

**STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
BUREAU OF HEALTHCARE SYSTEMS**

In re: Robban Sica, M.D.

Petition No. 2002-0306-001-043

CONSENT ORDER

WHEREAS, Robban Sica, M.D. of Trumbull, Connecticut (hereinafter "respondent") has been issued license number 026453 to practice as a physician and surgeon by the Department of Public Health (hereinafter "the Department") pursuant to Chapter 370 of the General Statutes of Connecticut, as amended; and,

WHEREAS, the Department alleges that:

1. Respondent has treated many patients with Ethylene Diamine Tetracetic Acid (EDTA). Respondent's use of EDTA has violated the applicable standard of care in that:
 - a) she has used it for conditions for which it is not indicated;
 - b) she has used it for diagnoses based on faulty test methodology;
 - c) she has used it based on incomplete and/or inaccurate informed consent

2. Respondent has administered Dimercapto Propane Sulfonic Acid (DMPS) as an agent to mobilize various metals for purpose of measuring body burden of metals and also has administered it as a chelator. Neither the United States Food And Drug Administration (hereinafter "FDA") nor the Connecticut Department of Consumer Protection (hereinafter "DCP") has approved DMPS for any purpose.

3. The above described facts, if proven, would constitute grounds for disciplinary action pursuant to the General Statutes of Connecticut, §20-13c(4).

WHEREAS, respondent, in consideration of this Consent Order and for the purpose of resolving the Department's statement of charges against her, has chosen not to contest the above allegations of wrongdoing but, while admitting no guilt or wrongdoing and specifically denying that her practice violates standard of care, agrees that for purposes of this or any future proceedings before the Connecticut Medical Examining board (hereinafter "the Board"), this Consent Order shall have the same effect as if ordered after a full hearing held pursuant to §§19a-10, 19a-14 and 20-13c of the General Statutes of Connecticut.

NOW THEREFORE, pursuant to §§19a-14, 19a-17, and 20-13c of the General Statutes of Connecticut, respondent hereby stipulates and agrees to the following:

1. Respondent waives her right to a hearing on the merits of this matter.
2. Respondent shall comply with all state and federal statutes and regulations applicable to her licensure, including but not limited to the Food, Drug and Cosmetics Act of the United States and regulations promulgated thereto and the Connecticut Food, Drug and Cosmetics Act and regulations promulgated thereto, and to all applicable statutes and regulations pertaining to the business organization of professional practices. With specific reference to chapter 594a of the Connecticut general statutes, while specifically denying that her ownership of shares and/or her appointment as an officer of professional corporations in other states violated any laws of those states, respondent agrees that she shall not at any time own shares or serve as an officer of any professional corporation or other form of medical practice in which she does not conduct a substantial practice of patient care.
3. Respondent shall not use DMPS for any purpose until such time as the FDA or the DCP approves its use or until its effectiveness and safety have been demonstrated by scientifically controlled and published human studies and then only for the specific conditions studied and at the doses found effective and safe in said studies.

4. Respondent's license shall be placed on probation for a period of one year under the following terms and conditions:

- a. Respondent shall successfully complete a duly certified Advanced Cardiac Life Support course within the first six months of probation. Respondent shall report her successful completion of said course within fifteen days of completing the course.
- b. Respondent shall not diagnose heavy metal toxicity in general, or any particular heavy metal toxicity, by use of a laboratory test that measures metal levels in a provoked sample against a reference range based on unprovoked samples;
- c. Respondent shall only use EDTA solutions and supplements that are compounded according to compounding practices outlined by the United States Pharmacopoeia ("USP") and shall maintain such records as are necessary to demonstrate compliance with any such USP practices. At the present time, respondent uses premixed solutions and does not perform any further compounding. If respondent uses premixed solutions, she shall supply the Department with the compounding protocol used by the manufacturer or distributor of such solutions, provided such records can be reasonably obtained. If respondent compounds her own solutions, the Department may obtain a blind review by a hospital pharmacist of any compounding protocol respondent uses, and respondent shall comply with any recommendations said reviewer makes.
- d. Respondent shall establish an acceptable baseline kidney function of each chelation patient by Blood Urea Nitrogen and creatinine testing, and shall perform kidney function testing at appropriate intervals during the course of chelation care. Respondent shall monitor the effect of the EDTA on other co-morbid conditions, such as diabetes, by performing appropriate tests. Respondent shall

adjust the dosage according to the age, gender, weight, and co-morbid conditions of the patient, in accordance with FDA warnings, by using an appropriate formula.

- e. Respondent shall not commence chelation without obtaining the patient's written consent on the attached forms. Respondent shall not vary the forms in any way, and shall not embed them in any other document.
- f. Respondent shall chart all adverse events. For purposes of this consent order, an "adverse event" is a discreet occurrence of an unintended or unanticipated injury or illness during EDTA treatment or associated with or caused by the EDTA treatment.
- g. Respondent shall inform the Department of any hospitalization or death that occurs within 24 hours of the commencement of any individual EDTA transfusion. Respondent shall report to the Department any patient who has a measured lead or mercury level specified by the Department regulations. At present, section 19a-36-A3 of the Regulations of Connecticut State Agencies requires a report of any patient found to have a blood lead level greater than or equal to 10 micrograms per deciliter and a mercury unprovoked urine level of greater than or equal to 35 micrograms per gram of creatinine or a mercury blood level of greater than or equal to 15 micrograms per liter.
- h. Respondent shall obtain at her own expense, the services of a physician, pre-approved by the Department (hereinafter "supervisor"), to conduct a random review of twenty of respondent's patient records for patients who she has treated by chelation, regardless of the particular chelator. In the event respondent has fewer than twenty such patients, the supervisor shall review all of respondent's chelation patient records. Respondent's supervisor shall be knowledgeable about

chelation and the protocols used by respondent, but does not have to use chelation or respondent's protocols in his or her practice.

(1) Respondent's supervisor shall conduct such review and meet with her not less than once every month for the first six months of her probationary period and not less than quarterly for the remainder of the probationary period.

(2) The supervisor shall have the right to monitor respondent's practice by any other reasonable means which he or she deems appropriate. Respondent shall fully cooperate with the supervisor in providing such monitoring.

(3) Respondent shall be responsible for providing written supervisor reports directly to the Department monthly for the first six months of the probationary period and quarterly for the remainder of the probationary period. Such supervisor's reports shall include documentation of dates and duration of meetings with respondent, number and a general description of the patient records and patient medication orders and prescriptions reviewed, additional monitoring techniques utilized, and statement that respondent is practicing with reasonable skill and safety and in compliance with this consent order.

5. All correspondence and reports are to be addressed to:

Bonnie Pinkerton, Nurse Consultant
Department of Public Health
Division of Health Systems Regulation
410 Capitol Avenue, MS #12HSR
P.O. Box 340308
Hartford, CT 06134-0308

6. All reports required by the terms of this Consent Order shall be due according to a schedule to be established by the Department of Public Health.

7. Respondent shall pay all costs necessary to comply with this Consent Order.

8. Any alleged violation of any provision of this Consent Order may result in the following procedures at the discretion of the Department:
 - a. The Department shall notify respondent in writing by certified mail, return receipt requested that the term(s) of this Consent Order have been violated, provided that no prior written consent for deviation from said term(s) has been granted.
 - b. Said notification shall include the acts or omission(s) which violate the term(s) of this Consent Order.
 - c. Respondent shall be allowed fifteen (15) days from the date of the mailing of notification required in paragraph 8.a. above to demonstrate to the satisfaction of the Department that she has complied with the terms of this Consent Order or, in the alternative, that she has cured the violation in question.
 - d. If respondent does not demonstrate compliance or cure the violation by the limited fifteen (15) day date certain contained in the notification of violation to the satisfaction of the Department, she shall be entitled to a hearing before the Board which shall make a final determination of the disciplinary action to be taken.
 - e. Evidence presented to the Board by either the Department or respondent in any such hearing shall be limited to the alleged violation(s) of the term(s) of this Consent Order.
9. In the event respondent violates any term of this Consent Order, said violation may also constitute grounds for the Department to seek a summary suspension of her license before the Board.
10. In the event respondent is not employed as a physician and surgeon for periods of thirty (30) consecutive days or longer, or is employed as a physician and surgeon less than twenty (20) hours per week, or is employed outside of the State of Connecticut, respondent

shall notify the Department in writing. Such periods of time shall not be counted in reducing the probationary period covered by this Consent Order.

11. Legal notice shall be sufficient if sent to respondent's last known address of record reported to the Office of Practitioner Licensing and Certification of the Bureau of Healthcare Systems of the Department and to Attorney Jacques Simon at his last known address or such other attorney as respondent may designate.
12. This Consent Order is effective on the first day of the month immediately following the date this Consent Order is accepted and ordered by the Board.
13. Respondent agrees that this Consent Order shall be deemed a public document, and the Department's allegations as contained in this Consent Order shall be deemed true in any subsequent proceeding before the Board in which her compliance with this Consent Order or with §20-13c of the General Statutes of Connecticut, as amended, is at issue. Further, respondent understands that unless the only discipline imposed by this Consent Order is a civil penalty, this action will be reported to the National Practitioner Data Bank and that all disciplinary actions will appear on her physician profile pursuant to Connecticut General Statutes 20-13j.
14. Any extension of time or grace period for reporting granted by the Department shall not be a waiver or preclude the Department from taking action at a later time. The Department shall not be required to grant future extensions of time or grace periods.
15. This Consent Order and terms set forth herein are not subject to reconsideration, collateral attack or judicial review under any form or in any forum. Further, this Order is not subject to appeal or review under the provisions of Chapters 54 or 368a of the General Statutes of Connecticut, provided that this stipulation shall not deprive respondent of any rights that she may have under the laws of the State of Connecticut or of the United States.

16. This Consent Order is a revocable offer of settlement which may be modified by mutual agreement or withdrawn at any time prior to its being executed by the last signatory.
17. Respondent permits a representative of the Legal Office of the Bureau of Healthcare Systems to present this Consent Order and the factual basis for this Consent Order to the Board. Respondent understands that the Board has complete and final discretion as to whether this executed Consent Order is approved or accepted.
18. Respondent has consulted with an attorney prior to signing this document.
19. The execution of this document has no bearing on any criminal liability without the written consent of the Director of the Medicaid Fraud Control Unit or the Bureau Chief of the Division of Criminal Justice's Statewide Prosecution Bureau. The Department is unaware of any such investigation.

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I, Robban Sica, M.D., have read the above Consent Order, and I stipulate and agree to the terms as set forth therein. I further declare the execution of this Consent Order to be my free act and deed.

[Signature]
Robban Sica, M.D.

Subscribed and sworn to before me this 31 day of January 2005.

[Signature]
Notary Public or person authorized by law to administer an oath or affirmation

CONNELLY LUNA
NOTARY PUBLIC
My Commission Expires April 30, 2008

The above Consent Order having been presented to the duly appointed agent of the Commissioner of the Department of Public Health on the 9th day of February, 2005, it is hereby accepted.

[Signature]
Marianne Horn, Director
Division of Health Systems Regulation
Bureau of Healthcare Systems

The above Consent Order having been presented to the duly appointed agent of the CMEB on the 15th day of February 2005, it is hereby ordered and accepted.

[Signature]
Connecticut Medical Examining Board

**PATIENT'S CONSENT FOR ETHYLEDIAMINETETRACETIC
ACID (EDTA) CHELATION**

***PATIENT IS TO READ AND INITIAL EACH PARAGRAPH
AND SIGN AT THE BOTTOM***

PATIENT'S NAME:

ADDRESS:

AGE: _____ **SEX:** Male Female

NAME AND ADDRESS OF PHYSICIAN

Malignancy, disease, illness or physical condition:

My physician has explained to me and I fully understand that EDTA chelation may or may not alleviate or cure the condition(s) for which it is offered and further that:

_____ (a) EDTA is administered either as a Calcium Disodium EDTA or Disodium EDTA.

_____ (b) The United States Food and Drug Administration ("FDA") has evaluated Calcium Disodium EDTA and approved its use only for the treatment of lead toxicity.

_____ (c) The United States Food and Drug Administration ("FDA") has evaluated Disodium EDTA and approved its use only for the treatment of hypercalcemia and digitalis toxicity. The FDA required label specifically states that Disodium EDTA is not indicated for treatment of systemic arteriosclerosis due to aging.

_____ (d) The FDA reviews the safety and effectiveness of particular uses of drugs but does not forbid physicians to use approved medications for off-label use.

_____ (e) No scientifically controlled studies (double-blind, randomized, placebo controlled trials) show that blood concentrations of lead less than 10 micrograms per deciliter cause any symptomatic illnesses or conditions. No scientifically controlled studies show that Calcium Disodium EDTA chelation of lead at blood concentrations less than 10 micrograms per deciliter will improve any symptom; several scientifically controlled studies show that chelation of lead at these concentrations does *not* improve mental or neurological functioning.

_____ (f) No scientifically controlled studies show that EDTA chelation is effective for the treatment of circulatory diseases, specifically including atherosclerosis, hardening of the arteries, vascular insufficiency or diabetes. Three scientifically controlled trials have concluded that Disodium EDTA treated these conditions no more effectively than placebo. The National Institutes of Health is presently conducting a nationwide study of the effectiveness of Disodium EDTA to benefit patients who have already suffered a heart attack (known as the Trial To Assess Chelation Therapy, abbreviated TACT).

_____ (g) There are no scientific studies that show that any chelator successfully removes heavy metals from the brain, and numerous scientific studies that show that chelators do not remove heavy metals from the brain. There are no scientific studies that show that chelation of heavy metals improves the symptoms of neurological dysfunction except in patients with extremely high levels of metal concentration. Scientific studies show that EDTA does not chelate organic compounds of mercury, such as methylmercury, which is the most common form of mercury in the human body.

_____ (h) The Connecticut Department of Public Health has determined that there is published scientific evidence that the use of EDTA chelation therapy may be harmful to a patient's health in that (a) patients may forego the use of medical treatments and drugs that controlled trials have shown are beneficial, and (b) that there have been reports of adverse effects from the use of Disodium EDTA including death, emergency hospitalization, and kidney damage. In addition, the Centers For Medicare and Medicaid

Services and the National Institutes of Health consider the use of EDTA chelation experimental. The Connecticut Department of Public Health warns that medical ethics typically do not permit a physician to use an experimental medication except in an approved, supervised experimental study, and that such studies generally do not charge a fee to participating patients. The Connecticut Department of Public Health notes that the United States Federal Trade Commission has issued an order to the American College For Advancement In Medicine ("ACAM") that advertising that EDTA chelation effectively treats atherosclerosis is misleading until such time as controlled studies demonstrate its effectiveness. **Therefore the Connecticut Department of Public Health strongly recommends that patients seek the advice of an internal medicine specialist or other specialist certified by a certification board recognized by the American Board of Medical Specialties for the condition being treated with EDTA chelation.** The American Board of Medical Specialties does not recognize the American Board of Chelation Therapists, the American Board of Clinical Metal Toxicology, the American Board of Chelation Therapy, and the Board Of Medical Toxicology.

_____ (i) Neither the American Medical Association, the American Osteopathic Association, the American College of Cardiology, the American Heart Association nor any other board or medical association that is recognized by the American Board Of Medical Specialties recommends the use of Calcium Disodium EDTA chelation for the treatment of any human disease, illness, malady or physical condition other than lead poisoning nor recommends the use of Disodium EDTA for the treatment of any human disease, illness, malady or physical condition other than hypercalcemia and digitalis toxicity;

_____ (j) The federal government, including Medicare and Medicaid, and most insurance companies do not pay for or reimburse for Disodium EDTA chelation for atherosclerosis or other cardiovascular illness.

_____ (k) My doctor will not begin Disodium EDTA chelation until three working days have expired after the date of my execution of this informed consent form;

_____ (l) My doctor will not begin Disodium EDTA therapy until it has been established by appropriate blood and urine tests that my kidney function is adequate. I understand that periodically I will be required to provide blood

and/or urine samples to monitor my kidney function during the course of treatment, and that my doctor will monitor the effect of the EDTA on other conditions such as diabetes by performing tests that may require me to provide blood or urine.

_____ (m) I may withdraw from EDTA therapy at any time

_____ (n) I have received a copy of the FDA approved product insert for Calcium Disodium EDTA or Disodium EDTA.

Physician

Date

I HAVE READ AND UNDERSTAND THE ABOVE. I HEREBY ELECT TO UNDERGO EDTA CHELATION UNDER THE PROTOCOL RECOMMENDED BY THE AMERICAN COLLEGE FOR THE ADVANCEMENT IN MEDICINE (ACAM).

Patient

Date