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JURISDICTIONAL STATEMENT

The Circuit Court entered "judgment" and affirmed the AHC decision on September 21, 2001 (App. A71). Appellant Board timely appealed to the Western District. On March 25, 2003, the Western District issued its Opinion and found in favor of Respondent on all but one issue (App. A72-A78). Timely requests for rehearing/transfer were filed. This Court sustained Respondent's application on July 1, 2003, and ordered transfer.

This Court now has jurisdiction the same as if on "original appeal." ***See,*** Mo. Const. Art. V, §10.

STANDARD OF REVIEW - GENERALLY

Appellant's "corrected" brief fails to comply with Rule 84.04. Accordingly, review pursuant to Supreme Court Rule 84.13(c) is limited to"plain error." ***Fidelity Sec. Life Ins. Co. v. Department of Revenue,*** 32 S.W.3d 527, 531 (Mo banc 2000); ***J.A.D. v. F.J.D.***, 978 S.W.2d 336, 338 (Mo. banc 1998). Review for "plain error" is discretionary and is reserved for cases where a manifest injustice or a miscarriage of justice will, absent such review, otherwise result. ***Nelson v. Waxman***, 9 S.W.3d 601, 605 (Mo. banc 2000).

Assuming, *arguendo*, that the Board has preserved for review its issues, this Court is to review the decision of the AHC – not the Circuit Court Judgment. ***Psychcare Management, Inc. v. Department of Social Services, Div. of Medical Services,*** 980 S.W.3d 311, 312 (Mo. banc 1998). Section 536.140 RSMo. sets forth the standards which govern review of agency decisions in "contested" matters.

Certain precepts bear noting. The Board, as the party seeking discipline, has the burden of proof. ***Missouri Real Estate Commission v. Berger,*** 764 S.W.3d 706, 711 (Mo. App. E.D. 1989); ***Weber v. Knackstedt***, 707 S.W.2d 800, 802 (Mo. App. E.D. 1986) .

The agency's decision is presumed correct. ***Bickl v. Smith,*** 23 S.W.3d 865 (Mo. App. E.D. 2000). Appellant has the burden to demonstrate its incorrectness. ***Hernandez v. State Board of Registration of the Healing Arts,*** 936 S.W.2d 894 (Mo. App. W.D. 1997).

Agency factual findings, where supported by substantial evidence on the whole record, must be affirmed. ***Six Flags Theme Parks, Inc. v. Director of Revenue,*** 102 S.W.3d 526, 527 (Mo. banc 2003). Substantial evidence is:

> . . . evidence which, if true, has probative force upon the issues, i.e., evidence favoring facts which are such that reasonable men may differ as to whether it establishes them; it is evidence from which the trier or triers of fact reasonably could find the issues in harmony therewith . . ..

State Bd. of Nursing v. Berry, 32 S.W.3d 638, 640-641 (Mo. App. W.D. 2000).

The admission of evidence in "contested" agency proceedings is governed by §536.070. This has been interpreted to mean that "while technical rules of evidence are not controlling in administrative hearings, fundamental rules of evidence do apply;" ***Kendrick v. Board of Police Comm'rs of Kansas City***, 945 S.W.2d 649, 654 (Mo. App. W.D. 1997); ***Missouri Church of Scientology v. State Tax Comm'n,*** 560 S.W.2d 837, 839 (Mo. banc 1977). See also, Neely, *Administrative Practice and Procedure,* 20 Mo Practice, 2nd Ed. §§10.60 and 10.61, West Group, © 2001.

Here, Professor Alfred S. Neely commented:

> ***A perusal of the subsections under § 536.070 reveals that this section relaxes the rules of evidence normally applied in a circuit court civil case.*** The traditional rules, however, are helpful guides when the MAPA is not clear. (§10.60 at 674) (emphasis supplied).

Evidence which may otherwise be inadmissible shall be considered competent and substantial evidence and may be relied upon by an administrative agency *absent* a timely and proper objection. Section 536.070(8), RSMo.; See ***Callahan v. Cardinal Glennon Hospital,*** 863 S.W.2d 852, 863 (Mo. banc 1993); ***Smith v. Morton***, 890 S.W.2d 403 (Mo. App. E.D. 1995).

The evidence is to be considered in the light most favorable to the AHC's decision. ***Sprint Communications Co., L.P. v. Director of Revenue,*** 64 S.W.3d 832, 834 (Mo. banc 2002). The court may not substitute its judgment with respect to factual matters for that vested in the agency, even in cases where the evidence might support different findings. ***State Board of Nursing***, *supra at 640*. The agency, not the court, determines the credibility of the witnesses. ***Dorman v. State Board of Registration for the Healing Arts***, 62 S.W.3d 446, 454 (Mo. App. W.D. 2001); ***Clark v. Bd. of Directors of School District of Kansas City,*** 915 S.W.2d 766 (Mo. App. W.D. 1996). Issues of law are, however, for the independent determination of the reviewing court. ***Sprint Communications Co. L.P.,*** *supra at 834*.

POINTS RELIED ON

POINT I.

<u>Deficient Statement of Facts and Points Relied On</u>

(Independent Issue - Not Responsive to a Specific Point)

THIS COURT SHOULD LIMIT ITS REVIEW TO ONE OF "PLAIN ERROR" PURSUANT TO RULE 84.13(C) IN THAT APPELLANT'S STATEMENT OF FACTS AND POINTS RELIED ON IN ITS "CORRECTED BRIEF" IS GROSSLY DEFICIENT, VIOLATE RULE 84.04(c) AND RULE 84.04(d)(2) SUCH THAT THE BOARD HAS FAILED TO PROPERLY RAISE OR PRESERVE ANY OF ITS ISSUES FOR REVIEW.

<u>Cases</u>:

Evans v. Groves Iron Works, 982 S.W.2d 760 (Mo. App. E.D. 1998)

Faulkerson v. Norman, 77 S.W.3d 43 (Mo. App. E.D. 2002)

J.A.D. v. F.J.D. III, 978 S.W.2d 336 (Mo. banc 1998)

Thummel v. King, 570 S.W.2d 679 (Mo. banc 1978)

<u>Rules</u>:

Supreme Court Rule 84.04(c) and (d)(2)

Supreme Court Rule 84.13(a) and (c)

POINT II.

Standards Governing Admission of Respondent's Expert Testimony.

(*Part 1 of Response to Appellant's Point I*)

THE ADMINISTRATIVE HEARING COMMISSION PROPERLY ADMITTED AND CONSIDERED RESPONDENT'S EXPERT MEDICAL TESTIMONY IN SUPPORT OF HIS USE OF EDTA CHELATION THERAPY TO TREAT ATHEROSCLEROSIS AND OTHER VASCULAR DISEASES BECAUSE §495.060 RSMo AND THE SUBSEQUENT DECISION OF THE U.S. SUPREME COURT IN *DAUBERT* WITH RESPECT TO ITS ALMOST IDENTICAL COUNTER PARTS -- FEDERAL RULES OF EVIDENCE 702 AND 703 -- NOT THE *FRYE* STANDARD – GOVERN THE ADMISSION OF EXPERT, SCIENTIFIC, EVIDENCE; BECAUSE THE BOARD HAS NOT ASSERTED ERROR IF §490.065 RSMo. IS THE CONTROLLING STANDARD; AND, BECAUSE, EVEN IF THE BOARD PRESERVED SUCH ISSUE, THE AHC DID NOT ABUSE ITS DISCRETION IN THAT RESPONDENT'S EXPERT WITNESSES, AS SHOWN BY SUBSTANTIAL EVIDENCE, WERE FULLY QUALIFIED AND THEIR TESTIMONY WOULD "AID AND ASSIST" THE TRIER OF FACT.

Cases:

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S.Ct. 2786 (1993)

Lasky v. Union Electric Co., 936 S.W.2d 797 (Mo. banc 1997)

Landers v. Chrysler Corp., 963 S.W.2d 275 (Mo. App. E.D. 1997)

Kendrick v. Board of Police Comm'rs, 945 S.W.2d 649 (Mo. App. W.D. 1997)

Statutes:

§490.065, RSMo.

Rules:

Federal Rule of Evidence 702 (pre 2000)

Federal Rule of Evidence 703 (pre 2000)

Other Authority:

Medical Heroes and Heretics, Chapter 1 entitled *God Loves a Good Heretic - Now and Then*, Wayne Martin, The Devin-Adair Company, © 1977

POINT III.

Admission of Expert Testimony - *Frye* as the Standard

(Part 2 of Response to Appellant's Point I)

ASSUMING, *ARGUENDO*, THAT *FRYE* IS STILL THE CONTROLLING STANDARD, THE ADMINISTRATIVE HEARING COMMISSION DID NOT ERR OR ABUSE ITS DISCRETION IN FINDING RESPONDENT'S EXPERT SCIENTIFIC EVIDENCE REGARDING EDTA CHELATION THERAPY ADMISSIBLE IN THAT IT IS A RECOGNIZED FORM OF TREATMENT AND HAS GAINED GENERAL ACCEPTANCE AMONG THE RELEVANT SCIENTIFIC COMMUNITY -- PHYSICIANS AND OTHER HEALTH CARE PROFESSIONALS WHO USE EDTA CHELATION THERAPY -- WHO ARE THOROUGHLY FAMILIAR WITH ITS SCIENTIFIC UNDERPINNINGS AND FAMILIAR WITH THE RESEARCH AND OTHER SCIENTIFIC LITERATURE.

Cases:

State v. Butler, 24 S.W.3d 21 (Mo. App. W.D. 2000)

United States v. Williams, 583 F.2d 1194 (2nd Cir. 1978)

Landers v. Chrysler Corp., 963 S.W.2d 275 (Mo. App. E.D. 1997)

Johnson v. State, 58 S.W.3d 496 (Mo. banc 2001)

POINT IV.

Standard of Care

(Response to Appellant's Point I(B) and Point II)

THE ADMINISTRATIVE HEARING COMMISSION DID NOT ERR OR ABUSE ITS DISCRETION IN CONSIDERING RESPONDENT'S TESTIMONY AND THE TESTIMONY OF RESPONDENT'S EXPERTS REGARDING RESPONDENT'S USE OF EDTA CHELATION THERAPY IN THE TREATMENT OF VASCULAR DISEASES, THAT HIS TREATMENT OF THE ENUMERATED PATIENTS SATISFIED THE "STANDARD OF CARE" OWED PURSUANT TO §334.100.2(5) RSMO., OR IN DETERMINING THAT RESPONDENT WAS NOT GUILTY OF "REPEATED NEGLIGENCE" IN THAT: (A) THE BOARD ONLY OBJECTED TO RESPONDENT'S EXPERT EVIDENCE UNDER *FRYE*, NEVER OBJECTED UNDER §490.065, AND NEVER OBJECTED ON THE GROUNDS NOW RAISED; (B) NEITHER RESPONDENT NOR RESPONDENT'S EXPERTS WERE REQUIRED TO SPECIFICALLY DEFINE SAID TERM OR TO SPECIFICALLY USE THE MAGIC PHRASE "STANDARD OF CARE AS DEFINED IN §334.100.2(5)" PRIOR TO EXPRESSING THEIR OPINIONS; AND (C), THERE WAS SUBSTANTIAL EVIDENCE IN THE RECORD TO SUPPORT THE COMMISSION'S FINDINGS.

Cases:

Concordia Pub. House, Inc. v. Director of Revenue, 916 S.W.2d 186 (Mo. banc 1996)

Callahan v. Cardinal Glennon Hospital, 863 S.W.2d 852 (Mo. banc 1993)

Haase v. Garfinkel, 418 S.W.2d 108 (Mo. 1967)

Landers v. Chrysler Corp., 963 S.W.2d 275 (Mo. App. E.D. 1997)

Statutes:

§536.070(8), RSMo.

POINT V.

<u>No Misrepresentation</u>

(Response to Appellant's Point IV)

THE ADMINISTRATIVE HEARING COMMISSION DID NOT ERR OR ABUSE ITS DISCRETION BY FAILING TO MAKE FINDINGS IN FAVOR OF THE BOARD TO THE EFFECT THAT RESPONDENT HAD MISREPRESENTED EDTA CHELATION THERAPY IN THAT: (A) THE AHC RULED AGAINST THE BOARD ON THIS ISSUE; (B) THERE IS SUBSTANTIAL EVIDENCE TO SUPPORT THE RULING; (C) THE EVIDENCE WAS DISPUTED; (D) THE AHC RESOLVED THE DISPUTED FACTS IN FAVOR OF RESPONDENT; (E) UNDER §536.090 RSMO., AN AGENCY IS ONLY REQUIRED TO MAKE FINDINGS OF FACT AND CONCLUSIONS OF LAW WHICH ARE SUFFICIENTLY SPECIFIC SO AS TO ENABLE THE REVIEWING COURT TO ASSESS THE AGENCY DECISION INTELLIGENTLY AND TO ASCERTAIN WHETHER FACTS FURNISH A REASONABLE BASIS FOR THE DECISIONS.

<u>Cases</u>:

Harrington v. Smarr, 844 S.W.2d 16 (Mo. App. W.D. 1992)

Droz v. Trump, 965 S.W.2d 436 (Mo. App. W.D. 1998)

Cummings v. Mischeaux, 960 S.W.2d 560 (Mo. App. W.D. 1998)

POINT VI.

Record Keeping

(Response to Appellant's Point IV)

THE ADMINISTRATIVE HEARING COMMISSION DID NOT ERR OR ABUSE ITS DISCRETION IN FINDING THAT RESPONDENT KEPT AND MAINTAINED ADEQUATE PATIENT RECORDS IN THAT: (A) THE STANDARD OF CARE WITH RESPECT TO WHAT RECORDS TO MAINTAIN AND THE DETAILS THEREIN WAS WITHIN THE DISCRETION OF EACH PHYSICIAN; (B) THE GENERAL ASSEMBLY HAD YET TO ENACT §334.097 RSMO. (2002 SUPP.) WITH RESPECT TO RECORD KEEPING; (C) THERE IS SUBSTANTIAL EVIDENCE TO SUPPORT THE COMMISSION'S FINDINGS; AND (D) THE COMMISSION, AS THE TRIER OF FACT, IS THE SOLE JUDGE OF CREDIBILITY AND WEIGHT THAT SHOULD BE GIVEN TO ANY PARTICULAR TESTIMONY.

Cases:

NME Hospitals, Inc. v. Dept. of Social Services, Division of Medical Services, 850 S.W.2d 71 (Mo. banc 1993)

Miller v. Scholl, 594 S.W.2d 324 (Mo. App. W.D. 1980)

Harrington v. Smarr, 844 S.W.2d 16 (Mo. App. W.D. 1992)

Greenbrier Hills Country Club v. Director of Revenue, 47 S.W.3d 346 (Mo. banc 2001)

POINT VII.

Allegations of Inappropriate and Unnecessary Testing

(Response to Appellant's Point V)

THE ADMINISTRATIVE HEARING COMMISSION DID NOT ERR OR ABUSE ITS DISCRETION IN FINDING THAT RESPONDENT DID NOT PERFORM INAPPROPRIATE AND UNNECESSARY TESTING IN THAT: (A) THE BOARD HAD THE BURDEN OF PROOF WHICH IT FAILED TO MEET; (B) CONTRARY TO THE BOARD'S ASSERTION, THE AHC DID MAKE FINDINGS BUT IN FAVOR OF RESPONDENT; (C) THERE IS SUBSTANTIAL EVIDENCE TO SUPPORT THE AHC'S FINDINGS; AND (D) THE AHC IS THE SOLE JUDGE OF CREDIBILITY AND WEIGHT THAT SHOULD BE GIVEN TO ANY PARTICULAR TESTIMONY.

Cases:

Haase v. Garfinkel, 418 S.W.2d 108 (Mo. 1967)

Cebula v. Benoit, 652 S.W.2d 304 (Mo. App. W.D. 1983)

Missouri Real Estate Commission v. Berger, 764 S.W.2d 706 (Mo. App. E.D. 1989)

Harrington v. Smarr, 844 S.W.2d 16 (Mo. App. W.D. 1992)

POINT VIII.

Patient's Freedom of Choice - Alternative Medicine

Constitutional Protections

(Independent Issue)

THE DECISION OF THE ADMINISTRATIVE HEARING COMMISSION SHOULD BE AFFIRMED IN THAT IT PROTECTS AND PRESERVES THE CONSTITUTIONAL RIGHT THAT ALL CITIZENS HAVE -- THE FREEDOM TO SELECT THEIR HEALTH CARE PROVIDERS AND THE RIGHT TO SELECT AND DETERMINE, AFTER BEING FULLY INFORMED OF THE RISKS AND BENEFITS, THE NATURE AND EXTENT OF THEIR MEDICAL TREATMENT, INCLUDING WHAT MAY BE CONSIDERED TO BE ALTERNATIVE MEDICINE, FREE FROM UNDUE RESTRICTION BY THE STATE, SUBJECT ONLY TO REASONABLE RESTRICTIONS TO PROTECT THE PUBLIC FROM HARM. THE BOARD'S POSITION WITH RESPECT TO EDTA CHELATION THERAPY, GIVEN ITS ADMISSION THAT IT CAUSES NO HARM, CONSTITUTES AN UNREASONABLE RESTRICTION UPON BOTH THE HEALTH CARE PROVIDER AND THE PATIENT AND THEIR CONCOMITANT RIGHT TO CHOSE ALTERNATIVE MEDICAL MODALITIES.

Cases:

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

Rogers v. State Board of Medical Examiners of Florida, 371 So.2d 1037 (Fla. App. 1st Dist. 1979)

Cruzan by Cruzan v. Director, Missouri Dept. of Health, 497 U.S. 261,

110 S.Ct. 2841 (1990)

Doe v. Bolton, 410 U.S. 179, 93 S.Ct. 739 (1973)

Constitutional Provisions:

U.S. Constitution, Amend. 14

Missouri Constitution, Article I, §10

STATEMENT OF FACTS

A.

Introduction, Nature of Case, and Procedural History

The Board's Statement of Facts in its "corrected" brief[1] is, in Respondent's view, grossly deficient and fails to comply with Rule 84.04(c). With minimal exception, it sets forth none of the evidence - pro or con. Respondent elects, pursuant to Rule 84.04(f), to submit his own Statement of Facts.

Nature of Case. This is a disciplinary proceeding instituted by the **State Board of Registration for the Healing Arts.** The Board claims there exists cause to suspend, revoke or otherwise discipline the medical license of Respondent, **Edward W. McDonagh, D.O.** In the Board's view, cause exists because Dr. McDonagh uses "chelation therapy," together with an FDA approved drug "EDTA," as an adjunct to and as an alternative form of medical treatment for atherosclerosis and other vascular diseases.

The Board's position is that because the"chelation therapy" Dr. McDonagh uses in his practice is generally rejected by mainstream, orthodox, medicine, it is therefore harmful and dangerous (Complaint, ¶¶ 8, 43, 71, 84, 92, 102, 125; ROA 2-22), and therefore does not

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[1]Appellant filed its "corrected" brief with the Western District February 22, 2002. Appellant elected to not file a substitute brief with this Court.

provide the requisite standard of care required for physicians (Tr. 25-27; FF 18; App.A39-A41; *App. Br. 16, 20*).[2]

Appellant contends that Dr. McDonagh's use of chelation therapy constitutes incompetence, misconduct, inappropriate treatment, gross negligence, and repeated negligence within the meaning of §334.100.2(4)(a), (c), (e) and (5) RSMo, as these sections existed in various forms from 1978 through 1996. The Board also asserts claims of misrepresentation, failure to keep proper medical records, and ordering inappropriate and unnecessary testing (*App. Br. 24, 25*).

AHC Proceedings. On December 19, 1994 , following the receipt of two inquiries and following an investigation into Respondent's practice – including culling through innumerable patient files (involving a span in excess of fifteen years) -- the Board filed a thirteen count Complaint pursuant to §334.100.2 and §621.145 RSMo. (Pet. Exh. B-2).

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[2] "FF" stands for Findings of Fact; "COL" for Conclusions of Law; "ROA" refers to the "legal file" portion of the proceedings; "Tr." refers to the transcript of the oral proceedings before the AHC; "SOF" refers to the Statement of Facts in the Briefs filed herein; "*App. Br.*" refers to Appellant's Brief; and "*App.R.Br.*" refers to Appellant's Reply Brief.

The AHC decision, the Cole County Judgment, the Western District Opinion, portions from the record, and several articles are included in the Appendix. References, by page number, to an item in the Appendix are denominated "App. A_".

For example, Counts II and III involve Respondent's treatment of L__ J__for the periods 1978 through 1980 and again in 1991; Count V involves Respondent's treatment of J__ H__ in 1982; and Count VIII involves Respondent's treatment of G__ H__ for the period 1987 through 1989. The Board dismissed this complaint without prejudice (*App. Br. 21*). The Board subsequently refiled its second Complaint on December 6, 1996, essentially asserting the same grounds (ROA 2-22). This appeal arises from the AHC's decision with respect to the second Complaint.

The AHC hearing commenced on November 11, 1997. The Commission heard testimony from eight witnesses with a transcript in excess of 1,300 pages; received extensive deposition testimony; heard conflicting expert testimony from four witnesses (one live and three by deposition) called by the Board and three expert witnesses (all live) called by Respondent -- together with his own expert testimony; and received testimony from three of Respondent's patients (two live and one by deposition) each of whom testified in support of Respondent and benefits derived from receiving EDTA chelation therapy.[3]

The Commission also received into evidence 189 exhibits including numerous medical treatises and several studies -- pro and con -- with respect to the efficacy of "EDTA chelation therapy" as an alternative form of medical treatment for atherosclerosis and other vascular diseases -- as opposed to the traditional surgeries and various other drugs.

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[3] These were: G__ H__(Tr. 458-496)[Count VIII]; T__ G__ (by deposition Exh. N) [Count IX]; and C__ H__ (Tr. 596-506).

Decision of AHC. Following the hearing and after receiving proposed Findings of Fact, Conclusions of Law and extensive memoranda of law, the AHC issued its 70 page Decision on January 26, 2000 (App. A1-A70).

The AHC found EDTA chelation therapy to be safe (FF 18; App. A5); found it beneficial and efficacious in many instances (FF 37-40; App. A13-A14); and as a result, found no cause to discipline (App. A68-A70). In addition to its general Findings of Fact and Conclusions of Law, the Commission also made specific Findings and Conclusions with respect to each of the thirteen Counts. The Commission included footnotes with cross-references to the transcript and/or exhibits for many of its Findings and Conclusions.

The Commission, as part of its decision, found:

> The Board asks us to equate these doctors' conduct [cases where the Commission had found cause to discipline] with McDonagh's conduct in this case, that of giving patients a treatment that has provided benefit to many patients, harms no one, and is given with informed consent and the information that this treatment may not work with all patients. This is a very different situation than the cases we have decided in the past. Despite the Board's experts, who testified that there is no benefit to be derived from chelation therapy, the evidence shows that patients are being helped. (Findings 37-40.) We cannot state that an entire treatment method that provides benefits to patients without harming them constitutes incompetent, inappropriate, grossly negligent, or negligent

treatment. Nor can we say that this treatment is misconduct, unprofessional, or a danger to the public. (App. A44).

Judicial Review – Judgment of Circuit Court. Appellant filed suit in the Circuit Court of Cole County, pursuant to §536.110, RSMo., for "judicial review." The Circuit Court entered judgment September 21, 2002, and affirmed the AHC's decision (App. A71). This appeal follows.

Western District -- Opinion. On March 25, 2003, the Western District issued its opinion and found in favor of Respondent on all but one issue – whether Respondent's experts employed the proper "standard of care" – i.e., to "use that degree of skill and learning ordinarily used under the same or similar circumstances by members of the applicant's or licensee's profession." (App. A72-78).

B.

Facts and Evidence Relevant to Issues on Appeal

Respondent - Edward McDonagh, D.O. – Qualifications. Dr. McDonagh has been licensed by Appellant since 1961 as an osteopathic physician (FF1; App. A2). He received his D.O. degree from the Kansas City College of Osteopathic Medicine (Tr. 859). He has never had any of his medical licenses suspended, revoked, or otherwise disciplined (Tr. 942-943).

Dr. McDonagh was board-certified in general practice in 1974 and re-certified by testing in 1995 by the American Osteopathic Board of Family Physicians (Tr. 859, 894-896; Resp. Exh. E-2; FF 2; App. A2). He primarily practices in the area of family medicine in Gladstone, Missouri (Tr. 1161; FF 3; App. A2).

A substantial part of Dr. McDonagh's practice is devoted to treating vascular disease in geriatric patients (Tr. 965, 1161; FF 14; App. A4). He also practices preventive medicine (Tr. 859) and utilizes the preventive approach to treating disease, including use of chelation therapy (FF 4; App. A2).

Dr. McDonagh became interested in chelation soon after completing osteopathic school and first learned about alternative medical treatment modalities at a seminar in 1962 (Tr. 863; FF 4; App. A2). His main interest in alternative medicine is the severe, unresponsive patient that has advanced, chronic diseases. Most of his patients come to him effectively as a last resort after they have seen numerous doctors and been on multiple prescriptions (Tr. 866-867). He visualizes the care that he provides as a "add-on" to standard treatment and insists that patients stay with their treating physicians (Tr. 867-868).

Dr. McDonagh has done significant research and writing, with some of his publications appearing in peer-reviewed journals (Tr. 884-885). He has presented at the American Osteopathic Association and at the Missouri Society of Osteopathic Family Physicians on chelation therapy (Tr. 890-891). He has taught chelation at the American College for Advancement in Medicine (ACAM) meetings (Tr. 889) and is widely read by his peers as an authority on chelation therapy (Tr. 901; Resp. Exh. E-4, p. 115).

EDTA Chelation Therapy – What it is, Theories, and Protocols for Use. EDTA (ethylene diamine tetraacetic acid) is a drug approved by the Federal Food & Drug Administration (FDA) for the removal of heavy metals in the body (FF 9; App. A3; Pet. Exh.13, p.20). Since the 1950s, a minority of physicians have treated vascular diseases with EDTA

chelation therapy which involves the intravenous administration of a diluted solution containing EDTA and magnesium (Pet. Exh. 18, p. 40, Pet. Exh. 29; FF 14; App. A4). Other vitamins and minerals may be added to the solution, depending on the particular needs of the patient (Tr. 13-14; Pet. Exh. 18, p. 40-41; FF 48; App. A16).

David G. Meyers, M.D., Appellant's primary expert witness, described EDTA as a complex chemical customarily used for chelating heavy metals, grabbing them much like a crab would grab, and containing that molecule within the EDTA molecule (Tr.74). He defined atherosclerosis as the accumulation of and deposits of blood fat and cholesterol in an artery wall resulting in scarring of the artery (Tr. 81).

EDTA binds with heavy metals in the blood such as iron, mercury, cadmium, lead and aluminum, and these are excreted through the urine. (Tr. 84; Pet. Exh. 18, p. 9, 13-14). It also binds with calcium which is excreted the same way (Tr. 84; FF 31; App. A2-A3, A12).

Proponents of chelation therapy have a good faith belief in its efficacy and believe that their treatment not only prolongs the lives of their patients but improves the quality of their lives as well (Tr. 10, 1219, 1347).

ACAM is a professional association of physicians who administer EDTA chelation therapy in clinical practice. ACAM has promulgated a protocol for the use of EDTA chelation therapy in treating atherosclerosis and other vascular diseases (Tr. 11; Pet. Exh. 11, 18, & 20; Resp. Exh. G-1; FF 41-51; App. A14-A17). The protocol is an educational tool and physicians trained in chelation therapy may vary from the protocol and still be within the standard of care.

It provides wide discretion to the judgment of the physician (Tr. 590-593; Pet. Exh. 11, 18; FF 41; App. A14).

A minority of physicians, estimated at approximately two percent (Tr. 1255) perform chelation. Some are members of ACAM, an organization of approximately 1,000 physicians worldwide (Tr. 589; FF 15; App. A4). Other organizations that support the use of EDTA chelation to treat atherosclerosis are the American Board of Chelation Therapy, the Great Lakes College for Clinical Medicine, the American Holistic Medical Society and the Orthomolecular Medical Society (Tr. 716-717).

Dr. McDonagh testified that EDTA is becoming of greater interest to the public, being noticed and recognized more, and there are more doctors interested in learning about it. He estimated that ACAM was growing 20% every six months (Tr. 995).

None of the following entities endorse chelation therapy for the treatment of atherosclerosis: American Osteopathic Association (Pet. Exh. 24), American Medical Association (Pet. Exh. 26), the American Heart Association (Pet. Exh. 25), or the American College of Cardiologists (Pet. Exh. 27). The public statements of each these entities is that there is a lack of scientific evidence to demonstrate benefit from this therapy.

Alleged Misrepresentations -- Informed Consent. As part of its Complaint, the Board charges Respondent with misrepresenting and making false statements to patients as to the efficacy of EDTA chelation therapy. (Complaint ¶¶ 7, 20, 42, 53, 70, 83, 91, 101, 106 124; ROA 2-22). The undisputed evidence shows that Dr. McDonagh has all of his patients sign a consent to medical treatment and agreement that discusses the positive and negative aspects

of chelation therapy and possible side effects (Resp. Exh. F-2, F-3; App. A4-A5, A47, A81, A82).

The agreement provides information as to the benefits that may be derived but states, "however, you must be aware that you may not receive all of these benefits as they do not occur predictably with every patient and in some cases may not occur at all." Dr. McDonagh tells patients that the therapy does not work on everyone and that the treatment will work better if the patient follows the diet, exercise and nutritional supplements that are recommended. The agreement specifically states that chelation therapy has not been approved by the AMA, the FDA, and others (Resp. Ex. F-2, F-3; App. A5, A47, A81, A82).

The AHC made a specific finding that Dr. McDonagh does not perform chelation therapy without informed consent from the patient (FF 16; App. A4). (See the AHC's commentary to Count IV; App. A47).

EDTA Chelation Therapy -- No Harm to Patients. In its Complaint, the Board repeatedly alleged that EDTA chelation therapy is dangerous and harmful to patients. (Complaint ¶¶ 8, 43, 71, 84, 92, 102, 125; ROA 2-22). During the hearing, Appellant retreated from this position and conceded during its opening statement that there was no evidence of harm (Tr. 12, 25, 771-773; App. A79, A80).

If a practitioner follows the ACAM protocol, the treatment is safe and has no dangerous side effects (Tr. 333). Appellant so admits (Tr. 12, 25, 771-773; App. A79-A80). In the 35 years he has used chelation, Dr. McDonagh has had no infections, injuries or deaths from the therapy (Tr. 872, 975).

The AHC made specific findings that EDTA therapy is not harmful. (FF 37-40; App. A15). In contrast, the AHC also made specific findings as to some of the risks associated with the more traditional means of treatment, including cardiovascular surgeries (FF 19; App. A5-A6).

Favorable Testimony of Patients. Three of Respondent's patients testified, two in person and one by deposition. G_ H_, the subject of Count VIII, is the wife of retired federal judge, C_ H_. She is college educated, independently researched chelation, and intelligently made the decision to try chelation therapy after being told by Dr. McDonagh that it was not an approved treatment by Medicare or insurance companies, that it might or might not help her, and was not a "mainstream" type treatment (Tr. 458-459; 493-494).

G_ H_ had three angioplasties in five months and, following each, her chest pains returned in approximately six weeks (Tr. 461). Her care was at St. Luke's Hospital in Kansas City, which is recognized as one of the best places for coronary care. After the last angioplasty, the arteries closed again and were about 95 percent blocked. Her cardiologist informed her that she needed quadruple bypass surgery immediately (Tr. 463-464). She began receiving chelation therapy in January 1987 and, as of the date of the hearing, she had not required bypass surgery or angioplasty and was able to discontinue, with the consent of her cardiologist, her main cardiac medication (Tr. 472-473). When she began treatment, she took nitroglycerin for chest pain, three or four at a time, two or three times per week. At the time of trial, she hadn't had chest pains in six years (Tr. 496-470). Her cholesterol level, when she began treatment, was 342 and reached a low in February 1991 of 229 (Tr. 460-464, Pet. Exh.

5, p. 58). Following her course of chelation, follow-up tests by her cardiologist showed no indication of atherosclerosis and no blockages (Tr. 468, 495). As of the time of the hearing she was able to walk two and a half miles per day (Tr. 480).

Further competent and compelling evidence came by deposition from the subject of Count IX, T_ G_, retired Vice President of Beneficial Corporation, who had angioplasty in 1991 and was told he could not have another angioplasty but would need bypass surgery (Exhibit N, p. 6). Within two weeks, his chest pain was back to almost as frequently as before the angioplasty (*Id. at 6*). T_ G_ commenced chelation therapy in June 1991 at age 68 and was, at the time of his deposition, 75 years old (*Id. at 17, 24*). He gets a physical from his family physician once a year and sees his cardiologist once a year (*Id. at 9*). His cardiologist raised no objection to him taking chelation but commented that "he wishes that they had the statistical information so that he could recommend it to his other patients" (*Id. at 36*). His cardiologist is amazed that the total blockage is now completely gone (*Id. at 10-11*). He described his family doctor's response as "sitting there and he's shaking his head, he said, I don't believe it can be this good." (*Id. at 15-16*). T_ G_ is the first male in the G_ family to reach the age of 75 (*Id. at 17*).

C_ H_, a retired federal judge and the husband of G_ H_, testified to the substantial benefits he received from chelation therapy as well (Tr. 496-501).

Frye v. Daubert. Appellant premises much of its argument on the proposition that the AHC erroneously admitted and considered Respondent's expert testimony, together with the testimony from his three experts as to the use, the efficacy, and the standard of care with

respect to EDTA chelation therapy. The Board argues is that none of Respondent's expert evidence qualifies for admission under ***Frye v. U.S.*** in that EDTA chelation therapy is not based on:

> ...well recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs. (*App. Br. 34-38*).

Appellant asserted before the AHC and now on appeal that the medical community has rejected the use of chelation therapy (*App. Br. 19-20, 21, 43, 50*). As a result, Appellant claims that such testimony does not constitute competent and substantial evidence and, therefore, cannot and could not be relied on by the Commission (*App. Br. 38, 42, 62*; *App.R.Br. 8-12*).

Respondent asserted that with the enactment of §490.065, RSMo., ***Frye*** has been overruled in civil and administrative proceedings and ***Daubert*** and its progeny under the then identical Federal Rule of Evidence 702 controls. Respondent further asserted that his expert evidence qualifies under either standard (Tr.578-579; ROA 55-57).

The AHC addressed the ***Frye/Daubert*** issue extensively; found Missouri decisional authority uncertain; evaluated Respondent's expert evidence using both standards; and found the testimony to be admissible under both (App. A34-A38). The AHC concluded:

> We find that the testimony in this case also satisfies both tests. [names and qualifications of Respondent's expert witnesses deleted].... These individuals are clearly qualified to testify as experts.

> Chelation therapy has been tested by both proponents and opponents as noted in our findings. There are specific standards set forth in the studies that support chelation therapy, and the methodology is clearly stated. [specifics deleted]... While acknowledging the limitations of these studies, as noted by the Board's expert, we find that the studies of chelation therapy pertain to scientific knowledge and assist us in determining the facts at issue. (App. A36-A37).
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> * * *
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> .... While the majority of doctors do not use chelation therapy in this way, it is an innovative use of a treatment by a minority of doctors. The off-label use of drugs is generally accepted by the medical profession. These facts indicate an "honest difference of opinion" under Missouri case law.
>
> The testimony is certainly relevant since McDonagh's defense against the Board's charges rests on his assertions that chelation therapy is appropriate treatment for conditions other than that for which it has been approved by the FDA. It will also aid this Commission in making our determination as to whether McDonagh's use of chelation therapy would subject his license to discipline as the Board maintains. (App. A37-A38).

EDTA Chelation Therapy Studies. EDTA chelation therapy has been the subject of numerous studies -- pro and con. Respondent offered into evidence, **without objection**,

thirteen scientific studies performed by scientists other than Respondent[4]; a chapter from *Cardiovascular Drug Therapy* entitled *Magnesium EDTA Chelation* ,(Second Edition 1996) by Messerli (Resp. Exh. A-3), a textbook widely used in medical schools in the United States; two scientific books on EDTA chelation therapy, one entitled *The Scientific Basis of EDTA Chelation Therapy* (second edition 1997) by Halstead & Rozema (Resp. Exh. A-2) and the other entitled *Textbook on EDTA Chelation Therapy* (Resp. Exh. M); a book for the public, *Bypassing Bypass* by Elmer Cranton, M.D. (October 1997) (Resp. Exh. A-1); a book by Respondent entitled *Chelation Can Cure* (Resp. Exh. C-1) and *A Collection of Published Papers Showing the Efficacy of EDTA Chelation Therapy* written by Respondent and his partner, Dr. Rudolph (Resp. Exh. C-3).

To demonstrate that EDTA chelation therapy is not an isolated, unknown, untested therapy, Respondent also offered transcripts of Peter Jennings *Health Report -- Unblocking Clogged Arteries -- Getting Insurance Companies to Pay for Chelation* (October 13, 1997) (Resp. Exh. K-2); a *Dateline* report from March 24, 1995, entitled *Balloon Angioplasty, An Over-Inflated Treatment* (Resp. Exh. K-3); and a videotape of a *48 Hours* television program featuring a segment on Dr. McDonagh and chelation therapy (Resp. Exh. K-8).

In the Messerli textbook, *Cardiovascular Drug Therapy*, the author of the chapter *Magnesium EDTA Chelation* concludes that "repetitive intravenous infusion of [magnesium]

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[4] The scientific studies were Respondent's Exhibits G-3(a), G-7, G-10, G-11, G-13, G-14, G-15, G-17, G-18, G-19, G-20, G-21 and G-23.

EDTA promotes the restoration of the plasma and tissue balance and metabolism of essential minerals . . .. This, in turn, permits the functional improvement of damaged vascular areas."

In the early 1990s, James P. Carter, M.D., Dr.PH, Director of the Tulane University School of Public Health and Tropical Medicine, Efrain Olszewer, M.D., and F.C. Sabbag, M.D., conducted the first double-blind study entitled *"A Pilot Double-Blind Study of Sodium-Magnesium EDTA in Peripheral Vascular Disease"*, published in the *Journal of the National Medical Association* (the "*Olszewer*" study), evaluating the effectiveness of magnesium EDTA on the treatment of peripheral vascular disease. Although the sample size was small, the patients infused with EDTA showed a marked improvement, with the "effect of treatment increased with time" (Resp. Exh. G-15, p. 173).

Respondent's expert, L. Terry Chappell, M.D., was the co-author of *The Correlation Between EDTA Chelation Therapy and Improvement in Cardiovascular Function: A Meta-Analysis* published in the *Journal of Advancement in Medicine*. The researchers were trying to determine if there was a correlation between improvement in vascular disease demonstrated by objective measurement and treatment with EDTA. 22,765 patients were included in the study. John Stahl, the co-author, a statistician, merged the data and found that it revealed a correlation coefficient of 0.88, meaning that 87% of the patients had documented improvement in their vascular disease (Tr. 827-828; Resp. Exh. G-11, p. 141-151).

The Board principally relies upon two studies. The *Guldager* study (FF 24-25; App. A8-A9) and the *van Rij* study (FF 26-27; App. A10). Respondent objected to the admission of these studies on the grounds there had been inadequate research (Tr. 575).

Testimony of Appellant's Expert. David G. Meyers, M.D., Appellant's primary expert, is a professor of internal and preventive medicine at Kansas University Medical Center. He received his M.D. in 1976, followed by a residency in internal medicine and a fellowship in cardiovascular disease and served as an assistant professor of medicine at the Nebraska Medical Center from 1981 until December 1993, when he accepted his position at KU. Dr. Meyers is board certified in internal medicine, cardiovascular diseases and preventive medicine (Tr. 69-71).

Dr. Meyers wrote an article, entitled *So Much Written, So Little Science* concerning EDTA chelation which was published in 1994 (Tr. 75-76). In preparing this article, Dr. Meyers used a Medline computer search. He said he made an effort to review all of the available literature of EDTA applied to atherosclerosis (Tr. 77). Out of 4,600-odd articles and publications, he found 50 that applied to EDTA in humans for treatment of atherosclerosis and used 15 (Tr. 119-120).

Dr. Meyers has never used chelation (Tr. 353) and observed it only once when he visited one doctor who used it (Tr. 397-398). Other than in this litigation, he never reviewed charts of chelation patients (*Id.*).

Dr. Meyers testified that the *Guldager* study, conducted in Denmark, and published in 1992, was a well-designed, well-carried out study of EDTA chelation therapy. The 153 patients in the study had leg artery disease and the end points were measured with how far they could walk before they got pain in their legs. He initially testified that the treatment was EDTA plus the usual ACAM recommended additives (Tr. 125). The study found no difference

between those treated with EDTA chelation therapy and the placebo (Tr. 123-125; FF 24 & 25; ROA 185-186). The majority of the medical community accepts *Guldager* (FF 25; App. A9). Dr. Meyers testified that the *Olszewer* study was a reasonably well-designed and scientifically valid study, but the sample size caused limitations (Tr. 121-123; FF 23; App. A8).

Dr. Meyers relied primarily on the *van Rij* study, conducted in New Zealand and published in the journal *Circulation*, where 32 patients had 20 treatments. He said it was the best designed and carried out study of chelation therapy. The majority of the medical community accepts this study (FF 26, 27; App. A10).

On cross-examination, Dr. Meyers admitted that in *Guldager*, the mechanism of randomization of the patients was not noted, other than stating they were randomized in blocks of ten; that the ACAM protocol was not followed, in that magnesium which is a required additive to the EDTA was omitted from the mixture, even though the paper delineated that the ACAM guidelines were followed (Tr. 341-343); that heparin was not used, which is required by the ACAM protocol to diminish pain and clot formation in the vein, and if the group receiving EDTA had pain and the other group did not, you would not have a "blinded" patient (Tr. 344-345). He acknowledged that the ACAM protocol requires there to be at least 20 treatments and recommends 30 or more and *Guldager* limited it to 20 infusions (Tr. 345-346).

Dr. Meyers acknowledged that he had no opinion regarding the efficacy of chelation therapy until the *van Rij* study was published in 1994 (Tr. 364). He testified that if data was

provided showing that the results of the study had not been adjusted for an "outlier," then "I would wish to reevaluate [my] position" regarding the efficacy of chelation (Tr. 374)[5].

Dr. Meyers testified that recent research published in *Heart* suggests that iron depletion could reduce heart attacks, strokes, and other vascular events by up to 30%, suggesting that iron depletion with chelation therapy, by chelating and removing iron chemically would have that effect (Tr. 86). Therefore, it is plausible that EDTA's impact on iron might influence atherosclerosis; and since EDTA chelates iron, then it would have a more long lasting effect (Tr. 84-85, 427).

Dr. Meyers described the double-blind placebo controlled parallel randomized clinical trial as the most scientifically valid study, the "gold standard" of scientific evidence (Tr. 99). He acknowledged that there were no such studies for angioplasty or bypass surgery as it would be unethical to perform them (Tr. 109, 322-324).

He also acknowledged that a difference of opinion on medical procedure is not necessarily unprofessional conduct or a breach of the standard of care (Tr. 385) and that few medical hypotheses are actually proven (Tr. 428).

Testimony from Respondent's Experts. Dr. McDonagh presented testimony from three experts: James P. Frackelton, M.D., L. Terry Chappell, M.D., and Charles J. Rudolph, Jr.,

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[5] An "outlier" is a patient who, without explanation, does very well in a placebo group (FF 27; App. A10).

D.O., Ph.D. The AHC, after describing their background, commented: "These individuals are clearly qualified to testify as experts." (App. A36-A37).

James P. Frackelton, M.D., is a senior partner in an Ohio preventive medicine group, is a member of the American College of Cardiology, a fellow in ACAM, a diplomate of the American Board of Chelation Therapy, and lists eight publications (Resp. Exh. D-1; COL 36). Dr. Frackelton personally participated in the investigation of the *Guldager* and *van Rij* studies (Tr. 626, 634).

With respect to *Guldager*, Dr. Frackelton testified that the study could not be evaluated without looking at the article which first was published in the *American Journal of Surgery* by Dr. Sloth Neilson nine months earlier and that 30 patients out of the 153 had been part of the *Sloth Neilson* study (Resp. Exh. G-29). Twenty-nine of those thirty patients smoked and had severe vascular disease. Making these same thirty part of the *Guldager* subjects was clearly not a random selection of subjects (Tr. 619). The fact that the *Sloth Neilson* study is not mentioned in *Guldager* is immediately suspect (Tr. 618-619).

Dr. Frackelton expressed the additional criticisms and flaws: (1) although the study stated that it used the same substances required by the ACAM protocol, that was not true -- they used disodium EDTA instead of magnesium EDTA; (2) patients were provided vitamin capsules during the chelation which included iron. Because iron is a major contributor to vascular disease, it is never to be given unless the patient is iron deficient; (3) 70% of the subjects smoked. Smoking is a great detriment to improvement with chelation; as the subjects were permitted to continue to smoke, smokers would need at least 30-40 treatments to show

any change (Tr. 629); (4) only 20 treatments were given to care for the subjects with severe vascular disease; (5) when the investigators of the study requested the raw study data they were refused (Tr. 622); (6) the study was not blinded -- patients with the EDTA were in one room and the ones with the placebo were in another room which is totally alien to double-blinding; (7) patients were told whether they were receiving the placebo or not, particularly when the IV infiltrated (i.e., when solution got underneath the skin) (Tr. 627); (8) Bottles were mixed up between the placebo and study groups; and (9) 30% of the patients had infections, needles were left in place, and patients were told to grab a bottle to start their own IVs (Tr. 629; FF 25; App. A9).

With respect to the *van Rij* study, Dr. Frackelton received and reviewed the raw data and concluded: (1) patients selected had extremely severe vascular disease (Tr. 634); (2) 80% of the patients smoked (Tr. 635); (3) patients with diabetes were excluded from the study, a serious omission as one of the most common problems for diabetics is peripheral vascular disease; (4) the ACAM protocol requires magnesium EDTA and no magnesium was given (Tr. 636); (5) the patients had only 20 infusions and, with the severity of disease indicated, they would have needed at least 40 (Tr. 635); (6) most importantly, a member of the placebo group was an outlier which, if not statistically removed, will make the statistics invalid. Once the outlier was removed, the study group did, in fact, improve (Tr. 636-637; FF 27; App. A10).

L. Terry Chappell, M.D., a graduate of the University of Michigan Medical School, is on the faculty of the Wright State School of Medicine (Tr. 829) and, at the time of trial, had signed a contract to be a consultant for the University of Missouri to participate in a study with

the Department of Cardiology of EDTA chelation therapy as an anti-anginal drug (Tr. 829-830). Dr. Chappell is certified by the American Board of Family Practice with an added qualification in geriatric medicine, the American Board of Pain Management, and the American Board of Chelation Therapy. He has served as a consultant for the Ohio State Medical Board for Disciplinary Investigations regarding family practice and alternative medicine since 1992 (Resp. Exh. D-2, p. 93).

Dr. Chappell is the author of many publications, the recipient of many awards, and has given many presentations (Resp. Exh. D-2; COL 214). He was asked by the head of the Office of Alternative Medicine at the NIH to serve as a consultant and to help design a treatment protocol for a study on EDTA chelation therapy because of his vast experience with chelation. The NIH proposal is for a large, double-blind study.[6] He has also worked with foreign physicians who are proposing to do or who are doing studies, assisting them in maximally effective treatment protocols (Tr. 830-831).

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[6] Following Dr. Chappell's testimony in 1997 and therefore not part of the official trial record, the study that he discussed has commenced (App. A88-A92). The National Center for Complimentary and Alternative Medicine (NCCAM), a component of the NIH, is currently conducting a formal "multi-center randomized clinical trial, double-blind, placebo control, efficacy" study of EDTA chelation therapy in individuals with coronary artery disease. See, **ClinicalTrials.gov:** *Trial to Assess Chelation Therapy (TACT)*, March 31, 2003 (App. A88).

Dr. Chappell was the primary author of *The Correlation Between EDTA Chelation Therapy and Improvement in Cardiovascular Function: A Meta Analysis*, published in the *Journal of Advancement in Medicine* (Volume 6, No. 2, 1993) (Resp. Exh. G-11), a study involving over 22,000 patients (Tr. 828; See SOF, p. 42).

Dr. Chappell also personally participated in review of *Guldager* and *van Rij*. He confirmed that *Guldager* did not use the same treatment nor the same protocol that "we use" although they said they did and that the study was criticized by the Danish Council for Scientific Dishonesty. With respect to *van Rij*, he stated that the biggest problem was that the outlier was not included in the original article. Once *van Rij* sent the raw data, they found that one patient in the placebo group had improved so much more than any other person that it completely distorted the study and, because it was a small study, it negated the effects. Since that was not mentioned in the original article, it was a major omission (Tr. 831-832).

Charles J. Rudolph, Jr., D.O., Ph.D., received his D.O. degree in 1977 from Texas College of Osteopathic Medicine (Tr. 1233). He previously earned his Ph.D., *summa cum laude*, in biochemistry from Oklahoma State University. Dr. Rudolph started the biochemistry program at the Texas College of Osteopathic Medicine where he taught for several years (Tr. 1233; Resp. Exh. D-3). He has been a partner at the McDonagh Medical Center since 1977 (Tr. 1232). Dr. Rudolph is board certified and a fellow in the American Board of Chelation Therapy and examines others who are seeking board certification (Tr. 1244-1245; COL 36; App. A36).

Dr. Rudolph presented numerous studies that he and Dr. McDonagh had performed which demonstrated significant improvement with their patients (Tr. 1288-1332; Resp. Exh. C-2, C-3, C-5, P-1, P-2, P-3). He described EDTA as an anti-calcification type substance that helps remove abnormally deposited calcium from tissue, which treats blood vessel disease. However, it would logically also assist other tissues because as we age, the hard tissue gets soft and the soft tissue gets hard. The joints and arteries get hard and the bones get soft. Chelation seems to reverse some of this (Tr. 1365-1366). Diet alone would not have the results that they have seen with their patients and in their studies (Tr. 1366).

Dr. Rudolph stated that chelation is always compared with the traditional methods of treating heart disease, including bypass and angioplasty and cited the Coronary Artery Surgery Study (CASS), published in the *New England Journal of Medicine* (Resp. Exh. L-2), which is recognized as a leading randomized trial regarding heart attack and mortality in coronary artery surgery. In this study, one group had nitroglycerin, beta blockers and traditional medical management and the other had bypass. After five years, there was no difference in mortality in the number of new heart attacks. It showed that bypass offered no more longevity nor protection against new heart attack rates than doing nothing (Tr. 1345-1346).

Further, there was no evidence bypass or angioplasty prolonged life, nor evidence in the literature that angioplasty was effective for any period of time. In fact, once angioplasty is started, it must be repeated because of the scar tissue build-up (Tr. 1346). He believes that chelation, as compared to bypass and angioplasty, both prolongs life and the quality of life (Tr. 1347).

Respondents Experts – Not Defining in giving Expert Testimony the "Standard of Care" Employed – Preservation of Issue for Appeal. Appellant claims the AHC erred and its decision is not supported by competent and substantial evidence in that:

> Respondent's experts, including respondent himself, testified in terms of his patient care meeting "the standard of care, "without ever defining that term in accordance with the statutory definition of negligence, "the failure... to use that degree of skill and learning ordinarily used under the same or similar circumstances by members of the ... licensee' profession." (*App. Br. 23, 38, 62*).

The Western District agreed with Appellant on this issue, reversed, and, then remanded "the Commission's decision on Counts I, II, III, IV, V, VII, IX, X, XI, XII and XIII for further consideration in light of the applicable standards set forth in Section 334.100.2(5)." (App. A76).

The record shows that the Board filed a written Motion in Limine (Tr. 5-7; ROA 39-54). As its sole ground, the Board asserted that Respondent's expert evidence would not qualify under ***Frye.*** The Board made no reference to any issue with respect to whether a physician's use of EDTA chelation therapy satisfied one's standard of care owed under §334.100.2(5). Respondent filed a written response (Tr. 578-579; ROA 55-57). The Board's motion was ordered "taken with the case" and the AHC permitted Appellant to have a continuing objection "subject to its written ***Frye/Daubert*** objection." (Tr. 579-580, 689-690).

The Board's motion in limine was a general objection (*App. Br. 22*). During the hearing, Appellant did not object to any specific testimony from Drs. Frackelton, Chappell, Rudolph, or even Respondent; and in particular did not object to their testimony regarding their opinions with respect to chelation being in accord with the "standard of care" on grounds they had failed to define the standard used. Nor did the Board, although it had the opportunity to, cross-examine Respondent's experts on this issue (Tr. 703-788, 809-822 [Dr. Frackelton's cross and re-cross]; Tr. 1353-1366 [Dr. Rudolph's cross]; the Board did not cross-examine Dr. Chappell).

History of Actions Taken by Appellant Regarding EDTA Chelation Therapy.

In 1984, John Renner, M.D., a self-described "quack hunter" (Tr.1042) gave a presentation on chelation therapy to the Board and asked for the Board's support in revoking licenses of doctors who practiced it (Resp. Exh. B-1, p. 1; Tr. 1042-1049). In 1985, the Board responded to a letter from the Missouri Society of the American College of General Practitioners, requesting the Board respond to their inquiry regarding the lawful use of EDTA chelation therapy with patients.

The Board responded that the FDA guidelines preside over this issue (Resp. Exh. B-1, p. 1). The FDA guidelines permit any approved drug to be used according to the best medical judgment of the physician (Resp. Exh. G-2; Tr. 118; FF 12; App. A4).

In December 1987, Appellant held a public hearing to take testimony on the issue of chelation therapy (Resp. Exh. B-1, p. 2). In December 1988, the Board publicly stated that it had not taken a position on chelation therapy and, if a position were to be taken, the Board

would do so by formal rule (*Id.*). In February 1989, the Board voted to draft a rule limiting the use of chelation therapy (*Id. at 3*). However, it did not do so.

In May 1989, following the submission of approximately 3,500 abstracts and studies by proponents of chelation therapy, the Board appointed a subcommittee to read and review the available information (*Id.*). The last pre-hearing action of the Board occurred in November 1989 when the subcommittee submitted its report. Following receipt of the report, the Board concluded that the supporters of chelation therapy had made an attractive but as yet unconvincing case for such treatment but noted that in the absence of strong evidence that EDTA chelation therapy was not effective, it would be unwise for the Board to restrict it (*Id.*).

The AHC made a specific finding on the fact that the Board had not promulgated a rule, but instead determined that it would consider the matter on a case by case basis (FF 10; App. A3). The AHC addressed this issue in its COL (App. A31-A32) and noted, in part:

> .... There is no information in the record to indicate what the Board did to notify its doctors about chelation therapy, but we believe that the Board should have informed the doctors, even if not in rule form, about its position on chelation therapy, rather than filing a discipline case against a doctor who has practiced with the Board's knowledge since 1962.....(App. A32).[7]

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[7] Following the Judgment of the Circuit Court that affirmed the decision of the AHC, Appellant promulgated 4 CSR 150-2.165, effective November 1, 2001. The rule states that EDTA chelation therapy is of no medical or osteopathic value for uses other than those

Alleged Failure to Maintain Proper Patient Records. Appellant, in several Counts, asserts that Respondent failed to maintain proper medical records, failed to properly document a diagnosis and/or failed to properly document the need for a particular treatment.

The AHC addressed each of Appellant's claims, by count, and found no cause to discipline.

Record Keeping -- General. Dr. Meyers testified that he had difficulty reading many of Respondent's notes (Tr. 333). Dr. McDonagh admitted that his handwriting was not as good as he would like because the tendons, arteries and nerves had been cut and he never really had the proper control and dexterity in his right hand (Tr. 999-1000). He testified that when he was in medical school in 1958-1961 they had no courses in appropriately charting patient progress; however, he had never received any complaints from any other agencies or entities regarding his charts (Tr. 946-947).

When he first began practicing, Respondent testified he sought legal advice regarding charting, was advised to protect the patient's privacy, and keep the records as brief as possible. Hence, in the early days, he minimized his charts. However, now with Medicare and HMO requirements, Respondent testified that he uses a "SOAP" for purposes of charting which is for subjective findings, objective findings, assessment and plan (Tr. 951).

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approved by the FDA and provides:

(2) The board shall not seek disciplinary action against a licensee based solely upon a non-approved use of EDTA chelation if the licensee has had the patient sign the Informed Consent . . . form included herein . . . (App. A85-A86).

His ordinary procedure was always to get histories with chief complaints noted, vital signs taken and discuss the patient's problem, examine the patient and make notes if he thought it was appropriate or if there was a positive finding. In the early years, if it was a normal check, it would not show up in the notes but it does now (Tr. 952-954). It is his policy to ask patients to either bring in records from other treating physicians or ask them to execute an authorization so his office can gather the records (Tr. 954).

Dr. Rudolph testified that there was no way to define the standards of taking a history but that they tried to take a thorough history, with the nurses taking a short history and then, with a form designed primarily for Medicare, taking a history of each of the organ systems. He stated the purpose of documentation was to recall what he did on the patient (Tr. 1358). With respect to the examination, he stated that they were looking mainly for vascular problems and, therefore, they check carotid arteries and arteries in the leg to check for circulation, and that they will be doing very sophisticated liver function tests, vascular testing, doppler testing, and other testing, and that everything is backed up with physical testing (Tr. 1359).

As of the time of the hearing and the AHC decision, there was no Missouri law or rule setting forth standards or recommendations for medical records charting (FF 7; App. A2).[10]

Record Keeping -- Specific Counts Dr. Meyers testified with respect to Count II (L_J_) that there was no record in the chart that either the evaluation or treatment was applied

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[10] In 2002, the General Assembly enacted §334.097 RSMo., The Medical Record's Maintenance Act.

to the presenting complaint, which he indicated was knee pain (Tr. 143); however, L__ J__ testified that the purpose of his visit to Dr. McDonagh in 1978 was to find out about chelation for his circulation and his heart. He did not even remember the knee pain which was noted in his chart and upon which Dr. Meyers focused (Resp. Exh. 16, pgs. 4-5; Tr. 136, 139)[11].

Petitioner's Exhibit 1 is the chart for patient L__ J__, which shows that he gave a history of having had open heart surgery for coronary artery disease and further shows numerous tests and a complete work-up and profile done in 1978 (Pet. Exh. 1, pgs. 1-7, 12-36). The chart also shows that patient L_ J_ returned to Dr. McDonagh in 1991 (Pet. Exh. 1, p. 8) and by that time had had two bypass surgeries and six balloon angioplasties. L_ J_ reported being tired for 14 years.

Although Dr. McDonagh believed chelation was appropriate, L__ J__ declined (Tr. 1008-1009). Following sophisticated testing, Dr. McDonagh diagnosed him with chronic fatigue syndrome caused by the Epstein Barr virus (Pet. Exh. 1, pgs. 8, 43-44; FF 60; App. A18).

Dr. Meyers testified with respect to Count IV, patient B__C__, that there was no documentation of a history, physical or diagnosis (Tr. 161, 166). Petitioner's Exhibit 2 is the

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[11]L__J__ had had 19 angioplasties and two bypass operations when his deposition was taken and was facing a third bypass (Resp. Exh. 16, p. 7, 16). His arteries block up every three months. He never completed a course of chelation with Dr. McDonagh. He quit going (*Id. at 5, 40-41*).

chart for B__C__. Page six shows a lengthy history and physical. Dr. McDonagh conducted carotid artery doppler scans (bilateral) to confirm the patient's report of 80% occlusion on both sides before putting her on chelation therapy (*Id.*; Tr. 1014). Numerous other tests were conducted during the course of her treatment for other complaints (FF 68 & 69; App. A20).

With respect to Count V, patient J__H__, Appellant's expert, Joseph L. Kyner, M.D., testified that he did not find much which indicated to what degree Dr. McDonagh examined the patient and opined that Dr. McDonagh failed to do an adequate history regarding J__H__'s condition and symptoms (Pet. Exh. 12, p. 11, 19).

The medical records indicate Respondent first saw J__H__ on July 6, 1982, pursuant to a request for consultation from Dr. A.L. Pfauth. Dr. Pfauth had been treating J__H__ and provided a history to Respondent by letter with attached records dated July 5, 1982 (Pet. Exh. 3, p. 1-8). Dr. Pfauth sought consultation over the holiday weekend because he would be out of town. Respondent's role was merely to provide care and consultation over that weekend (Tr. 1033). The AHC found that the history had been provided to Dr. McDonagh by letter and attached records from Dr. Pfauth (FF 71-73; App. A20).

With respect to Count X, patient L__M__, Dr. Meyers testified that he found no basis in the record for setting out to treat vascular disease (Tr. 286). Dr. McDonagh began caring for L__M__ in 1978 (Pet. Exh. 7, p. 1; Tr. 1074; FF 116; App. A26). He began seeing her when she was 61 years old and she was approximately 80 years old at the time of the trial and remains a patient (*Id.*). He is her family doctor and has seen her for a variety of conditions regularly over the years (Pet. Exh. 7, p. 1-87).

With respect to Count XII, patient J__C__, Appellant does not complain of inadequate records, but simply inadequate records to justify the administration of chelation therapy (Complaint ¶122). Dr. Meyers testified that the records were inadequate to diagnose congestive heart failure and that it is not enough to take the word of the patient (Tr. 296-297). However, on cross-examination, Dr. Meyers acknowledges that a three vessel bypass surgery documenting the presence of heart disease is sufficient evidence to confirm the presence of atherosclerosis (Tr. 302-303).

Petitioner's Exhibit 9 revealed that J__C__ was a 78 year old male, first seen on June 22, 1992, complaining that he could not control his balance when he walked. He had +III edema of both lower legs, which would be indicative of congestive heart failure. He had a family history of heart disease, with one brother dead of heart problems and four other siblings with heart problems. He had a three vessel bypass in November 1991 and was on the heart medication, Dijoxin (FF 130-132; App. A28).

Alleged Inappropriate and Unnecessary Testing – Hemoglobin A 1 c.

Lastly, Appellant further asserts cause exists to discipline in that Respondent, in several instances, ordered what the Board considered to be inappropriate and unnecessary testing contrary to §334.100. The AHC heard conflicting evidence, rendered specific FF and COL, and found no cause to discipline (FF 46 & 47; App. A15-A16 & A67).

Dr. David Meyers testified that even in a preventive medicine context, patient testing must be focused with targeted tests and that the most cost effective means of deducing the presence of disease or abnormality is through history and physicals (Tr. 184-185). He

acknowledged that in the past screening tests were applied routinely and the reason for the evolution was cost (Tr. 356-357). Dr. Meyers testified that the hemoglobin A1c tests for the average blood sugar level over the past few months (Tr. 220). He was critical of the test being given a number of times to G__ H__ over a two year period when she was not diabetic (Tr. 189).

Dr. Meyers was likewise critical of the test being repeated with patients T__ G__, (Count IX), D__ S___ (Count XI) and J__ C__ (Count XII) (Tr. 243, 287-288, 299-300). He indicated that without evidence of diabetes or glucose intolerance problems, this test was unnecessary and would violate the standard of care (Tr. 220).

Dr. Frackelton testified, in contrast, that the higher the level of hemoglobin A1c, the more of averaging of blood sugar occurs over the past month or so and thus the test is a very good analysis of the average blood sugar for the patient over the past month. If it's elevated, they give better nutrition and chromium which might be necessary for better utilization of sugar. They would see the hemoglobin A1c go down, whether the patient was diabetic or not, which would be an important sign of improvement. Thus, it would be a very appropriate test for a chelation practice (Tr. 665-666). Dr. McDonagh testified that EDTA could lower a patient's blood sugar, thus giving further reason for administering a test that monitors blood sugar and stated that he routinely gives the test for hemoglobin as a follow-up to see if there is any progress (Tr. 967, 969, 972). The AHC found that this test was part of the follow-up testing recommended by the ACAM protocol (FF 46, 47; App. A15-A16).

Dr. Chappell reviewed the charts of each of the patients at issue. He testified that the tests and the treatment were appropriate and met the standard of care (Tr. 837-839 related to patient L__ J__; Tr. 841 related to patient B__ C__; Tr. 842-843 related to patient R__ T__; Tr. 843-844 related to patient G__ H__; Tr. 844-846 related to patient T__ G__; Tr. 846-847 related to patient L__ M__; Tr. 847-848 related to patient D__ S__; Tr. 848-849 related to patient J__ C__).

ARGUMENT

POINT I.

<u>Deficient Statement of Facts and Points Relied On</u>

(Independent Issue - Not Responsive to a Specific Point)

THIS COURT SHOULD LIMIT ITS REVIEW TO ONE OF "PLAIN ERROR" PURSUANT TO RULE 84.13(C) IN THAT APPELLANT'S STATEMENT OF FACTS AND POINTS RELIED ON IN ITS "CORRECTED BRIEF" IS GROSSLY DEFICIENT, VIOLATE RULE 84.04(c) AND RULE 84.04(d)(2) SUCH THAT THE BOARD HAS FAILED TO PROPERLY RAISE OR PRESERVE ANY OF ITS ISSUES FOR REVIEW.

Standard of Review: The Board's opening "corrected" brief, as filed with the Western District, significantly fails to comply with the mandates of Supreme Court Rule 84.04. The question of whether Appellant's brief is deficient and whether, as a result, the Board has failed to properly raise, brief, or otherwise preserve for appellate review its claims is a matter for the independent determination of this Court. Review for "plain error" is discretionary and is reserved for cases where a manifest injustice or a miscarriage of justice will, absent such review, otherwise result. ***Rule 84.13(a) and (c).***

Compliance with Rule 84.04 is mandatory. These rules exist for a purpose. They ensure that appellate courts do not become advocates by speculating on facts and arguments that have not been asserted. ***Wilson v. Carnahan***, 25 S.W.3d 664, 667 (Mo. App. W.D. 2000). "It is not the function of the appellate court to serve as advocate for any party to an appeal." ***Thummel v. King,*** 570 S.W.2d 679, 686 (Mo. banc 1978); and ***Stickley v. Auto Credit, Inc.***,

53 S.W.3d 560, 562 (Mo. App. W.D. 2001). The briefing rules apply to the rich and poor alike, including *pro se* litigants. ***Watson-Tate v. St. Louis School Dist.***, 87 S.W.3d 358, 359 (Mo. App. E.D. 2002). Likewise the briefing rules apply equally to government and private litigants.

Sufficiency of Appellant's Statement of Facts. The purpose of the statement of facts is to provide the Court with an immediate, accurate, complete and unbiased understanding of the facts of the case. ***Faulkerson v. Norman***, 77 S.W.3d 43, 44 (Mo. App. E.D. 2002). In contrast, Respondent has no duty, or obligation, to include a statement of facts. ***Desai Corp. v. Colony Ins. Co.***, 30 S.W.3d 223, 224 (Mo. App. W.D. 2000).

Most importantly, an appellant's SOF must, given the standards which govern appellate review, include both the facts and evidence favorable to Respondent and which support the judgment -- not just those favorable to Appellant. ***Evans v. Groves Iron Works,*** 982 S.W.2d 760, 761 (Mo. App. E.D. 1998); ***Baris v. Layton***, 43 S.W.3d 390, 393 (Mo. App. E.D. 2001).

An appellant's brief with an insufficient, or improper, statement of facts preserves nothing for review and is grounds to dismiss the appeal. ***Rice v. State, Department of Social Services,*** 971 S.W.2d 840 (Mo. App. E.D. 1998). Alternatively, the Court may elect to review only for "plain error."

Here, the Appellant's Statement of Facts is clearly deficient. Appellant's statement is only 11 pages and most of those pages are devoted to setting forth a general description of the case and a synopsis of the procedural history. When Appellant does set forth information as to the evidence, it includes only those favorable to its position. Appellant completely ignores

the facts favorable to Respondent and the facts which support the judgment. Yet, as previously noted, the record here is quite extensive (SOF p. 29).

Sufficiency of Appellant's Points Relied On. Appellant's brief is deficient in another but equally serious respect. Each of the Board's Point's Relied On fails to comply with Rule 84.04(d)(2).

It's difficult, if not impossible, to determine with any degree of precision what the claimed error is or the basis therefor from each of Appellant's Points. The Points are so nebulous that it is impossible to identify which of several possible claims the Board is attempting to raise.

Appellant's argument under Points I and II each contain numerous subheadings which raise issues and grounds which are not fairly included within the Point. For example, the Board's argument under Point I contains ten separate subpoints, each with a different perspective and reason for why the Commission erred in accepting and relying upon Respondent's expert evidence. Likewise, in its argument under Point II, the Board has ten separate subpoints, each which presents a different reason why the AHC erred in accepting and relying upon Respondent's expert evidence.

In fact, it appears that several of the Board's points are duplicitous and assert but the same ground - just phrased another way. Points I and II are but an example. Each conclude with essentially the same words -- the AHC erred in that Respondent's expert evidence does not meet the requisite standard as to scientific general acceptance and, hence, such evidence could not constitute substantial evidence upon which the AHC could rely as support for its

conclusion that the use of chelation therapy is within the statutorily defined standard of care as set forth in §334.100.2(5) RSMo.

Similarly, Appellant's Points III through V are equally deficient.

Properly drafted Points are critical to the appellate process. The "point" frames and is to delineate for both the Court and Respondent the issues on appeal. ***Franklin v. Ventura***, 32 S.W.3d 801, 803 (Mo. App. W.D. 2000). Repeatedly, this Court, together with each district of the Court of Appeals have held that the requirements for properly drafted points are not merely word games or hyper-technicalities. Instead, the requirement for having properly drafted points is essential in order for an appellate court to discharge its responsibilities. ***Thummel v. King,*** *supra at 684;* ***Bussell v. Tri-County Humane Society,*** 50 S.W.3d 303, 307 (ftnt 2) (Mo. App. E.D. 2001).

The requirement for an appellant to properly frame the points of error but reflects the proper role of an appellate court. Hence, this Court in ***J.A.D. v. F.J.D. III***, 978 S.W.2d 336 (Mo. banc 1998), quoting from ***Thummel v. King***, commented:

> Ordinarily, an appellate court sits as a court of review. Its function is not to hear evidence and, based thereon, to make an original determination. Instead, it provides an opportunity to examine asserted error in the trial court which is of such a nature that the complaining party is entitled to a new trial or outright reversal or some modification of the judgment entered. It is not the function

of the appellate court to serve as advocate for any party to an appeal.... (*Id. at 339*).

Appellant's violations of this Court's briefing rules are so egregious so as to warrant its appeal being dismissed. Appellant filed its "corrected" opening brief with the Western District on February 22, 2002. Respondent filed its brief April 22, 2003, and, in connection therewith, brought to the attention of Appellant and the Court what he perceived to be significant and egregious violations of the briefing rules. Yet, even knowing the Western District agreed with Respondent in this regard, Appellant elected to not file a substitute brief with this Court. Appellant had the opportunity to correct the deficiencies but chose not to.

Alternatively, this Court should review each of Appellant's claims only for "plain error" as it did in ***J.A.D.***, *supra*.

POINT II .

Standards Governing Admission of Respondent's Expert Testimony.

(*Part 1 of Response to Appellant's Point I*)

THE ADMINISTRATIVE HEARING COMMISSION PROPERLY ADMITTED AND CONSIDERED RESPONDENT'S EXPERT MEDICAL TESTIMONY IN SUPPORT OF HIS USE OF EDTA CHELATION THERAPY TO TREAT ATHEROSCLEROSIS AND OTHER VASCULAR DISEASES BECAUSE §495.060 RSMO. AND THE SUBSEQUENT DECISION OF THE U.S. SUPREME COURT IN *DAUBERT* WITH RESPECT TO ITS ALMOST IDENTICAL COUNTER PARTS -- FEDERAL RULES OF EVIDENCE 702 AND 703 -- NOT THE *FRYE* STANDARD – GOVERN THE ADMISSION OF EXPERT, SCIENTIFIC, EVIDENCE; BECAUSE THE BOARD HAS NOT ASSERTED ERROR IF §490.065 RSMO. IS THE CONTROLLING STANDARD; AND, BECAUSE, EVEN IF THE BOARD PRESERVED SUCH ISSUE, THE AHC DID NOT ABUSE ITS DISCRETION IN THAT RESPONDENT'S EXPERT WITNESSES, AS SHOWN BY SUBSTANTIAL EVIDENCE, WERE FULLY QUALIFIED AND THEIR TESTIMONY WOULD "AID AND ASSIST" THE TRIER OF FACT.

Introduction. Appellant premises its entire case on the proposition that ***Frye v. U.S.,*** 293 F.1013 (D.C. Cir. 1923) is still the controlling law in Missouri. In the Board's view, the courts of this state have not accepted, despite the provisions of §490.065 RSMo.,[12] the

[12] The General Assembly enacted this provision in 1989. See, *L.1989, S.B. Nos. 127,*

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S. Ct. 2786 (1993) standard (*App. Br. 33-38).* Appellant cites and relies heavily upon the Eastern District's decision in ***M.C. v. Yeargin***, 11 S.W.3d 604, 619 (Mo. App. E.D. 1999) (*App. Br. 35-37, 41, 54).*

Thus, Appellant asserts that the AHC misapplied the law and abused its discretion in admitting and considering Respondent's expert evidence. In the Board's view, the use of chelation therapy does not constitute a "well recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs."*(App. Br. 41).*

Specifically, the Board asserts that the AHC erred in overruling its motion in limine and admitting Respondent's expert testimony in that, as a matter of law, there could be no evidence favorable to the use of chelation therapy from a scientific perspective for any purpose -- other than the specific FDA approved use for the removal of lead from the body -- such as an alternative method of treatment of atherosclerosis and other vascular diseases which could ever qualify for admission because orthodox, mainstream, medicine has rejected chelation therapy as having any therapeutic value. (*App. Br. 43-46).*[13]

72, et. al.

[13] Procedurally, as noted in the SOF (p. 52), the Board made only a general objection at the commencement of the hearing when it filed a motion in limine and was granted a continuing objection. Other than once renewing its general objection, the Board never

Respondent notes that the Board's position throughout this litigation is inconsistent and paradoxical. On one hand, the Board admitted at the commencement of the proceeding and at least twice thereafter that the use of EDTA chelation therapy, if used and prescribed in accordance with the ACAM protocol, was safe and there has been no evidence of harm. (Tr. 12, 25, 771-773; App. A79-A80). Yet, the Board repeatedly claims, on the other hand, that Respondent is negligent by using chelation therapy because it is an "off-label, non FDA approved use" and is negligent because mainstream medicine has deemed its use as being non effective. (*App. Br. 40, 60-61*).

But, in so arguing, the Board notes that off-label, non FDA approved use is not only legal, but is a generally accepted practice in the medical community.[14] (*App. Br. 40*). The Board then argues in the same sentence, with no citation of authority, that "the off-label use of EDTA to treat atherosclerosis and other vascular diseases [is] ***most certainly not.***" **(***App. Br. 40*, emphasis added). Why, the Board never explains.

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interposed an objection to any particular evidence. Nor did the Board ever assert an objection to Respondent's expert evidence on grounds other than its general objection.

[14]***Buckman Co. v. Plaintiffs' Legal Committee***, 531 U.S. 341, 350, 121 S.Ct. 1012, 1021 (2001).

Appellant argues later that "the FDA has also suggested that the off label use of certain drugs has caused thousands of adverse reactions, including deformation, disability and death."[15] (*App. Br. 60)*. Yet, the Board has admitted that EDTA chelation therapy causes no harm.

Rhetorically, one may ask if there has been no harm, how has Respondent been negligent? Harm, or damage, is one of the elements that must be proven in any medical negligence case. See, MAI Fourth §11.01.

Standard of Review. See, Standard of Review - In General, *supra*. Specifically, the question of whether ***Frye*** or ***§490.065 RSMo.*** and ***Daubert*** are now the governing standard with respect to admissibility and use of expert, scientific, evidence is a question of law for the independent determination of this Court. ***Callahan v. Cardinal Glennon Hospital***, 863 S.W.2d 852, 860 (Mo. banc 1993).[16] Moreover, the proper interpretation and construction of a statute, §490.065, is a question of law. ***Delta Air Lines, Inc. v. Director of Revenue,*** 908 S.W.2d 353, 355 (Mo. banc 1995).

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[15] Such is supported by the literature. See, Archives of Internal Medicine, *Legal Considerations in Off-Label Medication Prescribing,* Vol. 162(15), August 2003, p. 1777-1779, ©2000 (App. A97-A99).

[16] Here, this Court did not address the ***Frye/Daubert*** question with respect to the continued viability of ***Frye*** in that a timely and specific objection had not been made. (*Id. at* 860).

However, once this Court has determined the controlling legal standard, the question as to the sufficiency, the believability, and whether to admit the proffered expert testimony is generally a question of fact and review is limited for an abuse of discretion. ***Johnson v. State,*** 58 S.W.3d 496, 499 (Mo. banc 2001); ***Landers v. Chrysler Corp***., 963 S.W.2d 275, 281 (Mo. App. E.D. 1997).

A trial court [or, here the AHC] abuses its discretion:

> ... When its ruling is clearly against the logic of the circumstances and is so arbitrary and unreasonable that it shocks the sense of justice and indicates a lack of careful consideration. ***State v. Johns***, 34 S.W.3d 93, 109 (Mo. banc 2000).

There is no abuse of discretion if reasonable persons can differ about the propriety of the action taken by the trial court. ***Anglim v. Missouri Pacific R.R. Co.***, 832 S.W.2d 298, 303 (Mo. banc 1992) (cert. den'd).

Argument – Frye/Daubert – Which is the Governing Standard. Contrary to the Board's position, the ***Frye*** standard is not and has not been the controlling standard since 1989 with respect to the admission and use of expert, scientific, evidence in Missouri civil cases and in "contested case" administrative proceedings – notwithstanding certain opinions from the districts of the Court of Appeals which have continued to recognize and apply ***Frye.*** See,

M.C. v. Yeargin, *supra*; ***Brooks v. SSM Health Care,*** 73 S.W.3d 686, 694 (Mo. App. S.D. 2002); ***McReynolds. v. Mindrup,*** 108 S.W.3d 662 (Mo. App. W.D. 2002).[17]

The Appellant's position regarding ***Frye*** is not good law, is inconsistent with the scientific process, inconsistent with historical and current reality, inconsistent with how many scientific breakthroughs occur, and inconsistent with sound public policy which should foster innovation – not mediocrity. Yet, such is the byproduct of ***Frye***, given its rigid adherence to but a single factor – what, at the time is the general consensus of the scientific, or in this case the medical, community.

The admission of expert, scientific, evidence in civil cases and in "contested" administrative agency proceedings is now governed not by ***Frye*** and its Missouri progeny, but by §490.065. This section provides:

> 1. In any civil action, if scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue,

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[17] However, as the Western District also noted, the districts themselves have been internally inconsistent. (App. A75). Cf., ***Keyser v. Keyser,*** 81 S.W.3d 164, 169 (Mo. App. W.D. 2002) and ***Fierstein v. DePaul Health Center,*** 24 S.W.3d 220 (Mo. App. E.D. 2000). The cases cited by the Western District are, however, far from exhaustive. See, ***Peterson v. National Carriers, Inc.***, 972 S.W.2d 349 (Mo. App. W.D. 1998); ***Landers v. Chrysler Corp.***, *supra*.

> a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise.
>
> * * *
>
> 3. The facts or data in a particular case upon which an expert bases an opinion or inference may be those perceived by or made known to him at or before the hearing and must be of a type reasonably relied upon by experts in the field in forming opinions or inferences upon the subject and must be otherwise reasonably reliable.

These sections are virtually identical to the then Federal Rules of Evidence 702 and 703.[18] ***Landers v. Chrysler Corp.,*** *supra at 281*; ***Peterson v. National Carriers, Inc.,*** 972 S.W.2d 349 (Mo. App. W.D. 1998) (Rule 703).[19]

Although the U.S. Supreme Court had yet to issue its now famous opinion in ***Daubert,*** in enacting §490.065, the General Assembly is presumed to have been familiar with the ***Frye*** standard as it had been adopted and interpreted by this Court in ***State v. Stout,*** 478 S.W.2d 368,

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[18] See, PL 93-595 1975. Rules 702 and 703 have been revised effective December 1, 2000.

[19] Here, Judge Stith writing for the Western District noted:

> Prior cases have noted that, although the language of the federal rule [703] is more explicit than the language used in Section 490.065.3, they are nearly identical in application. (*Id. at 354*).

369 (Mo. 1972); ***State v. Biddle,*** 599 S.W.2d 182, 185 (Mo. 1980); ***Alsbach v. Bader,*** 700 S.W.2d 823, 828-829 (Mo. banc 1985) (*App. Br. 41).* Similarly, the General Assembly is also presumed to have been familiar with the provisions of Federal Rules of Evidence 702 and 703, together with their federal court's interpretation and application. ***Butler v. Mitchell-Hugeback, Inc.,*** 895 S.W.2d 15 (Mo. banc 1995); ***Citizens Electrical Corp. v. Director Dept. of Revenue,*** 766 S.W.2d 450 (Mo. banc 1989). The General Assembly is also presumed, in enacting §490.065, to have acted with a purpose and with an affirmative intent to change the law. ***Harrison v. King,*** 7 S.W.3d 558 (Mo. App. E.D. 1999).

Moreover, under the Missouri Constitution, the power to establish "rules of evidence" is vested in the legislature. ***Mo. Const., Art. V, §5.***[20] This Court has long so recognized. ***Rodriguez v. Suzuki Motor Corp.,*** 996 S.W.2d 47, 55 (Mo. banc 1999); ***State v. Williams***, 729 S.W.2d 197, 201 (Mo. banc 1987).

Since §490.065 is virtually identical to the then existing Federal Rules 702 and 703, federal decisions, including ***Daubert,*** although not necessarily controlling, are entitled to great weight. ***Committee for Educational Equality v. State,*** 878 S.W.2d 446, 451 (Mo. banc 1994).

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[20] This section provides in part:

.... The rules shall not change substantive rights, or the law relating to evidence, the oral examination of witnesses, juries, the right of trial by jury, or the right of appeal.

Next, although ***Frye*** and its Missouri progeny may, given the burden of proof, still reflect the public interest in criminal cases its continued application in civil cases and in "contested" administrative proceedings, is inconsistent with the scientific process, with how many scientific breakthroughs come about, and with public policy which should foster innovation – not mediocrity.

Innovation and discovery have to start somewhere. Under the Board's thesis, i.e, under what is at the time the generally accepted view, Columbus could never have obtained approval to sail to the new world much less discovered America -- for the prevailing thesis at the time was that the world was flat.[21] Similarly, under the Board's thesis, the Wright brothers could never have obtained approval for their flying machine – because the prevailing, or generally accepted, view at the time was: If God intended man to fly, man would have been given wings.

Discoveries and innovations in the medical field are no different. Absent the pioneering work of Theodor Billroth (1867-1894) the world of open heart surgeries and heart transplants that we know today would not exist.[22] Absent the pioneering work of Theophrastus Bombastus von Hohenheim (1493-1541), with his use of mercury for the treatment of syphilis, mercury

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[21] *They All Laughed at Christopher Columbus, Tales of Medicine and the Art of Discovery*, Gerald Weismann, M.D., Times Books, © 1987.

[22] *Medical Odysseys, The Different and Sometimes Unexpected Pathways to Twentieth-Century Medical Discoveries,* chapter entitled *Into the Heart,* p. 42-68, Allen B. Weisse, M.D., Rogers University Press, ©1991.

might still remain the medical poison it had been for centuries.[23] And, absent the pioneering work of Jonas Salk, we would not have today the near eradication of highly crippling polio.[24]

The foregoing examples are but a few. Yet, under the Board's thesis, evidence concerning their theories could not and would not have been admissible at the time in a Missouri court of law -- again, for the reason that such theories and inventions had not yet been "**sufficiently established to have gained general acceptance in the particular field in which it belongs."** Yet, because of the perseverance of Columbus we now know the world is not flat. Similarly, because of the perseverance of the Wright brothers, we have not only have the miracles of jet aviation, but less than 70 years after the first successful air flight, we landed a man on the moon.

Hence, as Wayne Martin so eloquently noted in his book *Medical Heroes and Heretics,* Chapter 1 entitled *God Loves a Good Heretic - Now and Then*, pages 1-2:

> We live in an age when science, government and industry have pooled their resources and efforts with fantastic results...
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> * * *
>
> Paradoxically, in man's oldest form of warfare – the continuing struggle against diseases which plague his environment and shorten his life span – epochal

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[23] *Id.*

[24] *Medical Heroes and Heretics*, Chapter 6 entitled *Salk, Sabin and Polio,* by Wayne Martin, The Devin-Adair Company, © 1977.

> discovery has rarely come about through such pooling of effort and thought. On the contrary, most of the truly significant discoveries have been made by men who, *by standards applicable to their time*, could only be considered scientific heretics – ... But the penalty for dreaming such dreams has been severe – derision from their professional contemporaries, the label of fraud, or worse. These men have willingly faced the threat of professional banishment and total loss of reputation....[25]

However, recent history also teaches that the scientific method, with its discoveries in modern medicine, is not always infallible. Thus, after all the testing, both here and abroad, the drug thalidomide was generally accepted by the medical community as being safe for treatment of morning sickness. Yet, the disastrous consequences of severely deformed children will never be forgotten.

More recently, after many studies, the use of hormone replacement therapy was generally accepted by the medical community and was touted as being safe, of little risk, and appropriate for long term use by post-menopausal women. Today, after further studies and with a population who have taken such drugs for extended periods, the efficacy and long term use of estrogen is now contra-indicated.[26]

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[25] *Id., Chapter 1*.

[26] Recommendations of the U.S. Preventative Services Task Force. See, *Hormone Replacement Therapy for the Prevention of Chronic Conditions: Recommendations and*

Therefore, Respondent respectfully suggests the U.S. Supreme Court's construction of Federal Rules of Evidence 702 and 703 in ***Daubert*** more properly reflect and balance the sometimes competing roles of innovation and discovery, the sometimes unconventional, and the scientific process.

In ***Daubert***, the U.S. Supreme Court properly noted that Rule 702 does not even mention the phrase "general acceptance." The Court rejected the single factor, "austere," standard of ***Frye*** and instead set forth a non-exclusive checklist of factors relating to scientific validity and reliability as follows: 1) whether the theory or technique can be (and has been) tested; 2) whether the theory or technique has been subjected to peer review and publication; 3) its known or potential rate of error; 4) the existence and maintenance of standards controlling the techniques' operation; and 5) the degree to which the theory or technique has been accepted in the relevant scientific community.

The ***Daubert*** court emphasized, however, that the inquiry was a flexible one and that the focus must be on the principles and methodology, and not on the conclusions they generate. (*Id.* at 593-594). The Court also noted:

> Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence. (*Id. at 595*).

Rationale, American Journal of Nursing, Vol. 103(6), June 2003, pp. 83-91, © 2003.

Noteworthy to the case at bar is the 1st Circuit's decision in ***Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.,*** 161 F.3d 77, 85 (1st Cir. 1998). In ***Ruiz,*** the 1st Circuit held that it is for the trier of fact (in this case -- a jury) and that "Daubert neither requires nor empowers trial courts (as the gatekeeper) to determine which of several competing scientific theories has the best provenance." (Id. at 84).

Hence, although this Court has never expressly overruled ***Alsbach v. Bader***, *supra*, or other Missouri appellate court decisions which continue to recognize ***Frye*** in civil cases, this Court has consistently recognized, since its adoption, that §490.065 is the standard to be used by the Missouri courts with respect to the qualification and admission of expert, scientific, evidence. ***Lasky v. Union Electric Co.,*** 936 S.W.2d 797, 801 (Mo. banc 1997) ("on remand the trial court shall be guided by 490.065"); ***Alcorn v. Union Pacific R.R.,*** 50 S.W.3d 226, 245 (Mo. banc 2001); ***Johnson v. State,*** 58 S.W.3d 496, 499 (Mo. banc 2001) (the Department of Corrections employee was not qualified as an expert within the meaning of §490.065).

Section 490.065, not ***Frye***, is the controlling standard. Yet, given the uncertainty and inconsistency in the decisional authority, this Court should clearly hold that ***Frye*** is no longer controlling or the applicable standard for the admission in civil cases for expert, scientific, evidence. This Court should explicitly overrule its prior holding in ***Alsbach*** and the decisions in ***M.C. v. Yeargin, Brooks v. SSM Health Care, and McReynolds v. Mindrup*** to the extent that they hold that ***Frye*** is still the applicable standard.

Lastly, in its Reply Brief to the Western District, Appellant asserts that the provisions of §490.065 apply only to civil proceedings – not to administrative agency proceedings under the MAPA – in that administrative agency cases are not civil proceedings and that the AHC is not a court. (*App.R.Br. 3-6)*.

The Board's position hardly merits discussion. As previously noted in Standards of Review – Generally, *supra*, in agency proceedings, the technical rules of evidence do not apply -- only the fundamental rules of evidence. ***Kendrick v. Board of Police Comm'rs***, 945 S.W.2d 649, 654 (Mo. App. W.D. 1997). Generally, this means the civil rules of evidence, but less formally. See, Neely, *Administrative Practice and Procedure,* 20 Mo Practice, 2nd Ed. §§10.60, 10.61, West Group, © 2001. Thus, if anything, in administrative proceedings even a strict application of §490.065 may not be required.

Argument -- §490.065 and Daubert held to be applicable -- Board's failure to preserve issue.

A review of the Board's brief reveals that nowhere has the Board asserted, either in its Point Relied On or Argument, a claim that the AHC erred in admitting or in relying upon Respondent's expert testimony should this Court hold §490.065, and not ***Frye,*** is the controlling standard. The Western District so noted. (App. A75-A78).

Decisional authority is well settled. Issues neither raised in a Point Relied On nor argument are preserved for appeal. ***Thummel v. King,*** 570 S.W.2d 679, 686 (Mo. banc 1978)*;* ***Smith v. Hammons,*** 63 S.W.3d 320 (Mo. App. S.D. 2002). Instead, all such issues are

presumed to have been abandoned. ***Kerr Const. Paving Co. v. Khazin***, 961 S.W.2d 75 (Mo. App. W.D. 1997).

The AHC made extensive findings relative to the benefits that some derive from chelation therapy (FF 37-40; App. A13-A14). The AHC extensively set forth in its COL its reasons for finding Respondent's expert evidence, including a recitation as to the qualifications of Respondent's experts, to be admissible (App. A34-A38).

Clearly, as reflected in the SOF (p. 45-51), Respondent's experts were fully qualified to provide expert testimony. Respondent's expert evidence served to "aid and assist" the trier of fact. The AHC did not abuse its discretion. ***Peterson v. National Carriers, Inc.,*** *supra at 354*. Once again, this Court may not substitute its judgment for that vested in the AHC with respect to factual matters – even in cases where the evidence might support different findings. ***State Board of Nursing v. Berry,*** 32 S.W.3d 638, 640-641 (Mo. App. W.D. 2000).

POINT III.

Admission of Expert Testimony - *Frye* as the Standard

(Part 2 of Response to Appellant's Point I)

ASSUMING, *ARGUENDO*, THAT *FRYE* IS STILL THE CONTROLLING STANDARD, THE ADMINISTRATIVE HEARING COMMISSION DID NOT ERR OR ABUSE ITS DISCRETION IN FINDING RESPONDENT'S EXPERT SCIENTIFIC EVIDENCE REGARDING EDTA CHELATION THERAPY ADMISSIBLE IN THAT IT IS A RECOGNIZED FORM OF TREATMENT AND HAS GAINED GENERAL ACCEPTANCE AMONG THE RELEVANT SCIENTIFIC COMMUNITY -- PHYSICIANS AND OTHER HEALTH CARE PROFESSIONALS WHO USE EDTA CHELATION THERAPY -- WHO ARE THOROUGHLY FAMILIAR WITH ITS SCIENTIFIC UNDERPINNINGS AND FAMILIAR WITH THE RESEARCH AND OTHER SCIENTIFIC LITERATURE.

Introduction. The AHC, as noted in Point II, found Respondent's expert evidence to be admissible under both ***Daubert*** and ***Frye.*** Assuming, *arguendo*, the continued viability of ***Frye*** in civil cases and in administrative agency proceedings, the AHC did not err or abuse its discretion in so finding.

Standard of Review. See, Standard of Review – Point II.

Argument. The Board, even under ***Frye,*** would have this Court believe that the admission of expert evidence is a popularity contest – he who has 51 % or more is who

determines that which is "generally accepted."[27] The Board would have this Court hold that the AMA and AOA are the final arbiters of what constitutes good and bad medicine (*App. Br. 43-45*).

Under its thesis, the Board would have this Court deny Respondent the very right and ability to defend himself against its charges of misfeasance, misrepresentation, negligence, and other misconduct since it claims Respondent's expert evidence should be excluded *in toto*. It is only through his experts in chelation therapy that Respondent is able to demonstrate the fallacies and errors with respect to Appellant's experts and evidence.

Besides the obvious due process implications of the Board's thesis, its position is not good law. Although the ***Frye*** single factor standard may be austere and rigid in contrast to ***Daubert,*** even ***Frye*** recognizes there is room for experimentation, innovation, and dissent.

The Western District, in ***State v. Butler,*** 24 S.W.3d 21, 39 (Mo. App. W.D. 2000) quoting from ***Frye***, commented:

> Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from

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[27]Such, however, is not the law. Hence, the 2nd Circuit, in a case cited by the Board noted:

A determination of reliability cannot rest solely on a process of "counting (scientific) noses." ***United States v. Williams,*** 583 F.2d 1194, 1198 (2nd Cir. 1978)

> well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs. (*Frye at 1014).*

See also, ***Turner v. Fuqua Homes, Inc.,*** 742 S.W.2d 603, 612 (Mo. App. W.D. 1987).

Thus, the real question under ***Frye*** is what constitutes the relevant scientific community and what constitutes "the particular field in which it belongs." ***United States v. Williams***, *supra at 1198*. Is it expert testimony such as given by Respondent's experts, whom Commissioner Reine found to be highly qualified and knowledgeable with respect to chelation therapy, who have extensive first hand experience, and who are thoroughly familiar with all the literature, the studies, the studies in process, and the flaws in their methodology (App. A36-A37).

Clearly, the credentials of Respondent and his experts are impeccable and the AHC so found.[28] (App. A37). ***Landers v. Chrysler Corp.***, 963 S.W.2d 275 (Mo.App. E.D. 1998) (neuro-psychologist may testify as to medical causation of organic brain syndrome). Their credentials are hardly so lacking as was the situation present in ***Johnson v. State,*** 58 S.W.3d 496, 499 (Mo. banc 2001) (unlicensed counselor in training not qualified to express opinion as to mental disorder).

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[28]In fact, Dr. Chappell has served as a consultant for the Ohio State Medical Board for disciplinary investigations with respect to family practice and alternative medicine since 1992. (Resp. Exh. D-2, p. 93).

Or, is it an expert such as the Board's Dr. David Meyers? Dr. Meyers may be highly qualified on paper but even he acknowledged he has no first hand experience with chelation therapy. (Tr. 353). Instead, he has observed it only once when he visited one doctor who used it. (Tr. 381). Other than reviewing the few charts of the patients involved in this case, he reviewed ***no other*** charts of patients who have undergone chelation therapy. (Tr. 397-398).

On direct examination, he is the one who testified to the so called definitive studies – upon which the Board relies – that purport to find against chelation therapy -- the *Guldager* and the *van Rij* studies – which constituted the "gold" standard for medical research; one who testified on direct that none of the criticism's of the *Guldager* study were valid (Tr. 129), but who later, during cross, acknowledged the existence of significant flaws with both studies with respect to their methodology – including a failure to use the prescribed ACAM protocols (Tr. 341-345).

Dr. Meyers is one who confessed to have no knowledge as to other studies presented by Respondent's experts. He never saw the book *The Scientific Basis of EDTA Chelation Therapy* by Halstead (Tr. 329). He did not recall reviewing the citations in *The Correlation Between EDTA Chelation Therapy and Improvement in Cardiovascular Function: A Meta-Analysis*, by L.. Terry Chappell, M.D. and John P. Stahl, Ph.D., from the *Journal of Advancement in Medicine*, Vol. 6, No. 3, Fall 1993, using over 22,000 patients (Tr. 332). He did not obtain the *Olszewer* study (Tr. 122).

The methodology employed by Respondent and his experts was hardly that which the Western District condemned and found so inadequate in ***Turner v. Fuqua Homes, Inc.***, *supra*. Hence, in ***Turner*** the Western District noted:

> Dr. Garriott's own testimony establishes that (a) there is no scientific literature which supports his modified test procedure; (b) he had not done any studies to verify the accuracy of his theory upon which he based the modification; (c) the possibility exists that his theory is invalid;.... (Id. at 700).

In contrast, Respondent's experts, Drs. Frackelton and Chappell, personally participated in the investigation of both the *Guldager* and the *van Rij* studies and testified extensively as to significant flaws with respect the methodology and conclusions of both (Tr. 618-619, 627, 634-637, 832; SOF 46-49). Dr Rudolph and Dr. Chappell provided extensive testimony concerning numerous other studies involving chelation therapy including one which, as of the time of the hearing, was being conducted under the auspices of the National Institutes of Health (Tr. 830-831).[29]

In summary, the AHC did not err or abuse its discretion either in admitting or in considering, over Appellant's general objection, Respondent's expert testimony, even assuming ***Frye*** is still the controlling standard.

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[29] Reports concerning the current status of Phase III of these studies are reproduced and included as items 10 and 11 Appendix A88-A98).

POINT IV.

Standard of Care

(Response to Appellant's Point I(B) and Point II)

THE ADMINISTRATIVE HEARING COMMISSION DID NOT ERR OR ABUSE ITS DISCRETION IN CONSIDERING RESPONDENT'S TESTIMONY AND THE TESTIMONY OF RESPONDENT'S EXPERTS REGARDING RESPONDENT'S USE OF EDTA CHELATION THERAPY IN THE TREATMENT OF VASCULAR DISEASES, THAT HIS TREATMENT OF THE ENUMERATED PATIENTS SATISFIED THE "STANDARD OF CARE" OWED PURSUANT TO §334.100.2(5) RSMO., OR IN DETERMINING THAT RESPONDENT WAS NOT GUILTY OF "REPEATED NEGLIGENCE" IN THAT: (A) THE BOARD ONLY OBJECTED TO RESPONDENT'S EXPERT EVIDENCE UNDER *FRYE*, NEVER OBJECTED UNDER §490.065, AND NEVER OBJECTED ON THE GROUNDS NOW RAISED; (B) NEITHER RESPONDENT NOR RESPONDENT'S EXPERTS WERE REQUIRED TO SPECIFICALLY DEFINE SAID TERM OR TO SPECIFICALLY USE THE MAGIC PHRASE "STANDARD OF CARE AS DEFINED IN §334.100.2(5)" PRIOR TO EXPRESSING THEIR OPINIONS; AND (C), THERE WAS SUBSTANTIAL EVIDENCE IN THE RECORD TO SUPPORT THE COMMISSION'S FINDINGS.

Introduction. The Board in Point I (b) and in Point II of its brief would have this Court conclude that Respondent's use of chelation therapy for the treatment of atherosclerosis or

other vascular diseases constitutes acts of "repeated negligence" within the meaning of §334.100.2(5) in that such treatment does not meet the "standard of care" to wit:

> (5) .... For the purposes of this subdivision, "repeated negligence" means the failure, on more than one occasion, to use that degree of skill and learning ordinarily used under the same or similar circumstances by the member of the applicant's or licensee's profession . . . [30]

The Board further would have this Court find that the AHC erred and abused its discretion in admitting and then considering Respondent's testimony and that of his experts to the effect that his use of chelation therapy for treating vascular diseases met the "standard of care" in that either prior to or during their testimony they failed to define said term as they used it, i.e., failed to recite the ritualistic phrase "as defined in §334.100.2(5)." *(App. Br. 38-39, 46-47, 51, 56*).[31]

The precise nature of the Board's claims of error is unclear. On one hand, the Board would have this Court find that Commissioner Reine erroneously "uses a negligence standard to decide an evidence question." (*App. Br. 46)***.** Yet, on the other, the Board repeatedly claims that Respondent's use of chelation therapy violates Missouri substantive negligence law, that

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[30]This is essentially the same definition used in MAI §11.01 with respect to professional malpractice claims.

[31]The Western District agreed and directed that the proceedings be remanded to the AHC to reconsider its findings. (App. A72).

Missouri substantive negligence law bars physicians from using any alternative forms of treatment (regardless of harm) unless the medical profession recognizes it generally, and that Missouri substantive negligence law does not recognize the "two schools of thought" or the "respected minority" doctrine. (*App. Br. 67-69).*

It would also appear that the Board is equating and applying ***Frye*** in determining what constitutes the required "standard of care."

Standard of Review. The question as to whether the Board properly objected, at the time, to Respondent's and his expert's testimony with respect to meeting the "standard of care" and thus preserved such issues for appellate review is a question of fact to be determined from the record.

Assuming, *arguendo,* that the Board properly preserved its "standard of care" objections, the question with respect to the admission and subsequent use by the Commission of such evidence is limited to one for "abuse of discretion." ***Wingate v. Lester E. Cox Medical Ctr.***, 853 S.W.2d 912, 918 (Mo. banc 1993); ***Peterson v. National Carriers, Inc.,*** 972 S.W.2d 349, 354 (Mo. App. W.D. 1998). See, Point II – Standard of Review, *infra,* "abuse of discretion."

Lastly, the ultimate question as to whether Respondent's use of chelation, either generally or with respect to the particular patients referenced herein, complies with the requisite standard of care under Missouri substantive law of negligence, or whether such use constitutes cause to discipline presents a mixed question of law and fact. Insofar as this

involves matters of fact, this Court's review is governed by §536.140 RSMo. See Standard of Review - Generally at 13-15).

Argument.

Appellant's Use of Unreported Western District Decision. The Board asserts on pages 38-39 of its brief:

> Indeed, all of respondent's experts, including respondent himself, spoke in terms of his patient care meeting "the standard of care" without ever defining that term in accordance with the statutory definition of negligence. [ftnt 8 omitted] Therefore, under the authority of *Bever v. State Board of Registration for the Healing Arts*, 2001 WL 68307 *5, *7 (Mo. App. W.D. 2001)(Opinion No. WD57880), [ftnt 9 omitted] respondent's defensive testimony in support of EDTA chelation therapy failed to rise to the level of substantial evidence [ftnt 10 omitted]. The *Bever* decision extended to licensing discipline cases the rule established in *Ladish v. Gordon*, 879 S.W.2d 623 (Mo. App. W.D. 1994), that shorthand phrases like "standard of care"are not substantial evidence of medical negligence.

The Board then notes this Court granted transfer from the Western District, but then states that following transfer it dismissed the appeal with Dr. Bever's consent (*App. Br. 38-39, ftnt 9).* The Board then includes copies of the *Bever* AHC and the Western District decisions as part of its appendix.

The Board's reference to, reliance upon, and inclusion of the AHC and Western District decisions is improper and must be disregarded. Decisional authority has long been clear: following transfer, the opinion from the Court of Appeals is considered a "nullity" and is without precedential value. ***Philmon v. Baum,*** 865 S.W.2d 771, 772 (Mo. App. W.D. 1993); and ***Carroll v. Loy-Lange Box Co.,*** 829 S.W.2d 86, 90 (Mo. App. E.D. 1992).

Failure to Object – Issue not Preserved. The Board, despite its strong objection now that the AHC should never have admitted and could not rely on Respondent's testimony and that of his experts to the effect that a physician's use of EDTA chelation therapy in the treatment of vascular diseases is within the "standard of care" and does not constitute acts of negligence, fails to note certain critical facts.

The Board fails to point out that throughout the trial it never objected to Respondent's testimony or his expert's testimony on such grounds. It fails to note that it did not object to any specific testimony from Respondent or his experts, much less object to their "standard of care" testimony. Nor did it cross examine Respondent or his experts either as to what they meant or how they defined the term "standard of care."

As noted in the SOF, p.51-52, the record is clear. The Board only interposed a general objection through its motion in limine with respect to the admissibility of Respondent's proposed expert evidence on the basis of ***Frye.*** Nowhere did the Board even reference in its Motion in Limine the phrase "standard of care" or whether Respondent's expert testimony with

respect to the use of chelation therapy would or would not constitute repeated negligence under Missouri substantive negligence law.

The Board's failure to interpose any objection, much less a timely and specific objection is significant. The Board simply has not preserved for appellate review its claims of error. ***Callahan v. Cardinal Glennon Hospital***, 863 S.W.2d 852, 860 (Mo. banc 1993); ***Brooks v. SSM Health Care,*** 73 S.W.3d 686, 694 (Mo. App. S.D. 2002). Hence, in ***SSM***, the Southern District commented "to hold otherwise would encourage delay that might be remedied with a few questions." (*Id. at 894*).

But, the Board may claim that no objection was required in that the issue is not one of admissibility but one of "legal sufficiency" upon which a finding of negligence or repeated negligence may be based. But, under the law, such is irrelevant.

First, §536.070(8) RSMo. is clear and specific:

> (8) Any evidence received without objection which has probative value shall be considered by the agency along with the other evidence in the case. ...

Once un-objected to evidence is admitted, it is within the discretion of the agency to determine its probative value. ***Concordia Pub. House, Inc. v. Director of Revenue,*** 916 S.W.2d 186, 195-196 (Mo. banc 1996). Here, this Court commented:

> In fact, all probative evidence received without objection in a contested case must be considered in administrative hearings. § 536.070(8). The Director did not object or move to strike a majority of Mr. Caldwell's testimony. Having waived the admissibility issue as to this evidence, ***appellant may not raise it***

now by arguing the sufficiency of the evidence to support the AHC's findings. Washington by Washington v. Barnes Hosp., 897 S.W.2d 611, 616 (Mo. banc 1995). (Id. at 196)(emphasis supplied).

Secondly, in this case there is not even an issue with respect to the legal sufficiency of this evidence - vis a vis Respondent -- to support a claim that cause to discipline exists for repeated acts of negligence. The evidence at issue was proffered by Respondent -- not Appellant.

Respondent has no burden. It is the Board, as the party seeking to impose discipline, that has both the burden of proof and the burden of persuasion. ***Missouri Real Estate Commission v. Berger,*** 764 S.W.3d 706, 711 (Mo. App. E.D. 1989); ***Weber v. Knackstedt***, 707 S.W.2d 800, 802 , (Mo. App. E.D. 1986).

Here, if the Board had doubts whether Respondent or his experts were using the statutory definition of the "standard of care," it could have easily remedied any concern through a few questions on cross. But it was the Board, not Respondent, who elected not to cross on this issue. Having failed to object and having failed to cross on the issue, the Board can not now be heard to complain. Nor should the Board be allowed to sandbag Respondent at this late date.

Consequently, despite their not using the magical phrase as defined in §334.100.2(5) or MAI Fourth §11.06, Respondent's evidence was not only admissible, but also constitutes substantial evidence upon which Commissioner Reine was entitled to rely. (§536.070(8)).

Failure to define "standard of care." Substantively, the Board's assertion that Respondent and his experts had to define the phrase "standard of care" in their testimony and a failure to do so renders their testimony incompetent, is without merit. The Board and then the Western District cite and rely upon ***Ladish v. Gordon,*** 879 S.W.2d 623 (Mo. App. W.D. 1994). However, in citing ***Ladish***, the Board fails to point out that the Court specifically held that no ritualistic words had to be used so long as it was clear what standard was being used. (*Id. at 634*). The Board's witness had already defined the term "standard of care." (*App. Br. 39, ftnt 10).*

Moreover, ***Ladish*** and the cases upon which it relied were all jury cases. The holding in ***Ladish*** is prophylactic - to ensure that the finders of fact, being lay persons, know the meaning of the phrase "standard of care." Otherwise, the jury might have a "roving commission" to define the phrase for itself.

Here, the situation is substantially different. Here, the finder of fact is an attorney who, from his own questioning of the expert witnesses and from his findings demonstrated that he thoroughly understood the dichotomy between the Board's experts and Respondents (App. A37-A38).

The Use of EDTA Chelation Therapy Satisfies the Standard of Care. Contrary to the Board's opinion, the "standard" for proper non-negligent medical care is not the ***Frye*** standard. The standard of care in Missouri is clearly set forth in §334.100.2 and in *MAI*

Fourth Edition §11.06: "The failure to use that degree of skill and learning ordinarily used under the same or similar circumstances by the members of defendant's profession."

Under this Court's holding in ***Haase v. Garfinkel***, 418 S.W.2d 108 (Mo. 1967), physicians are entitled to a wide range in the exercise of their judgment and discretion and cannot be found guilty of malpractice unless it is shown that the course pursued was clearly against the course recognized as correct by the profession generally. As long as there is room for an honest difference of opinion amongst competent physicians, a physician who uses his own best judgment cannot be convicted of negligence. *(Id. at 114)*.

Moreover, what the Board completely ignores is that for negligence to be actionable, there is one other element required in the evidence. There must be evidence of damage to a person before negligence becomes full-blown and actionable. Here, there is no evidence that chelation therapy used for the treatment of vascular conditions causes harm to any patient. Peculiarly, the Board now complains of Commissioner Reine's finding in this regard (App. A42). Yet, it is the Board that now forgets. It was the Board which conceded during its opening statement, and twice thereafter that there is no evidence that the use of EDTA therapy for the treatment of vascular diseases, if administered according to the ACAM protocol, has ever harmed anyone. (Tr. 12, 25, 770-773; App. A70-A80).

Appellant also seeks to impose upon the definition of negligence that the members of Respondent's profession be only those members who practice traditional medicine. If this Court imposes that restriction, then it has given the Board of Healing Arts absolute power to destroy what has become a large portion of the medical field known as alternative medicine.

Alternative Medicine. The Board's repeated assertion that physicians can only practice medicine within the limits approved as being acceptable by the AMA or the AOA and its passion for traditional, orthodox, medicine and its almost virulent dislike for alternative medicine is contrary to the wishes of the people government is to serve.

Hence, the Board's counsel herein in a law review article entitled *The Legal and Regulatory Climate in the State of Missouri for Complimentary and Alternative Medicine — Honest Disagreement Among Competent Physicians or Medical McCarthyism?, 70 UMKC L. Rev. 55, © 2001* wrote:[32]

> One essential philosophical difference between the alternative medicine practitioners and orthodox physicians is that the former claim to be treating the well being of the body as a whole as a form of preventative medicine, while the latter more typically focus on and reserve their interventions to documented ongoing disease processes. A strong underlying theme in the recent rise in interest in alternative medicine is the dissatisfaction of many patients with, what many perceive as the traditional allopathic medicine's paternalistic approach to patient care. The desire for increased patient autonomy has manifested itself in

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[32] In its brief, the Board cites to this article in support of its proposition that Missouri should not adopt the "two schools" or the "respected minority" doctrines. (*App. Br. 52*, ftnt 17).

> a burgeoning interest in complimentary and alternative treatment choices. (*Id. at 67*).

Yet, even more telling is his further comment:

> Right or wrong, state medical boards, Missouri included, have used the tools of unlawful practice acts and the related disciplinary statutes mandating non-negligent (standard of care) practice of medicine to restrict the use of alternative and complimentary treatment modalities by both physician and non-physician practitioners. Alternative providers and treatments have been measured through the traditional prism of whether the treatment in question meets the existing medical standard of care. Almost by definition, many of the alternative treatment modalities have not been generally accepted by the medical profession as safe and effective to treat particular human diseases and conditions.... (*Id. at 75*).

Fortunately, most practitioners and medical researchers do not adhere to such a rigid position. As noted in Point II, had the Board's position been the absolute law or so rigidly enforced, most of the advances in medical science would not have occurred.

Aspirin for the treatment and prevention of heart disease is an off-label use which at one time was not accepted by the medical community[33]. Even bypass surgery and heart

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[33] Dr. McDonagh and Dr. Rudolph have been ahead of the traditional medicine curve in various respects. They studied and began using Vitamin E as an antioxidant which proved useful

transplants at one time were not viewed by the traditional medical community as appropriate treatments. In the treatment of vascular disease, open heart surgery and angioplasty have never been subjected to a double-blind placebo controlled study which Appellant claims as necessary to prove the effectiveness of any treatment.

The lack of general acceptance is not equal to a breach of the standard of care. If that were the case, every doctor who uses an FDA-approved drug for an off-label use would be breaching the standard. There is no evidence that Dr. McDonagh breached the standard of care of physicians practicing chelation for vascular diseases; there is substantial evidence that he met the standard (Tr. 839, 841, 842-849, 1103-1105, 1219). Contrary to the Board's position throughout its opening and reply briefs, chelation therapy is not "witchcraft." It is not "voodooism." It is not quackery.

The proponents of chelation are not advocating a return to the days of the traveling medicine man with his golden "elixirs." There simply is no comparison between the use of chelation therapy and Heil Crum's "coetherator" so rightly condemned by the Indiana Supreme Court in ***Crum v. State Board of Medical Registration and Examination,*** 219 Ind. 191, 37

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in reducing heart disease more than 30 years before mainstream medicine acknowledged its usefulness (Tr. 1235-1237). They used the LDL/HDL cholesterol ratios in determining what was high cholesterol, rather than total cholesterol, before traditional medicine even recognized the difference and well before Medicare would pay for such testing. Now it is considered state-of-the-art (Tr. 1259-1260).

N.E.2d 65 (Ind. 1941) but which the Board so strongly relies upon in its Reply brief. (*App.R.Br. 17-18).*

The Board claims that Missouri has, however, not adopted, either "two schools of thought" or the "respected minority" doctrines. (*App. Br. 67-69*). Respondent respectfully suggests that the current Missouri standard, as enunciated in MAI Fourth §11.06, is sufficiently flexible so that this Court need not specially adopt such a standard similar to the one approved by Pennsylvania in ***Jones v. Chidester,*** 531 Pa. 31, 610 A.2d 964, 965-966 (Pa. 1992).[34]

Competency of Testimony from Patients. Next, the Board asserts that the Commission improperly considered favorable the testimony from patients who had undergone chelation therapy. The Board would have this Court conclude that patients, because they are not medically trained, may not provide testimony of medical causation. The Board would have this Court hold that patients can never express personal opinions as to whether they did or did not benefit from certain treatment.

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[34]Here, after and analyzing the pros and cons of various definitions, the Court held:

We, therefore, provide the following as a correct statement of the law:

> Where competent medical authority is divided, a physician will not be held responsible if in the exercise of his judgment he followed a course of treatment advocated by a considerable number of recognized and respected professionals in his given area of expertise. (*Id at 969*).

Hence, the Board expends substantial pages in both of its briefs discussing its version of the testimony given by several chelation patients and why Commissioner Reine improperly considered it. (*App. Br. 775-80*; *App.R.Br. 15-19)*. The details concerning this testimony have been fully covered in the SOF pages 36-38. However, that the Board did not object at trial to any of this testimony.

The Board's position is without merit. Its view of Missouri law with respect to lay persons testifying with respect to medical matters is not so absolute.

Certainly, one who has had a hip replacement, a spinal fusion, or other treatment knows whether he/she is out of pain. It does not take a physician with a magic talisman to so pronounce. Such position defies logic, common sense, and everyday experience. ***Zumwalt v. Koreckij,*** 24 S.W.3d 166, 169 (Mo. App. E.D. 2000)(application of *res ipsa loquitur*).

The cases cited by the Board, ***McGrath v. Satellite Sprinkler Systems, Inc.***, 877 S.W.2d 704, 708 (Mo. App. E.D. 1994) and ***Knipp v. Nordyne, Inc.***, 969 S.W.2d 236, 240 (Mo. App. W.D. 1998), are not so absolute in their pronouncements as the Board would lead this Court to believe. Hence, the Eastern District in ***Landers*** commented:

> ... The testimony of a lay witness can constitute substantial evidence of the nature, cause, and extent of disability when the facts fall within the realm of lay understanding.[35] (*Id. at 279*).

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[35]Moreover, although the Board now suggests that the lay opinion testimony is inadequate, it never interposed such an objection during trial.

Thus, contrary to the Board's assertions, Commissioner Reine clearly was acting within his province as a neutral, unbiased, hearing officer in considering the compelling personal testimonials of G_ H_, T_ G_ and C_ H_.

Substantial Evidence. A detailed review of the Board's briefs demonstrates the essence of the Board's view of this appeal. It wants this Court to accept its version of the facts and, based upon such version, to substitute its judgment for that vested in the AHC.[36] Such, however, is not the province or role of this Court. This Court may not substitute its judgment for that vested in the AHC. ***State Board of Nursing v. Berry,*** 32 S.W.3d 638, 640-641 (Mo. App. W.D. 2000). It is the AHC, not this Court, which determines credibility and the weight which should be accorded to Respondent's experts versus the Board's expert. Same is simply

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[36]At pages 60 –83 of its brief, Appellant engages in an extensive discussion which sets forth its view as to the relevant facts, as to how such facts should be evaluated, and as to how the AHC should have decided this case – based upon its interpretation of the evidence, its interpretation as to what "hierarchy of proof" is required, its interpretation of Dr. Meyers' testimony versus that of Respondent's experts, etc.

In fact, the Board in advancing its argument as to how this Court should substitute its view for that of the Commissioner, even has the temerity to suggest that "Commissioner Reine has fallen victim to the fallacy of the *post hoc ergo procter hoc* method of proof...." (*App. Br. 74-75).*

beyond the purview of this Court on review. ***Dorman v. State Board of Registration for the Healing Arts***, 62 S.W.3d 446, 454 (Mo. App. W.D. 2001).

Alleged Arrogance of Commissioner Reine. The Board's position is that the AMA and the AOA, not the AHC, should be the sole arbiter as to what and what is not good medicine. Hence, the Board in its brief argues:

> ... This statement demonstrates Commissioner Reine's misunderstanding of his duty as fact finder under Missouri law. Under Missouri law the issue is not whether Commissioner Reine can be convinced that chelation therapy provides "relief to some people," but *rather whether the medical profession has been convinced* that chelation therapy is generally effective to treat vascular and other diseases. Commissioner Reine's personal opinion on the matter is clearly irrelevant. (*App. Br.* 58)(emphasis supplied).

Thus, in its Reply Brief, Appellant asserts: "Commissioner Reine ***arrogates to himself*** the responsibility to determine if EDTA therapy [is] effective. (*App.R.Br. 15)(emphasis supplied)*.

With all due respect, it is the Board that is arrogant. It is the Board which has forgotten the General Assembly's intent in creating the Administrative Hearing Commission. ***Geriatric Nursing Facility, Inc. v. Department of Social Services***, 693 S.W.2d 206, (Mo. App. W.D. 1985) and *Special Project, Fair Treatment for the Licensed Professional: The Missouri*

Adm. Hearing Comm., 37 Mo.L.Rev. 410 (1972). It is not the Board or the medical profession that is or should be the final arbiters.[37]

Contrary to the Board's assertion, or belief, Commissioner Reine in hearing and deciding this case was ***not*** simply expressing his personal opinion. Contrary to the Board's assertion, Commissioner Reine was ***not*** "viewing Board discipline as a punishment for a license." Contrary to the Board's assertion, or belief, Commissioner Reine was **not** deciding this case "as if he believes that it is a foregone conclusion that the Board will revoke Dr. McDonagh's license . . .".[38] Instead, Commissioner Reine was fulfilling his statutory duty, no different than does a judge, to decide the case upon the law and facts adduced.

In summary, the record is replete with substantial evidence to support the Commission's findings with respect to EDTA chelation therapy. It is neither the role, nor the function, of this Court to make credibility determinations or to assess the weight which should

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[37]In ***U.S. v. Williams***, *supra*, (a case cited and relied on by the Board) the 2nd Circuit commented in this respect:

> ... In testing for admissibility of a particular type of scientific evidence, whatever the scientific "voting" pattern may be, the courts cannot in any event surrender to scientists the responsibility for determining the reliability of that evidence. (*Id. at 1198*).

[38] The question of the discipline, if any, that might be imposed is premature. Missouri law is clear -- unless and until the AHC finds cause exists, the question of whether the Board may even discipline is irrelevant.

be accorded to particular evidence. It is neither the role, nor function, of this Court to substitute its judgment for that vested in the AHC merely because the evidence might support a different result.

POINT V.

<u>No Misrepresentation</u>

(Response to Appellant's Point IV)

THE ADMINISTRATIVE HEARING COMMISSION DID NOT ERR OR ABUSE ITS DISCRETION BY FAILING TO MAKE FINDINGS IN FAVOR OF THE BOARD TO THE EFFECT THAT RESPONDENT HAD MISREPRESENTED EDTA CHELATION THERAPY IN THAT: (A) THE AHC RULED AGAINST THE BOARD ON THIS ISSUE; (B) THERE IS SUBSTANTIAL EVIDENCE TO SUPPORT THE RULING; (C) THE EVIDENCE WAS DISPUTED; (D) THE AHC RESOLVED THE DISPUTED FACTS IN FAVOR OF RESPONDENT; (E) UNDER §536.090 RSMO., AN AGENCY IS ONLY REQUIRED TO MAKE FINDINGS OF FACT AND CONCLUSIONS OF LAW WHICH ARE SUFFICIENTLY SPECIFIC SO AS TO ENABLE THE REVIEWING COURT TO ASSESS THE AGENCY DECISION INTELLIGENTLY AND TO ASCERTAIN WHETHER FACTS FURNISH A REASONABLE BASIS FOR THE DECISIONS.

Introduction. The Board in Count I, ¶7 of its complaint alleged: Respondent has misrepresented that atherosclerosis and various other diseases, ailments, and infirmities can be cured by EDTA. The Board in its brief claims that the AHC totally ignored this issue and failed to render any "findings or conclusions whatsoever" on the subject. (*App. Br. 84).*

Standard of Review. The question as to whether the AHC addressed this issue in its decision is a question of fact. The sufficiency of the AHC's findings and conclusions with respect to the Board's misrepresentation claims is a question of law. **Deaconess Manor Ass'n**

v. Public Service Com'n of State of Mo., 994 S.W.2d 602 (Mo. App. W.D. 1999). Lastly, review as to the sufficiency and propriety of the Commission's ruling is governed by §536.140, RSMo. See, Standards of Review – Generally.

Argument. Contrary to the Board's assertion, the Commission addressed the issue of misrepresentation and held against the Board. The Commission held:

> The Board alleges that McDonagh's license is subject to discipline for obtaining a fee by deception, fraud or misrepresentation, for wilfully performing unnecessary treatment, and for misrepresenting a disease can be cured by a treatment. We have found that chelation therapy is not an unnecessary treatment. McDonagh does not obtain a fee by deception, fraud, or misrepresentation because he does not state that chelation cures everyone. In the notice given to new patients [Resp. Exh. F-2; App. A5] it is made very clear that this treatment is not approved by the AMA, the FDA, and others. The notice lists benefits that may be derived from treatment, but states: "however, you must be aware that you may not receive all of these benefits as they do not occur predictably with every patient and in some cases may not occur at all."(COL- Count IV-B.C.; App. A47).

It also did so indirectly through many of its findings, such as the ones addressing informed consent, the efficacy of EDTA chelation therapy, its safety, benefits, etc. (FF 16, 18, 22, 28, 29, 31, 37-40, 97-98, 101, 107, 115; A4-A45). It also did so through an additional COL, to wit:

> McDonagh has provided us with evidence that chelation therapy treatments provide relief to some people and cause physical harm to no one. Studies, whether the perfect double-blind studies or something less than those, show patients whose statistics in certain areas are definitely improving. (Findings 37-40). Something – chelation therapy alone, or chelation therapy combined with the nutrition and exercise regime - is making these patients feel better, walk farther, and experience less pain. These reports and studies are based on, not just one patient or ten patients, but thousands of patients. *These patients are not being used as guinea pigs because they are fully informed about the treatment, and they are not the victims of a hoax or fraudulent practice because the treatment does benefit some patients.* (COL 42; App. A42).

The Commission's findings and conclusions with respect to the misrepresentation claims, although perhaps not models of precision, are more than sufficient. They are sufficiently specific so as to enable this Court to assess the Commission's decision intelligently and to ascertain, without having to resort to the evidence, whether the found facts and conclusions furnish a reasonable basis for its decision. ***Cummings v. Mischeaux,*** 960 S.W.2d 560, 563 (Mo. App. W.D. 1998).

Hence, this is not a case where, as Appellant claims, the Commission made no findings. Unlike the case cited by the Board, ***Mineweld, Inc. v. Board of Boiler & Pressure Rules,*** 868 S.W.2d 232 (Mo. App. W.D. 1994), the Commission did make findings. It simply chose to find against the Board's position. But such is not error.

Turning now to the merits. A review of the Board's argument reveals, once again, a re-hash of its assertions that chelation therapy helps no one, is not accepted by the medical profession generally, and cures no one. The Board then claims because Respondent disagrees with the Board's position about chelation therapy, all statements Respondent makes to his patients, verbally and through pamphlets and other literature, constitutes false representation. *(App. Br. 85-97).*

In so doing, the Board ignores the AHC's explicit findings and the record which is replete with evidence which shows that Respondent and his fellow EDTA adherents have a good faith belief in their position (Tr. 784, 1219, 1347). These facts, as well as all others are, under the standard of review, deemed true. Again, the Commission, not this Court determines credibility. ***Harrington v. Smarr,*** 844 S.W.2d 16, 19 (Mo. App. W.D. 1992)

Assuming, *arguendo*, that the Board is correct – EDTA is no cure — the Board is not entitled to prevail. More is required. A simple falsehood is not enough.

There must be an affirmative intent to deceive or a complete and utter disregard as to the truth or falsity of the alleged misrepresentation. ***Droz v. Trump,*** 965 S.W.2d 436, 441 (Mo. App. W.D. 1998).

Most importantly, the Board would have this Court view the facts anew, consider the Board's version of the facts, and then have the Court substitute its judgment for that vested in the AHC. Such is simply not within the purview or role of this Court.

Finally, Respondent would note: The Board further claims certain misrepresentation by ACAM and references a Federal Trade Commission Consent Order. (*App. Br. 97-102).* But

the Board, in referencing such Order, ignores one salient but highly pertinent fact. Respondent is not ACAM.

In summary, the Commission did not err or abuse its discretion in failing to find any misrepresentation.

POINT VI.

Record Keeping

(Response to Appellant's Point IV)

THE ADMINISTRATIVE HEARING COMMISSION DID NOT ERR OR ABUSE ITS DISCRETION IN FINDING THAT RESPONDENT KEPT AND MAINTAINED ADEQUATE PATIENT RECORDS IN THAT: (A) THE STANDARD OF CARE WITH RESPECT TO WHAT RECORDS TO MAINTAIN AND THE DETAILS THEREIN WAS WITHIN THE DISCRETION OF EACH PHYSICIAN; (B) THE GENERAL ASSEMBLY HAD YET TO ENACT §334.097 RSMO. (2002 SUPP.) WITH RESPECT TO RECORD KEEPING; (C) THERE IS SUBSTANTIAL EVIDENCE TO SUPPORT THE COMMISSION'S FINDINGS; AND (D) THE COMMISSION, AS THE TRIER OF FACT, IS THE SOLE JUDGE OF CREDIBILITY AND WEIGHT THAT SHOULD BE GIVEN TO ANY PARTICULAR TESTIMONY.

Introduction. The Board claims the Commission erred in rejecting its evidence that Respondent failed to keep and maintain adequate patient records on the grounds that there was, at the time, no statute or rule which defined or set objective standards with respect to record keeping. The Board further claims that the Commission erred in rejecting the testimony of its expert, Dr. Meyers; that Respondent's record keeping was insufficient; and, was not within the "standard of care." (*App. Br.105-107).*

The Commission in this regard found:

.... The Board's expert testified that McDonagh failed [with respect to patient B_C_] to document a diagnosis and did not document a complete medical history, and that this falls below the standard of care. However, McDonagh's records show that he diagnosed B.C. as having several problems, including a blocked artery....

McDonagh admitted that his record-keeping was minimal, and stated that he had been advised to keep them so in order to protect his patient's privacy. He stated that doctors have changed their attitude about record-keeping because of Medicaid and HMOs, and that he currently uses the SOAP method of charting.[39] The Board admits that there is no rule in Missouri that attempts to set forth what records must be kept by a doctor in order to constitute professional [mis]conduct. There is no rule setting forth an objective standard for a doctor to follow regarding medical record-keeping. Meyer testified that the record keeping fell below the standard of care of the profession and definitely fell below the standard currently set by the HCFA for Medicaid patients. McDonagh testified that his record-keeping fell within the standard of care and allowed him to adequately treat his patients. (COL 48-49; App. A48-A49).

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[39] [Commission's footnote 128] Subjective findings, objective findings, assessment of the case, plan of treatment. (Tr. 951).

Standard of Review. The issue of whether Respondent can be disciplined for inadequate record keeping in the absence of a statute or Board rule which sets forth objective standards or criteria with respect to record keeping and the details thereof is a question of law for the independent determination of this Court ***NME Hospitals, Inc. v. Dept. of Social Services, Division of Medical Services,*** 850 S.W.2d 71, 74 (Mo. banc 1993).

The question, in the absence of any statute or regulation, as to the type and details with respect to record keeping, which was within the then existing standard of care is a question of fact. Review is limited to a determination as to whether the Commission's decision is supported by substantial evidence and for an abuse of discretion. §536.140 RSMo. See also, Standard of Review – Generally.

Argument --Absence of Any Statute or Regulation. First, the question of whether or not a physician's conduct measures up to the requisite standard of care must be determined in light of facts **existing and known at the time in question**, rather than on the basis of facts revealed by subsequent developments. ***Miller v. Scholl***, 594 S.W.2d 324, 329 (Mo. App. W.D. 1980). Except for Respondent's testimony, there simply was no evidence regarding the changing standards over the years for record keeping from the time Respondent was licensed until the present. (Tr. 946-954).

There is no question. Until the General Assembly enacted§334.097 in 2002, there was no statute or Board rule. Instead, the Board seeks to define and impose upon Respondent, after the fact, a standard through an "adjudicated" order.

Missouri law is clear. The Board's enunciated record keeping policy, as defined during the testimony of its expert, Dr. Meyers, constitutes a rule withing the meaning of §536.010(4). As such, the Board may only enforce the same if it has followed the formal rule making procedures set forth in Chapter 536; otherwise, the Board's policy is, pursuant to §536.021.7 "null, void, and unenforceable." ***NME Hospitals, Inc.,*** *supra*; ***Greenbrier Hills Country Club v. Director of Revenue,*** 47 S.W.3d 346, 357 (Mo. banc 2001).

In ***Greenbrier*** this Court made explicitly clear: "Agencies cannot promulgate, or repeal, a rule by an adjudicated order." (*Id.*). Yet, that is precisely what the Board claims should have occurred here. It seeks to enforce a perceived record keeping policy through an "adjudicated order."

Substantial Evidence – Credibility. Once again, a review of the Board's argument demonstrates that the Board would have this Court accept its version of the facts, accept as being the more credible the testimony of its expert, Dr. Meyers, discount Respondent's contrary evidence, and substitute its judgment for that vested in the Commission as to how the case should be decided (*App. Br. 105-116).*

But again, such is not the function, role, or purview of this Court to do. See, Standard of Review – Generally. Once again, witness credibility is for the Commission, not this Court. ***Harrington v. Smarr,*** 844 S.W.2d 16, 19 (Mo. App. W.D. 1992). Because the AHC chose to believe Respondent and disbelieve Dr. Meyers on this issue is not grounds to reverse.

Lastly, as the SOF herein at pages 56-57 reflects, there is substantial evidence to support the Commission's decision. The Commission clearly was acting within its discretion in finding no basis to discipline for alleged inadequate record keeping.

POINT VII.

Allegations of Inappropriate and Unnecessary Testing

(Response to Appellant's Point V)

THE ADMINISTRATIVE HEARING COMMISSION DID NOT ERR OR ABUSE ITS DISCRETION IN FINDING THAT RESPONDENT DID NOT PERFORM INAPPROPRIATE AND UNNECESSARY TESTING IN THAT: (A) THE BOARD HAD THE BURDEN OF PROOF WHICH IT FAILED TO MEET; (B) CONTRARY TO THE BOARD'S ASSERTION, THE AHC DID MAKE FINDINGS BUT IN FAVOR OF RESPONDENT; (C) THERE IS SUBSTANTIAL EVIDENCE TO SUPPORT THE AHC'S FINDINGS; AND (D) THE AHC IS THE SOLE JUDGE OF CREDIBILITY AND WEIGHT THAT SHOULD BE GIVEN TO ANY PARTICULAR TESTIMONY.

Introduction. In its Complaint, the Board claimed as additional grounds to discipline that Respondent "willfully and continually performed inappropriate and unnecessary treatment, diagnostic tests or medical or surgical services." See, Complaint, Count VII (R__T__); Count VIII (G__L__); Count IX (T__G__); Count XI (D__S__); and Count XII (J__C__). (ROA 2-

22).[40] The Board focuses primarily on Respondent's use of "hemoglobin A1c testing." (*App. Br. 119; App.R.Br. 29).*

Standard of Review. Appellant had the burden to prove there had been inappropriate and unnecessary testing. ***Missouri Real Estate Commission v. Berger,*** 764 S.W.2d 706, 711 (Mo. App. E.D. 1989). The question of whether the AHC addressed this issue in its decision is a question of fact. The sufficiency of the Commission's findings and conclusions is a question of law. ***Deaconess Manor Ass'n v. Public Service Com'n of Missouri***, 994 S.W.2d 602 (Mo. App. W.D. 1999).

This Court may not substitute its judgment as to factual matters for that vested in the AHC even where the evidence might support different findings. ***State Board of Nursing v. Berry,*** 32 S.W.2d 638, 640-642 (Mo. App. W.D. 2000). See, Standard of Review – Generally.

Argument. The Commission found against the Board, found no cause to discipline and issued FOF and COL on this issue as well. (FF 46 & 47, 91, 92, 94, 99, 100, 110, 122, 125, 128, 133; COL 56-57, 59, 62-63, 66-67). In several of its COL, the Commission noted the conflicting evidence which it had heard.

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[40]Interestingly, in some other counts, the Board charges Respondent with failing to perform other tests it claims should have been performed. In at least one count, Count VII the Board charges both - having unnecessary tests performed and simultaneously a failure to perform other tests the Board believes should have been performed. (See, among others, Counts IV (B__C__) and Count VII (R__T__)).

Hence in COL for Count VII (R__T__) the Commission noted:

> Meyers testified that he saw no indications in the chart to justify the cytotoxic food allergy test, pulmonary function test, HIV test, Heidelberg pH gastrogram test hair analysis test, hemoglobin A1c test, and hepatitis B antigen test. McDonagh and Chappell testified that the tests were appropriate and necessary. McDonagh's expert, Dr. James P. Frackelton, testified that the tests were valid because of the preventative nature of his and McDonagh's practice. [ftnt 134] [Commission cites to Tr. 660-68] (App. A57).

Even so, the Board asserts error and claims, in part:

> Without providing any real rationale for his decision, Commissioner Reine concluded that Respondent had not at any time violated the standard of care with respect to patient testing, apparently relying on Respondent's general claim to be entitled to test broadly as part of a preventative approach....
>
> * * *
>
> ... The Commissioner did not specifically find that any of respondent's expert witnesses had testified that the testing was "necessary", the "objective legal standard" set out in Section 334.100.2(4)(c), RSMo. (*App. Br. 118).*

Once again, the Board claims error in that the Commission did not decide this issue in its favor and did not make findings accordingly. But, this does not constitute grounds for reversal. The Commission, not this Court, is the trier of fact. As the trier of fact, the Commission had the

discretion to believe all, part, or none of the testimony of any witness. ***Harrington v. Smarr,*** 844 S.W.2d 16, 19 (Mo. App. W.D. 1992).

A detailed review of the Board's brief demonstrates that, in reality, it wants this Court to accept its version of the facts on this issue and, based upon such version, substitute its judgment for that vested in the AHC.

Thus, the Board sets forth what it believes to be the "true" facts, the reasons why the Commission should have accepted the testimony of its expert, Dr. Meyers, instead of Respondent's, the reasons why it believes that many of the tests, particularly the hemoglobin A 1c test, were both inappropriate and unnecessary, and its reasons why Respondent's testing for hemoglobin A1c is contrary to the "standard of care." (*App. Br. 121-130*).

Such, however, is irrelevant. It was within the Commission's prerogative, despite the Board's protestations to the contrary, to disbelieve the testimony of its expert Dr. Meyers. After all, it was Dr. Meyers who admitted that he has never used chelation. (Tr. 353). It was Dr. Meyers who admitted he only observed chelation therapy once when he visited one doctor who used it (Tr. 397-398) and it was also Dr. Meyers who admitted that, other than those patients who were the subject of this litigation, he had never reviewed charts of chelation patients (*Id.*).

To say the least, the Board's position on Respondent's testing is paradoxical.

On one hand, through "Monday morning quarter-backing" by a person who does not believe in chelation and who has no personal experience, he claims through a cold review of less than 20 patient records that Respondent's decision to test for hemoglobin A1c is both unnecessary and inappropriate. Yet, on the other hand, the Board also claims, through this very

same expert - that Respondent in other instances should have ordered more tests. No wonder Commissioner Reine chose to disregard Dr. Meyers' opinions with respect to which tests should and should not have been performed.

Lastly, and most importantly, Appellant ignores one overriding but salient fact. Physicians are entitled to a wide range in the exercise of their judgment and discretion and cannot be found guilty of having violated the "standard of care" unless it has been shown that the course pursued was clearly against the course recognized as correct by the profession generally. ***Cebula v. Benoit,*** 652 S.W.2d 304, 308 (Mo. App. W.D. 1983). And, as long as there is room for an honest difference of opinion amongst competent physicians, a physician who uses his own best judgment cannot be convicted of negligence. ***Haase v. Garfinkel,*** 418 S.W.2d 108, 114 (Mo. 1967).

The Board, not Respondent, bore the burden of proof. Respondent has done no more, with respect to his choice of when and what tests should and should not be performed, than to exercise his best judgment.

In summary, the Commission did not err or abuse its discretion in finding against the Board on its claim that there had been inappropriate testing.

POINT VIII.

Patient's Freedom of Choice - Alternative Medicine

Constitutional Protections

(Independent Issue)

THE DECISION OF THE ADMINISTRATIVE HEARING COMMISSION SHOULD BE AFFIRMED IN THAT IT PROTECTS AND PRESERVES THE CONSTITUTIONAL RIGHT THAT ALL CITIZENS HAVE -- THE FREEDOM TO SELECT THEIR HEALTH CARE PROVIDERS AND THE RIGHT TO SELECT AND DETERMINE, AFTER BEING FULLY INFORMED OF THE RISKS AND BENEFITS, THE NATURE AND EXTENT OF THEIR MEDICAL TREATMENT, INCLUDING WHAT MAY BE CONSIDERED TO BE ALTERNATIVE MEDICINE, FREE FROM UNDUE RESTRICTION BY THE STATE, SUBJECT ONLY TO REASONABLE RESTRICTIONS TO PROTECT THE PUBLIC FROM HARM. THE BOARD'S POSITION WITH RESPECT TO EDTA CHELATION THERAPY, GIVEN ITS ADMISSION THAT IT CAUSES NO HARM, CONSTITUTES AN UNREASONABLE RESTRICTION UPON BOTH THE HEALTH CARE PROVIDER AND THE PATIENT AND THEIR CONCOMITANT RIGHT TO CHOSE ALTERNATIVE MEDICAL MODALITIES.

Argument. Without question, the doctor-patient relationship has evolved in recent history from a state of strong paternalism to an era of self-determination that largely exists today. At one time, doctors commanded and decided virtually all treatment options for a patient with no obligation to consider the patient's values or decisions. The assumption existed

that the physician unequivocally knew what was best for his or her patient and that the physician's decisions on the medical benefits or potential harms of a given treatment were dispositive factors in making treatment decisions. In recent years, however, paternalism has given way to an era of patient self-determination as consumers have become aware of treatment alternatives and that different doctors favor different approaches, as well as the potentially profound effects that a treatment decision may involve.

Patients are increasingly asserting their right to be intimately involved in the decision-making process. As stated by J. Cardozo in ***Schloendorff v. Society of New York Hospital***, 211 N.Y. 125, 105 N.E.2d 92, 93 (1914) "every human being of adult years and sound mind has a right to determine what shall be done with his own body."[41]

This includes a woman's right to have an abortion. ***Roe v. Wade,*** 410 U.S. 113, 93 S.Ct. 705 (1973).[42] This includes the right to refuse any medical treatment - even life saving treatment. ***Cruzan by Cruzan v. Director, Missouri Dept. of Health,*** 497 U.S. 261, 110 S.Ct. 2841 (1990). This also includes a woman's and her doctor's rights to determine by which, among competing medical procedures, to have an abortion -- even in cases where the fetus is viable. ***Stenberg v. Carthard,*** 530 U.S. 914, 120 S.Ct. 2597 (2000).

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[41] This is contrary to the belief of Dr. Meyers who testified that the American public is not smart enough to make such choices (Tr. 410).

[42] The Supreme Court recently reaffirmed a woman's freedom to have or forego birth as enunciated in **Roe.** ***Lawrence v. Texas,*** __ U.S.__, 123 S.Ct. 2472, 2477 (2003).

Courts have uniformly recognized a patient's right to receive medical care in accordance with their licensed physician's best judgment and the physician's rights to administer it as it may be derived therefrom. Thus, a statute that required concurrence of a second opinion in a decision to perform an abortion was void as without a rational connection to the patient's needs as an undue infringement on the physician's right to practice. ***Doe v. Bolton,*** 410 U.S. 179, 93 S.Ct. 739 (1973). See also, ***Beal v. Doe,*** 432 U.S. 438 (1977).

Hence, in ***Stenberg,*** the U.S. Supreme Court commented:

> Doctors often differ in their estimation of comparative health risks and appropriate treatment. And Casey's words "appropriate medical judgment" must embody the judicial need to tolerate responsible differences of medical opinion--differences of a sort that the American Medical Association and American College of Obstetricians and Gynecologists' statements together indicate are present here. [530 U.S. 914 at 937]

The U.S. Constitution, Missouri Constitution, and state common law protect the patient's right to choose among licensed practitioners for treatment of illnesses and the right of licensed practitioners to determine appropriate treatment within the scope of their license. ***U.S. Const. Amend's 1, 9 & 14; Missouri Const. Article I, §§ 8 & 10.*** The special nature of the doctor/patient relationship precludes unjustifiable state presence. ***Stenberg v. Carhart,***

supra; ***Pharmaceutical Society v. Lefkowitz,*** 454 F. Supp. 1175, 1181 (***1978), aff'd.,*** 586 F. 2d 953 (2nd Cir. 1979).

The Board, in singling out only physicians who utilize EDTA chelation therapy for treatment of atherosclerosis, violates the equal protection and due process clauses of both the federal and Missouri Constitutions. ***U.S. Const. Amend. 14; Missouri Const. Article I, §10.*** Given that neither angioplasty, bypass, or chelation therapy have met the "gold standard" of clinical testing, if physicians who prescribe chelation therapy are potentially subjected to discipline, then those physicians who do not offer such services as an alternative treatment for vascular occlusive disease should be subject to a similar sanction.

In the leading case which is on all fours with the case at bar, the Supreme Court of Florida, in ***State Board of Medical Examiners v. Rogers***, 387 So.2d 937 (Fla. 1980) (App. A105) quashed an order of reprimand and probation imposed against a physician and held that the Board had acted unreasonably with the physician's right to practice medicine by curtailing the exercise of his professional judgment to administer chelation therapy to patients suffering from atherosclerosis where there was no evidence of harm and where the physician was practicing no fraud or deception on his patients.

Following an administrative hearing, Dr. Rogers was reprimanded, ordered to immediately cease and desist from utilization of chelation therapy and placed on probation. Rogers appealed. In its opinion, the court discussed the history and theory of chelation therapy, as well as the evidence of dramatic restoration of blood flow. The intermediate appellate court recognized that over one million persons die each year in the United States

from the effects of vascular occlusive disease and that bypass surgery may be effective if the patient can tolerate same, if the occlusion is localized, and if it is accessible to the surgeon. However, if this does not exist, the only alternative treatment is chelation. ***Rogers***, 371 So.2d 1037, 1039 (Fla. App. 1st Dist. 1979) (App. A100).

The court found it highly relevant that neither the Board nor the hearing officer made any finding that chelation therapy was in any respect harmful or hazardous to the patient. "Rather, the Board's decision appears to have been based upon [its belief] that chelation therapy is 'quackery under the guise of scientific medicine.'" *Id. at 1040*.

The court focused on a patient's right to privacy as set forth in ***Roe v. Wade***, *supra*, where the United States Supreme Court spoke of the relationship between the patient and physician and held that the decision as to whether or not to terminate a pregnancy is one that is purely personal to the mother, is between the mother and her attending physician, and that any unreasonable governmental interference must yield to the mother's right of privacy. The Florida court held that under the Constitution, in the absence of a demonstration of unlawfulness, harm, fraud, coercion, or misrepresentation, the Board was without authority to deprive petitioner's patients of their voluntary election to receive chelation therapy simply because that mode of treatment has not received the endorsement of a majority of the medical profession. ***Rogers*** *at 1041*.

The Supreme Court of Florida in ***Rogers***, 387 So.2d 937 (Fla. 1980), in affirming the intermediate appellate court, recognized that chelation therapy is widely used as a treatment

for atherosclerosis by a definite minority of the medical profession and, that 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 must reasonably be 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, 93 S. Ct. 739 (1973) and ***Dent v. State of W. Va.,*** 129 U.S. 114, 9 S.Ct. 231 (1889).

The court found that sanctions were imposed upon Dr. Rogers because he utilized a modality not accepted by the Board as having been *proven* effective, not because the Board found the treatment was harmful or that he had defrauded his patients into believing that chelation was a cure for their conditions. Accordingly, the state imposed limitation on chelation treatment was not shown to have a reasonable relationship to the protection of the health and welfare of the public. ***Rogers*** *at 940*.

The applicable Florida disciplinary statute criticized by the Florida Supreme Court is surprisingly similar to the Missouri statute cited by the Board as being violated. The Florida statute provided for discipline when a physician was found:

> . . . 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 preceding actual injury to a patient need not be established . . .."

The language in the Florida statute "any departure from, or failure to conform to, the standards of acceptable and prevailing medical practice in his area of expertise" is far stronger language than that relied upon by the Missouri Board, i.e., "failure . . . to use that degree of skill and learning ordinarily used under the same or similar circumstances by the member of the applicant's or licensee's profession." 334.100.2(5). The Florida court found the requirement that a physician do only what all other physicians do (i.e., majority rules) was an unconstitutional infringement upon the right to practice one's profession is protected by the due process clause, absent evidence of harmfulness, fraud, or deception.

Accordingly, the AHC decision should be affirmed.

CONCLUSION

For the foregoing reasons, the January 26, 2000, decision of the Administrative Hearing Commission in Cause No.96-2543 HA, together with the September 21, 2002, judgment of the Circuit Court of Cole County in Cause No. 00CV323233, should be affirmed in all respects.

There is no error of law. The decision is supported by competent and substantial evidence on the whole record. There has been no abuse of discretion. Chelation is a well recognized form of medical treatment, albeit an "alternative" to orthodoxy. It is for some, as found by the AHC, efficacious and beneficial. There exists no cause to discipline Dr. McDonagh's medical license.

Respectfully submitted

CARSON & COIL, P.C.

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Lori J. Levine MBE #26172
515 East High Street, P.O. Box 28
Jefferson City, MO 65102
Tel:(573) 636-2177; Fax:(573) 636-7119

BEETEM LAW OFFICES, P.C.

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Daniel P. Card II MBE # 24272
Daniel P. Card II, L.L.C., of counsel
P.O. Box 476
Jefferson City, Missouri 65102-0476
Tel: (573) 635-6659; Fax: (573) 635-6520

ATTORNEYS FOR RESPONDENT
EDWARD W. McDONAGH, D.O.

CERTIFICATE OF COMPLIANCE
PURSUANT TO RULE 84.06(c) and (g)

COMES NOW Daniel P. Card II, co-counsel for Respondent, and pursuant to Supreme Court Rule 84.06(c) and (g), hereby certifies that:

1. The Respondent's Substitute Brief submitted in the above-styled cause includes the information required by Rule 55.03;

2. The substitute brief submitted complies with the limitations contained in Rule 84.06(b).

3. As reported by the undersigned's copy of Word Perfect 10, the word count is 27,494, excluding therefrom the cover page, signature block, certificate of service and certificate of compliance.

4. The diskettes submitted to the Court and to counsel of record have been scanned for viruses using Norton Anti-Virus, Corporate Edition, with virus definitions as of August 27, 2003, and they are virus free.

_____
Lori J. Levine MBE #26172
Daniel P. Card II MBE #24272
ATTORNEYS FOR RESPONDENT

CERTIFICATE OF SERVICE

I hereby certify that two complete copies of the foregoing were mailed via United States Mail, first-class postage prepaid, this 29th day of August, 2003, to Appellant's attorney, at his last known address as follows:

Glenn E. Bradford
Attorney at Law
The Palace Building
1150 Grand Avenue
Suite 230
Kansas City, MO 64106

_____
Lori J. Levine