^{14}$C-labeled Chelates.
3) vacuolization can occur independent of changes in the metal spectrum.
4) Kidneys with pre-existing or evolving damage due to vitamin $D_2$ or lead intoxication did not appear to be more vulnerable to the action of Chelates.
5) Sucrose and mannitol produce similar vacuoles.

In summary, the conclusion of the article is as Dr. Gordon stated: the advice to follow renal function with the administration of EDTA is sound, but the label "nephrotoxin" is unjustified. As Attorney Seeley so cogently observed in another matter, what we have here is a distinction without a difference.

In any event, the issue of kidney damage or impairment is but one item in a laundry list of EDTA hazards (Appendix 4) and the hazards of EDTA are only one part of the reason why EDTA should be done only in an investigational, not a clinical setting.

D. Calcium Antagonism in Heart and Smooth Muscle Albrecht Fleckenstein, M.D. John Wiley and Sons, NY 1983.

This exhibit consists of a variety of materials (preface, contents, introduction) from a text book. The only substantive portion is two pages (130 & 131) from the text chapter titled "Prevention by Calcium Antagonists of Deleterious Calcium Overload: A new Principle of Cardioprotection".

EDTA is not a calcium antagonist, it is a Chelating agent. This exhibit is without relevance and should be stricken from the record. Alternatively, respondent could submit an offer of proof for p. 121 from this exhibit (Tr. 155).

E. "Free Radical Pathology in Age-Associated Diseases: Treatment with EDTA Chelation, Nutrition and Anti-oxidants." Cranton and Frackelton J. of Holistic Medicine vol. 6, No. 1 Spring/Summer, 1984.

The authors, the past vice-president and president elect of the American Academy of Medical Preventics, have written a retrospective justification of EDTA Chelation Therapy. EDTA is touted as a therapy for arteriosclerosis, dementia, cancer, arthritis and numerous other age related diseases.

Free radicals are familiar to the chemist and theories abound as to the relationship between environmental free radicals and aging. This article furthers this hypothesis by stating that the activity level of the free radical control enzyme superoxide dismutase (SOD) is directly proportional to the mammalian life span. Humans have the highest level of SOD. Therefore, life expectancy seems to be highly dependent on free radical regulation. No cite is given for this observation except to a lecture at an AAMP convention. Similarly Progeria, with a citation to a paper read at an AAMP convention, is observed to be a disease resulting from a hereditary absence of free radical protective enzymes.

Schizophrenia and Alzheimer's disease are also attributed to free radical pathology. The authority for this assertion are papers read before a meeting of the Orthomolecular Society.

The claimed mechanism by which EDTA reverses atherosclerosis is by inhibiting free radicals. If free radical protection is inadequate, the vessel walls become excessively attractive to platelets causing atherosclerosis. The only cite is to the Journal of Holistic Medicine.

This article is not a scientific treatise nor is it a journal article. This is a broad review or overview of the topic. This exhibit cites the same studies that all the other articles by proponents of Chelation Therapy cite. This cross citation to each others work builds up an impressive pile of cites. This is consistent with Gresham's Law of Therapeutics (App. 2). This exhibit concludes that "lasting benefits are possible from intravenous EDTA in conjuction with other preventive nutritional and therapeutic measures." The therapeutic effects, if any, of EDTA will never be proven if EDTA is not tested by itself without the confounding effect of other therapeutic interventions.

F. Position Paper of American Academy of Medical Preventics by its counsel, Selley, Savidge and Aussem - undated. (15 pages - unsigned)

Most of the arguments in respondent's position paper are either irrelevant to this forum, such as restraint of trade; or are simply wrong, such as the statement that Connecticut law requires that physicians utilize full methods of diagnosis and treatment. Connecticut law requires that physicians practice competently and safely, there is no prescriptive requirement that they must utilize the most comprehensive treatment available. Likewise, the assertion that failure to suggest Chelation Therapy could expose the physician to criminal liability is without foundation in law.

The only real issue raised in respondents position paper concerns State Board of Medical Examiners v. Rogers 387 So 2d 937 (Florida S. CT. 1980) App. 5). The Florida Supreme Court upheld the lower count finding that the Florida Board

of Medical Examiners had unreasonably and arbitrarily used its power to restrict the practice of Dr. Rogers.

This Board is not bound by Rogers. This Board, unlike Florida, has ample evidence that EDTA can be harmful and fatal (App. 4). The problem with the Rogers decision is that the court used sound legal reasoning based on sloppy and inaccurate science. The decision is replete with error: "Therosclerosis" for atherosclerosis, "vasil dilator" for vasodilator.

The Rogers court accepted without examination the arguments of proponents of Chelation Therapy. The court stated as fact that EDTA binds ionic $Ca^{+2}$ in blood causing temporary hypocalcemia which is rapidly replaced by "...calcium in precipitate form ionizing in the bloodstream". This statement makes no sense.

The court continued to observe that this calcium, called metastatic calcium, comes from the walls of blood vessels and from the calcium precipitate in every cell. Statements of proponents of Chelation Therapy are repeated without examination or corroboration:

> "Many experts believe that the metastatic calcium sludge in each cell causes the cells to gradually disfunction." "Chelation therapy is specifically intended to treat arteriosclerosis and atherosclerosis and other generalized circulatory deficiencies caused by excess $Ca^{+2}$ in the circulating vessels."
>
> "The record is replete with claimed instances of dramatic restoration of blood flow."

Even if the decision of the Florida court were precedent for the case against respondent, this Board has ample testimony and reliable exhibits which indicate that the Connecticut Medical Examining Board can restrict the use of Chelation Therapy consistent with the position of the American Academy of Cardiology. California dealt similarly with this issue in 1978 (App. 6).

Conclusion

This Board has heard ample evidence upon which it could find that:

1. Respondent Robert Harris practiced Chelation Therapy for the treatment of Arteriosclerosis.
2. Respondent Robert Harris practiced Chelation in a clinical setting.

This Board should further find that this conduct is negligent or incompetent practice by a physician.

OCT 17 1984
Date

David J. Pavis
Staff Attorney
Division of Medical Quality Assurance

cc: Henry Mannix, M.D.
Christie McLeod, M.D.
Joan Blakeslee, M.D.
Shirley Williams, M.D.
Thomas Spackman, M.D.
Attorney Harvey Katz
Paula Savary
AAG Robert Statchen
Gregory Seeley, counsel for respondent

## FOOTNOTES

1. The only reference or citation given to animal research (Resp. Ex. A) cites nontoxic life extension in research animals. The animals in question are rotifers; minute, multicellular aquatic organisms.

2. Although used interchangeably, arteriosclerosis and atherosclerosis are not synonymous. Arteriosclerosis is a generic term covering a number of diseases of blood vessels. Atherosclerosis, the most important of these diseases, is an arterial lesion characterized by intimal thickening due to localized accumulations of lipids, known as artheromas (The Merck Manual-Twelfth Edition - 1972 - p. 363).

3. Chelation Therapy Alfred Soffer, M.D. et al, Charles C. Thompson Publishing, Springfield, Ill. 1964.

## APPENDIX


1. "Myocardial Infarction and Mortality in the Coronary Artery Surgery Study (CASS) Randomized Trial" N. Engl. J. of Med. March 1984.

2. "Randomized Controlled Clinical Trials: The Behavioral Case." David H. Spodick, M.D., DSc JAMA Special Communication 23 April 1982, Vol. 247, No. 16.

3. "Chelation Clinics: An Abuse of the Physician's Freedom of Choice" Editorial by Alfred Soffer, M.D. Chest Vol. 86, No. 2, August 1984.

4. Public Health Service Assessment of Ethylene Diamine Tetra Acetic Acid Chelation Therapy for Atherosclerosis, 1981.

5. State Board of Medical Examiners v. Rogers 387 So.2d 937 (Florida Sct. 1980).

6. "Notice to All California Physicians" 6 Nov. 1978 State of California Department of Health Services.