☞ **05hr_JC-Au_Misc_pt36f**

☞ 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**

* Contents organized for archiving by: Stefanie Rose (LRB) (July 2012)

May 14, 2003

Member of the Board
Wisconsin State Medical Examining Board
1400 East Washington Avenue
Madison WI 53703

Dear Board Member,

My name is Robert S. Waters, M.D., and I have been practicing Complementary and Alternative Medicine (CAM) for 22 years. I have had two cases pending before the Board since 1997. We are all victims of the information we have or fail to have in forming our opinions in many areas of our lives. I wouldn't expect Medical Board members to be any more or less fortunate. In that regard, I am enclosing herewith an article written by a colleague of mine who also practices CAM[1]. This article may, I hope, give you a different perspective in your mission to protect the citizens of Wisconsin from problems arising from their medical care.

Because Eleazar Kadile, M.D., one of my Wisconsin colleagues, and I are the subjects of an ongoing investigation by your Board for our use of EDTA Chelation Therapy, I would like to give you a brief update on some recent research on this treatment. I am enclosing an article that appeared in the New England Journal of Medicine on January 23, 2003 on the efficacy of EDTA Chelation Therapy in the treatment of moderate renal failure[6]. The study showed that patients with renal failure and mild lead accumulation were able to delay having to undergo dialysis treatment as a result of undergoing EDTA Chelation Therapy. This is an example of how even relatively small amounts of toxic metal exposure may be an underlying etiologic factor in the diseases of aging and may help explain why those of us using EDTA Chelation Therapy routinely see patients improve in reference to their vascular and other degenerative disease states after undergoing a series of EDTA Chelation Therapy treatments.

The same authors, in a series of papers published in peer-reviewed medical journals starting in 1999, have shown that lead accumulation leads to renal dysfunction[2,3,4]. Their 2003 paper verifies that EDTA Chelation Therapy can partially reverse this process. The economic savings and reduction in human suffering that can be achieved as a result of a much wider use of this treatment is awesome.

In December 2001, my colleagues at the US Department of Agriculture, Human Nutrition Requirements Laboratory and I published an article also enclosed with this communication. We showed that in 16 patients undergoing Chelation Therapy in my office not known to have obvious environmental exposure to lead and cadmium, a 38 fold rise in 24-hour urine lead was measured as compared to a 24 hour urine lead the day before their Chelation treatment. Cadmium, an element also etiologically linked to a number of disease states also rose seven fold

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in the 24-hour urines before and after EDTA Chelation Therapy. We also were able to document an 83% retention of the IV magnesium that is contained in the chelation solution[5]. This percentage retention is far in excess of what the medical literature has indicated for the documentation of magnesium deficiency (generally less than 20-30%). There is extensive scientific literature linking magnesium deficiency as a concomitant or etiologic factor in diabetes mellitus, hypertension and occlusive vascular disease. Recent work has shown that magnesium deficiency leads to reduction in the efficiency of the antioxidant defense system. Our 2001 paper, along with the observation of chelation therapists that patients with these medical diagnoses improve clinically after a series of EDTA treatments, dovetails with the enclosed 2003 paper of Lin, *et al* on renal function improvement in non-diabetic renal failure patients after EDTA Chelation Therapy[6].

Work I am doing in association with the USDA scientist Richard Anderson, PhD and Joseph Fourier University chemist and free radical biologist Ann-Marie Roussel, PhD in Grenoble France has revealed a reduction of free radical markers in the blood along with an increase in the antioxidant defense system enzyme glutathione peroxidase after 10 EDTA Chelation treatments over a five-week interval. This work may reveal the underlying biochemical mechanism by which EDTA treatment improves the symptoms of degenerative diseases. Biomedical researchers now universally accept free radical damage to cell membranes, enzyme systems and DNA itself as the etiology of disease at the molecular level.

It is becoming clear through my research as well as that of others that the use of EDTA in the treatment of degenerative diseases is accomplishing just what the original FDA package insert stated under "indications" – the removal of heavy metals. The research of the past few years is steadily revealing that even relatively mild (compared to gross poisoning in e.g. industrial settings) accumulation of lead, cadmium, mercury, arsenic, antimony and aluminum result in adverse biological effects. In addition, excess iron and the resultant oxidative damage there from is reduced by EDTA. Reduction of toxic metal burdens and administration of magnesium in the IV infusion is the basis of the "push-pull" mechanism of Chelation Therapy originally described by Dr. Mordechia Chevion of Hebrew University in Jerusalem, Israel and discussed in my 2001 article[7].

This is particularly interesting since research done by a Swiss colleague of mine by the name of Walter Blumer, MD, who gave EDTA Chelation Therapy to many of his patients in Glarus, Switzerland revealed that as compared to patients from the same town who hadn't had Chelation Therapy, the chelated patients had one ninth the rate of cancer. Lead is known to poison all biological systems/tissue; it isn't a surprise that it could induce immune dysfunction. Work done by Lustberg has revealed that lead accumulation is related to all-cause mortality[8].

Another recent study on lead has revealed that there is no safe level of lead (see enclosed article and perspective)[9]. In accessing children with blood leads below 10mcg/dL, (the current "standard" of toxicity) for each 1mcg/dL above zero, the children lost 0.82 I.Q. points. This means that on average a child with 10 mcg/dL will have an I.Q. of 8.2 points lower than a child with no lead at all. This represents a significant loss in life possibilities for even an "unpoisoned" child. Mr. Thexton's witness, Dr. Baratz, would have us wait until a child's lead rises to 70mcg/dL before we would have any concern (this is from his Wisconsin testimony in Dr. Kadile's case).

An article published in the Journal of Cardiology revealed that patients with cardiomyopathy had 22,000 times more mercury and 12,000 times more antimony than controls, while patients with secondary cardiac dysfunction had lesser increases (5-fold) in myocardial toxic and trace element accumulation[10]. The authors discuss the idea that toxic and trace element accumulation may adversely affect mitochondrial activity and myocardial metabolism and worsen cellular function in cardiomyopathy patients. Could lesser amounts of toxic and trace elements in the heart be the basis of "secondary cardiac dysfunction"

such as ischemic heart disease? The evidence mounts that toxic metal accumulation may be a major factor in the etiology of vascular and other degenerative diseases. A November 28, 2002 article in the New England Journal of Medicine reported that toenail mercury level directly correlated with the risk of myocardial infarction[11]. The Journal of the American Medical Association reported in the March 26, 2003 issue that "levels well below the current US occupational exposure limit" of 40mcg/dL, blood lead is positively associated with both systolic and diastolic blood pressure and risk of hypertension in woman 40-59 years old[12].

Again, is this why we see our patients get better with Chelation Therapy? There is some scientific basis for the effectiveness of EDTA being related to the alteration in calcium biology via parathormone, reduction in platelet adhesiveness, and effects on oxidation-reduction state. As a matter of fact, Martin Rubin, PhD, Professor Emeritus of Chemistry at Georgetown University in Washington D.C., has told me that he postulates as many as 22 possible mechanisms of action for EDTA. Dr. Rubin has the original patent on EDTA for use as an anticoagulant in the laboratory. He was also the first scientist to research EDTA's use in humans in a breast cancer trial done with nickel EDTA in 1947. He also published the first study showing increased lead excretion after calcium EDTA administration almost exactly 50 years ago. Studies done in the Czech Republic revealed that EDTA infusions decalcify atherosclerotic aortas in rabbits and minipigs. More research is needed in non toxic-metal mechanisms of therapeutic action for this drug. However, the explanation for effectiveness may be based solely on toxic metal reduction.

I would also like to make you aware of the fact that the National Institutes of Health, through its National Heart, Lung and Blood Institute and its CAM Institute have begun a $30 million study of EDTA Chelation Therapy on 2300 patients with known coronary artery disease. The medical scientists in those Institutes believe that there is enough evidence of the safety and efficacy of this treatment to warrant such an expenditure.

My purpose in writing you is also to put you on notice that one of the Prosecutors for the Department of Regulation and Licensing, Arthur Thexton, is engaging in a campaign to stop the citizens of Wisconsin from having access to this treatment. He is also trying to restrict the use of CAM practices in Wisconsin on a larger scale and is harassing practitioners who engage in such practices. My belief is that your Board is not cognizant of Mr. Thexton's actions and may not in fact support his intentions. He has engaged a politically motivated "expert witness" from the State of Massachusetts who has exaggerated and falsified his qualifications to be an expert in these cases and has charged our State over $50,000 in "expert witness" fees. Dr. Baratz is the President of a group known as the National Council Against Health Fraud (NCAHF) who identify themselves as "quackbusters." To see what preposterous and archaic ideas these groups promulgate, please look at their websites www.ncahf.com, www.quackwatch.com and www.acsh.com. For example, at a time when we as a nation are finally addressing the damage we have caused to our environment by toxic metals and other chemicals, these groups have called for lowering air pollution standards, ignoring lead accumulation in children until it reaches extremely high levels, the reintroduction of DDT to kill mosquitoes and have suggested that there is no evidence that PCB's are harmful to living creatures. In my mind, it is a disgrace for Mr. Thexton to have caused the State to give over $50,000 to an individual with such a mindset. Were the Board or any Board advisors aware of Dr. Baratz' background or was Mr. Thexton operating autonomously?

When Mr. Thexton asks you to support his campaign to eliminate Chelation Therapy or other CAM practices, please ask yourself how you will feel if these very safe practices are later proven to be effective in the treatment of human diseases. I was forced to come to you directly with this information because I don't believe Mr. Thexton can be trusted to give you balanced information. He is presently only relying on the biased views of the members of the "quackbusters." If you believe that JAMA, NEJM, Archives of Internal Medicine and the Journal of the American College of Cardiology are reputable sources, you are

obliged to stop the prejudiced, anti-scientific harassment by Mr. Thexton and his pseudoexpert, Dr. Baratz.

Recently a California Appeals Court Panel has decided that the NCAHF's measuring stick for health care was bogus and the witnesses espousing their theories were not credible. These witnesses were the Vice President, Steven Barrett, MD and another Board member, Wallace Sampson, MD (whom Mr. Thexton has threatened to bring in to the case against Dr. Kadile as a second witness). The Court held that the witnesses "were found to be biased and unworthy of credibility." Dr. Baratz is President and Chief spokesperson for the Plaintiff organization in that case and he is the only expert witness that Mr. Thexton is relying on for his unfair and unjust attacks on CAM doctors.

In a private conversation with Dr. Terry Chappell of Ohio, Mr. Thexton stated he was thinking of buying some expensive Natural Medicine textbooks to use in attacking more doctors in Wisconsin for doing CAM. He is using his position as a prosecutor to further the aims of radical special interest groups. This doesn't even appear to be legal, let alone ethical.

There have been no complaints by patients who have undergone EDTA Chelation Therapy in the State of Wisconsin. Is it appropriate for the DORL to expend the kind of resources and to cause the kind of misery to innovative CAM practitioners that Mr. Thexton has at the behest of a small political group? Is allowing this to happen part of your mission as a Board member? The State of Wisconsin is a leader in the Nation on many fronts. We should be proud to accept innovative medicine and lead the way for other States when it comes to offering the best possible medical care for our citizens. I respectfully suggest you govern the behavior of Mr. Thexton in these matters. He has already caused my practice, patients, staff, family and me untold damage. I also suggest you close cases 97MED101 and 97MED108 due to no violation having occured. Back in 1991, case 91MED365 was also generated by the complaint of another physician because he objected to my use of Chelation Therapy and was closed in 1993 for lack of evidence that a violation occurred. Cases 97MED101 and 97MED108 clearly represent harassment and have caused, and continue to cause, me great damage on a number of levels.

I thank you for bearing with me in this rather lengthy communication. Hopefully, it has been informative. I look forward to a prompt resolution of these matters.

Sincerely,

Robert S. Waters, M.D.

RSW:sbc

CC: Governor James Doyle
Attorney General Peg Lautenschlager
Senator Dale Schultz
Representative Sheryl Albers
Donsia Strong Hill

ENC: 4

References

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4. Lin, J., et al. Chelation therapy for patients with elevated body lead burden and progressive renal insufficiency. *Ann Intern Med.* 1999, 130: 7-13.

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10. Fructaci, A., et al. Marked elevation of myocardial trace elements in idiopathic dilated cardiomyopathy compared with secondary cardiac dysfunction. *Journal of American College of Cardiology*, 2000, 35(3): 819-820.

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WISCONSIN DEPARTMEN 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
Voice: 608-266-2112
FAX: 608-267-0644
TTY: 608-267-2416

June 11, 2002

Robert S. Baratz, MD
159 Bellevue Street
Newton, MA 02458-1834

RE: 97 Med 101/108, Robert S. Waters MD

Dear Dr. Baratz:

Enclosed are what counsel for Dr. Waters represents as two charts, per his attorney's letter. These are the other two "insulin potentiation" charts; you have already received one such chart.

Please review all 3 of these charts as you have reviewed the other charts you have received in this matter.

Sincerely yours,

Arthur Thexton
Prosecuting Attorney
608-266-9814
FAX 266-2264
arthur.thexton@drl.state.wi.us

cc: Case Advisor (w/out encl.)

Encl: letter from Atty Whipple with enclosures

I:\waters.ltx.doc

Enclosure 10

Sarah Chapman

From: Erika Elliott [ehelliott@sse-law.com] on behalf of GREG [gdseeley@sse-law.com]
Sent: Thursday, April 04, 2002 10:09 AM
To: becky@watersmedcenter.com
Cc: Douglas P. Whipple
Subject: FW: Waters

Bob,

Thexton has informed me that a new complaint was received that they are investigating, and this is what he is proposing (see below). Review your files and call me.

-Gregory D. Seeley, Esq.
Seeley, Savidge & Ebert Co., L.P.A.
800 Bank One Center
600 Superior Avenue, East
Cleveland, Ohio 44114
216-566-8200 - phone
216-566-0213 - fax
gdseeley@sse-law.com

-----Original Message-----
From: Thexton, Arthur [mailto:arthur.thexton@drl.state.wi.us]
Sent: Tuesday, April 02, 2002 3:21 PM
To: GREG
Subject: Waters

Per our telephone conversation and past practice in this case, I request that your client select three patient charts from his patients who have been administered insulin potentiation therapy. I hereby request certified and complete copies of those charts, including billing records, pursuant to our authority under s. 146.82(2)(a)5., Wis. Stats.

In making the selection, I express a strong desire that these patients have completed the course of therapy.

Arthur Thexton, Prosecuting Attorney
Department of Regulation & Licensing
Division of Enforcement
1400 E. Washington Ave
Madison, WI 53708-8935
608-266-9814
FAX 266-2264
arthur.thexton@drl.state.wi.us

Enclosure 11

Jan 26, 2002

Dear Dr.

I've started IPT with Dr. Waters and will be done Feb. 7. To check on the progress of IPT, I would like to have an X-ray (not a CT-Scan) before leaving for Florida on Feb. 12, and then another X-ray later in the spring.

Can you arrange for a chest X-ray for me sometime between Feb. 7 and Feb. 12?

Thank you,

[redacted]

1/29/02 – Discussed with pt that this is not an approved therapy and injecting insulin could be harmful and possibly fatal. Advised against such treatments, and to discuss c

Date: February 13, 2002
To: State Medical Society ,Legal Department

Please see the enclosed brochure from a Dr. Waters.
I have personal knowledge that this physician is performing this procedure and charging 900.00 per session. According to one of my patients he is injecting insulin and following it up with glucose, and proposing that it shrinks tumors. Enclosed is the brochure and insight of what one of my patients interpreted what his therapy would do for her and asked me for a follow up chest xray to follow the progress. By the way this patient was not undergoing any standard chemotherapy at this time, and has metastatic non small cell lung cancer for which she had completed radiation therapy.

I prefer to remain anonymous, enclosed is the physicians brochure for your review.

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State Medical Society of Wisconsin
Working together, advancing the health of the people of Wisconsin

February 20, 2002

Wayne R. Austin, JD
Wisconsin Department of Regulation and Licensing
Medical Examining Board
1400 East Washington Avenue
Madison, WI 53703

Dear Wayne:

Enclosed are a brief note and a copy of a brochure that was recently sent anonymously to the State Medical Society of Wisconsin ("SMS") by a Wisconsin physician. The note suggests that the physician is concerned about the fact that another doctor, Robert S. Waters, appears to be treating cancer patients with insulin potentiation therapy.

When the SMS reviewed the information in the brochure, we noted that Dr. Waters described himself as board certified in chelation therapy. Our limited research indicates that a person can obtain a certification to perform chelation therapy from either the American College for Advancement in Medicine or the American Board of Chelation Therapy. However, it does not appear that the American Board of Medical Specialties either certifies or recognizes the certification of chelation therapists. The American Medical Association has a policy on chelation therapy, a copy of which is enclosed.

The SMS is forwarding all of the aforementioned information to you. By forwarding the information to you, we are not filing a complaint against Dr. Waters, because we have not determined that a complaint is appropriate or that the health and safety of the public is at risk. We are merely passing along the information that was sent to us and we trust that you will take any steps that you deem appropriate under the circumstances.

Sincerely,

Ruth M. Heitz, JD
Associate General Counsel

Enclosures

cc: Mark Adams, General Counsel

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CORRESPONDENCE/MEMORANDUM

STATE OF WISCONSIN

DATE: February 1, 1993

FILE REF: 91 MED 365, Waters

TO: Case File

FROM: Stuart Engerman

SUBJECT: CASE SUMMARY

RESPONDENT:

Robert Scott Waters, M.D.
S1363 Larue Road
LaValle, WI 53941

COMPLAINANT:

Richard O. Sarnwick, D.O.
Gillett Family Medical Center
119 Main Street
Gillett, WI 54124

INVESTIGATIVE STAFF:

Walt Neverman

ATTORNEY:

Pam Stach

I. COMPLAINT:

Dr. Sarnwick contacted our office to express concern about one of his patients who was considering chelation therapy treatment from Dr. Waters for his coronary artery disease. Dr. Sarnwick said he was not certain whether chelation therapy is a legitimate treatment for coronary artery disease, and he was concerned that patients may not receive optimal treatment if they undergo this therapy.

II. INVESTIGATIVE SUMMARY:

During the course of the investigation we spoke briefly with Dr. Waters regarding this complaint. Subsequent communication was with Dr. Waters' attorney, Mr. Patrick McIntyre.

Mr. McIntyre provided copies of numerous articles regarding the effectiveness of chelation therapy in the treatment of coronary artery

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disease. Mr. McIntyre also cited Dr. Waters' own experiences using chelation therapy, which he termed "overwhelmingly positive". He indicated that Dr. Waters has treated arteriosclerosis of coronary, carotid and peripheral vascular blood vessels, hyperlipidemia, hypertension, diabetes mellitus, scleroderma, arthritic conditions and heavy metal intoxication using chelation therapy. Dr. Waters was noted to do a complete history, physical and laboratory evaluation of each patient before deciding whether chelation therapy is indicated for that patient.

The written correspondence, as well as articles and other written materials, were reviewed by a physician member of the Medical Board.

III. ALLEGED VIOLATIONS AND APPLICABLE STATUTORY/CODE CITATIONS:

Wisconsin Administrative Code MED 10.02 (2)(h), "Any practice or conduct which tends to constitute a danger to the health, welfare or safety of patient or public".

IV. FINAL BOARD ACTION:

Based on the recommendation of the Board member who reviewed the case, the Medical Board voted on January 21, 1993 to close this case due to insufficient evidence that a violation had occurred.

(2)

State of Wisconsin \ DEPARTMENT OF REGULATION & LICENSING

Marlene A. Cummings
Secretary

1400 E. WASHINGTON AVENUE
P.O. BOX 8935
MADISON, WISCONSIN 53708
608 266-2112

Tommy G. Thompson
Governor

February 8, 1993

Robert Scott Waters, M.D.
S3163 Larue Rd
La Valle. WI 53941

RE: 91 MED 365
Robert Scott Waters, M.D.

Dear Dr. Waters:

The Medical Examining Board received information complaining about your actions as a licensee of this Department. The information was reviewed for the purpose of determining whether disciplinary proceedings should be brought against you.

The information received was screened and opened for investigation. An attorney and a regulation compliance investigator were assigned to this matter.

Upon completion of this investigation, representatives of the Division of Enforcement presented the relevant facts to the Medical Examining Board.

After considering the matter, the Board voted to close the case without further action for the following reason: There is insufficient evidence to meet the standard of proof required to prove that a violation occurred. A memorandum summarizing the case is enclosed.

If you have questions concerning this file, please write to the Division of Enforcement, Room 194, P.O. Box 8935, Madison, WI 53708-8935. In the event you write, please refer to the file number of the case.

Sincerely,

Stuart Engerman
Investigator
Division of Enforcement
(608) 266-3315

Encl.

John Temby
Dept Regd Lic
D.O.J. - Ed Fee Rec
Box 8935
Madison
53708

Enclosure 15

Robert S Winters MD.

FEDERATION OF STATE MEDICAL BOARDS OF THE UNITED STATES, INC.

The Restructure of Change They want to retain Power.

HOUSE OF DELEGATES ANNUAL BUSINESS MEETING
CHICAGO, ILLINOIS
APRIL 19, 1997

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1.	Call to Order, 2:00 pm *James E. West, MD*	
2.	Roll Call of Member Boards *James R. Winn, MD*	
3.	Announcement of Parliamentarian and Tellers *James E. West, MD*	
4.	In Memoriam: Honoring Deceased Members *James R. Winn, MD*	A
5.	Approval of Minutes of April 1996 Business Meeting	B
6.	Report of the Rules Committee *William H. Fleming, III, MD*	C
7.	President's Report of the Board of Directors *James E. West, MD*	D
8.	Report of the Executive Vice President *James R. Winn, MD*	E
9.	Report on the FSMB Long-Range Plan *James R. Winn, MD*	F
10.	Treasurer's Report of the Finance Committee *Bruce H. Hasenkamp, JD*	G

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E. National Commission on Certification of Physician Assistants *Bruce H. Hasenkamp, JD*	O
15. Announcement of 1998-2000 Annual Meeting Sites	
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REPORT OF THE BOARD OF DIRECTORS

Subject: Special Committee on Health Care Fraud

Referred to: Reference Committee A

The Special Committee on Health Care Fraud was established by Dr. Robert E. Porter in April 1995 to accomplish the following objectives:

> To research, review, and evaluate the current status of questionable health care treatments, procedures, and/or promotions which may be unsafe and thereby considered a risk to the public's health, safety, and welfare;
>
> To research, review, and evaluate the current status of questionable health care treatments, procedures, and/or promotions which may be worthless and thereby likely to deceive or defraud the public; and
>
> To develop strategies for recommendation to state medical boards for the regulation and discipline of physicians who engage in unsafe and/or deceptive practices.

The committee met several times since its establishment and submitted its report and recommendations to the Board of Directors in February 1997. Federation President, James E. West, MD, has extended the committee's charge to allow the committee to provide information to state medical boards on an ongoing basis or as specifically requested.

The committee's report contains eleven (11) recommendations designed to assist state medical boards in identifying, evaluating, investigating, and prosecuting cases involving health care practices which may be unsafe and thereby pose a risk to the public health and safety and/or which may be worthless and thereby likely to deceive or defraud the public. The committee's recommendations also address legislative and educational initiatives as well as to encourage collaboration with other agencies and organizations. Following each recommendation, the committee offers specific suggestions pertinent to the recommendation.

Upon the recommendation of the Board of Directors, the House of Delegates is asked to adopt the following recommendations of the Special Committee on Health Care Fraud:

1. State medical boards should develop mechanisms to identify physicians who may be engaging in questionable health care practices.

2. State medical boards should develop criteria for evaluating any health care practice which has been called into question.

3. State medical boards should utilize reliable information resources in their evaluation of questionable health care practices.

4. State medical boards' ancillary staff, including board investigators, should utilize methods to effectively investigate questionable health care practices.

5. State medical boards should work in conjunction with state prosecutors in the initiation, development, and disposition of cases involving questionable health care practices.

6. State medical boards should carefully evaluate all avenues of potential prosecution and coordinate such with appropriate federal, state, and local agencies.

7. State medical boards should review their Medical Practice Acts and pursue legislative support for revisions to strengthen the medical board's ability to regulate physicians engaging in questionable health care practices.

8. State medical boards should notify the Federation of State Medical Boards of any state legislative initiatives identified that could diminish the state medical board's ability to regulate questionable health care practices.

9. The Federation of State Medical Boards should monitor federal and state legislative activities regarding health freedom issues and develop strategies to assure that the authority of state medical boards is maintained.

10. State medical boards, with the assistance of the Federation of State Medical Boards, should develop educational opportunities for licensees regarding the prevalence, risks, and efficacy of questionable health care practices.

11. On behalf of state medical boards, the Federation of State Medical Boards should collaborate with other agencies and organizations in efforts to identify and eliminate questionable health care practices that are adverse to the public health, safety, and welfare.

RECOMMENDATION:

The Board of Directors recommends that:

The recommendations of the Special Committee on Health Care Fraud be approved as policy and the remainder of the report be filed.

These were adopted unanimously @ the 4/19 meeting

FEDERATION OF STATE MEDICAL BOARDS OF THE UNITED STATES, INC.

REPORT OF THE SPECIAL COMMITTEE ON HEALTH CARE FRAUD

SECTION I: PREAMBLE

In April 1995, Federation President Robert E. Porter, MD, established a special committee on health care fraud. The need for such a committee arose from the proliferation of unconventional and unproven medical practices and promotions in the United States, some of which may be questionable and thereby pose a risk to the public health, safety, and welfare. Recent national and state legislative initiatives prompted further concern because they could result in restricting state medical boards' ability to provide appropriate regulation of such practices. The committee was directed to research, review, and evaluate questionable health care treatments, procedures, and promotions which may be worthless and therefore deceptive and/or that pose a risk to the public health, safety, and welfare. The committee was also charged with developing strategies which could be recommended to state medical boards for the regulation and discipline of physicians who engage in unsafe, worthless, and/or deceptive practices.

The committee met several times since its inception and developed recommendations designed to assist state medical boards in evaluating, investigating, and prosecuting physicians engaged in such practices. The committee limited its review to those practices, procedures, and/or promotions which may be offered by allopathic or osteopathic physicians and, therefore, subject to medical boards' jurisdiction and are not widely taught in medical schools nor generally available in hospitals. Additionally, the committee has expanded its charge to include an educational component to develop recommendations for state medical boards in educating licensees, consumers, and legislators on issues regarding unconventional and/or unproven health care treatments, procedures, and promotions.

The committee recognized that the primary responsibility of state medical boards is to protect the public from the incompetent, unprofessional, improper, and unlawful practice of medicine and further that the authority for state medical boards to regulate medical practice is determined by each state's medical practice act. In its capacity as a resource for research, policy development, education, and information, the Federation has developed a model medical practice act *(A Guide to the Essentials of a Modern Medical Practice Act)* to assist state medical boards in developing legislative language necessary to effect regulation of medical practice. Accordingly, the committee's initial recommendations included a proposal to revise pertinent sections of *A Guide to the Essentials of a Modern Medical Practice Act* in order to strengthen the ability of state medical boards to regulate fraudulent behavior. These recommendations were adopted by the Federation's House of Delegates during its April 1996 meeting and have been incorporated in the policy document. The revisions expand the responsibilities of the medical board to include protection against the fraudulent and/or deceptive practice of medicine and render the unlicensed practice of medicine a felonious offense.

The following objectives were identified by the committee:

- To develop recommendations to assist state medical boards in identifying, evaluating, investigating, and prosecuting cases involving questionable health care practices.

- To develop strategies to monitor legislative initiatives supporting increased access to unconventional and unproven treatments and assist state medical boards in responding to such initiatives in the interest of the public health, safety, and welfare.

- To solicit support for the Federation's efforts to control health care fraud from medical professional organizations, governmental agencies, and other interested organizations.

- To develop and implement educational opportunities for state medical board members, executive directors, and investigative staff on effective regulation of questionable health care practices.

The recommendations contained in this final report of the Special Committee on Health Care Fraud are designed to achieve the above objectives.

SECTION II: DEFINITIONS

The committee recognizes the practice of medicine (defined in *A Guide to the Essentials of a Modern Medical Practice Act)* as - - -

1. advertising, holding out to the public, or representing in any manner that one is authorized to practice medicine in the jurisdiction;

2. offering or undertaking to prescribe, order, give, or administer any drug or medicine for the use of any other person;

3. offering or undertaking to prevent or to diagnose, correct, and/or treat in any manner or by any means, methods, devices, or instrumentalities any disease, illness, pain, wound, fracture, infirmity, defect, or abnormal physical or mental condition of any person, including the management of pregnancy and parturition;

4. offering or undertaking to perform any surgical operation upon any person;

5. using the designation Doctor, Doctor of Medicine, Doctor of Osteopathy, Physician, Surgeon, Physician and Surgeon, Dr., MD, DO, or any combination thereof in the conduct of any occupation or profession pertaining to the prevention, diagnosis, or treatment of human disease or condition unless such a designation additionally contains the description of another branch of the healing arts for which one holds a valid license in the jurisdiction.

Additionally, for the purposes of this report, the terms "alternative medicine/therapy" and/or "complementary medicine" have not been utilized by the committee due to a lack of consensus among both practitioners and the public as to their meaning. The committee has chosen to use the term "questionable health care practices" to include those treatments, procedures, and/or promotions, conventional or unconventional, which may be unsafe and thereby considered a risk to the public's health, safety, and welfare AND/OR which may be worthless and thereby likely to deceive or defraud the public.

SECTION III: IDENTIFICATION

Recommendation One:

State medical boards should develop mechanisms to identify physicians who may be engaging in questionable health care practices.

In order to offer reasonable protection to the public, state medical boards must be able to identify physicians who engage in questionable health care practices which may endanger the public, either directly or indirectly. Direct harm may result in adverse patient outcomes and indirect harm may result in delay of appropriate diagnoses and/or treatments.

The committee suggests the following mechanisms to facilitate the identification of physicians engaging in questionable health care practices:

- Encourage consumer/patient reporting by increasing awareness among the public through distribution of educational materials and utilizing media sources.

- Encourage and expand reporting from licensees and other health care professionals by increasing awareness of reporting requirements through newsletters, announcements, alerts, advisory opinions, and collaboration with state and local medical professional organizations and societies.

- Expand liaison efforts with regulatory agencies (federal, state, and local), including the Federal Trade Commission, other state licensing authorities, state attorneys general, district attorneys, and public health departments.

- Improve reporting from third party payers and peer review organizations (PROs).

- Periodically monitor health care promotional materials, including random review of newspapers, periodicals, and other advertising mediums.

SECTION IV: EVALUATION AND INVESTIGATION

Recommendation Two:

State medical boards should develop criteria for evaluating any health care practice which has been called into question.

In order to effectively process a complaint or report involving questionable health care practices, state medical boards must determine whether the practice in question is (1) indicated (2) appropriate and (3) reasonably safe as compared to established treatment models. The committee strongly supports the concept that the prevailing standard of care used in evaluating health care practices be consistent, whether such treatment is regarded as "conventional" or "unconventional". Such standards include appropriate documentation, informed consent, appropriate monitoring and follow-up, rationale for treatment, and periodic review of efficacy of treatment.

The committee suggests the following criteria be utilized in evaluating health care practices:

- Has an adequate patient assessment been conducted, including history and physical examination, laboratory studies, x-rays, and other evaluative measures, to determine that the patient has the condition for which the treatment is being prescribed?
- Is the methodology promoted for diagnosis as reliable as other available methods of diagnosis?
- Is the risk/benefit ratio greater or less than that for other treatments for the same condition?
- Is it based upon competent and reliable scientific evidence, including properly conducted clinical trials, and/or is it supported by a scientific rationale?
- Is there logical and reasonable expectation that the treatment offered will result in a favorable patient outcome?
- Is the practitioner excessively compensated for the service provided?
- Are the practitioner's promotional claims supported by competent and reliable scientific evidence?
- Is the benefit achieved greater than that which can be expected by placebo alone?
- *Has the patient's informed consent been adequately documented in the medical record?*

Recommendation Three:

State medical boards should utilize reliable information resources in their evaluation of questionable health care practices.

Reliable information may be obtained by utlizing databases such as Medline. NEXIS/LEXIS or Westlaw by searching the (1) name of the practice/therapy/treatment/promotion (2) provider and/or promoter and (3) organizations involved in the promotion of such practice/therapy/treatment.

The committee suggests state medical boards query the following organizations to provide reliable information regarding specific questionable health care practices:

- Federation of State Medical Boards Library Services, 400 Fuller Wiser Road, Suite 300, Euless, Texas 76039; (817) 868-4000; FAX (817) 868-4099;
- National Council Against Health Fraud (NCAHF), P.O. Box 1276, Loma Linda, California 92354; FAX (909) 824-4848;
- Consumer Health Information Research Institute (CHIRI), 300 East Pink Hill Road, Independence, Missouri 64057; (816) 228-4595; FAX (816) 228-4995;
- Food and Drug Administration, Office of Health Affairs; 5600 Fishers Lane, HFY-1, Rockville, MD 20857; (301) 443-6143; and
- Federal Trade Commission, Division of Service Industry Practices, Washington, DC 20580; (202) 326-3291; FAX (202) 326-3392.
- Office of Alternative Medicine, National Institutes of Health, 6120 Executive Boulevard, EPS, Suite 450, Rockville, MD 20892; (301) 402-2466; FAX (301) 402-4741.

The committee suggests state medical boards obtain reference materials such as the following to provide a foundation for research into questionable health care practices:

- *Reader's Guide to Alternative Health Methods*, Zwicky, John F, PhD, Hafner, Arthur W., PhD, Barrett, Stephen, MD, and Jarvis, William T., MD. American Medical Association 1993.
- *Alternative Medicine: What Works*, Fugh-Berman, Adriane MD, Odonian Press, 1996.
- *The Vitamin Pushers: How the "Health Food" Industry is Selling America A Bill of Goods*, Stephen Barrett, MD, and Victor Herbert, MD, JD, 1994, NY: Prometheus Press.

- *The Health Robbers: A Close Look at Quackery in America*, edited by Stephen Barrett, MD and William T. Jarvis, PhD, Foreword by Ann Landers, 1993. NY: Prometheus Press.

- *HealthSmarts*, John H. Renner, MD, 1990, Health Facts Publishing, 300 E. Pink Hill Road, Independence, MO 64057-3220.

- *The Honest Herbal*, 3rd Edition, Varro E. Tyler, PhD, 1993, Pharmaceutical Products Press, Division of The Haworth Press, Inc., 10 Alice St., Bighampton, NY 13904-1580.

- *Examining Holistic Medicine*, edited by Douglas Stalker, PhD and Clark Glymour, PhD, 1985, Prometheus Press, NY.

Recommendation Four:

State medical boards' ancillary staff, including board investigators, should utilize methods to effectively investigate questionable health care practices.

State medical boards must rely heavily on their investigative staff to aggressively develop and present evidence that is thorough, cohesive, sequential, and well-documented. It is necessary for investigators to remain abreast of trends in and promotions of questionable health care practices within the jurisdiction of the agency.

The committee suggests the following guidelines be implemented during the investigative stage:

- Select a reliable expert, familiar with the practice in question, and willing to assist in the investigative stage.

- Gather evidence to include (1) promotional and other materials used to produce patient consent (2) drug samples or medical devices together with manufacturers package inserts and specifications (3) proponent literature describing the practice in question together with medical/scientific justification and (4) competent and reliable scientific evidence on the efficacy/safety of the practice.

- Conduct a thorough review of the Medical Practice Act to determine all applicable breaches to be included in the board's complaint.

SECTION V: DISCIPLINARY ACTION/DISPOSITION

Recommendation Five:

State medical boards should work in conjunction with state prosecutors in the initiation, development, and disposition of cases involving questionable health care practices.

It is necessary to employ procedures to effectively present cases in the disciplinary process. The committee identified elements that are commonly utilized by respondents in cases involving questionable health care practices, specifically the use of testimonials and anecdotal evidence. Proponents of questionable health care practices likely hold strong views and convictions regarding the therapeutic approach and may have a large cadre of devotees, willing to testify on the respondent's behalf. In order to successfully prosecute such cases, it is imperative that state attorneys be familiar with medical practice and terminology and be able to apply and argue case law and rules of evidence in terms of generally accepted scientific standards so that unreliable evidence may be excluded and not used by respondents in defense of prosecution. Following a determination by the state medical board to prosecute a complaint, the committee suggests the following elements be utilized in the disposition of cases involving questionable health care practices:

- Conduct thorough prehearing discovery to obtain additional information and the names and qualifications of defense expert witnesses.

- Conduct careful research of defense experts and their writings.

- Request a prehearing conference or evidentiary hearing to suppress unreliable evidence and exclude testimony of unqualified proponents testifying on behalf of the respondent as unreliable and inadmissible. Review Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786 (1993) and relevant state law to establish legal precedent on admissibility of disputed scientific evidence.

- Strategize trial presentation to not only prove the board's case but to disprove the proponent of the practice in question.

- Utilize expert witnesses who can not only establish the board's case but also who can provide credible rebuttal of the evidence in support of the practice in question.

Recommendation Six:

State medical boards should carefully evaluate all avenues of potential prosecution and coordinate such with appropriate federal, state, and local agencies.

Certain breaches of the medical practice act may be subject to civil action or criminal prosecution in other forums. These breaches may include (1) the unlicensed practice of medicine (2) deceptive advertising (3) violations regarding controlled substances and/or (4) fraudulent billing practices.

The committee suggests that state medical boards coordinate with and among the following agencies in their respective potential areas of prosecutorial concern(s):

- Federal Trade Commission (deceptive/fraudulent health care promotions/claims);
- State Attorney General (consumer complaints/protection and deceptive/fraudulent health care promotions/claims);
- State Insurance Board/Commission (billing practices);
- Health Care Financing Administration (Medicare claims);
- U.S. Postal Service (mail fraud);
- U.S. Customs Service (import of unapproved/illicit drugs/devices);
- Food and Drug Administration (unapproved drugs/devices);
- District Attorney (unlicensed practice of medicine and related criminal offenses).

SECTION VI: LEGISLATIVE STRATEGIES

Recommendation Seven:

State medical boards should review their Medical Practice Acts and pursue legislative support for revisions to strengthen the medical board's ability to regulate physicians engaging in questionable health care practices.

There are increasing political and social pressures to provide the public with access to unconventional medical treatments, as evidenced by various recent federal and state legislative proposals. The committee believes that there may be substantial direct and indirect harm to patients resulting from enactment of such legislation unless appropriate safeguards are included. In order to fulfill state medical boards' responsibility to protect the public from incompetent, unprofessional, improper, unlawful, fraudulent and/or deceptive medical practice, it is necessary for state medical boards to maintain legislative authority adequate to regulate all practices constituting the practice of medicine.

The committee suggests the following elements be included in all state Medical Practice Acts:

- The unlicensed practice of medicine should be deemed a felonious offense.
- State medical boards should be granted authority to use injunctive powers to order physicians and others engaged in questionable health care practices to immediately cease such practice pending hearing.
- State medical boards should be granted authority to monitor physicians engaged in questionable health care practices, including, but not limited to, requirements that physicians: (1) file treatment plans with the board (2) report patient outcomes and (3) file periodic reports regarding the efficacy of treatment.

Recommendation Eight:

State medical boards should notify the Federation of State Medical Boards of any state legislative initiatives identified that could diminish state medical boards' ability to regulate questionable health care practices.

The committee suggests that the following mechanisms be implemented for monitoring and opposing such legislative measures:

- Request assistance from the Legislative Services Department of the Federation of State Medical Boards in analyzing and developing strategies in opposition to such state legislative measures.
- Identify individuals within the state willing to educate state legislators and legislative staff on the potential effects of such legislative initiatives.
- Assist legislators in soliciting written comments from the Food and Drug Administration and the Federal Trade Commission on the potential consumer health and economic effects of such legislative initiatives (requests are honored only if submitted by legislator).

Recommendation Nine:

The Federation of State Medical Boards should monitor federal and state legislative activities regarding health freedom issues and develop strategies to assure that the authority of state medical boards is maintained.

Through its Legislative Services Department and government relations firm, the Federation monitors federal legislative initiatives to identify proposals that could impact state medical boards. Upon the

identification of such measures, the Federation develops strategies to intervene and oppose measures that could negatively affect state medical boards. The committee supports and encourages the Federation in its legislative efforts to protect the authority of state medical boards to regulate the practice of medicine, both conventional and unconventional.

SECTION VI: EDUCATION

Recommendation Ten:

State medical boards, with the assistance of the Federation of State Medical Boards, should develop educational opportunities for licensees regarding the prevalence, risks, and efficacy of questionable health care practices.

In order to contain the proliferation of questionable health care practices, it is necessary to increase awareness among licensees. State medical boards may wish to develop educational programs in cooperation with state and local medical professional societies, organizations, and hospital medical staff organizations. The committee supports and encourages education of medical board members and staff, legislators, and consumers. The committee also supports the Federation of State Medical Boards in its continuing development of educational programs through forums such as the Annual Meeting, workshops, and publications as well the dissemination of timely information to its member boards on related issues via the FSMB computer network.

The committee suggests state medical boards use the following methods in developing educational opportunities for their licensees and publics:

- Present educational information at meetings of state and local medical professional societies and associations and other organized physician educational forums.

- Include educational information in board newsletters and other communications with licensees.

- Utilize media sources, public service announcements, consumer advocacy groups, and other means to disseminate information to the public.

SECTION VII: COLLABORATION

Recommendation Eleven:

On behalf of state medical boards, the Federation of State Medical Boards should collaborate with other agencies and organizations in efforts to identify and eliminate questionable health care practices that are adverse to the public health, safety, and welfare.

The committee recognizes that the scope of this issue reaches far beyond the jurisdiction of state medical boards and, therefore, strongly encourages that a network of cooperation and collaboration be established to coordinate efforts to stop the spread of questionable health care practices.

The committee suggests the following forums for collaboration:

- Explore opportunities for mutual cooperation, including information sharing and education, with the American Medical Association and the American Osteopathic Association.

- Develop working relationships with other interested organizations, including, but not limited to, the National Association of Attorneys General, the National Conference of State Legislatures, American Legislative Exchange Conference, the Food and Drug Administration, and the Federal Trade Commission in promoting responsible medical practices.

SECTION VIII: CONCLUSION

It has been estimated that up to $100 billion is lost to health care fraud in the United States annually *(Stern, 1994)*. Medical interventions that do not conform to prevailing scientific standards are becoming increasingly popular. It is estimated that, in 1990, Americans made 425 million visits to providers of "unconventional" medicine, exceeding the number of visits to all US primary care physicians, at a cost of approximately $13.7 billion *(Eisenberg et al, 1993)*. It may be recognized that some alternative therapies may be beneficial and therefore warrant further investigation and possible integration into mainstream medical practice. However, because of the lack of reliable scientific evidence and clinical validation, safety has not been established for most of these modalities. Questionable health care practices can pose significant risks to the public safety, either by causing direct patient harm, or indirectly, by being needlessly expensive, delaying a more effective treatment, or from being administered in an incompetent manner. This proliferation of questionable health care practices and promotions will continue if left unchecked and unregulated. State medical boards are charged with protecting the public from the unprofessional, improper, incompetent, unlawful, fraudulent and the deceptive practice of medicine *(Essentials, Section I)* and, therefore, state medical boards must assure that physicians practice responsible medicine.

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Model Guidelines for the Use of Complementary and Alternative Therapies in Medical Practice

Approved by the House of Delegates of the Federation of State Medical Boards of the United States, Inc., as policy April 2002

Introduction

Physicians, indeed all health-care professionals, have a duty not only to avoid harm but also a positive duty to do good— that is, to act in the patient's best interest[s]. This duty of beneficence takes precedence over any self-interest.[1]

Because of the increasing interest in and use of complementary and alternative therapies in medical practices (CAM), state medical boards have a responsibility to assure that licensees utilize CAM in a manner consistent with safe and responsible medicine. On behalf of the Federation of State Medical Boards and its continued commitment to assist state medical boards in protecting the public and improving the quality of health care in the United States, the Special Committee for the Study of Unconventional Health Care Practices (Complementary and Alternative Medicine),[2] undertook an initiative in April 2000 to develop model guidelines for state medical boards to use in educating and regulating (1) physicians who use CAM in their practices, and/or (2) those who co-manage patients with licensed or otherwise state-regulated CAM providers.

CAM is a fluid concept that has been defined differently by various organizations and groups. For the purposes of these guidelines, the Committee has chosen to use the term CAM as defined by the National Institutes of Health (NIH) National Center for Complementary and Alternative Medicine (NCCAM) (see Definitions). The Committee acknowledges that some therapies deemed CAM today may eventually be recognized as conventional, based on evidence over time.

This initiative focuses on encouraging the medical community to adopt consistent standards, ensuring the public health and safety by facilitating the proper and effective use of both conventional and CAM treatments, while educating physicians on the adequate safeguards needed to assure these services are provided within the bounds of acceptable professional practice. The Committee believes adoption of guidelines based on this model will protect legitimate medical uses of CAM while avoiding unacceptable risk.

The intention of the Committee is to provide guidelines that are clinically responsible and ethically appropriate. These guidelines are designed to be consistent with what state medical boards generally consider to be within the boundaries of professional practice and accepted standard of care.

Model Guidelines for the Use of Complementary and Alternative Therapies in Medical Practice

Section I. Preamble

The (*name of board*) recognizes that the practice of medicine consists of the ethical application of a body of knowledge, principles and methods known as medical science and that these objective standards are the basis of medical licensure for physicians of the state of (name of state). These standards allow a wide degree of latitude in physicians' exercise of their professional judgment and do not preclude the use of any methods that are reasonably likely to benefit patients without undue risk. Furthermore, patients have a right to seek any kind of care for their health problems. The Board also recognizes that a full and frank discussion of the risks and benefits of all medical practices is in the patient's best interest.

There are varying degrees of potential patient harm that can result from either conventional medical practices or CAM:

- Economic harm, which results in monetary loss but presents no health hazard;
- Indirect harm, which results in a delay of appropriate treatment, or in unreasonable expectations that discourage patients and their families from accepting and dealing effectively with their medical conditions;
- Direct harm, which results in adverse patient outcome.

Regardless of whether physicians are using conventional treatments or CAM in their practices, they are responsible for practicing good medicine by complying with professional standards and regulatory mandates. In consideration of the above potential harms, the (name of board) will evaluate whether or not a physician is practicing appropriate medicine by considering the following practice criteria. Is the physician using a treatment that is:

- **effective and safe?** (having adequate scientific evidence of efficacy and/or safety or greater safety than other established treatment models for the same condition)
- **effective, but with some real or potential danger?** (having evidence of efficacy, but also of adverse side effects)
- **inadequately studied, but safe?** (having insufficient evidence of clinical efficacy, but reasonable evidence to suggest relative safety)
- **ineffective and dangerous?** (proven to be ineffective or unsafe through controlled trials or documented evidence or as measured by a risk/benefit assessment)

Inasmuch as the (name of board) is obligated under the laws of the state of (name of state) to protect the public's health, safety and welfare and recognizes that the standards used in evaluating health care practices should be consistent, whether such practices are regarded as conventional or CAM, the Board recognizes that a licensed physician shall not be found guilty of unprofessional conduct for failure to practice medicine in an acceptable manner solely on the basis of utilizing CAM. Instead, the Board will use the following guidelines to determine whether or not a physician's conduct constitutes a violation of the state's Medical Practice Act.

Section II. Definitions

For the purposes of these guidelines, the following terms are defined as indicated:

Complementary and Alternative Therapies in Medical Practices (CAM)

CAM refers to a broad range of healing philosophies (schools of thought), approaches and therapies that mainstream Western (conventional) medicine does not commonly use, accept, study, understand, or make available. A few of the many CAM practices include the use of acupuncture, herbs, homeopathy, therapeutic massage, and traditional Oriental medicine to promote well-being or treat health conditions. People use CAM treatments and therapies in a variety of ways. Therapies may be used alone, as an alternative to conventional therapies, or in addition to conventional, mainstream therapies, in what is referred to as a complementary or an integrative approach. Many CAM therapies are called holistic, which generally means they consider the whole person, including physical, mental, emotional and spiritual aspects.[3]

Conventional Medical Practices

Conventional medical practices refer to those medical interventions that are taught extensively at U.S. medical schools, generally provided at U.S. hospitals, or meet the requirements of the generally accepted standard of care.

Section III. Guidelines

The (*name of board*) has adopted the following guidelines when evaluating the delivery or co-management of CAM:

1. Evaluation of Patient

Parity of evaluation standards should be established for patients whether the physician is using conventional medical practices or CAM.

Prior to offering any recommendations for conventional and/or CAM treatments, the physician shall conduct an appropriate medical history and physical examination of the patient as well as an appropriate review of the patient's medical records. This evaluation shall include, but not be limited to, conventional methods of diagnosis and may include other methods of diagnosis as long as the methodology utilized for diagnosis is based upon the same standards of safety and reliability as conventional methods, and shall be documented in the patient's medical record. The medical record should also document:

- what medical options have been discussed, offered or tried, and if so, to what effect, or a statement as to whether or not certain options have been refused by the patient or guardian; that proper referral has been offered for appropriate treatment;
- that the risks and benefits of the use of the recommended treatment to the extent known have been appropriately discussed with the patient or guardian;
- that the physician has determined the extent to which the treatment could interfere with any other recommended or ongoing treatment.

2. Treatment Plan

The physician may offer the patient a conventional and/or CAM treatment pursuant to a documented treatment plan tailored to the individual needs of the patient by which treatment progress or success can be evaluated with stated objectives, such as pain relief and/or improved physical and/or psychosocial function. Such a documented treatment plan shall consider pertinent medical history, previous medical records and physical examination, as well as the need for further testing, consultations, referrals or the use of other treatment modalities.

The treatment offered should:

- have a favorable risk/benefit ratio compared to other treatments for the same condition;
- be based upon a reasonable expectation that it will result in a favorable patient outcome, including preventive practices;
- be based upon the expectation that a greater benefit will be achieved than that which can be expected with no treatment.

3. Consultation and/or Referral to Licensed or Otherwise State-Regulated Health Care Practitioners

The physician may refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives and may include referral to a licensed or otherwise state-regulated health care practitioner with the requisite training and skills to utilize the CAM therapy being recommended. However, the physician is responsible for monitoring the results and should schedule periodic reviews to ensure progress is being achieved.

4. Documentation of Medical Records

The physician should keep accurate and complete records to include:

- the medical history and physical examination;
- diagnostic, therapeutic and laboratory results;
- results of evaluations, consultations and referrals;
- treatment objectives;
- discussion of risks and benefits;
- appropriate informed consent;
- treatments;
- medications (including date, type, dosage and quantity prescribed);
- instructions and agreements;
- periodic reviews.

Records should remain current and be maintained in an accessible manner, and readily available for review.

5. Education

All physicians must be able to demonstrate a basic understanding of the medical scientific knowledge connected with any method they are offering or using in their medical practices as a result of related education and training.

6. Sale of Goods from Physician Offices

Due to the potential for patient exploitation, physicians should not sell, rent or lease health-related products or engage in exclusive distributorships and/or personal branding;

- Physicians should provide a disclosure statement with the sale of any goods, informing patients of their financial interest; and
- Physicians may distribute products to patients free of charge or at cost in order to make products readily available.
- Exceptions should be made for the sale of durable medical goods essential to the patient's care, as well as nonhealth-related goods associated with a charitable or service organization.[4] [Language on the sale of goods from physician offices is contained in the report of the Special Committee on Professional Conduct and Ethics as adopted in April 2000.]

7. Clinical Investigations

As expected of those physicians using conventional medical practices, physicians providing CAM therapies while engaged in the clinical investigation of new drugs and procedures (a.k.a. medical research, research studies) are obligated to maintain their ethical and professional responsibilities. Investigators shall be expected to conform to the following ethical standards:

- Clinical investigations should be part of a systematic program competently designed, under accepted standards of scientific research, to produce data which are scientifically valid and significant.
- A clinical investigator should demonstrate the same concern and caution for the welfare, safety and comfort of the patient involved as is required of a physician who is furnishing medical care to a patient independent of any clinical investigation.[5]

Furthermore, investigators shall be expected to abide by all federal guidelines and safeguards, such as approval and monitoring of the clinical trial by an Institutional Review Board (IRB), when applicable, to ensure the risks to the patient are as low as possible and are worth any potential benefits.

In Conclusion

The Committee recognizes that legitimate standards of medical practice are rooted in competent and reliable scientific evidence and experience. However, these standards are subject to continual change and improvement as advances are made in scientific investigation and analysis. In addition, standards of medical practice to some degree, and the provision of medical services in individual circumstances in particular, are influenced by psychological, social, political and market forces. It is the responsibility of state medical boards to balance all of these considerations in fulfilling their mission of protecting the public through the regulation of the practice of medicine.

Public protection is carried out, in part, by ensuring physicians in all practices, whether conventional or CAM, comply with professional, ethical and practice standards and act as responsible agents for their patients. Accordingly, the Federation encourages state medical boards to adopt these guidelines to assist them in educating and regulating physicians who are (1) engaged in a practice environment offering conventional and/or CAM treatments; and/or (2) engaged in cooperative therapeutic relationships for their patients with a non-physician licensed or otherwise state-regulated health care practitioner offering CAM.

State medical boards should ensure a balance between the goal of medical practices being evidence-based while remaining compassionate and respectful of the dignity and autonomy of patients. This balance should also ensure informed consent and minimize the potential for harm.

The Federation reaffirms its commitment to cooperate with physicians and professional, governmental and other organizations and agencies in supporting the further study of all health care practices that offer promise.

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for the Study of Unconventional Health Care Practices
(Complementary and Alternative Medicine): 2001-2002

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[1]Schneiderman L. Medical ethics and alternative medicine. The Scientific Review of Alternative Medicine. Spring/Summer 1998;2,(1):63-66.

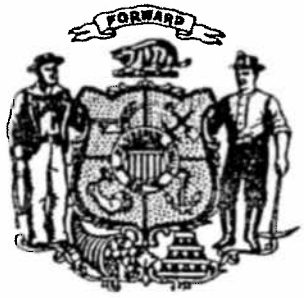
STATE OF WISCONSIN

DEPARTMENT OF REGULATION & LICENSING
DIVISION OF ENFORCEMENT

THE

CASE HANDLING

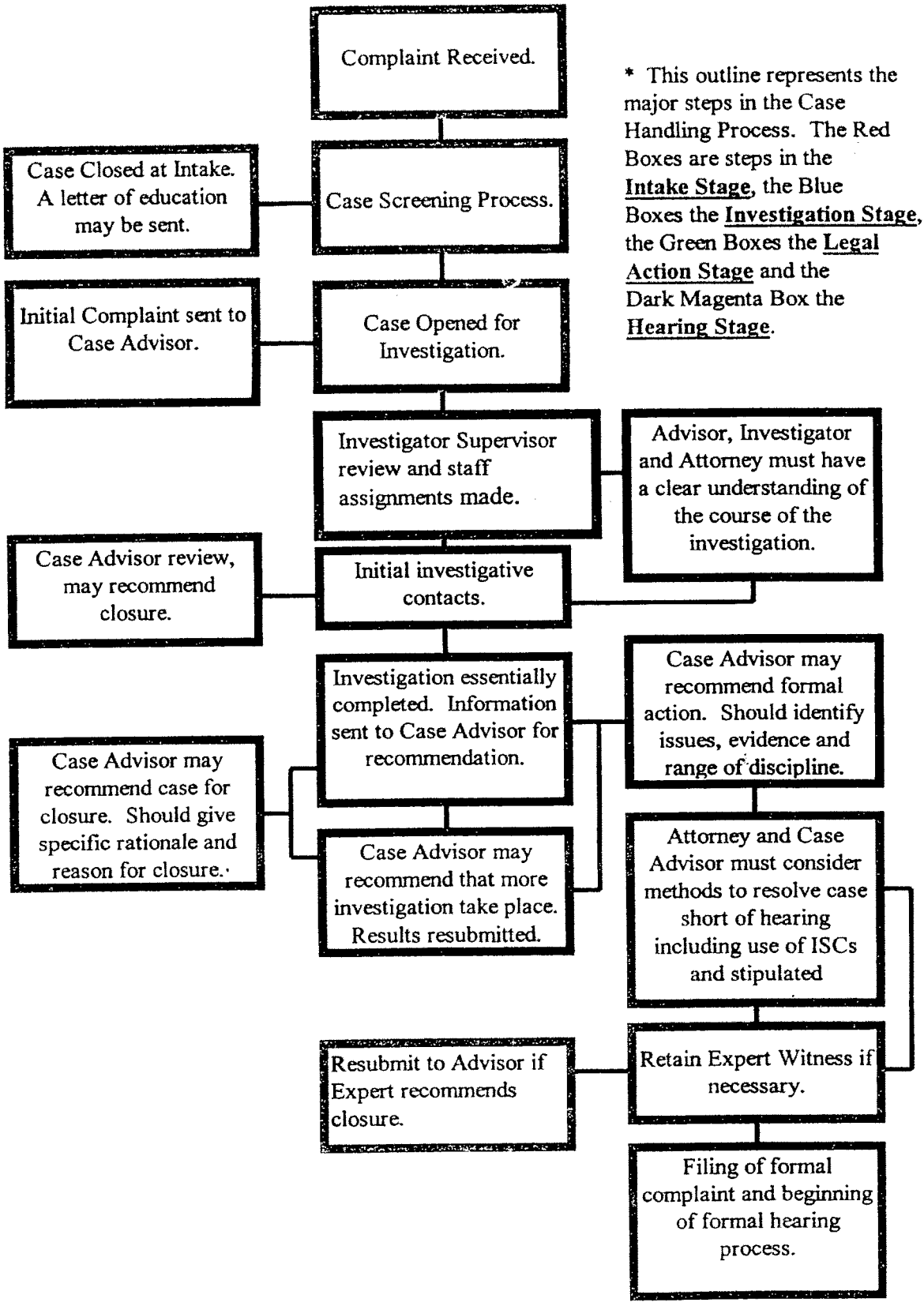
PROCESS



(Revised 6/19/02)

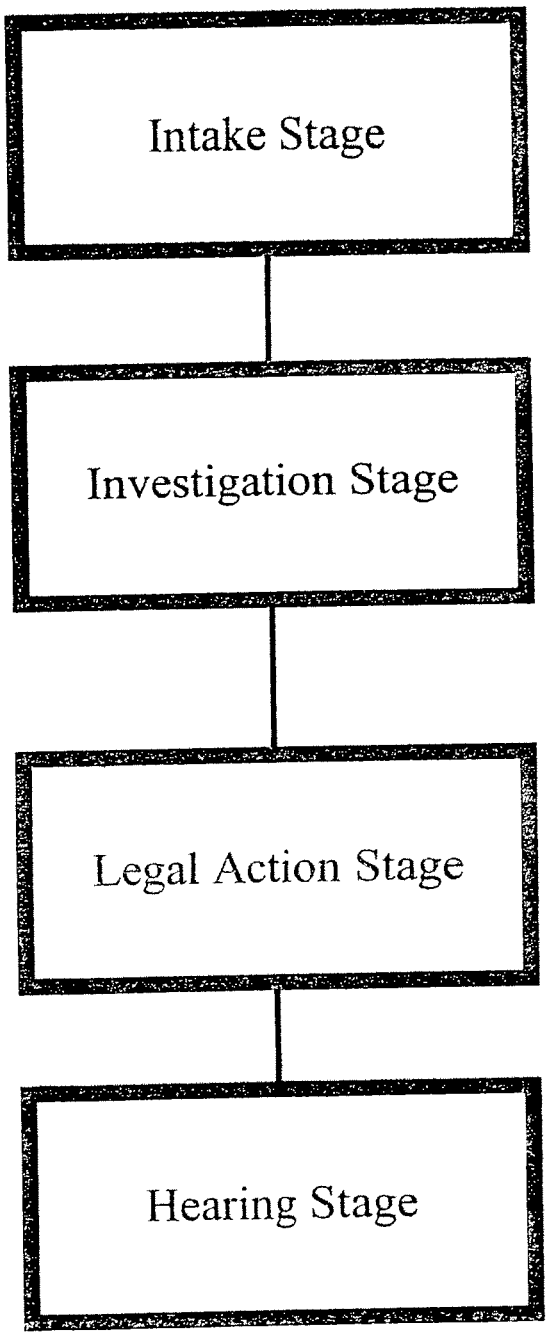
Enclosure 18

Steps in the Case Handling Process*



* This outline represents the major steps in the Case Handling Process. The Red Boxes are steps in the **Intake Stage**, the Blue Boxes the **Investigation Stage**, the Green Boxes the **Legal Action Stage** and the Dark Magenta Box the **Hearing Stage**.

Outline of the Case Handling Process



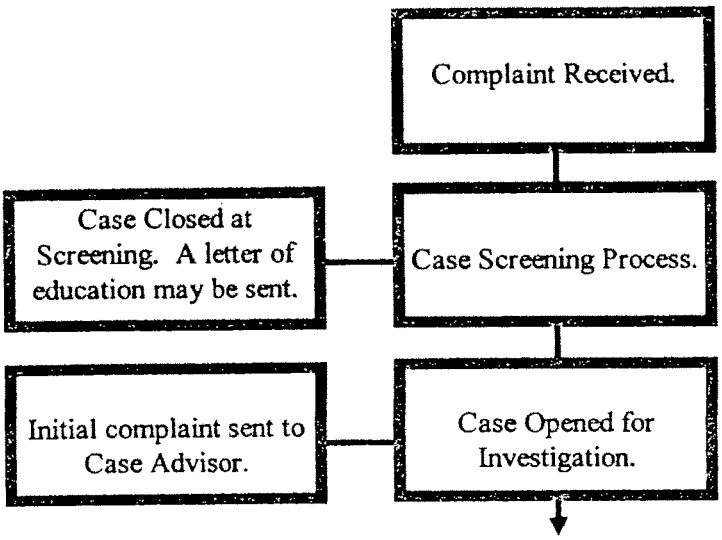
The **Intake Stage** is the first stage in the case handling process. Cases are screened by Screening Panels to determine if an investigation is warranted. Cases that do not warrant investigation are quickly closed. Cases that appear to have merit are identified for investigative action.

The **Investigation Stage** is the next stage in the case handling process. Investigative staff gather necessary evidence and make contacts with witnesses as needed. The results of the investigation are discussed with a case advisor and a department attorney. Cases that do not warrant professional discipline are closed. Cases with violations proceed to the next stage for legal action.

The third stage is the **Legal Action Stage**. In this stage, department prosecuting attorneys, in conjunction with case advisors, review the results of the investigation and pursue disciplinary action when appropriate. Cases may resolve by means of stipulated agreements, informal settlement conferences or administrative warnings.

The fourth stage is the **Hearing Stage**. This is a formal legal process. The department attorney litigates the case before an administrative law judge. The law judge makes a proposed decision which is reviewed by the licensing board. If a violation is found, discipline may be imposed. Disciplines include reprimand, limitation, suspension and revocation.

Intake Stage



The Intake Stage is an essential part of the case handling process. If good decisions are made at this stage, then cases without merit can be promptly closed using a minimum of resources and cases with merit can be identified for action.

Case proceeds to the Investigation Stage

Detailed Description of the Intake Stage

Complaints may be received from any source. All complaints are logged into the computer system by a Complaint Intake Program Assistant. Records may be obtained to assist in the evaluation of the complaint.

The complaint is then routed to a screening panel consisting of members of the credentialing authority, and an attorney from the Division of Enforcement. The panel brings together the professional expertise of the board members and the case handling expertise of the department staff.

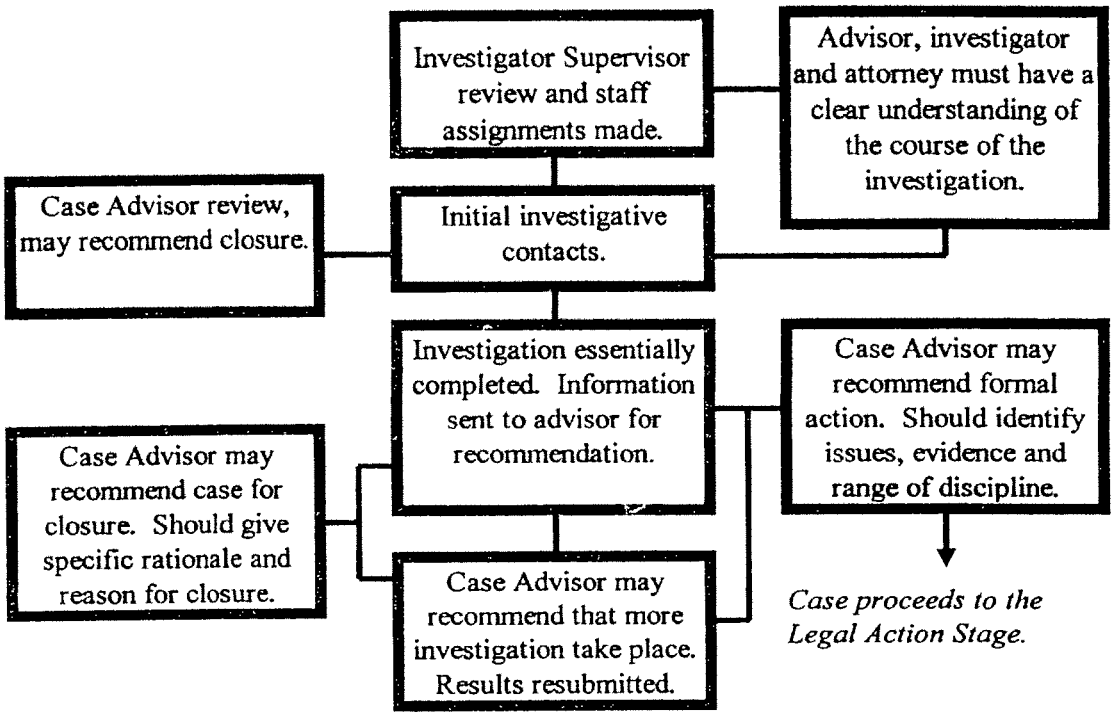
Since the implementation of the screening panel process, approximately 50% of the 2,000 plus complaints received each year are closed at screening. The panel may close a complaint for no violation, lack of jurisdiction, administrative closure or screening decision.

When discretion is exercised to close a complaint based on a screening decision, the panel may consider the seriousness of the allegations, the harm or threat of harm, the prior complaint history, the past handling of prior similar cases, whether the complaint is a fee dispute, whether the matter if taken as a whole is trivial, whether the dispute is already resolved, whether the matter is primarily a civil or private dispute, whether a letter of education may be sufficient and any other relevant factors identified by the panel.

If a complaint is closed at the Intake Stage, the parties are notified in writing of the closure of the complaint. If the complaint is opened for investigation, then it is routed to an investigator supervisor to assign staff to the case. Cases are then distributed to the appropriate staff for investigation. The panel may note special instructions regarding the case and may identify the case as a priority. A copy of the initial complaint is sent to the case advisor by the Complaint Intake Program Assistant.

Investigation Stage

During the Investigation Stage, evidence regarding the alleged violations is obtained and evaluated.



Detailed Description of the Investigation Stage

An investigator is assigned to each new case. A member of the board acting as a case advisor is also assigned.

Upon receipt, case advisor should review the initial complaint and should contact the assigned investigator if it is apparent that the case should be closed, if the advisor has a conflict or if there are any special instructions the advisor may wish to communicate to the investigator.

The investigator proceeds with the investigation by collecting necessary evidence and making witness contacts as needed. Throughout this process it is essential that the case advisor, the investigator and the attorney have a clear understanding of the intended course of the investigation. An investigation that is not focused will waste time and the evidence needed to make a recommendation may not be obtained.

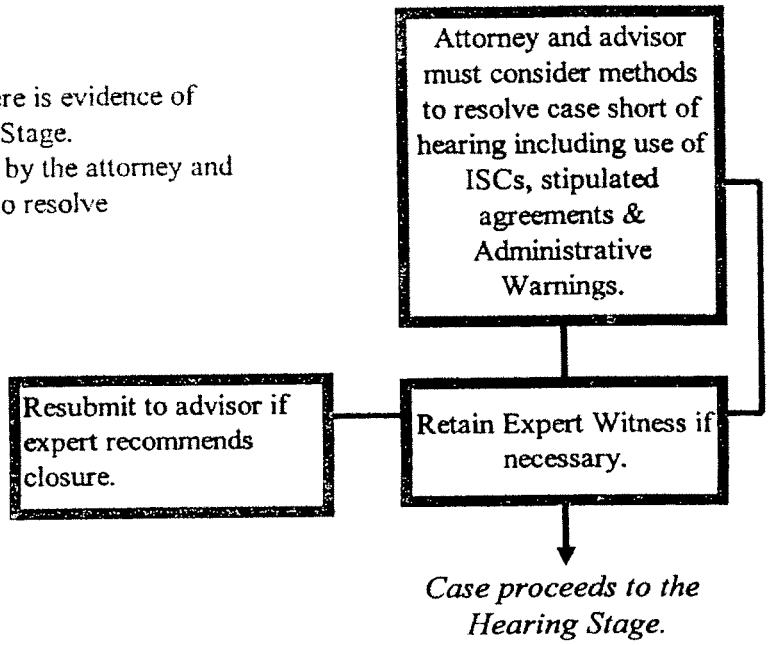
When the most significant evidence has been obtained, the investigator summarizes the case and sends the evidence to the advisor for a recommendation.

If the advisor recommends closure, then there should be specific rationale and reasons for closure identified. Closure is accomplished by presenting the case to the board. If the advisor recommends formal action, then the issues warranting formal action should be identified as well as a range of discipline.

In some instances more investigation may be requested.

Legal Action Stage

Only the more serious cases in which there is evidence of a violation proceeds to the Legal Action Stage.
It is critical that good decisions be made by the attorney and the case advisor as to the methods used to resolve the case and as to appropriate outcomes.



Detailed Description of the Legal Action Stage

Only the more serious cases in which there is evidence of a violation tend to progress to the Legal Action Stage. The critical step in this stage is the communication between the DOE attorney and the case advisor. These two must agree on an appropriate method to resolve the case and, if formal discipline is recommended, on a range of desired outcomes.

There are a number of ways to resolve a case short of a formal administrative hearing. Methods of resolution include a stipulated agreement, Informal Settlement Conference or an Administrative Warning. When formal discipline is recommended a range of desired outcomes should be identified. Clear and precise communication between the DOE attorney and the case advisor is essential.

In some cases an expert witness must be retained. An expert is necessary in cases where the case advisor is unable to render an opinion and in cases where an agreement to resolve the case is unlikely to result. If an expert witness provides an opinion that no violation of practice standards has occurred, then the case is resubmitted to the advisor for review and potential closure.

If a case can not be resolved in this stage by agreement of the parties, then the case must proceed to resolution through a formal administrative hearing.

Hearing Stage

Cases that do not resolve by agreement of the parties progress to the Hearing Stage. A small percent of cases are resolved through this formal process. The procedures followed in this stage are defined in the administrative rules and the statutes.

Filing of formal complaint and beginning of formal hearing process.

Detailed Description of the Hearing Stage

When a case can not be resolved through agreement of the parties, it proceeds to the Hearing Stage. Only a small percent of cases progress to this stage. However, the cases that are resolved through formal hearings often represent the most serious cases pending before each of the boards.

Most of the procedures followed in this stage are set out in Chapter RL 2, Wisconsin Administrative Code. This is a very formal process. The first step in the process is the filing of a Formal Administrative Complaint by the DOE attorney. A response to this complaint, called an Answer, is then filed by the Respondent. The Respondent has a right to be represented by an attorney.

After the complaint and answer are filed, an administrative law judge will set a prehearing conference to talk about resolving the case and to set deadlines for various steps to be completed. The administrative law judge is a department attorney and serves the function of presiding over the formal hearing process, including the actual hearing.

Both the Complainant and the Respondent have the right to engage in discovery, such as taking depositions of the witnesses that may be called to testify at the hearing. Both parties also have the right to file motions and briefs for the purpose of arguing legal issues relevant to the case.

Sometimes during this process a case will still resolve through a stipulated agreement. However, if no such agreement results, a hearing will occur. At this hearing, which is presided over by the administrative law judge, the parties will call witnesses and present evidence in support of their positions. The state has the burden of proving that some violation of a rule or statute occurred.

Following the hearing, the administrative law judge prepares a Proposed Decision, which is submitted to the board. The parties may file objections to the proposed decision. The board considers the record in the case and issues a Final Decision and Order. The Final Decision and Order may be appealed to the Circuit Court.

The allowable purposes of discipline are protection of the public, rehabilitation of the credential holder and deterrence. Punishment is not an allowable purpose. Disciplines include reprimand, limitation, suspension, revocation and monetary forfeitures. Costs of the proceeding may also be assessed.

WISCONSIN DEPARTMENT OF
REGULATION & LICENSING

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January 7, 2003

ROBERT S. WATERS MD
P.O. BOX 357
WISCONSIN DELLS, WI 53965

RE: 97 Med 101/108

Dear Dr. Waters:

I have received your letter of December 30, 2002. I respectfully suggest that you are not in a position to make demands, or to set conditions upon our investigation. The Board licenses you, and is responsible to the public for that license. The Board can, and will, conduct the investigation that it deems appropriate. Your options are to cooperate with that investigation, or cease being licensed by this Board. The choice is entirely yours, of course.

It appears that you have discharged Mr. Seeley's firm; this is certainly your right, and I will certainly communicate directly with you if you have no other attorney. However, if you have an attorney, the rules applicable to lawyers clearly require that I communicate with you ONLY through the lawyer, unless the lawyer consents to direct communication.

It appears that we have a dispute over the completeness of the records the Board has requested of you, and which you have supplied. I am reluctant to copy dozens of copies, as this is a significant waste of time and paper. There are only a couple of pages which appear to be missing, and I am sure that this was due to human error. I am not interested in making a big deal out of this: I just want the pages.

The chart for patient Shelby Thompson appears to have an omission: the Bates stamped page 00001 has a visit from 9/17/01 and at the bottom of the page, it says "(over)" but there is no back of the page; the next page (Bates stamped 00002) is a visit on 9/25/01. Also, the top of Bates stamped page 00003 is not legible; please redo this page in a legible manner.

And, as to patient Margaret Barry, we are missing the second page of the Informed Consent (see Bates stamped pages 42 and 43, which are pages 1 and 3 of the consent form).

I have enclosed all of the pages referred to above. Please supply only the requested missing and illegible pages.

Additionally, I would like to have a full copy of your article: "EDTA chelation effects on urinary losses of cadmium, calcium, chromium, cobalt, copper, lead, magnesium, and zinc." (Biol Trace Elem Res 2001 Dec; 83(3):207-21).

Enclosure 19

Enclosed are the only two letters I have received from Mr. Seeley's law firm. I have not sent any letters via US mail to Mr. Seeley or his firm; virtually all of our contact has been by telephone or e-mail. I am also enclosing all of the e-mails which I have in my file or on my computer.

As to your last question, the matter of IPT has not been given a separate case number, and the issue is being considered along with the other issues in the two open investigations.

I also have your letter to Dale Nash, also dated 12/30/02. Inv. Nash was unfortunately forced to retire due to ill health, some time ago. The answers to your questions are:

1, 2. No.
3. I am the assigned attorney, and am responsible for directing the investigation of this matter.
4,5. These cases are both open.
6. An outside expert has been retained in this matter (Dr. Robert Baratz); the matter has also been reviewed by the Case Advisor (the physician-member of the Board assigned to this case).

The so-called statute of limitations does not apply to this case, which was open before the law was passed. The motives of the persons who supply information to the Board are not as important as the actions of the physician. The apparent satisfaction or dissatisfaction of lay patients, who cannot be objective, is not nearly as important as the judgment of experienced physicians who understand the standard of care. Your understanding of "guidelines" regarding CAM is incorrect: no such guidelines were adopted or are contemplated. I am enclosing the minutes of the Board meeting of July 24, 2002, which include no discussion or mention of such. As to the FSMB guidelines, with which I am well familiar, I will keep them in mind as we determine whether your practice comports with the minimum standards of competence and the other rules of the Board.

Sincerely yours,

Arthur Thexton
Prosecuting Attorney
608-266-9814
FAX 266-2264
arthur.thexton@drl.state.wi.us

encl: *per* above

cc: Case Advisor, w/ Waters letters of 12/30/02

I:\waters.ltr.doc

Thexton, Arthur

From: Engerman, Stuart
Sent: Wednesday, March 27, 2002 11:08 AM
To: Thexton, Arthur
Subject: FW: Dr. Waters

Arthur, FYI please note the information forwarded to us from Sen. Schultz's aide. I have responded to her and thanked her for the information, and indicated we will contact her further if we need to discuss this matter further with Mr. Kurandt.

BTW, who is the investigator assigned to this case? CTS does not reflect any assignment. Have you been working with someone in particular? If not I'll just assign someone.

Thanks. Stu

-----Original Message-----
From: ONeill, Eileen
Sent: Wednesday, March 27, 2002 10:43 AM
To: Engerman, Stuart; Berndt, Michael; Wanner, Barry - DRL
Cc: 'target@mwt.net'
Subject: Dr. Waters

I just wanted to let you know that Senator Schultz's office received a phone call from a patient of Dr. Waters, Mr. Rolf Kurandt. He asked me to pass along a message to those people who had some involvement in the Dr. Waters investigation that he is concerned about his physical well being if Dr. Waters can no longer practice.

He was also concerned with a report that was filed by a Dr. Robert Baratz and his criticisms of alternative medicine.

If you would be interested in talking with him, I'm sure he would be willing to give you some form of statement. If you would like to contact him, let me know and I can get you in touch.

Eileen O'Neill
Office of Senator Dale Schultz
608-266-0703
800-978-8008

Enclosure 20

Thexton, Arthur

From: Robert Baratz [imcsi@rcn.com]

Sent: Sunday, March 03, 2002 7:05

To: Thexton, Arthur

Subject: more on IPT

In reviewing the document you sent it would appear that it was written by Ayre orHauser, or at least adopted from their writing as theypresented before CAPCAM. Much of this seems similar..

If Waters is passing this out it is a form of advertising, and you know the law on that.

The document makes a number of unsupported and/or unsubstantiated statements regarding cancer, cancer cells, their cell biology, etc.

Here is Ayre's web site:

http://www.contemporarymedicine.net/

There is a reference on page 3 of the document you supplied to the "Contemporary Medical Center".

I couldn't find the exact document on either Hauser's or Ayre's web sites, (maybe I missed it, or was just not looking carefully enough)(perhaps too, this may be a handout from a course that Ayre teaches) which makes me wonder whether Waters copied pieces of it from both of them. It is clear that it didn't originate with Waters and he likely plagiarized it since it has reference to Ayre's clinic in it.

Ayre, by the way, is in Illinois too, near Chicago. He apparently moved around a bit. If you look carefully at his CV he did only one year of internship, no residency in anything.
Hauser, if I recall, did a residency in rehab medicine.

I guess that is all it takes to treat cancer these days.

Bob

Enclosure 21