

☞ **05hr\_JC-Au\_Misc\_pt36h**



☞ Details: Audit requests, 2005

(FORM UPDATED: 08/11/2010)

## WISCONSIN STATE LEGISLATURE ... PUBLIC HEARING - COMMITTEE RECORDS

### 2005-06

(session year)

### Joint

(Assembly, Senate or Joint)

### Committee on Audit...

### COMMITTEE NOTICES ...

- Committee Reports ... **CR**
- Executive Sessions ... **ES**
- Public Hearings ... **PH**

### INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL

- Appointments ... **Appt** (w/Record of Comm. Proceedings)
- Clearinghouse Rules ... **CRule** (w/Record of Comm. Proceedings)
- Hearing Records ... bills and resolutions (w/Record of Comm. Proceedings)
  - (**ab** = Assembly Bill)                      (**ar** = Assembly Resolution)                      (**ajr** = Assembly Joint Resolution)
  - (**sb** = Senate Bill)                              (**sr** = Senate Resolution)                              (**sjr** = Senate Joint Resolution)
- Miscellaneous ... **Misc**

WISCONSIN DEPARTMENT OF  
REGULATION & LICENSING

Scott McCallum  
Governor  
Oscar Herrera  
Secretary



1400 East Washington Avenue  
PO Box 8935  
Madison WI 53708-8935  
Email: [dorl@drl.state.wi.us](mailto:dorl@drl.state.wi.us)  
Voice: 608-266-2112  
FAX: 608-267-0644  
TTY: 608-267-2416

September 7, 2001

Robert S Baratz MD  
159 Bellevue St  
Newton MA 02458-1834

COPY

RE: 97 MED 101, 97 MED 108

Dear Dr. Baratz:

I am enclosing an original and a copy of the Contract for Personal Service as an expert witness regarding Robert S. Waters, MD. Please date, sign, have witnessed and return the original contract to me not later than September 18, 2001. You may retain the copy for your files.

Payment will be at a rate of \$175.00 per hour conference fee, \$175.00 per hour appearance fee and \$30.00 per hour for secretary/assistant time.

**Please submit your billing monthly. You may expect payment within 4 to 6 weeks.**

In submitting your billing, please send to:

Wisconsin Department of Regulation and Licensing  
ATTN: Fiscal Office  
P.O. Box 8935  
Madison, WI 53708-8935

Feel free to contact me at (608) 267-5224 if you have any questions, or if payment is not received.

With respect,

DIVISION OF ENFORCEMENT

Dennie Petersen  
Administrative Staff Supervisor

Enclosures

**Enclosure 38**



97 MED 101 ✓  
97 MED 108

STATE OF WISCONSIN  
DEPARTMENT OF REGULATION AND LICENSING  
CONTRACT FOR PERSONAL SERVICES-EXPERT WITNESS/CONSULTANT

THIS AGREEMENT, is made and entered into this    day of September, 2001, by and between the State of Wisconsin (State) represented by its Department of Regulation and Licensing (Department) and Robert S. Baratz, MD (Contractor).

The Department deems it advisable to engage the services of the Contractor to furnish certain professional services in connection with a hearing on a complaint involving Robert S. Waters, MD, a licensee of the Medical Examining Board.

The Department has authority to engage such services, and

The Contractor has signified a willingness to furnish professional services to the Department as follows:

I. SCOPE OF SERVICES

- A. The Contractor shall provide the services (not limited by enumeration) described in this Section. The Contractor shall be responsible for the quality, quantity, and timeliness of the service. The Contractor shall manage the employees and other resources required to complete the contract.
- B. The services to be provided by the Contractor consist of acting as an expert witness in the matter of the Disciplinary Proceedings of Robert S. Waters, MD. The Contractor shall perform those duties assigned to the Contractor by the Department or board chairperson. These duties may include the following:
  - 1. Reviewing file materials to ascertain if the conduct under review met the minimum standards of conduct for the profession in question.
  - 2. Assisting the complainant's attorney in the preparation of evidence for a hearing concerning the above mentioned matter.
  - 3. Testifying on behalf of the complainant at a hearing held concerning the above mentioned matter.
- C. Nothing in this contract shall be construed to mean the Contractor will alter his or her testimony in any way so as to conflict with his or her true expert opinion.

## II. TIME FOR PERFORMING SERVICES

The Contractor shall complete a review of the file contents and provide the complainant's attorney, or that person's designee, with a written or verbal evaluation of the file contents as specified by the complainant's attorney within thirty (30) days from the date on which the file contents are received by the Contractor.

## III. PAYMENT FOR SERVICES

- A. Payment to the Contractor by the Department for services performed under Section I of this agreement shall be at a rate of one hundred seventy-five dollars (\$175.00) per hour for preparation and conference fees, and one hundred seventy-five dollars (\$175.00) per hour for preparation and appearance fees, payable to the Contractor upon submission to the Department of a bill stating the dates worked, the number of hours worked on each date, and the type of service performed. The types of services which will be paid are: conference services, hearing services, preparation for conference and hearing services, and travel time. Travel time is paid at the rate applicable to the purpose of the travel (i.e., travel time to and from a conference is paid at the conference rate; travel related to an appearance at a hearing or deposition is paid at the appearance rate). **Dr. Baratz will be reimbursed at a rate of thirty dollars (\$30.00) per hour for his secretary/assistant's time.**
- B. Expenses Reimbursable. Actual and necessary expenses incurred by the Contractor for travel, meals, and lodging shall be reimbursed by the Department upon receipt of an invoice requesting reimbursement. Reimbursement to the Contractor by the Department for the Contractor's expenses related to travel, meals, and lodging shall be made on the same terms and conditions as govern the reimbursement of those expenses by the Department for members of the examining boards.

The current in-state rates as of 7/1/01 are:

- \$0.325 per mile for travel by automobile
- \$8.00 for breakfast, provided the contractor leaves home before 6:00 a.m.
- \$9.00 for lunch, provided the contractor leaves before 10:30 a.m. and returns after 2:30 p.m.
- \$17.00 for dinner, provided the contractor arrives home after 7:00 p.m.
- \$62.00 for lodging, including sales tax.

Current rates for out-of-state expenses are obtainable upon request from the Department.

- C. Expenses Not Reimbursed. All costs and expenses incurred by the Contractor other than the costs and expenses described in Subsection B, including but not limited to the costs of mail, telephone calls, rent, utilities and taxes, shall be borne by the Contractor and shall not be reimbursed or reimbursable to him or her by the Department.

- D. Invoices. Invoices shall be submitted monthly. Invoices presented for payment must be submitted in accordance with the instructions contained in this Agreement. All invoices shall include the Contractor's name, FEIN (federal employer identification number) or Social Security number, and the address to which payment is to be sent. The invoice shall indicate the case(s) worked on, the time spent in each of the four categories described in Subsection A, and the total amount due. **The attached sample invoice may be used.** All other invoices shall contain the aforementioned information. Invoices shall be submitted to:

Wisconsin Department of Regulation and Licensing  
ATTN: Fiscal Section  
P.O. Box 8935  
Madison, WI 53708-8935

#### IV. TERMINATION AND RENEWAL

This Agreement shall remain in force until completion of the duties set forth in Paragraphs I and II, unless it is terminated by the Department or by the Contractor under Paragraph V (g) or V (h).

#### V. GENERAL PROVISIONS

- A. The Contractor shall provide the services set forth herein in accordance with the recognized standards of the profession.
- B. Subletting Or Assignment Of Agreement. The Contractor shall not sublet or assign all or any part of the work under this Agreement without prior written approval of the Department.
- C. Employment. The Contractor shall not engage the services of any person or persons now employed by the State, including any department, commission, or board thereof for all or any part of the work under this Agreement without the written consent of the employer of such person(s) and of the Department.
- D. Nondiscrimination In Employment. In connection with the performance of work under this Agreement, the Contractor agrees not to discriminate against any employee or applicant for employment because of age, race, religion, color, handicap, sex, physical condition, developmental disability as defined in WI Stats. §51.01 (5), sexual orientation, or national origin. This provision shall include, but not be limited to, the following: employment, upgrading, demotion or transfer, recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection of training, including apprenticeship. Except with respect to sexual orientation, the Contractor further agrees to take affirmative action to ensure equal employment opportunities. The Contractor agrees to post in conspicuous places, available for employees and applicants for employment, notices

to be provided by the contracting officer setting forth the provisions of the nondiscrimination clause.

- E. Legal Provision. The Contractor shall at all times comply with and observe all federal and State laws, local laws, and regulations which in any manner affect the work or its conduct. In carrying out any provisions of this Agreement or in exercising any power or authority granted to the Contractor, there shall be no personal liability upon the Department, it being understood that in such matters the Department acts as an agent and representative of the State.
- F. Review. Liaison with the Department shall be through Oscar Herrera, Secretary of the Department, who shall represent the Department's interests in review of quality, quantity, rate of progress, timeliness of services and related considerations as outlined in this Agreement.
- G. Early Termination Of The Agreement. The Department reserves the right to terminate this Agreement at any time provided the Contractor is given a thirty (30) day written notice. In the event of termination, the Department will pay the Contractor for that portion of the work completed and accepted by the Department. The Contractor may terminate this Agreement at any time provided the Department is given a thirty (30) day written notice.
- H. Act Of God Provision. The Contractor may withdraw from the project prior to its completion without providing the thirty (30) day notice required by Subsection G only for circumstances over which the Contractor has no control.
- I. Extra Services And Compensation. If the Department desires to have the Contractor perform services other than those expressly provided for by this Agreement, they shall be considered Extra Services subject to a written extension of this Agreement executed by and between the Department and by the Contractor setting forth the nature and scope thereof and the compensation therefor as determined by mutual agreement between the Department and the Contractor. Services under such extension shall not be performed unless and until so agreed upon by the Department and the Contractor.
- J. Cancellation. The Department reserves the right to cancel any contract in whole or in part without penalty due to non-appropriation of funds or for failure of the Contractor to comply with the terms, conditions, and specifications of this Agreement.

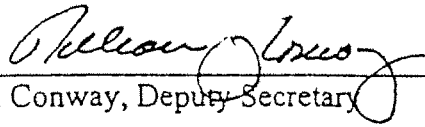
NOW, THEREFORE, in consideration of the premises and of their mutual and dependent agreements, the parties hereby agree as set forth in the foregoing pages which are attached and made a part of this contract. (Pages 1 to 5, inclusive)

IN WITNESS, the Department and the Contractor have executed this Agreement as of the date written above.

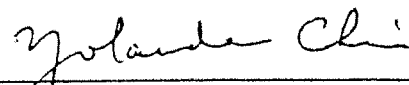
In the presence of:

STATE OF WISCONSIN  
DEPARTMENT OF REGULATION & LICENSING

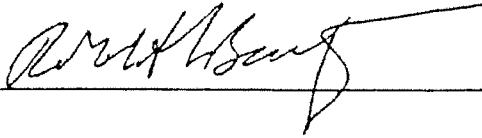
\_\_\_\_\_  
Witness

  
\_\_\_\_\_  
William Conway, Deputy Secretary

In the presence of:

  
\_\_\_\_\_  
Witness  
YOLANDA CHIN  
Notary Public  
My Commission Expires Dec. 8, 2006

9/14/01

  
\_\_\_\_\_  
Contractor

040 36 4311  
\_\_\_\_\_  
Contractor's Social Security Number or FEIN

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1 Turn to page 498. Would this be reflective of the next time  
2 you spent devoted in this case?

3 A. I'm sorry, I -- I'm not clear on your question.

4 Q. Well, assuming the complaint was filed in December  
5 of '01 would this next bill dated July 25th representing  
6 services rendered in June '02, would that be the next  
7 entries, the next time submissions you submitted to the  
8 state?

9 A. Well, it's the next -- it's the next page after  
10 497. And if they're in time sequence then that should be  
11 the next effort that was put forward.

12 Q. Doctor, this invoice from you reflects June 12th  
13 and June 13th. You traveled from your home in Newton,  
14 Massachusetts to Green Bay to attend the deposition of Dr.  
15 Kadile, is that correct?

16 A. That's my recollection.

17 Q. And you were paid 26 hours times \$175 an hour,  
18 right?

19 A. That's what it says.

20 Q. Plus expenses? So the State of Wisconsin pays you  
21 a total of \$5,289.50 for sitting in at Dr. Kadile's  
22 deposition, is that correct?

23 A. Well --

24 MR. THEXTON: Objection. Your honor, this is not  
25 cross-examination. This is argument. That's all that's

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1 Q. And is it your testimony that this matter went on  
2 for 12 hours or 11 hours each of those days?

3 A. No, the record is clear as to how long the court  
4 proceedings lasted. That's not the total amount of time I  
5 spent on those days.

6 Q. You spent more?

7 A. I did spend more time on those days. There was  
8 preparation time and discussions with Mr. Thexton.

9 Q. Doctor, if you'd look at page 511 it's a statement  
10 from you for \$18,415. And page 512 has the "okay to pay" --  
11 or somebody with the state. You received that, did you not?

12 A. To the best of my knowledge I did.

13 Q. Now, Doctor, correct me if I'm wrong but these  
14 documents were produced by the state and they reflect no  
15 billings from you in the year '03?

16 A. That's correct.

17 Q. Why is that?

18 A. Because they're still being processed.

19 Q. Well, it seems like in Exhibit 24 you were very  
20 timely submitting the billings almost monthly. And yet here  
21 we are in July of '03 and you've not submitted the first  
22 bill?

23 A. Well, they weren't submitted monthly, they were  
24 submitted in batches about every three months because that's  
25 -- that's the way we did it. And the effort this year has

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1 going on here. He's objecting to the amount of the bill.  
2 He's not questioning -- this has -- also has nothing to do  
3 with Dr. Baratz' credibility whatsoever.

4 LAW JUDGE: Mr. Recker, I will note that you seem  
5 to have made a point about the billing and we may have  
6 commentary on that later. If you intend to go through the  
7 record simply verifying the amounts I don't think that's  
8 necessary.

9 MR. RECKER: All right.

10 LAW JUDGE: If there are specific dates on which  
11 you think there's misbilling then we would certainly like to  
12 look at that.

13 Q. Doctor, considering all the time and reports you  
14 generated prior to June '02 why did you feel it necessary to  
15 expend 26 hours and bill the state over \$5,000 to sit in on  
16 Dr. Kadile's deposition?

17 A. That wasn't my decision, that was Mr. Thexton's.

18 Q. Doctor, if you'd turn to page 508. This reflects  
19 billing for October of '02, is that correct?

20 A. That is correct.

21 Q. And it indicates that you were here in court -- I  
22 guess that means the administrative hearing -- for four  
23 days. Each day was over 11 hours, 11 to 12 hours, is that  
24 right?

25 A. I believe so.

Page 1020

1 been sporadic and that's why -- and I -- and my secretary  
2 had left in January so it's taken some time to get the bills  
3 done.

4 Q. Doctor, you recall that sometime after November of  
5 '02 Dr. Kadile was without legal counsel, do you know that?

6 A. I don't know that officially. I think I heard  
7 that.

8 Q. And at some point the administrative law judge  
9 directed that your remaining direct testimony in this matter  
10 be submitted in writing, correct?

11 A. I don't know that. I don't know that he directed  
12 that. I -- I don't know that.

13 Q. All right. Well, now, you spent a lot of time on  
14 this matter on January 30th, '03, did you not?

15 A. I spent sometime in January of '03, that's  
16 correct.

17 Q. Well, I said January 30th, '03.

18 A. That was one of the days that we were doing added  
19 testimony, that's correct.

20 Q. And when you say doing added testimony I'm  
21 referring to January 30, '03 where you and Mr. Thexton met  
22 in your attic, do you recall that?

23 A. We met.

24 Q. In your attic? Correct?

25 A. Pardon me? I have an office in my home and we met



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STATE OF WISCONSIN

DEPARTMENT OF REGULATION AND LICENSING

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In the matter of the disciplinary proceedings against:

Eleazar Kadile,  
Respondent.

Case Number LS-0112061-MED  
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Day 6 Hearing before John N. Schweitzer

July 15, 2003

1400 East Washington Avenue

Madison, Wisconsin

APPEARANCES

For the State of Wisconsin:

Department of Regulation and Licensing

Arthur K. Thexton

1400 East Washington Avenue

Madison, Wisconsin

# Department of Regulation & Licensing

State of Wisconsin  
 (608) 267-5224  
 TTY# (608) 267-2416  
 TRS# 1-800-947-3529

P.O. Box 8935, Madison, WI 53708-8935  
 E-Mail: <http://www.drl.state.wi.us>  
 FAX# (608) 266-2264

INVOICE FOR SERVICES RENDERED TO WISCONSIN DEPARTMENT OF REGULATION AND LICENSING

DIVISION OF ENFORCEMENT

Send Invoice To:

WI Department of Regulation and Licensing  
 ATTN: Fiscal Office  
 P.O. Box 8935  
 Madison WI 53708-8935

Rebill Payment To:

ROBERT S. BARTZ  
 159 BELLEVUE ST.  
 NEWTON, MA 02458-1834

Invoice Date: 7/1/03

CASE # (s) 97 Med 101

FEIN/SS # 040 36 4311

DATE	DESCRIPTION	HOURS	RATE	TOTAL
MAR 9, 2003	New Client Ref 4 hrs	1.5	105	262.50
MAR 17	TC Thurston	0.5	175	87.50
MAR 31	TC Thurston	0.5	175	87.50
Various in	work on 3 reports	9	175	1575
MAR, 03	Seaboard 9 hr @ 35/hr.	9	35	315
	Reverend 15 hr @ 35/hr.	15	35	525
RECEIVED	OFF to pay, Denise			
	165 1400 HT			
JUL 14 2003				2952.50
*TOTAL TRAVEL EXPENSES TO BE REIMBURSED*				
x \$0.325/mile =				
DEPT. OF REGULATION & LICENSING		MEALS	LODGING	TOTAL
DIVISION OF ENFORCEMENT				

Receipts are required for lodging

SIGNATURE

*Robert S. Bartz*

**Keo, Cortney - DRL**

---

**From:** Berndt, Michael  
**Sent:** Wednesday, December 03, 2003 7:04 PM  
**To:** Cramton, Beth  
**Cc:** Keo, Cortney - DRL  
**Subject:** research for Thursday

Beth,

Please do some research regarding the Waters cases, 97MED101 and 97MED108. The cases involve Chelation Therapy and Insulin Potentiation Therapy (commonly called IPT).

One area for research is what are chelation therapy and IPT. Are there any studies in the US that support these therapies? I do not want quantity, but good quality articles or studies.

Another area to research is whether there have been disciplines in other states or Canada for chelation or IPT. We would want the final decisions and orders.

Another area is laws related to chelation or IPT. Have states enacted laws regulating these procedures? If so, we want the text of those laws and info as to when they were enacted. If the laws require disclosures to the patient, what are the disclosures?

Dr. Waters has a web site I believe. This may be a very good place to look for links to other sites. I would also like a complete copy of his site (unless it is 100's of pages).

The NIH or National Institute (or Institutes) of Health is doing a study now or in the very near future on chelation therapy. I would like to know what the study is going to involve and we want to know if sites for the study have been identified. Is Waters involved in the study?

Do any federal agencies such as the FDA, DEA or DHFS have positions on chelation or IPT? What about the drugs that are used as part of these procedures? Have they issued any statements about the off-label use of drugs for these procedures?

You are welcome to ask Cortney to help with some of this research and she is cc'd on this memo.

The purpose of the research is to try to find out if these procedures actually represent a threat of harm to patients and to get an idea of what is happening in other states. My major concern is the threat of harm. We would also like to know the federal government's position if possible as articulated by the various agencies.

Please read and think creatively about the articles and things that you find. You may think about some other issue or idea that I have not listed that would give us helpful information as to an appropriate resolution or approach to the case.

I expect this may take some time. Sorry the email is so long.

Thanks, Mike

**Enclosure 41**

# Supreme Court of Florida

RECEIVED SEP 08 1980

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No. 56,096

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STATE BOARD OF MEDICAL EXAMINERS OF  
FLORIDA, Appellant.

vs.

ROBERT J. ROGERS, M.D., Appellee.

[September 4, 1980]

ALDERMAN, J.

This cause is before us on direct appeal to review the decision of the District Court of Appeal, First District, in Rogers v. State Board of Medical Examiners of Florida, 371 So.2d 1037 (Fla. 1st DCA 1979), which construed a provision of the Florida Constitution. Although we find it unnecessary to the disposition of this cause to reach the constitutional construction given article I, section 2, Florida Constitution,<sup>1</sup> by the district court, we affirm the result of the district court's decision because, under the particular facts of this case, it appears that the action of the Board of Medical Examiners restraining Dr. Rogers from further utilization of chelation treatment was an arbitrary and unreasonable exercise of the state's police power.

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<sup>1</sup>Article I, section 2, Florida Constitution, provides:

All natural persons . . . have inalienable rights, among which are the right to enjoy and defend life and liberty, to pursue happiness . . . .

Dr. Rogers, a practicing physician in Brevard County, was ordered by the Brevard County Medical Association to discontinue the use of chelation therapy<sup>2</sup> in the treatment of

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<sup>2</sup>The district court in its decision here under review explained in detail the nature of chelation therapy:

The record reveals that chelation therapy consists of a series of intravenous injections of a chelating drug, usually disodium ethylenediamine tetraacetic acid (hereafter disodium EDTA, Na<sub>2</sub> EDTA, or EDTA). Each injection takes approximately three to four hours to administer, and a normal course of treatment usually involves twenty such injections. The treatments are specifically intended to treat arteriosclerosis (hardening of the arteries), atherosclerosis (deposits on the inner lining of the arteries), and other generalized circulatory deficiencies caused by excess calcium in the circulatory vessels. The common chelating agent, Na<sub>2</sub> EDTA, was originally discovered by I. C. Farben in the 1930's and is widely used as a food preservative. EDTA intravenous treatment is often recommended for lead poisoning and other diseases requiring removal of heavy metals from the body. Chelation treatments were widely used during World War II in treating sailors who had contracted poisoning from leaded paint. Since World War II more than 1500 scientific articles and studies have been published concerning practically every application of the chelating process in the body. Many of those articles are contained in the record.

The precise chemical reaction whereby metals, or calcium, are removed from the body through chelation is not yet completely known nor understood. However, through the years, many doctors have observed that after EDTA infusion, the urine calcium level rises and remains at relatively high levels for some months after administration of the treatments. The theory, now generally agreed upon by chelation proponents, is that the chelating salt binds with ionic calcium in the blood, causing a temporary calcium deficiency in the blood. This is rapidly replaced by calcium in precipitate form ionizing in the bloodstream. This calcium, known as metastatic calcium, comes from the walls of the blood vessels and from calcium precipitate in every cell. Many experts believe that the metastatic calcium sludge in each cell causes the cells gradually to disfunction. This phenomenon, coupled with the better known effects of calcium deposits on the interior walls of the blood vessels, results in a gradual decline in blood flow and cell function. Thus, if the pernicious calcium buildup can be prevented or reversed, cells and vessels can continue to function well into old age, reducing the inevitable effects of hardening of the arteries and other vascular occlusive diseases.

The record is replete with claimed instances of dramatic restoration of blood flow to the extremities resulting in arrest of gangrene, restored sensation, increased temperature and return of normal color to toes, fingers, hands and feet after chelation treatment. In one exceptionally dramatic case history, Reynolds Hall, a patient of petitioner, allegedly regained his sight during his seventh chelation treatment.

arteriosclerosis. As a result of his refusal to discontinue its use, Dr. Rogers was expelled from the association. Subsequently, pursuant to section 458.1201(1)(p), Florida Statutes (1975),<sup>3</sup> the Florida State Board of Medical Examiners filed an administrative complaint charging Dr. Rogers with unprofessional conduct as defined by section 458.1201(1)(m), Florida Statutes (1975).<sup>4</sup>

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<sup>2</sup> (Continued)

Chelation therapy is, then, infusion of a chelating agent (generally Na<sub>2</sub> EDTA) into the bloodstream over several hours, a treatment which is repeated about 20 times, generally over a period of a month or more.

371 So.2d at 1038-39.

<sup>3</sup>Section 458.1201(1)(p), Florida Statutes (1975), provides:

(1) The board shall have authority to deny an application for a license or to discipline a physician licensed under this chapter or any antecedent law who, after hearing, has been adjudged unqualified or guilty of any of the following:

...

(p) Being removed or suspended, or having disciplinary action taken, by his peers within any professional medical association, society, professional standards review organization established pursuant to s. 249F of Public Law 92-603, or similarly constituted professional body, whether or not such association, society, organization, or body is local, regional, state, national, or international in scope, or by being disciplined by a licensed hospital or medical staff of said hospital for immoral or unprofessional conduct or willful misconduct or negligence by the person in his capacity as a physician licensed pursuant to this chapter. Any body taking action as set forth in this paragraph shall report such action to the board within 30 days of its occurrence or be subject to a fine assessed by the board in an amount not exceeding \$500.

<sup>4</sup>Section 458.1201(1)(m), Florida Statutes (1975), provides:

(1) The board shall have authority to deny an application for a license or to discipline a physician licensed under this chapter or any antecedent law who, after hearing, has been adjudged unqualified or guilty of any of the following:

...

(m) Being guilty of immoral or unprofessional conduct, incompetence, negligence, or willful misconduct. Unprofessional conduct shall include any departure from, or the failure to conform to, the standards of acceptable and prevailing medical practice in his area of expertise as determined by the board, in which proceeding actual injury to a patient need not be established when the same is committed in the course of his practice, whether committed within or without this state.

The hearing officer, whose findings and conclusions were adopted by the Board, concluded that chelation therapy can best be classified as investigational, that it more likely can be classified as quackery, and that its use outside a controlled environment such as a research institute fails to conform to acceptable and prevailing medical practice. Although not finding that chelation therapy is in any manner harmful to the patient or that Dr. Rogers misled his patients into believing that this methodology of treatment was a cure for arteriosclerosis, the hearing officer determined that Dr. Rogers failed to demonstrate that chelation therapy results in any patient benefit in terms of organic process and recommended that Dr. Rogers be reprimanded, be ordered to cease and desist from employing this treatment, and be placed on probation for one year during which time he should demonstrate the type of exemplary conduct required of a duly licensed physician.

Quashing the Board's order, the district court determined that neither the Board nor the Brevard County Medical Association had made any finding that chelation therapy is in any respect harmful or hazardous to the patient, that Dr. Rogers allowed his patients to make their own choice as to whether to begin this treatment after full disclosure that this methodology has not been proven effective, that chelation therapy is widely used as a treatment for arteriosclerosis by a definite minority of the medical profession, that Dr. Rogers never claimed it was a cure, and that there was no allegation or proof of fraud, misrepresentation, coercion, or overreaching. The district court acknowledged the state's authority to regulate the medical profession but held that the Board's action was not reasonably related to the public's health and welfare. It concluded that the Board, on the record presented for review, could not prohibit Dr. Rogers from administering chelation therapy.

Entrusted with the enforcement of appropriate standards for the practice of medicine, the Board, in restricting Dr. Rogers' 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 with the right to practice one's profession which is a valuable property right protected by the due process clause. Doe v. Bolton, 410 U.S. 179 (1973); Dant v. West Virginia, 129 U.S. 114 (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. McCarty, 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 procedure 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 because the Board found that the treatment was harmful or that Dr. Rogers had defrauded his patients into believing that chelation treatment was a cure 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.



Accordingly, based upon the record in this case, we hold that the Board's action is an unreasonable exercise of the police power, and we affirm the result of the decision of the district court quashing the order of the Board.

It is so ordered.

SUNDBERG, C.J., ADKINS, BOYD, OVERTON, ENGLAND and McDONALD, JJ.,  
Concur

NOT FINAL UNTIL TIME EXPIRES TO FILE REHEARING MOTION AND, IF  
FILED, DETERMINED.

An Appeal from the District Court of Appeal,  
First District, Case No. EE-454

Michael I. Schwartz, Tallahassee, Florida,  
for Appellant

Andrew A. Graham of Rainman, Harrell, Silberhorn, Moule and  
Boyd, Melbourne, Florida,  
for Appellee

**ROBERT WATERS, MD**  
**97 MED 101**  
**97 MED 108**

Dr. Johnson is the case advisor.  
These cases are on page 1 of your case status list.

Dr. Waters operates a clinic in Wisconsin Dells that specializes mainly in nutritional counseling and alternative therapies.

Both of these cases involve Dr. Water's practice of Chelation therapy for the treatment of occlusive vascular diseases. 97 MED 101 resulted from a complaint from another physician that Dr. Waters was offering Chelation therapy. 97 MED 108 resulted from a similar complaint from an insurance company.

As you probably know, E.D.T.A. Chelation is a standard treatment for heavy metal poisoning. It has been used since the 1950s and is FDA approved. Over the years some physicians began to notice that EDTA Chelation seemed to improve symptoms of arteriosclerosis in the patients that had it. Some physicians began offering off label EDTA Chelation as an alternative treatment for vascular occlusion. Last year, the National Institute of Health began a study of the effectiveness of Chelation for vascular occlusion, and Dr. Waters has signed on as a regional test site in that study.

Dr. Waters is very clear with his patients that Chelation is an experimental therapy. He gives them a 35 page booklet that tells them about the history of EDTA Chelation, informs them of the risks, emphasizes the lack of scientific support for the benefits, and lets them decide whether they want to try it or not. He also has them sign consent forms prior to Chelation treatments, which state very clearly that the treatment is controversial and experimental, and that the treatments are accepted by only a small minority of the medical community. The consent forms reiterate the possible risks and side effects.

During the course of the Chelation investigation, we received a letter from a physician complaining that Dr. Waters was practicing insulin potentiation therapy. As I understand it, in IPT a patient is given a dose of insulin, which supposedly opens up certain receptors in the cancer cells, and if a low dose of chemotherapy is given at the right moment, the chemo drugs are taken into the cancer cells and kill off the cancer much faster and easier than regular chemo. This, of course, is another alternative and controversial therapy. We have not opened a case relating to the IPT yet, but we did investigate Dr. Water's IPT use.

Dr. Waters has not practiced IPT in about a year and a half, and has no intention to practice IPT in the future. When he did practice IPT, he gave his patients very clear notice of the risks and explained that the benefits were not proven. He described the procedure to me and it sounded very safe. He was present at all times, and blood sugar

**Enclosure 43**

levels were monitored carefully and frequently. He was prepared with an infusion of glucose in the event that blood sugar dropped too low.

In the course of the investigation a question arose regarding Dr. Water's record keeping. His records could have been better in 1997, but no patients were harmed as a result, he has made improvements and I think it would be appropriate to consider that a technical violation for which compliance has been gained.

I am asking you to close both of the Chelation cases, and I'm asking that you decline to open a case with regard to the IPT therapy. I don't believe that the board has a stated policy on alternative medicine, but I know that the Federation of State Medical Boards has issued model guidelines that state, essentially, that practicing alternative medicine is not a basis for discipline in and of itself. As long as the physicians practicing in a safe and effective manner, and are following professional standards with regard to evaluation, diagnosis, and informed consent to treatment, etc., then there is no reason for discipline.

I believe that Dr. Waters is practicing EDTA in a safe manner, and that his patients are very well informed about the experimental nature of the treatment. He is practicing Chelation in accordance with an NIH study, which has strict guidelines with regarding to treatment protocols. Dr. Waters follows those same treatment protocols in his non-study patients. Further, I do not see a reason to open a case relating to the IPT treatments. I believe that they were performed in a safe manner, and that his patients were well informed of the experimental nature of the treatment. In addition, Dr. Waters is no longer doing IPT, so we have compliance gained.

I have discussed these cases in detail with Dr. Johnson. He has asked me to let you know that he supports closing the cases.

### **Compliance gained.**

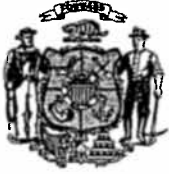
Kadilly comparison:

- One major difference is that Waters is part of the NIH study, Kadile was not.
- In the Kadile case, we had concerns about the quality of care of particular patients, there are no such concerns with Waters.
- The Kadile case resulted in a stipulation whereby Dr. Kadile agreed to give his patients certain consent forms and notices. I have reviewed the material that Dr. Waters gives his patients and compared it to those consent forms and notices, and in my opinion they are as good or in some places better than what we required of Dr. Kadile in the stipulation.

- During the pendency of the investigation, it was noted that Dr. Waters' records at times lacked sufficient detail. However, it is our belief that his current record-keeping practice is much improved, and therefore compliance has been gained.

If questions are asked comparing this case to that of Eleazar Kadile:

- In the Kadile case, there were concerns about the quality of care provided to individual patients. There were no such concerns in the Waters investigation.
- Dr. Waters is part of an NIH research study on the use of EDTA chelation for occlusive vascular diseases and therefore administers chelation in keeping with strict NIH guidelines. Dr. Kadile was not a part of that study.
- The Kadile case was resolved with a stipulation that provided for certain notices and consent forms to be given to patients. Dr. Waters already provides patients with comprehensive information similar to that which we required Dr. Kadile to provide as a condition of resolving his case.



**State of Wisconsin**  
**DEPARTMENT OF REGULATION AND LICENSING**  
**CORRESPONDENCE / MEMORANDUM**

**DATE:** January 5, 2004

**FILE REF:** 97 MED 101

97 MED 108

**TO:** Sandy Rowe, Mike Berndt

**FROM:** Jeanette Lytle

**SUBJECT:** Waters

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This memo summarizes the Waters complaints, and suggests strategy.

**Background**

**I. Previous case:**

In 1991, DRL investigated Dr. Waters regarding "whether Chelation therapy is a legitimate treatment for coronary artery disease." 91 MED 365. The Board Advisor recommended closure due to insufficient evidence that a violation had occurred.

**II. Complaints in the 1997 cases:**

**A. First complaint regarding Chelation:**

The initial complaint in the 1997 cases was a March 21, 1997 letter from Dr. William West, MD. Dr. West had a patient who went to Dr. Waters for Chelation treatments. The patient showed him a booklet about Chelation authored by Dr. Waters, which is handed out to his patients. Dr. West believed that the information in the booklet is false and misleading, and that the patient could have been injured in the treatment. Dr. West did not identify the patient so we did not investigate the specifics of her or his situation.

The file contains a booklet written by Waters, called Chelation Therapy, An alternative Treatment for the Diseases of Aging. The booklet discusses EDTA Chelation in detail. It describes the history of EDTA Chelation. It emphasizes lifestyle changes and flatly states that if you don't stop smoking, you shouldn't waste your money on Chelation.

The booklet does not discuss FDA approval or off-label use. It does report that the AMA and most cardiologists would say that no studies have shown that Chelation works, but then it goes on to cite to studies that show it does various wonderful things (without explaining or evaluating the studies).

It discusses effectiveness of treatment only in anecdotal terms, saying that "most" doctors report that "at least" 75% of patients experience definite improvement in symptoms, including increased exercise tolerance, reduction in chest pain, improved vision, reduced joint pains, and better memory. It says that the other 25% "usually" report "some" positive changes, although less dramatic. However, in the booklet's Conclusions section, it states that Chelation "has been documented to be safe and effective in numerous studies done around the world over the past 30 years." Again, it does not discuss the validity of those studies.

The booklet does address side effects. It even addresses kidney function, which seems to be the highest risk identified by opponents of Chelation. It also discusses tests that would be needed before Chelation, including an EKG if you haven't had one in the last few months.

To his credit, Waters states: "You should take all medications as directed on the day of Chelation as you would any other day. Only after we have a chance to assess your progress, do we consider reducing your medication. In most cases, it is appropriate for you to continue seeing your family doctor or cardiologist."

In general, although the references to Chelation studies arguably could be misleading in that the booklet does not mention the size of the sample or the reliability of the research, my overall impression was that he did communicate that this was experimental treatment and that many people opposed it.

It is also notable that on his website, Dr. Waters states:

It should be understood that this treatment is not widely considered effective by most medical doctors. Except for very clear cases of heavy metal intoxication, it is considered an experimental treatment.

#### **B. Second complaint regarding Chelation:**

We also received a March 31, 1997 letter from Blue Cross Blue Shield, which questioned Dr. Waters' treatment of patient R.A. The letter stated that R.A. was seen on January 23, 1997 for a complaint of chest pain and pressure in his chest. He could walk only one block. Dr. Waters did not evaluate R.A.'s cardiac status (no stress test, EKG, etc). No cardiac meds were prescribed. Instead, the records indicated that R.A. should "continue with Chelation therapy." No records indicate that R.A. was seeing any other physician for his cardiac condition.

The records actually state:

c/o chest pain- pressure x 1 yr. He probably had it before \_\_\_\_ ("not"? "rest"?). Now he is getting it after only walking 1 block. It goes away after rest. He is taking acupuncture RX & is eating more veggies.

Importantly, however, a medical summary suggests that the chest pain had been ongoing for several years, and that R.A. had come to Dr. Waters because he believed he had coronary heart disease with angina pectosis and he wanted non-invasive, non-surgical treatment. Therefore, investigating the cause of the chest pain with EKGs would probably not have been necessary – R.A. knew he had heart disease, he appeared to have been diagnosed by someone else, and he was choosing Chelation anyway. Later records indicate that he is doing well.

Under the circumstances, I do not fault Dr. Waters for not ordering additional cardiac tests. Those tests would only have confirmed what R.A. already knew, that he had coronary heart disease with angina pectosis.

(Also note that in another case I have, a physician missed an EKG in an emergency setting, diagnosing bronchitis instead, and the guy died the next day, and all that was recommended by the BA was education, with no findings).

### **C. First complaint regarding insulin potentiation therapy:**

On February 20, 2002, we received an anonymous letter complaining that Dr. Waters was performing insulin potentiation therapy. It enclosed a brochure from Dr. Waters. The letter said that one of the author's patients said Dr. Waters was injecting insulin and following it up with glucose for \$900 per session, and saying that it would shrink tumors. The patient referred to in the anonymous letter was not identified, so we did not investigate the individual situation.

Dr. Waters' brochure on IPT clearly states that the results are so far anecdotal, and he is offering the treatment based on the hope that it will help. It explains in detail the mechanism by which IPT is thought to work.

The file also contains a signed informed consent document for IPT that quite clearly says it is an experimental treatment, using an off-label drug. It says the treatment is an attempt to reproduce anecdotal experiences noted outside this country and to encourage clinical studies in the US. It explains the procedure. Dr. Baratz rips the informed consent form apart, and he makes a couple of points, but I think in some respects he is being too picky. It probably could have been better written, but I didn't see anything that was shockingly bad.



## **Standards**

Arthur's letter to Dr. Baratz indicates that, to be unprofessional conduct, the conduct complained of must not be accepted by any respectable minority school of thought in the medical community. It is not enough that the treatment is non-standard. It must be outside all respectable practice is allopathic or osteopathic medicine.

The model guidelines for the use of complementary and alternative medicine ("CAM") from the Federation of State Medical Boards basically says that CAM is not in and of itself a reason for discipline. All physicians need to properly evaluate the patient, form a treatment plan, consult with and/or refer to others as necessary, and document. The offered treatment should have a favorable risk/benefit rationale compared to other possible treatments, it should be based on a reasonable expectation that it will result in a favorable patient outcome, and it should be based on the expectation that a greater benefit will be achieved than that which can be expected with no treatment. All physicians should have a basic understanding of the medical scientific knowledge connected with any method they are offering or using as a result of related education and training.

Both EDTA Chelation and IPT involve off-label drug use. Off-label drug use is perfectly legal, and quite common. The mere fact of off-label use is irrelevant.

## **Previous settlement attempt**

Arthur apparently sent a proposed stipulation already, as there was an open letter from Waters in a healthcare newsletter begging for legal defense money that describes one. Basically, Water's interpretation of what Arthur wanted is this:

- a. Waters can't use certain labs unless he gets patients to sign something saying the tests may be harmful and the MEB recommends they not undergo such unapproved tests and therapy.
- b. He may not use any off-label drug
- c. he cannot write prescriptions for compounded medicine without having the patient sign something saying it may be harmful and the MEB recommends against it
- d. He must inform the patient's other physicians of what he is doing
- e. Patients undergoing Chelation must sign something saying that Chelation doesn't work and it is dangerous to their health.

It was obvious from the newsletter that Dr. Waters had no intention of stipulating to these terms.

## **The Baratz opinion:**

I did not give the Baratz opinion much credit in terms of his evaluation of Chelation and IPT in general, because it was so obvious that he was biased against alternative medicine.

He did bring up several problems, however, that are worth noting and perhaps investigating further.

### **I. Record keeping**

Dr. Waters apparently did not keep good records. He reportedly made many infusions in multiple patients without any documentation of what was infused, the quantity, or the circumstances. This is significant in my mind and should be addressed.

### **II. Insurance fraud**

It also appears that Dr. Waters may have participated in insurance fraud. Most of his patients received a diagnosis of MTMP ("multiple toxic metal problem"). However, he failed to report any of these patients to the State Health Department, as would be required if they had any exposure to toxic metals. Also, there was no record that any of the patients had any exposure to toxic metals and there was no report that they had any of the symptoms of such exposure, and there were no confirming laboratory reports. However, the patients did have cardiac problems. Most likely, the diagnosis was given for the purpose of trying to get the treatments covered by insurance.

It also appears that Dr. Waters required patients to give up coverage for their initial testing and examination under Medicare. Dr. Baratz hypothesized that he did not want the scrutiny of the federal government.

### **III. Board certification**

Waters does say, in his brochures, that he is "board certified in Chelation therapy, without specifying the complete name of the specialty board that conferred the certification, in violation of MED 10.02(2)(w). In my mind this is a minor technical violation, but a violation nonetheless.

### **IV. Refusing to divulge methods**

Dr. Waters refused to detail information about Chelation therapy during the course of this investigation, in violation of 10.02 (2)(k) ("offering, undertaking, or agreeing to treat or cure a disease or condition by a secret means, method, device or instrumentality; or refusing to divulge to the board upon demand the means, method, device, or instrumentality used in the treatment of a disease or condition. Given the adversarial nature of the investigation, and the posturing of the parties, I don't see this to be as serious as I otherwise would. However, we might be able to use it in future negotiations.

### **V. Other**

The rest of Dr. Baratz's concerns seem to center around his belief that Chelation and IPT are themselves suspect. He faults Dr. Waters for failing to refer and consult with other physicians for patients with significant medical problems, but he assumes that Dr. Waters

was not treating those problems himself and needed consultation. Dr. Baratz also believed that Dr. Waters did not take an adequate medical history, did not conduct adequate physical examinations, did not order appropriate tests, and did not appropriately follow up, but again, Dr. Baratz assumes that the Chelation and IPT were inappropriate and therefore discounts the strategy of the treatment and replaces Dr. Waters' and the patients' goals with his own.

### **Additional information**

Dr. Waters reportedly is now involved in an NIH research study on EDTA Chelation. If so, then his practice of Chelation has the blessing of the federal government and we should not challenge it.

Also, note that on 5/29/02, Waters' attorney called and told Arthur that Waters would be willing to give up IPT therapy to settle the case. Arthur declined.

### **Conclusions**

I don't see any major violations. I think that there is a respectable minority school of thought that Chelation and IPT may work, and are therefore worth a try. I think Dr. Waters' patients are being sufficiently informed of the experimental nature of the process. That said, there are some minor violations that we could pursue.

There are other complications to consider, though. We will have to be able to explain what may be perceived as a lack of consistency between this case and Kadilly. We should also consider the effects of a lack of consistency with Arthur's approach (he already has Arthur pegged as a bad guy, and if we drastically change our approach we might confirm that in his mind).

It seems that we have had some very poor communication with Dr. Waters in the past. This may be a good chance to try to improve that communication. We could inform Dr. Waters of the change in attorneys, and invite him to come here to discuss his case. We could find out what is going on with his research study participation in Chelation, and we could find out if he is still willing to give up IPT. We may be able to find some areas of agreement and at least, narrow the issues, and possibly resolve the case.

Prior to any such meeting, of course, we would have to meet with the Board Advisor (Dr. Johnson), and make sure he agrees with the basic theory that Chelation and IPT are not inherently evil. If he disagrees, we will have to identify his specific concerns and address them before proceeding.

**Sarah Chapman**

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**From:** Pat Simms [PSimms@madison.com]  
**Sent:** Friday, July 18, 2003 12:53 PM  
**To:** 'sarah@watersmedcenter.com'  
**Subject:** FW: Inaccurate Reporting: to the Managing Editor of the Wisconsin State

-----Original Message-----

**From:** Pat Simms  
**Sent:** Friday, July 18, 2003 12:24 PM  
**To:** 'info@watersmedcenter.com'  
**Subject:** FW: Inaccurate Reporting: to the Managing Editor of the Wisconsin State Journal

-----Original Message-----

**From:** Pat Simms  
**Sent:** Friday, July 18, 2003 12:22 PM  
**To:** 'rwaters@mwt.net'; 'sara@watersmedcenter.com'  
**Subject:** FW: Inaccurate Reporting: to the Managing Editor of the Wisconsin State Journal

-----Original Message-----

**From:** Robert S. Baratz, MD, PhD [mailto:imcsi@rcn.com]  
**Sent:** Friday, July 18, 2003 7:50 AM  
**To:** psimms@madison.com  
**Subject:** Inaccurate Reporting: to the Managing Editor of the Wisconsin State Journal

To: Cliff Behnke, Managing Editor, Wisconsin State Journal

cc: to Jay Eastlick, news editor; Phil Glende, city editor; Pat Simms, Health Care Reporter

At the beginning, let me say that this is not a "letter to the editor". This is an administrative letter and is **not** meant for publication. I regret a slight delay in writing in a timely fashion, but I was testifying and then travelling yesterday. Today I had patient duties which consumed most of the day.

Dear Mr. Behnke:

I wish to take issue with the reporting and portrayal of the Kadile trial which appeared in a story on Page 1 of your July 14/15, 2003 edition (copy below), "Controversial Medical Procedure Under Fire" on several fronts.

First, the reporter (Simms) seemed to present a number of items as fact that apparently were not checked or researched, and are not accurate. They appear to have been taken verbatim from "spin" being advanced by a paid publicist who regularly propagates false and misleading information. (see: <http://www.quackwatch.org/11/nd/bolen.html> ).

In contrast to what is said in the article, chelation therapy, where appropriate, is an accepted standard, conventional, medical treatment. It is entirely "Western" medicine. Chelation agents are administered in intravenous solutions to treat real but rare medical problems, such as lead poisoning in children and iron overload in hemolytic anemia. Specific agents are used for each. Regarding coronary artery disease, however, rigorous, scientific reviews in major journals, and governmental monographs by authoritative groups, in this country and abroad (cites available), and recent, well-designed, double-blind, clinical trials have failed to demonstrate any benefit of EDTA chelation therapy for this problem. Multiple professional and patient advocacy groups, including the American Heart Association, concur. The FDA does not approve nor license any drug for the intravenous chelation treatment of arteriosclerosis or atherosclerosis

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(hardening of the arteries or cholesterol plaques in the arteries). Chelation therapy with EDTA is **not** alternative medicine or even alternative therapy, it is conventional medicine, but is a non-evidence based treatment, with high risk, and no benefit. One must surely raise ethical concerns about any such treatment or those who advocate its use. Your article did not.

In the article, Eleazer Kadile is called a "provider of natural medicine". After investigation I cannot find that Kadile advertises himself as a naturopath, nor does he claim a degree in naturopathy. Naturopathy is a philosophy which uses "natural healing" to treat disease, and decries the use of pharmaceuticals. Intravenous infusion of drugs is obviously not "natural". Further, the charges against Dr. Kadile (which can be read here: <http://www.quackwatch.org/11Ind/kadile.html>) detail his alleged misuses of conventional pharmaceuticals. Those charges, by the way, do not charge him with practicing "alternative" or "complementary" medicine. The charges are replete with details of how the State says he has markedly deviated from basic and fundamental medical practices, such as addressing patients' complaints, and treating illnesses that can have serious consequences if not treated. The State also charges that he failed to use basic methods such as use of differential diagnosis(es), and regularly did not monitor or treatments he has given. Regardless of one's philosophy of care, the profession of medicine demands that these precepts be followed.

The reference to my testimony this week is inaccurate. The purpose of the hearing this week was to continue my testimony, started last October, and interrupted by a request of Dr. Kadile, through his counsel, to settle the case by stipulation. A carefully negotiated settlement agreement was never signed by Dr. Kadile. He subsequently dismissed his counsel, and postponed the resumption of the hearing three times, each time requiring a change in schedule and my flight arrangements. I had to cancel my patients, appointments, and other work for three separate weeks, and then was told not to come. The testimony this week was not a special event regarding my credentials, as reported, but merely cross examination on prior testimony. Any limitations on the scope of the cross-examination were at the request of Dr. Kadile's counsel, not the court. Kadile's counsel made the decision not to cross examine me on the medical facts of the case, even though my testimony on these matters was essentially complete.

Thus, the reporting of the limitations of the testimony of this week is misleading at best and implies that I was on trial, which I was not.

The article went on to state, "As head of the Massachusetts-based National Council Against Health Care Fraud, Baratz is well-known for his anti-quackery testimony in other states." First, the National Council Against Health Fraud is misnamed. Moreover, I was not appearing representing the National Council Against Health Fraud, but appeared merely as an individual, something I have done for many years.

I have been President of the NCAHF less than two years, but have been a licensed clinician, researcher, scientist and expert in certain areas for more than 30 years. Second, a pejorative, inaccurate, and potentially libelous statement is made about me. The statement implies that I am a regular testifier, and suggests I have a bias in my testimony, neither of which is true. In keeping with the traditions of responsible journalism, I request, please, to have you produce and send to me a list of places, dates, and circumstances where I have "testified" in official legal proceedings and the circumstances had a charge of "quackery". Additionally I would like documentation on how I am "well known" for this alleged activity.

**Should you be unable to produce such within one day (since the reporter (Simms) should have checked her facts in advance and have facts to support her statement), I would instead be willing to accept a written apology from the Simms, and a retraction on the front page of your paper (since that is where the original story appeared), with language acceptable to me. I would also ask for and expect an op-ed forum in your paper to elaborate on the other inaccuracies in the story.**

Despite the fact that I am named and discussed several times in the article, Simms made no attempt to contact me in any way to verify her facts or collect my opinion. My email addresses and phone numbers are readily available. As I am a physician with patient care responsibilities, I carry a cell phone twenty-four hours a day. Additionally, all of my phones, including my cell phone, have voice mail, which I regularly check. Further, I was, in fact, in Madison on July 13, and 14 and could have easily met the reporter in person. I am one of the easiest people to contact and usually answer my phone personally. I regularly work with the press, and have given hundreds of interviews to the media over many years.

Your article reports what appears to be a large sum of money with my name attached, implying that I was excessively "paid"(or excessively billed) and kept all of this money personally. That is not true. Some simple facts are in order. My effort on this case goes back to 2000 and the reported sum covers more than two years worth of work, and numerous reimbursed expenses. My work involved going through thousands of pages of documents, and writing lengthy reports, having multiple conferences, and reviewing hundreds of pages of filings and transcripts for accuracy. I have two full boxes of documents in this case, not counting the discarded, multiple drafts of several lengthy documents. I charge only for my time, my hourly charges are modest, and they reflect the fact that I must pay my office expenses and staff, even when I am working for the State of Wisconsin and unable to generate revenue in my medical practice. I do not make a profit in this work. My work is a professional duty and one I accept.

I have had to work unexpectedly on many weekends, late at night, and often at the last-minute to meet deadlines for this case. At the request of the State of Wisconsin I made two trips to Wisconsin, one a three day trip for a deposition and one for a week-long trial, where I was on the witness stand for four straight, long days last October. Additionally, I was deposed twice by Dr. Kadile's counsel, which consumed a whole day each time. As noted earlier, on several occasions I had cancelled days of patients in my practice to come to the resumption of the trial, but it was then postponed, once at the last minute. On each occasion I had to prepare in advance for several days, by reviewing hundreds of pages of complex medical documents. Further, about 100 detailed scientific papers, books, and monographs had to be analyzed, discussed, and critiqued. It should be noted that in the figure you reported, my reimbursement expenses included two costly, separate plane tickets to Wisconsin, copying charges, secretarial and typing expenses, research materials, and multiple lengthy telephone conferences with the prosecutor. The time spent on this case may appear excessive, but is not of my doing. Rather it is a direct result of the delays, postponements, and activities of Dr. Kadile. I note further that all effort by me was at the request of, and approved by, the Department of Regulation and Licensing.

Simply put, your article suggests that the Kadile matter is focused on the "issue of alternative/complementary medicine" There are those who would want to try to politicize and portray this matter in that fashion to drag a red herring across the field and distract the public from the actual charges and issues in the case. Unfortunately that is the spin that apparently rubbed off on Simms.

The other spin was that I was "on trial". An average reader would walk away with both of those notions. Neither is true. If one simply reads the charges it is quite clear the Kadile case is sharply focused on multiple allegations by the State of bad care. While chelation therapy was part of this care, it is incidental to the issues the State has raised regarding his management and care of patients, and Kadile's competence as a physician. Please read the charges and read them carefully.

Your reporter refers to a statistic which has no original source. "Federal officials estimate that at least 800,000 visits to receive chelation therapy are made in the United States every year." There is no Federal Official who has made this statement to whom it can be attributed. If I am mistaken, please cite the person (s). The actual source of this number is from a chelation advocacy group, however, even they have no data to support it. Careful research will find that there is no study which one can reference for this number. It is simply made up.

The article goes on to quote a Dr. Robert Waters. On the one hand Waters claims to be one of several "investigators" in a large study funded by the National Institutes of Health to see if chelation therapy is effective for coronary artery disease, yet Waters already claims to be using this unproven therapy and is on the record as saying it is safe and effective. A review of the grant proposal fails to show Dr. Waters as an "investigator" or "co-investigator" in this project. Second, if Waters has already pronounced that the therapy works, how can he be an unbiased site supervisor for the study? How could the data he collects be considered to be reliable? Third, and most important, why has Waters been using a therapy that NIH and the FDA say is unproven and ineffective, but only now is under investigation, and on his patients? There is a clear logical inconsistency in this paradigm which your reporter should have easily seen and questioned.

I fully realize that journalism is an imperfect field, and that deadlines and other concerns may affect reporting. I also would like to believe Simms had no motives behind her writing. But, the essence of reporting should be accuracy, and a fair portrayal of the facts. As I have noted, in my opinion, this article fails these standards on several bases. I ask you to remedy these deficiencies..

7/18/2003

W L Simon @ aol.com

There is much, much more I could say about this case, however, as I am a witness, any opinions and other knowledge I have of the case must await its conclusion. Until then, my "on the record testimony" (which is public), particularly from the second, third and fourth days of trial (last October) should give you adequate instruction in what this case is all about. My reports and other documents I generated which were put into the record will also make most interesting reading. For balance it would be worthwhile for Simms to expand her reporting and tell the public about those aspects of Dr. Kadile's activities and care. There is indeed a story there which your readers should know about.

I sincerely appreciate you taking the time to read this necessarily long and detailed letter and would be happy to speak with you about any of its content.

Cordially,

Robert S. Baratz, MD, PhD, DDS

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> HEADLINE: CONTROVERSIAL MEDICAL PROCEDURE UNDER FIRE;

> MEDICAL REGULATORS OUT TO STOP USE OF CHELATION TO TREAT CORONARY DISEASE.

>

> BYLINE: Patricia Simms Health reporter

>

> BODY:

>

> Wisconsin's medical regulators are trying to punish doctors who use a  
> controversial but popular procedure called chelation to treat coronary heart  
> disease.

>

> The case, which is likely to affect the practice of other kinds of  
> alternative medicine in Wisconsin, reflects a national battle fiercely fought  
> between complementary medicine advocates and those who deride procedures not  
> used in traditional Western practice.

>

> The state Department of Regulation and Licensing has accused Dr. Eleazar  
> Kadile, a Green Bay psychiatrist and provider of natural medicine, with using  
> chelation therapy to inappropriately treat at least five patients suffering from  
> heart and other diseases.

>

> In chelation, a man-made amino acid is generally delivered through the veins  
> so that it can bind to toxic or excess metals and help flush them from the body,

- > according to the National Center for Complementary and Alternative Medicine.
- >
- > Three days of hearings are expected to begin today before Administrative Law
- > Judge John N. Schweitzer on the qualifications of the state's expert witness,
- > Dr. Robert Baratz.
- >
- > As head of the Massachusetts-based National Council Against Health Care
- > Fraud, Baratz is well-known for his anti-quackery testimony in other states.
- >
- > But chelation advocates argue that Baratz isn't an expert and has padded his
- > resume.
- >
- > Del Bickle, a Janesville machinist, heads the Wisconsin Association for
- > Health Freedom. "This is a grass-roots organization formed to protect these
- > doctors," Bickle said. "We are all patients who were getting excellent results
- > (from chelation therapy). The Department of Regulation and Licensing is trying
- > to tell us that we can't have this any more, that if you're not a doctor that
- > does drugs or surgery, you're a quack."
- >
- > The department has already paid Baratz \$48,806 in expert witness fees and
- > expenses through Dec. 26, 2002, according to records custodian Dave O'Connell.
- >
- > Arthur Thexton, the state's prosecuting attorney, last week acknowledged that
- > chelation is not the only alternative medicine targeted in the Kadile case.
- > "Chelation is only one of a number of issues in this case," Thexton said in an
- > e-mail. "Even if chelation were shown to be an effective therapy, we would still
- > be proceeding against Dr. Kadile on these other issues."
- >
- > The state has also accused Kadile of:
- >
- > \* Billing for treatments like "oxidative therapy" and hair analysis and a
- > test for allergies called provocation neutralization.
- >
- > \* Prescribing and selling the debunked Dimethyl Sulfoxide (DMSO) to patients
- > for memory failure and stroke rehabilitation.
- >
- > \* Lying to insurers about a patient's diagnosis so chelation therapy would be
- > covered.
- >
- > The use of chelation "by a physician for circulatory problems,
- > arteriosclerosis or for removal of metals other than lead and other heavy metals
- > is an unacceptable risk to the patient and is unprofessional conduct," the
- > complaint said.
- >
- > Chelation is approved by the U.S. Food and Drug Administration (FDA) for
- > treating lead poisoning and other heavy-metal toxicity, but the FDA has not
- > approved it to treat coronary disease.
- >
- > Federal officials estimate that at least 800,000 visits to receive chelation
- > therapy are made in the United States every year.
- >
- > For the past six years, the state has also been investigating Dr. Robert
- > Waters, who operates the Waters Preventive Medicine Center in Wisconsin Dells
- > and provides chelation therapy for heart disease.
- >
- > Waters is also one of 62 investigators in a \$30 million National Institutes
- > of Health study to decide whether chelation works to treat heart disease.
- > Marshfield Clinic is also a clinical test site.
- >
- > "Chelation has enough promise that the government feels it is worth \$30
- > million (in study)," Waters said Monday. "It is very inappropriate that the

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- > state continues to harass people like myself for doing this treatment."
- >
- > After hearings this week on Baratz are done, the case against Kadile is
- > expected to resume Aug. 6, said Sandy Rowe, enforcement division administrator.
- >
- > After that, the administrative judge will make a recommendation to the state
- > Medical Examining Board.
- >
- > Hearing scheduled
- >
- > A hearing in the state's continuing case against Dr. Eleazar Kadile has been
- > scheduled for 9 a.m. today in Room 291, state Department of Regulation and
- > Licensing, 1400 E. Washington Ave., Madison.
- >

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# LOCAL NEWS

Capital Newspapers

## Area doctor chosen to help with chelation study

The study will either prove or disprove that chelation therapy can aid in the fight against heart disease

By Sarah Estrella  
Events Reporter

The Waters Preventative Medical Center in Wisconsin Dells will take part in a \$30 million nation-wide study of chelation therapy for treatment of coronary disease.

"Chelation removes toxic metals and reduces formation of free radicals, the by-product of damage to biological membranes, and DNA," said Wisconsin Dells researcher Dr. Robert S. Waters.

The therapy is given by pumping a man-made amino acid through the veins via an intravenous tube. The amino acid is said to work by binding with toxic and excess metals that are flushed out of the body, clearing the vascular system.

Waters was chosen by the National Center for Comple-

mentary and Alternative Medicine and the National Heart, Lung and Blood Institute to take part in a double-blind study called the Trial to Assess Chelation Therapy. About 2,372 people will take part in the study conducted by 62 clinics.

Waters has 20 years of experience in chelation therapy and his clinic, Waters Preventative Medical Center, is one of two sites in Wisconsin that will participate in the study. The Marshfield Clinic was also chosen.

Chelation therapy is controversial, but very popular. The state Department of Regulation is investigating the appropriate use of chelation by Green Bay psychiatrist, Eleazar Kadile.

Meanwhile, an administrative law judge is hearing arguments that challenge the qualifications of an expert witness the state of Wisconsin paid almost \$50,000 to testify against the therapy.

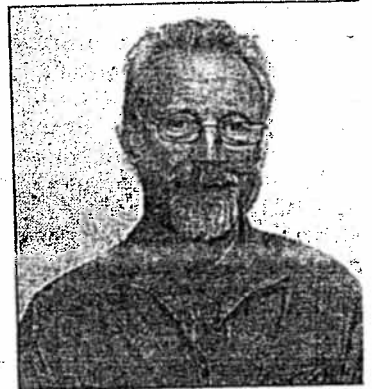
Many doctors welcome the big-bucks study and believe it will put to rest the controversies surrounding chelation.

Dr. Waters studied biology and genetics and attended medical school at the University of Illinois-Chicago. "I was going to be a surgeon, but then I got really interested in nutritional medicine" he said, noting that "traditional" medicine practiced in the U.S. is not the only, nor the best way to fight disease.

Federal officials estimate that Americans make 800,000 visits to receive chelation therapy in the U.S. every year. Chelation is approved by the FDA, but only for removal of heavy metals to treat lead poisoning.

"The study will be done by a mix of medical doctors. The institute wanted both chelation and non-chelation doctors for a complete assessment," Waters said. "I'm very happy and honored to be chosen as one of the investigators. We're finally going to get a fair look at chelation therapy."

Waters told Events that he took part in an earlier study of chelation conducted by Walter Reed Army Hospital in the late 1980s, "but it was



WATERS

shut down when the Gulf War occurred and military doctors were needed".

Waters is seeking candidates who are at least 50 years old, who have heart disease and do not smoke or have not received chelation therapy in the last five years.

"This study is funded and fully backed. It's going to happen," Waters said.

The Waters Preventative Medical Clinic will accept at least 24 volunteers.

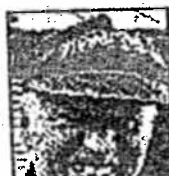
For more information on the study or chelation therapy, call 800-200-7178 or visit [www.tactnih.com](http://www.tactnih.com).

## County drops Weedstock case

Court dismisses \$120,000 civil case between county, local landowner.

By Brian Riddnower

The dismissal was actually requested by Sauk County's legal counsel.



restricted First Amendment rights too much.

The legal tussle with Gumz and Masel stems from Sauk County's shut down of Weedstock on May 26, 2000, after

property on County Highway U in Fairfield Township was used as the site of the festival.

As part of the enforcement of the ordinance, lawyers for Sauk County filed a suit

# FDA

New Angina Drugs  
Sucralfate Approved for Duodenal Ulcers  
Ritodrine Update  
Use of Approved Drugs for Unlabeled Indications

Hepatitis B Vaccine for Use in Selected Populations  
Advice on Limiting Intake of Benzocaine  
Bendectin PPI Available  
Class I Recalls

# Drug Bulletin

## Use of Approved Drugs for Unlabeled Indications

The appropriateness or the legality of prescribing approved drugs for uses not included in their official labeling is sometimes a cause of concern and confusion among practitioners.

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, a drug approved for marketing may be labeled, promoted, and advertised by the manufacturer only for those uses for which the drug's safety and effectiveness have been established and which FDA has approved. These are commonly referred to as "approved uses." This means that adequate and well-controlled clinical trials have documented these uses, and the results of the trials have been reviewed and approved by FDA.

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 precisely, "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.

The term "unapproved uses" is, to some extent, misleading. It includes a variety of situations ranging from un-studied to thoroughly investigated drug uses. Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigations. Before such advances can be added to the approved labeling, however, data substantiating the effectiveness of a new use or regimen must be submitted by the manufacturer to FDA for evaluation. This may take time and, without the initiative of the drug manufacturer whose product is involved, may never occur. For that reason, accepted medical practice often includes drug use that is not reflected in approved drug labeling.

With respect to its role in medical practice, the package insert is informational only. FDA tries to assure that prescription drug information in the package insert accurately and fully reflects the data on safety and effectiveness on which drug approval is based.