

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 incompetent 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 competence 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 incompetent 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 November

CONNECTICUT BOARD OF
MEDICAL EXAMINERS

By: Henry Mannix M.D.
Henry Mannix, M.D., Chairman