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Missouri Public Service Commission

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MGE Rate Case Case No. GR-2004-0209

MGE Exhibit No. A

Case No(s). GR-2004-0209

Date 4-3-04 Rptr JL

Missouri Revised Statutes

Chapter 490 Evidence Section 490.065

August 28, 2003

Expert witness, opinion testimony admissible--hypothetical question not required, when.

490.065. 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, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise.

- 2. Testimony by such an expert witness in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact.
- 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.
- 4. If a reasonable foundation is laid, an expert may testify in terms of opinion or inference and give the reasons therefor without the use of hypothetical questions, unless the court believes the use of a hypothetical question will make the expert's opinion more understandable or of greater assistance to the jury due to the particular facts of the case.

(L. 1989 S.B. 127, et al.)

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Missouri General Assembly

123 S.W.3d 146, *; 2003 Mo. LEXIS 173, **

STATE BOARD OF REGISTRATION FOR THE HEALING ARTS, Appellant, v. EDWARD W. McDONAGH, D.O., Respondent.

No. SC85275

SUPREME COURT OF MISSOURI

123 S.W.3d 146; 2003 Mo. LEXIS 173

December 23, 2003, Filed

SUBSEQUENT HISTORY: [**1] Rehearing overruled by State Bd. of Registration for the Healing Art v. McDonagh, 2004 Mo. LEXIS 21 (Mo., Jan. 27, 2004)

PRIOR HISTORY: APPEAL FROM THE CIRCUIT COURT OF COLE COUNTY. Honorable Byron Kinder, Judge.

State Bd. of Registration for the Healing Arts v. McDonagh, 2003 Mo. LEXIS 110 (Mo., July 1, 2003)

CORE TERMS: therapy, chelation, patient, expert testimony, vascular, disease, standard of care, repeated, discipline, skill, admissibility, doctor, medicine, admissible, treating, profession, learning, scientific, reasonably relied, licensee, rules of evidence, off-label, ulcer, legal standard, atherosclerosis, inappropriate, antibiotic, reliable, stomach, forming

JUDGES: LAURA DENVIR STITH, JUDGE. White, C.J., Benton, Price, Teitelman and Limbaugh, JJ., concur; Wolff, J., concurs in part and dissents in part in separate opinion filed.

OPINIONBY: LAURA DENVIR STITH

OPINION:

[*148] The State Board of Registration for the Healing Arts (the Board) initiated a
disciplinary complaint against Dr. Edward McDonagh primarily alleging that he violated
[*149] section 334.100, n1 a part of the Missouri Healing Arts Practice Act, through his
representations regarding and use of chelation therapy in the treatment of patients with
vascular disease. The Administrative Hearing Commission (AHC) found no cause to discipline
Dr. McDonagh's medical license. The circuit court affirmed the AHC's decision. The Board
appeals, alleging the AHC erred by failing to apply the standard for admission of expert
testimony set out in Frye v. United States, 54 U.S. App. D.C. 46, 293 F. 1013 (D.C. Cir.
1923), and that the testimony of Dr. McDonagh's experts should have been excluded.
~ Footnotes

n1 All statutory references are to RSMo 2000 unless otherwise indicated.[]

This Court reaffirms its holding in Lasky v. Union Electric Co., 936 S.W.2d 797 (Mo.

banc 1997), that the standard for the admission of expert testimony in civil cases is that set forth in section 490.065. As discussed herein, this is also the standard to be applied in administrative cases. To the extent that civil cases decided since *Lasky* apply *Frye* or some other standard, they are incorrect and should no longer be followed. Section 490.065.3 requires that the facts and data on which an expert relies must be those reasonably relied on by experts in the relevant field. Here, the relevant field is physicians treating persons with vascular disease. Because the AHC failed to properly apply this standard, this Court reverses the circuit court's judgment and remands the case. On remand, the circuit court should remand to the AHC for reconsideration of the AHC's decision in light of this standard.

This Court also remands for reconsideration of the issue whether Dr. McDonagh committed repeated negligence because his experts did not identify the standard of care by which they judged his treatment of his patients and it appears the AHC judged his conduct by reference to the treatment advocated by other doctors using chelation therapy. Under section 334.100.2(5), the AHC should have judged the conduct by the standard of care of those treating patients with vascular disease.

Because the principles stated herein may also affect the AHC's determination of the

remaining issues regarding record keeping, testing, and misrepresentation, this Court remands the case in its entirety for reconsideration in light of this opinion. n2
n2 The Court does not reach Dr. McDonagh's argument that the Board's brief does not comply with Rule 84.04, as, given the fundamental nature of the errors alleged, the result would be the same whether reviewed as plain error or as preserved error.[]
I. FACTUAL AND PROCEDURAL BACKGROUND
The Board is authorized by section 334.120.1 to register, license, and supervise physicians and surgeons practicing in Missouri. The Board licensed Dr. McDonagh, D.O., as an osteopathic physician and surgeon in 1961. Soon after becoming licensed, he began employing alternative medical treatments in his family practice, including EDTA n3 chelation therapy to treat atherosclerosis and other diseases. He also became certified by the American Board of Chelation Therapy, and has conducted research and written extensively on the use of this therapy.
n3 EDTA is an acronym for ethylene diamine tetra-acetic acid. This substance was developed in the 1930s.[]
End Footnotes
Regulation of Chelation Therapy by the Board.

http://www.lexis.com/research/retrieve?_m=32accb92b83b9c9b00eb532e6060bdb0&_brow... 6/2/2004

Chelation therapy has been approved by the federal Food and Drug Administration (FDA) only as a means for the removal of [*150] heavy metals from the body. However, non-

FDA-approved, or "off-label," use of medications by physicians is not prohibited by the FDA
and is generally accepted in the medical profession. See 21 U.S.C. Sec. 396 (2000);
Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350-51 & n.5, 148 L. Ed. 2d
854, 121 S. Ct. 1012 (2001). Approximately 1,000 physicians in the United States engage
in the off-label use of chelation therapy to treat atherosclerosis and other vascular
conditions. n4 Of these 1,000 United States-based physicians, 750 belong to the American
College for Advancement in Medicine (ACAM), which has 1,000 members worldwide and
which endorsed chelation therapy as a valid course of treatment for occlusive vascular and
degenerative diseases associated with aging. n5 To that end, ACAM developed a protocol,
followed by Dr. McDonagh, for using chelation therapy to treat such diseases.

n4 This practice, which began to emerge in the 1950s, involves the intravenous administration of a diluted solution containing EDTA, as well as various vitamins and minerals. Proponents contend EDTA "chelates" - or bonds - with substances that accumulate and block arteries, and, then, flushes these compounds from the body through the urine.[]

n5 In 1999, the Federal Trade Commission and ACAM entered into a consent agreement under which ACAM agreed not to make any representations regarding EDTA chelation therapy's effectiveness as a treatment for atherosclerosis. *In re Am. Coll. for Advancement in Med.*, No. C-3882 (Fed. Trade Comm'n June 22, 1999) at http://www.ftc.gov/os/1999/07/9623147c3881acam.do.htm. See also American College for Advancement in Medicine, 64 Fed. Reg. 12,338 (Fed. Trade Comm'n Mar. 12, 1999) (extension of public comment period on consent agreement).[]

In 1989, the Board made an in-depth study of the efficacy of chelation therapy, but did not thereafter adopt any rules, regulations, or position papers on the use of this therapy. Then, in 1992 and 1994, two controlled studies were published that suggested that chelation therapy was ineffective in treating vascular disease. n6 Dr. McDonagh disputes the validity of these studies. But, after the publication of the studies, the American Medical Association (AMA) adopted a position statement on chelation therapy, declaring that: "(1) there is no scientific documentation that the use of chelation therapy is effective in the treatment of cardiovascular disease, atherosclerosis, rheumatoid arthritis, and cancer"; (2) chelation therapy proponents should conduct controlled studies and adhere to FDA research guidelines if they want the therapy to be accepted more broadly; and (3) "the AMA believes that chelation therapy for atherosclerosis is an experimental process without proven efficacy."

AMA, AMA Policy Compendium H-175.994, H-175.997 (1994).

----- Footnotes -----

n6 The first of these studies was the Guldager study, published in 1992, and the second was the van Rij study, published in 1994. These studies tested the efficacy of EDTA chelation therapy in treating intermittent claudication, which is "an aching, crampy, tired, and sometimes burning pain in the legs that comes and goes . . . due to poor circulation of blood in the arteries of the legs." MedicineNet.com, Medical Dict., at http://www.medicinenet.com/script/main/art.asp?ArticleKey=92 18&pf=3&track=qpadict (last visited Oct. 30, 2003).[]

------ End Footnotes------

In spite of these developments, neither the FDA, the AMA, or the Board banned the use of chelation therapy to treat vascular disease, and Dr. McDonagh continued to prescribe and administer the therapy in his practice.

Effective October 30, 2001, the Board adopted a rule stating that chelation therapy was of no medical value but that it would not seek to discipline a physician for using it on a patient from whom appropriate informed consent is received:

- [*151] (1) Pursuant to authority granted to the board by section 334.100.2(4)(f), RSMo, the board declares the use of ethylinediaminetetracetic acid (EDTA) chelation on a patient is of no medical or osteopathic value except for those uses approved by the Food and Drug Administration (FDA) by federal regulation.
- (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 the patient sign the Informed Consent for EDTA Chelation Therapy form, included herein, before beginning the non-approved use of EDTA chelation on a patient.

4 CSR 150-2.165.

B. Complaints Against Dr. McDonagh.

In 1994, seven years prior to the adoption of 4 CSR 150-2.165, and shortly after the two noted controlled studies, the Board filed a complaint against Dr. McDonagh arising out of two inquiries regarding his use of chelation therapy. This complaint was later dismissed without prejudice. In 1996, the Board filed a thirteen-count complaint alleging cause to discipline Dr. McDonagh's medical license for violating section 334.100 n7 by, among other things: endangering the health of patients through the inappropriate provision of chelation therapy; misrepresenting the efficacy of this therapy for atherosclerosis and other diseases; conducting unnecessary testing and treatment in some instances, and insufficient testing and treatment in others; and failing to maintain adequate medical records. n8

n7 The Board alleged violations of numerous versions of the statute from 1976 through at least 1994.[]
n8 Count VI, which alleged improper delegation of professional responsibilities to unqualified personnel, was not raised on appeal.[]
End Footnotes

Dr. McDonagh denied that his treatments endangered his patients, denied using inappropriate testing or treatment, and denied inadequate record keeping. He also denied making misrepresentations to patients, noting that, prior to receiving chelation therapy, his patients signed a consent form explaining the possible benefits and side effects of the treatment (very similar to that later approved in 4 CSR 150-2.165), and stating that the treatment was not approved by the FDA, the AMA, or other recognized medical organizations for the treatment of vascular disease. In addition to chelation therapy, Dr. McDonagh encouraged patients to follow a diet and exercise plan, and did not discourage patients from seeing other physicians, including specialists.

The AHC held a hearing in November 1997. The Board introduced expert testimony that the use of chelation therapy to treat vascular disease is not generally accepted in the field of treatment of vascular disease and does not meet the standard of care for treatment of vascular disease. Dr. McDonagh offered expert testimony that supported his off-label use of chelation therapy to treat vascular disease. The Board objected. The AHC heard all of the evidence without ruling on its admissibility, as permitted by section 536.070(7), which provides that evidence subject to an objection "nevertheless be heard and preserved in the record." The AHC ultimately ruled that the testimony was admissible, found no evidence of harm from chelation therapy, rejected all thirteen counts, and found no cause to discipline Dr. McDonagh's medical license.

The circuit court affirmed the AHC's decision. The Board appealed. Following opinion by the Missouri Court of Appeals, Western District, this Court granted [*152] transfer to address the standards for admission of expert testimony in civil and administrative cases. *Mo. Const. art. V, secs.* 10, 18.

II. STANDARD OF REVIEW

On appeal, this Court reviews the AHC's decision, rather than that of the trial court, to determine whether the agency action:

- (1) Is in violation of constitutional provisions;
- (2) Is in excess of the statutory authority or jurisdiction of the agency;
- (3) Is unsupported by competent and substantial evidence upon the whole record;
- (4) Is, for any other reason, unauthorized by law;
- (5) Is made upon unlawful procedure or without a fair trial;
- (6) Is arbitrary, capricious or unreasonable;
- (7) Involves an abuse of discretion.

Sec. 536.140.2; Sec. 621.145; Psychcare Mgmt., Inc. v. Dep't of Soc. Servs., Div. of Med. Servs., 980 S.W.2d 311, 312 (Mo. banc 1998). Here, the Board argues that the decision was not "supported by competent and substantial evidence upon the whole record" and that "it was arbitrary, capricious, unreasonable or an abuse of discretion." Ross v. Robb, 662 S.W.2d 257, 259 (Mo. banc 1983). A reviewing court will refrain from substituting its judgment for that of the AHC on factual matters. Psychcare Mgmt., Inc., 980 S.W.2d at 312. Questions of law are matters for the independent judgment of this Court. Gammaitoni v. Dir. of Revenue, 786 S.W.2d 126, 128 (Mo. banc 1990).

III. STANDARD FOR ADMISSIBILITY OF EXPERT TESTIMONY

Section 490.065 Provides the Standard for Admission of Expert Testimony in Civil Actions.

The Board suggests the standard for admission of expert testimony is that set out in *Frye* and previously applied by this Court. *See Alsbach v. Bader*, 700 S.W.2d 823, 828-30 (Mo. banc 1985). *Frye* states that, for expert testimony to be admissible, "the thing from which the [expert's] deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs." 239 F. at 1014.

Dr. McDonagh counters that, although this Court once adopted the *Frye* test, the relevant standard for admission of expert testimony is now either that set forth by the Supreme Court of the United States in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, **509 U.S. 579**, **125 L. Ed. 2d 469**, **113 S. Ct. 2786 (1993)**, for application in the federal courts, or that set out in section 490.065. The latter statute says:

- 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, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise.
- 2. Testimony by such an expert witness in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact.
- 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 [*153] in forming opinions or inferences upon the subject and must be otherwise reasonably reliable.
- 4. If a reasonable foundation is laid, an expert may testify in terms of opinion or inference and give the reasons therefor without the use of hypothetical questions, unless the court believes the use of a hypothetical question will make the expert's opinion more understandable or of greater assistance to the jury due to the particular facts of the case.

Although section 490.065 on its face states that it applies in civil actions and sets out the relevant standard for admission of expert testimony in such actions, various decisions of Missouri's court of appeals since section 490.065 was enacted in 1989 have expressed confusion as to whether it is the statute, *Frye*, or *Daubert* that supplies the relevant standard for admission of expert testimony. n9

n9 See, e.g., McReynolds v. Mindrup, 108 S.W.3d 662, 665-66 & n.2 (Mo. App. W.D. 2002) ("whether [section] 490.065 supersedes the Frye doctrine . . . has not yet been decided by our Supreme Court" and "no Missouri case has yet decided what, if any, impact adoption of [section] 490.065 has on the application of the Frye 'general acceptance' rule, much less whether it compels application of the Daubert standard," citing section 490.065 for the admissibility of expert testimony, and stating that Frye is the proper standard for analyzing the admissibility of expert testimony related to scientific techniques); Keyser v. Keyser, 81 S.W.3d 164, 169 (Mo. App. W.D. 2002) (citing section 490.065.3 as the standard for the admissibility of expert testimony without reference to either Frye or Daubert); Long v. Mo. Delta Med. Ctr., 33 S.W.3d 629, 642-43 (Mo. App. S.D. 2000) (noting that section 490.065's "adoption may create the question if Missouri courts should continue to apply the Frye standard to the admissibility of expert testimony, or if Daubert would be more appropriate," then applying Frye to the admissibility of expert testimony regarding scientific techniques, and holding that section 490,065 applies to the admissibility of expert testimony regarding non-scientific evidence); M.C. v. Yeargin, 11 S.W.3d 604, 619 (Mo. App. E.D. 1999) (noting that "the Missouri Supreme Court continues to apply the Frye test to the admissibility of expert testimony in criminal cases and in civil cases," and finding that "the trial court abused its discretion in admitting [the expert's] testimony because the court did not find that he based it on scientific principles generally accepted in the relevant scientific community or within the boundaries of Section 490.065"); Whitman's Candies, Inc. v. Pet, Inc., 974 S.W.2d 519, 528 (Mo. App. W.D. 1998) ("because the expert testimony at issue in the case at bar satisfies the requirements of both Frye and

Daubert , this court need not determine whether [section] 490.065 supersedes the Frye test in Missouri" (emphasis in original)).[]
End Footnotes
Any such confusion should have been resolved by this Court's 1997 decision in <i>Lasky</i> holding that section 490.065 provides the applicable standard "in evaluating the admission of expert testimony" in civil cases. 936 S.W.2d at 802 . While <i>Lasky</i> did not further expressly state that to the extent that prior civil cases applied a different rule they should no longer be followed, such a holding was implicit in <i>Lasky</i> 's direction that "on remand the trial court shall be guided by section 490.065, RSMo, in evaluating the admission of expert testimony." <i>Id.</i> at 801.
To clarify, however, this Court expressly holds that to the extent that cases since <i>Lasky</i> have suggested that the standard of admissibility of expert testimony in civil cases is that set forth in <i>Frye</i> or some other standard, they are no longer to be followed. The relevant standard is that set out in section 490.065.
B. Section 490.065's Applicability to Contested Administrative Proceedings.
The Board alternatively argues that because the first four words of section 490.065 are "in any civil action," the standard for admission of expert testimony it sets out could have no application to administrative [*154] actions such as this one. In support, the Board cites cases that have noted that administrative actions generally are tried in accordance with various rules of administrative procedure rather than in accordance with Missouri's rules of civil procedure, except to the extent that the latter have been adopted by statute for use in administrative cases. See, e.g., Wheeler v. Bd. of Police Comm'rs of Kansas City, 918 S.W.2d 800, 803 (Mo. App. W.D. 1996); Dillon v. Dir. of Revenue, 777 S.W.2d 326, 329 (Mo. App. W.D. 1989). The admission of expert testimony is not determined by rules of civil or administrative procedure, however, but by principles governing the admissibility of evidence. The relevant evidentiary principles are not set out in any set of rules, but rather have been developed by common law and by statute. n10 These principles govern the admission of evidence in civil and criminal cases.
n10 Indeed, although Missouri's Constitution leaves it to this Court to develop rules of procedure, it specifically prohibits the Supreme Court from creating rules of evidence. <i>Mo. Const. art. V, sec. 5. See State v. Williams</i> , 729 S.W.2d 197, 201 (Mo. banc 1987) ("The legislature has plenary power to prescribe or alter the rules of evidence").[]
Cases brought before administrative agencies generally are less formal and structured than are civil proceedings in the circuit courts. That does not mean that evidentiary rules developed in civil cases have no application to administrative actions, however. To the contrary, the legislature has specifically directed that many evidentiary principles developed in civil actions be applied in administrative ones, including those regarding privilege, judicial notice, admission of writings and documents, depositions, and so forth. n11

n11 See, e.g., secs. 536.070(6) ("Agencies shall take official notice of all matters of which the courts take judicial notice."); 536.070(8) ("The rules of privilege shall be effective to the same extent that they are now or may hereafter be in civil actions." (emphasis added)); 536.070(9) (As to "copies of writings, documents and records," "the agency may, nevertheless, if it believes the interests of justice so require, sustain any objection to such evidence which would be sustained were the proffered evidence offered in a civil action in the circuit court. . . ." (emphasis added)); 536.073.1 ("Any party may take and use depositions in the same manner, upon and under the same conditions, and upon the same notice, as is or may hereafter be provided for with respect to the taking and using of depositions in civil actions in the circuit court. . . ." (emphasis added)).[]

This Court has further held that other, basic principles of evidence also apply in administrative proceedings. Thus, in *Missouri Church of Scientology v. State Tax Commission*, 560 S.W.2d 837, 839 (Mo. banc 1977), this Court stated, "although technical rules of evidence are not controlling in administrative hearings, fundamental rules of evidence are applicable." The principle set out in *Missouri Church of Scientology* reiterates a principle this Court recognized at least as long ago as *State ex rel. De Weese v. Morris*, 359 Mo. 194, 221 S.W.2d 206, 209 (Mo. 1949), in which this Court stated, "the fact that technical rules of evidence do not control has been considered to permit of leading questions and other informalities but not to abrogate the fundamental rules of evidence." *See also State ex rel. Bond v. Simmons*, 299 S.W.2d 540, 545 (Mo. App. 1957) (accord).

The approach set out in these cases applies here. While contested administrative proceedings are not required to follow the "technical rules of evidence," the "fundamental rules of evidence" applicable to civil cases also are applicable in such administrative hearings. **See**Mo. Church of Scientology, 560 S.W.2d at 839; De Weese, 221 S.W.2d at 209. The standards for admission of expert testimony constitute [*155] such a fundamental rule of evidence. The standards set out in section 490.065 therefore guide the admission of expert testimony in contested case administrative proceedings such as this one.

C. Comparison of Section 490.065 with FRE 702, FRE 703, and Daubert.

The parties and the AHC seem to assume that section 490.065 and FRE 702 and FRE 703, as interpreted in *Daubert*, are effectively identical, and that the standard set out in section 490.065 mirrors that *Daubert* adopted for use in the federal courts.

Daubert held "that the **Frye** test was displaced by the [Federal] Rules of Evidence." **509 U.S. at 589**. It found that FRE 702 provides a more "flexible" standard for admissibility focused on "the scientific validity and thus the evidentiary relevance and reliability - of the principles that underlie a proposed submission." **Id. at 594-95** (noting that "the focus . . . must be solely on principles and methodology, not on the conclusions that they generate").

Daubert set out a non-exclusive list of factors for consideration in determining whether the evidence in question meets the flexible standard, including: (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) "the known or potential rate of error"; and (4) "'general acceptance.'" *Id.* at 593-94.

The Supreme Court summarized its holding by emphasizing the difference between **Daubert** and the **Frye** test that the federal courts had previously employed, stating: "'General acceptance' is not a necessary precondition to the admissibility of scientific evidence under the Federal Rules of Evidence" **Id.** at **597**.

Few cases have interpreted section 490.065. To the extent that section 490.065 mirrors FRE 702 and FRE 703, as interpreted and applied in *Daubert* and its progeny, the cases interpreting those federal rules provide relevant and useful guidance in interpreting and applying section 490.065. *See Giddens v. Kansas City S. Ry. Co.*, 29 S.W.3d 813, 820 (Mo. banc 2000) ("The construction given by the federal courts to their rules does not control the interpretation of our state rules, even if the rules themselves are nearly identical. However, the experiences of those courts in applying rules similar to our own are illustrative"). To the extent that the two approaches differ, however, the standard set out in section 490.065 must govern.

The standard set out in section 490.065 is very similar to that initially adopted by the federal courts in *Daubert* and set out in FRE 702. Indeed, at the time *Daubert* was decided, FRE 702 was identical to section 490.065.1, stating, "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise," except that section 490.065.1 added a preliminary phrase "in any civil action." n12

n12 The effect of the addition of the phrase "in any civil action" is discussed *supra*. In 2000, language was added to the end of FRE 702 setting out in greater detail how the trial court, in its role as gatekeeper, should review the expert's testimony, stating that the court should find the testimony admissible "if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case."[]

----- End Footnotes------

[*156] While the parties presume that section 490.065.3 is also effectively identical to FRE 703, review of the two rules reveals important differences. Section 490.065.3 begins by stating, "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." The first sentence of FRE 703 is identical except for minor stylistic variations.

But, section 490.065.3 goes on to require that the facts or data on which an expert bases an opinion or inference "must be of a type reasonably relied upon by experts in the field in forming opinions or inferences upon the subject" and that these facts and data "must be otherwise reasonably reliable." Sec. 490.065.3. Thus, section 490.065.3 expressly requires a showing that the facts and data are of a type reasonably relied on by experts in the field in forming opinions or inferences upon the subject of the expert's testimony. The court must also independently assess their reliability. Id.

By contrast, under FRE 703 whether the facts or data relied upon are "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject" is relevant only to determine whether the facts or data must be otherwise admissible in evidence. For this reason, unlike in Missouri, *Daubert* held that in the federal courts an expert need not necessarily identify the relevant scientific community, or field, in which the data and facts are accepted. *Daubert*, 509 U.S. at 594.

APPLICATION OF SECTION 490.065 TO DR. McDONAGH'S EXPERTS

The differences between section 490.065 and FRE 703 as interpreted in **Daubert** take on

great importance here because a key area of disagreement of the parties concerns identification of the relevant scientific field by which Dr. McDonagh's practices are to be judged. This is essential because the statute requires that to be admissible expert opinion must be based on facts or data of a type reasonably relied upon by "experts in the field."

A, Identification of Relevant Field of Experts.

Dr. McDonagh argued, and the AHC appeared to determine, that the relevant "field" for purposes of this inquiry is the universe of medical practitioners who utilize chelation therapy. And, as the record shows that Dr. McDonagh followed the protocol for use of chelation therapy approved by the approximately 1,000 doctors who are organized into ACAM, it concluded that his experts' testimony as to whether his treatments were appropriate was admissible. But, to limit the relevant "field" to only those doctors who have already expressed their view that the therapy in question is appropriate would make the inquiry into acceptance by experts in the field pointless, for, by definition, only those who had accepted the therapy would be asked for their opinion.

The relevant field must be determined not by the approach a particular doctor chooses to take, but by the standards in the field in which the doctor has chosen to practice. As relevant here, Dr. McDonagh chose to treat patients with vascular disease. The Board's claim is that Dr. McDonagh engaged in repeated negligence or misrepresentation and was otherwise in violation of the relevant statutes in his provision of chelation therapy for these patients. Therefore, the relevant field is doctors treating persons with vascular disease. The facts or data on which Dr. McDonagh's experts rely, therefore, [*157] must be those perceived by them at trial or must be of a type reasonably relied on by doctors treating vascular disease. n13

Footnotes
n13 <i>Cf. Yantzi v. Norton</i> , 927 S.W.2d 427 (Mo. App. W.D. 1996) (negligence of professional engineer engaging in foundation repair was to be judged by standards of those with expertise in foundation repair, not merely by those who are professional engineers).[]
End Footnotes
By so stating, this Court is not in effect readopting the <i>Frye</i> standard under another name.

By so stating, this Court is not in effect readopting the *Frye* standard under another name. Nothing in section 490.065 suggests that the conclusions reached in reliance on these facts and data must be in conformity with the general medical consensus or must be generally accepted. As under *Daubert* and cases applying it, such acceptance is but one factor of the relevant inquiry. Section 490.065.3 simply requires the court to consider whether the facts and data used by the expert are of a type reasonably relied on by experts in that field or if the methodology is otherwise reasonably reliable. If not, then the testimony does not meet the statutory standard and is inadmissible.

B. Necessity of Controlled Studies.

The Board argues that, even if **Daubert** - for which section 490.065 n14 is interpolated - provides the standards for admission of expert testimony, the testimony of Dr. McDonagh's experts should have been excluded because controlled studies supporting use of chelation therapy to treat vascular disease do not exist.

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n14 Dr. McDonagh objects that the Board has not preserved its objections to admission of his experts' testimony under section 490.065, and instead merely argued the testimony was inadmissible under *Frye* or *Daubert*. But, because the parties and AHC used the term "*Daubert*" to refer generally to any non-*Frye* approach to expert testimony, this Court finds it appropriate to reach the merits of the Board's arguments in this regard.[]

----- End Footnotes------

Nothing in section 490.065 expressly requires such studies. The Board cites to no case decided under section 490.065 requiring that an expert opinion be supported by controlled studies in order to be admissible. To the contrary, section 490.065.3 states that an expert's opinion is admissible if the facts or data on which the opinion is based are "of a type reasonably relied upon by experts in the field in forming opinions or inferences upon the subject" and are "otherwise reasonably reliable." Controlled studies are a form of data. Therefore, the admissibility of an expert's opinion depends not on some immutable, external standard - such as the presence of controlled studies - but on whether experts in the particular field can reasonably rely on other types of data in forming their opinions, or whether in that field controlled studies are required. But, the AMA has suggested that controlled studies must be done before chelation therapy will be generally recognized as effective. See AMA, AMA Policy Compendium H-175.994 (1994) supra. Of course, section 490.065.3 also imposes an independent duty on the court to determine whether the facts and data relied on are otherwise reasonably reliable. The lack of controlled studies presumably would be relevant, but not necessarily dispositive, in making this determination. This is consistent with the approach under **Daubert** and FRE 703. **Daubert** says that whether the theory is or can be tested - as a controlled study would do - is merely one factor, albeit an important one, in determining its admissibility. 509 U.S. at 593-94.

As applied here, it was up to the AHC to consider Dr. McDonagh's experts' testimony, along with the other evidence offered on the issue, and determine whether experts in the field could reasonably rely on the data those experts relied on in reaching [*158] their conclusions about the use of chelation therapy. Because of the confusion in the cases in regard to the standard for admission of expert testimony, the AHC did not apply these standards in evaluating the expert testimony offered. On remand, the AHC may permit the parties to supplement the record with additional expert testimony addressing the issues relevant under the statute.

V. REMAINING ISSUES ON APPEAL

A. Necessity of Expert Testimony on Standard of Care for Repeated Negligence Under Section 334.100.2(5).

The Board alternatively argues that, even were the testimony of Dr. McDonagh's experts otherwise admissible under the relevant evidentiary standard, it was insufficient to counter the Board's allegations in various counts, and through expert and other evidence, that Dr. McDonagh's use of chelation therapy constituted "repeated negligence" as that term is used in section 334.100.2(5). n15 That section defines "repeated negligence" as "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 members of the applicant's or licensee's profession." **Sec. 334.100.2(5)**.

n15 The Court notes that the term "repeated negligence" was not added to the statute until 1987. Therefore, although much of the conduct discussed at the hearing and that forms the

basis	of the	Board's	s action	occurre	d prior	to	1987, th	e "repe	eated	negli-	gence"	aspe	ect of	the
Board	l's asse	ertions	of misco	onduct a	igainst	Dr.	McDona	gh can	be b	ased	only or	n his	condu	uct
after	that pr	rovision	was ad	lded to t	the sta	tute	.[].:							

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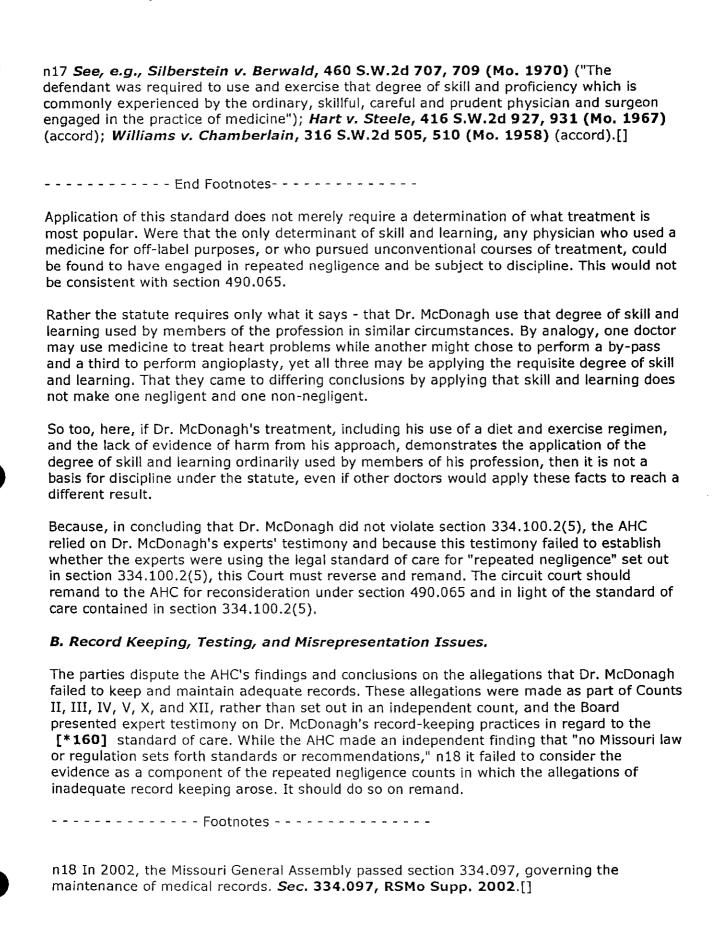
The Board submits that, in order to counter the Board's experts, Dr. McDonagh's experts needed to testify as to whether he used the degree of skill and learning ordinarily used by members of his profession. But, while his experts testified that his treatment of his patients met "the standard of care," they never identified that standard of care. The Board argues that the standard of care he met must be the standard of care generally accepted in the profession, and this means that Dr. McDonagh is negligent if he treats his patients in a way other than the treatment generally offered by doctors in the field. And, given Dr. McDonagh's experts' admission that mainstream doctors generally do not use chelation therapy to treat vascular disease, the Board suggests, Dr. McDonagh's experts cannot have used the correct standard of care in giving their opinion that his treatment met the required standard.

Dr. McDonagh admits that his experts did not state by what standard of care they were evaluating his treatment of his patients, but argues, to the extent testimony as to the standard of care was necessary, n16 the standard is that used by [*159] doctors who apply chelation therapy. In effect, he argues that, because he used the protocol approved by ACAM, he could not be found to be negligent and necessarily met the requisite standard of care.

n16 Dr. McDonagh argues that expert testimony on the standard of care was not necessary. This Court disagrees. Because this case deals with complex issues as to the appropriate medical care for patients with vascular disease, a matter not within lay competence, expert testimony was necessary to determine what standard of care was required of Dr. McDonagh and whether he met that standard of care. See, e.g., Swope v. Printz, 468 S.W.2d 34, 40 (Mo. 1971) (in medical malpractice cases, experts must incorporate the legal standard of care into their testimony to show that it is not "based upon [the expert's] own undisclosed subjective conception of acceptable medical standards" rather than the required, objective legal standard of care); Ladish v. Gordon, 879 S.W.2d 623, 634-35 (Mo. App. W.D. 1994) ("it is not necessary that the legal standard be recited in ritualistic fashion, but generally it must appear somewhere in the context of the expert's testimony that the proper objective legal standard is the standard being employed by this expert"); Dine v. Williams, 830 S.W.2d 453, 456 (Mo. App. W.D. 1992) (accord).[]

Neither party's argument is correct. The relevant standard of care is neither a reformulation of the *Frye* general acceptance test, nor blind acceptance of the views of a subgroup of treaters. The relevant standard of care for discipline for repeated negligence is necessarily that set out in the statute addressing that conduct, section 334.100.2(5). That standard, similar to Missouri's standard for proof of negligence in civil cases, n17 requires a showing whether the doctor showed the "skill and learning ordinarily used under the same or similar circumstances by the members of [the doctor's] profession." Sec. 334.100.2(5) (emphasis added). As the issue here is the treatment of persons with vascular disease, the appropriate standard of care is that used by doctors treating persons with vascular disease.

- - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - - - -



- **-** - - - - - - End Footnotes- - - - - - - - - - -

VI. CONCLUSION

Because the expert testimony upon which the AHC relied failed to furnish the appropriate legal standard of care, the circuit court's judgment is reversed, and the case is remanded. On remand, the circuit court is directed to remand to the AHC on all counts for further review in light of section 490.065 and in light of the standard of care set out in section 334.100.2(5) and this opinion.

LAURA DENVIR STITH, JUDGE

White, C.J., Benton, Price, Teitelman and Limbaugh, JJ., concur; Wolff, J., concurs in part and dissents in part in separate opinion filed.

CONCURBY: Michael A. Wolff (In Part)

DISSENTBY: Michael A. Wolff (In Part)

DISSENT: OPINION CONCURRING IN PART AND DISSENTING IN PART

I concur that section 490.065 sets the standards for admissibility and use of expert testimony. Because I believe that the Administrative Hearing Commission was correct in concluding that Dr. McDonagh was not subject to discipline for any of the acts alleged by the State Board of Registration for the Healing Arts, I would affirm the commission's decision, as the circuit court did.

I write separately to offer advice to lawyers on expert witnesses and gentle advice for the board on the future of this case against Dr. McDonagh.

Advice for Lawyers on Expert Witnesses

The principal opinion's [**2] discussion of section 490.065 is worth reading for its excellent legal analysis. I would only add a helpful summary for practitioners in Missouri courts and administrative agencies:

Forget Frye. Forget Daubert. Read the statute. Section 490.065 is written, conveniently, in English. n1 It has 204 words. Those straightforward statutory words are all you really need to know about the admissibility of expert testimony in civil proceedings. Section 490.065

| allows expert opinion testimony where ' | "scientific, | technical or | other | specialized | knowledge |
|---|--------------|--------------|-------|-------------|-----------|
| will assist the trier of fact" n2 | | | | | |

----- Footnotes ------

n1 All statutory references are to RSMo 2000.

n2 Section 490.065, in its entirety, provides:

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, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise.

Testimony by such an expert witness in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact.

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.

If a reasonable foundation is laid, an expert may testify in terms of opinion or inference and give the reasons therefor without the use of hypothetical questions, unless the court believes the use of a hypothetical question will make the expert's opinion more understandable or of greater assistance to the jury due to the particular facts of the case.

-----[**3] [*161]

Dr. McDonagh and the physicians he called as expert witnesses surely were "qualified" as experts by "knowledge, skill, experience, training, or education...." The board argued that these witnesses' testimony was inadmissible under *Frye v. United States*, 54 U.S. App. D.C. 46, 293 F. 1013 (D.C. Cir. 1923). *Frye* was remarkably beside the point.

Neither party gave the statute due regard. The board conceded that the testimony of Dr. McDonagh and his experts was admissible under section 490.065 but inadmissible under *Frye*. Why would an 80-year-old federal court of appeals case trump a Missouri statute directly on point?

Dr. McDonagh argued, by contrast, that the applicable standard was that of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993). Again, why would a Missouri statute directly on point be disregarded in favor of a United States Supreme Court decision on the Federal Rules of Evidence, which have not been adopted in Missouri?

What I think the parties are trying to get to is the relevant standard of care, discussed in the principal opinion. There is a problem here: in the proceedings [**4] before the commission, the board raised only the general objection that Dr. McDonagh's expert evidence would not qualify under Frye. The board did not object to any specific testimony from Dr. McDonagh or his experts. The board also did not raise the point it now presses in this appeal - that Dr. McDonagh's experts did not define the standard used when they stated that his use of chelation therapy was in accord with the "standard of care." The board's evidentiary motion

before the commission made no reference to "standard of care," nor did the board take the opportunity to cross-examine Dr. McDonagh's expert witnesses as to the standard of care. It was not Dr. McDonagh's burden to establish the relevant standard of care.

But the question of "standard of care" may be beside the point, as I will discuss in the next section in offering advice to the board.

Advice for the Healing Arts Board

The board should drop this case. It should not waste another dollar of public money on its case against Dr. McDonagh.

The board's case against Dr. McDonagh is premised on its contention that Dr. McDonagh's use of chelation therapy constitutes repeated negligence for which he should [**5] be disciplined. The board lost its case before the administrative hearing commission and then appealed to the circuit court, where it also lost.

Less than a month after the board filed its notice of appeal in 2001, the board promulgated a rule, 4 CSR 150-2.165, that declares the use of chelation on a patient is of "no medical or osteopathic value" except for such uses as approved by the federal Food and Drug Administration (FDA). The rule also says that the board "shall not seek disciplinary action" against a licensee where the licensee uses a patient consent form prescribed by the rule.

[*162] The board concedes, and the principal opinion appropriately notes, that the consent form that Dr. McDonagh has used for many years is very similar to the consent form in the board's rule.

How can the board take the position that Dr. McDonagh's practice was repeatedly negligent under the disciplinary statute, section 334.100, when the board has a rule saying that it will not seek discipline against physicians engaging in this practice? What, exactly, is the standard of care?

The real question is: Is the healing arts board's use of section 334.100 [**6], which prescribes discipline for repeated acts of "negligence," an inappropriate use of the disciplinary process to impose the board's sense of orthodoxy? n3

n3 Section 334.100.2 provides, in pertinent part:

The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered the person's certificate of registration or authority, permit or license for any one or any combination of the following causes: (5) Any conduct or practice which is or might be harmful or dangerous to the mental or physical health of a patient or the public; or incompetency, gross negligence or repeated negligence in the performance of the function or duties of any profession licensed or regulated by this chapter. 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[.]

· - - - - - - - - - - End Footnotes- - - - - - - - - - [**7]

Dr. McDonagh's use of chelation therapy to treat atherosclerosis and other vascular diseases may be unorthodox. None of the mainstream medical organizations endorse its use for vascular diseases. But, until 2001 - after the acts the board complains of in this proceeding - there was no law or regulation regulating its use. Chelation therapy, which consists of administering the drug EDTA intravenously, is standard treatment for removal of heavy metals from the body. The FDA approves the chelation therapy medications for this use. Its use in attempting to clear vascular blockage is called an "off-label" use, referring to the use of a standard therapy for another purpose. There are many off-label uses of medicines that are generally accepted by the medical profession.

An organization called the American College for Advancement in Medicine, consisting of about 1,000 physicians worldwide including Dr. McDonagh, endorses the off-label use of chelation therapy, along with various vitamins and minerals, for treating vascular disease.

The administrative hearing commission heard evidence for eight days on the board's complaint against Dr. McDonagh for his use of chelation therapy and related [**8] matters. n4 The commission, in its 70 pages of findings of fact and conclusions of law, found no cause for discipline.

n4 The board's complaint also relates to record keeping and use of diagnostic tests, but these charges seem to be premised on the board's objection to Dr. McDonagh's practice of chelation therapy for treating vascular disease. There may be a question whether Dr. McDonagh ordered unnecessary tests, without reference to chelation therapy, or whether the tests Dr. McDonagh ordered were deemed by the board to be unnecessary because they were part of chelation therapy that the board believes is useless.

Specifically responding to the board's position that the use of chelation therapy is cause for discipline, the commission concluded: "It is not an unnecessary, harmful or dangerous treatment." The commission characterized McDonagh's conduct as "giving [*163] 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 [**9] may not work with all patients." The commission further stated, "The evidence shows that patients are being helped. 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."

The commission, based on the record, does acknowledge that chelation therapy involves risks, as of course do other treatments for vascular disease, such as coronary artery surgery. The risks of chelation therapy are disclosed, according to the commission, in the informed consent form that Dr. McDonagh has used with all his patients. The form gives notice that chelation therapy for vascular disease is not approved by the FDA, the American Medical Association, or others. It lists possible benefits, but also notes "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 his patients that "the treatment will work better if the patient follows the diet, exercise and nutritional supplements that are [**10] recommended," according to the commission's findings.

There are scientific studies discussed in the commission's findings as to the efficacy of chelation therapy for vascular conditions. The mainstream organizations accept the

conclusions of studies that found no value in treating vascular disease by chelation therapy. Dr. McDonagh and other like-minded physicians, including their American College for Advancement in Medicine, cite case reports and studies - arguably of less validity than the studies relied upon by the mainstream - that show benefits in such use of chelation therapy.

There is a provision of section 334.100 that would seem to cover unorthodox treatments that are of no value. Section 334.100.4(f) provides for discipline where a licensee performs or prescribes "medical services which have been declared by board rule to be of no medical or osteopathic value." But the board did not have a rule against chelation therapy that would apply to Dr. McDonagh's acts, which occurred from 1978 to 1996. The board, long after the acts included in its complaint against Dr. McDonagh, promulgated a rule relating to chelation therapy, [**11] 4 CSR 150-2.165 (Effective October 30, 2001), quoted in full in the principal opinion.

More to the point, when the board finally promulgated its rule that declares chelation therapy to be "of no medical or osteopathic value," the board's rule goes on to provide that the board "shall not seek disciplinary action against a licensee based solely upon a non-approved use of EDTA chelation if the licensee has the patient sign" the informed consent form that accompanies the regulation. As noted here and in the principal opinion, the consent form that Dr. McDonagh used for these patients - long before the consent form promulgated by the board - is very similar to the consent form accompanying the 2001 rule.

At this point, the question becomes: what's going on here? In fairness to the board, I should note that the hearing before the administrative hearing commission in Dr. McDonagh's case was held in 1997, four years before the board promulgated its rule. But it seems strange that the board, having lost in the commission and in the circuit court, would press its claims on appeal after publishing the 2001 rule that undercuts its position.

[*164] As to the board's [**12] claims heard in 1997 that are the subject of this appeal, it appears that the absence of a rule left the board to proceed against Dr. McDonagh under 334.100.2(5) for repeated acts of negligence. The board's complaint alleged that Dr. McDonagh's practice of chelation therapy constituted repeated negligence in violation of section 334.100.2. Section 334.100.2(5) allows for discipline for "any conduct or practice which is or might be harmful or dangerous to the mental or physical health of a patient or the public," and for "incompetency, gross negligence or repeated negligence" in professional duties. Section 334.100.2(5) defines "repeated negligence" as "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." This definition establishes the legal standard of care that must be applied in determining the board's claims of repeated negligence.

So is this off-label use of chelation therapy negligence? The real question - the answer to which is fatal to the board's position [**13] - is whether acts of negligence, as defined by this statute, can be cause for discipline if there is no showing that the physician's conduct "is or might be harmful or dangerous." If there is no harm or danger, there is no cause for discipline under this section. Section 334.100.2(5) is a catchall provision; read in the context of the entire statute, it does not make negligent acts actionable unless there is harm or danger. n5 This subdivision cannot be read to make acts subject to discipline where there is no prospect of harm. If it were so read, the reading would make superfluous other provisions of the statute, such as 334.100.2(4)(f) as to treatments deemed by rule to have no medical value. There are provisions in section 334.100, including 334.100.2(4)(f), for disciplining medical quackery - even where it causes no harm. But section 334.100.2(5), under which the board complains of Dr. McDonagh's practice, is not one of those sections.

- **- - - - - - -** - - - - Footnotes **- - - - - - - - - - - -**

n5 For those who like the comfort of case citations, Missouri's common law of negligence is consistent with this reading of section 334.100.2. In common law actions for negligence, the concept of negligence is inextricably linked to the causation of harm. All actions for negligence require a plaintiff to establish that "the defendant had a duty to protect her from injury, that the defendant breached that duty, and that the defendant's failure directly and proximately caused her injury." *Robinson v. Health Midwest Development Group*, 58 S.W.3d 519, 521 (Mo. banc 2001). For a medical negligence action, a plaintiff must prove that the defendant failed to use that degree of skill and learning ordinarily used under the same or similar circumstances by members of defendant's profession and that the negligent act or acts caused plaintiff's injury. *Washington by Washington v. Barnes Hosp.*, 897 S.W.2d 611, 615 (Mo. banc 1995).

Under section 334.100.2(5), no harm, no foul.

Physicians are afforded considerable leeway in the use of professional judgment to decide on appropriate treatments, especially when applying the negligence standard. For instance, Haase v. Garfinkel, 418 S.W.2d 108, 114 (Mo. 1967), a medical negligence case, holds that "as long as there is room for an honest difference of opinion among competent physicians, a physician who uses his own best judgment cannot be convicted of negligence, even though it may afterward develop that he was mistaken." "Negligence" does not seem an appropriate concept where the physician has studied the problem and has made a treatment recommendation, even though that is not the prevailing view of the majority of the profession. The lack of general acceptance of a treatment does not [*165] necessarily constitute a breach of the standard of care. The use of negligence in licensing situations, in the absence of harm or danger, is particularly inappropriate.

One could argue that because chelation therapy is not accepted by mainstream medicine and is an off-label practice not approved by the FDA, it is therefore harmful and dangerous.

[**15] If that were the board's position, the licensing statute would thwart advances in medical science. A dramatic example is the treatment of stomach ulcers, which were long thought to be caused by stress. In 1982, two Australians found the bacterium helicobacter pylori in the stomach linings of ulcer victims. Because helicobacter pylori is a bacterium, some physicians - a minority to be sure - began prescribing antibiotics to treat stomach ulcers as an infectious disease. The National Institutes of Health did not recognize antibiotic therapy until 1994; the FDA approved the first antibiotic for use in treating stomach ulcers in 1996; and the Centers for Disease Control began publicizing the treatment in 1997. Today's physicians accept as fact that most stomach ulcers are primarily caused by helicobacter pylori bacteria infection and not by stress.

n6 But, by the chronology of this discovery, if a physician in the late 1980s or early 1990s had treated ulcers with antibiotics, that treatment would have been "negligent" as the board in this case interprets that term because inappropriate use of antibiotics can be dangerous.

n6 The treatment of stomach ulcers by antibiotic therapy is cited as one of the top innovations in medicine in the past 25 years in a study sponsored by the Robert Wood Johnson Foundation and the Henry Kaiser Foundation. Its conclusions are summarized at www.MedTech1.com.

-----[**16]

I do not mean to suggest that chelation therapy for vascular disease is of the same order as the use of antibiotics for treating stomach ulcers. In fact, I doubt it. But my point is that medicine is not readily regulated by a standard cookbook or set of rules. The board's position in publishing its 2001 rule on chelation therapy seems to recognize this point better than its position in this disciplinary action. If chelation therapy for vascular disease were dangerous, the board's rule that allows its use would be unconscionable.

In Dr. McDonagh's practice, all of his patients signed a consent to medical treatment and agreement that discusses the positive and negative aspects of chelation therapy and possible side effects. The patients are told that the therapy is not approved by the FDA, AMA or others. The patients consented nonetheless. Some of Dr. McDonagh's patients chose chelation therapy after exhausting more traditional medical treatments. Some may have benefited, perhaps because Dr. McDonagh accompanied the chelation treatment with recommendations for diet and exercise that are well known to be helpful for preventing and resolving some vascular disease. The record shows no [**17] harm to any patient.

In the absence of harm, or the probability of harm, can the repeated negligence standard of the licensing statute legitimately be used to enforce the board's opinion of what is conventional and, therefore, acceptable medicine?

The board conceded that there was no evidence of harm from chelation therapy. In the 35 years that he has used chelation therapy, Dr. McDonagh reports that the therapy has not resulted in infection, injury, or death for any of his patients. The commission repeatedly found that chelation therapy "harms no one" and provides "benefit to many patients." n7

n7 In contrast, according to the commission, cardiac bypass surgery - an approved therapy for severe athlerosclerosis - has an operative mortality rate of between two and 30 percent, depending on where you are in the United States, and mental impairment occurs in as many as 18 percent of cardiac bypass patients.

----- End Footnotes------

[*166] Medicine is an art, as well as a science, as its practitioners are taught. It is also a dynamic field, [**18] where beliefs about what is conventional therapy can change over time. What is effective treatment is often a combination, not just of art and science, but of belief. The patient may get better if the patient is convinced of the usefulness of the therapy. The commission concluded that some of Dr. McDonagh's patients got better. Even if it is hard to believe these patients got better because of chelation therapy, the fact that some of Dr. McDonagh's patients got better is hardly cause for discipline. On this record, the absence of harm from chelation therapy, as I read the statute, negates the board's claim of repeated negligence.

Nor can it be said that the board or the commission believes that Dr. McDonagh's practice constitutes a danger to the public. The board has the power to move quickly to end practices that it considers dangerous. Section 334.102. The board sought no such immediate action.

This disciplinary action has, if anything, been conducted in slow motion. The healing arts board in 1989 apparently studied chelation therapy and issued a public statement that it chose "to take no action concerning chelation therapy" and would consider cases as [**19] they arose. Its first complaint against Dr. McDonagh was filed in 1994 but later dismissed

without prejudice. The current complaint, in 13 counts, covers practices going back to 1978 and was filed in 1996. As noted, the current case was tried before the commission in 1997, but the commission's decision was not issued until 2000. There has been a noticeable lack of urgency by all concerned.

If this matter comes before the commission on remand, the commission is to review the evidence on the basis of the evidentiary principles in section 490.065. In my view, the commission should reach the same conclusion as before. In any event, to the extent that Dr. McDonagh's practice - though it pre-dated the board's 2001 regulation - conformed to the board's regulation on chelation, the board ought to be bound by its own standard. Dr. McDonagh has not yet raised the issue of whether the board should be bound by its own standard as expressed in its 2001 rule. But he will have the opportunity to do so on remand.

This case needs to be over. The board should end the case itself rather than suffer the indignity of further adverse commission and judicial rulings, to say nothing [**20] of the waste of public resources that such proceedings will entail.

Michael A. Wolff, Judge

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State Board of Registration for the Healing Arts v. McDonagh

123 S.W. 3d 146 (Mo. Sup. Ct. December 23, 2003):

• "[T]he standard for the admission of expert testimony in civil cases is that set forth in section 490.065. As discussed herein, this is also the standard to be applied in administrative cases."

Standard for Admissibility of Expert Testimony

- "Section 490.065 Provides the Standard For Admission of Expert Testimony in Civil Actions."
- "While contested administrative proceedings are not required to follow the technical rules of evidence, the fundamental rules of evidence applicable to civil cases are also applicable in such administrative hearings. The standards for admission of expert testimony constitute such a fundamental rule of evidence. The standards set out in section 490.065 therefore guide the admission of expert testimony in contested case administrative proceedings such as this one." (emphasis added)
- "Daubert set out a non-exclusive list of factors for consideration in determining whether the evidence in question meets the flexible standard, including: (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) the known or potential rate of error; and (4) general acceptance."
- "Few cases have interpreted section 490.065. To the extent that section 490.065 mirrors FRE 702 and FRE 703, as interpreted and applied in *Daubert* and its progeny, the cases interpreting those federal rules provide relevant and useful guidance in interpreting and applying section 490.065."

- "[S]ection 490.065.3 goes on to require that the facts or data on which an expert bases an opinion or inference must be of a type reasonably relied upon by experts in the field in forming opinions or inferences upon the subject and that these facts and data must be otherwise reasonably reliable."
- "Thus, section 490.065.3 expressly requires a showing that the facts and data are of a type reasonably relied on by experts in the field in forming opinions or inferences upon the subject of the expert's testimony." (emphasis in original)
- "The court must also independently assess their reliability."
- "The statute requires that to be admissible expert opinion must be based on facts or data of a type reasonably relied upon by experts in the field."
- "[U]nlike in Missouri, Daubert held that in the federal courts an expert need not necessarily identify the relevant, scientific community, or field, in which that data and facts are accepted."
- "The relevant field must be determined not by the approach a particular [witness] chooses to take, but by the standards in the field in which the [witness] has chosen to practice."
- "Section 490.065.3 simply requires the court to consider whether the facts and data used by the expert are of a type reasonably relied on by experts in that field or if the methodology is otherwise reliable. If not, then the testimony does not meet the statutory standard and is *inadmissible*." (emphasis added)

May 2001 Deposition of David Murray

| Q. | Would I be correct if I said that for the most part, for the most part, your direct testimony in this case is very similar, if not almost word for word identical, to Mr. Bible's testimony in Case GR-98-140? |
|-----------|--|
| A. | I would say we have department policy, and some of those policies were followed. (p. 44) |
| A. | The two primary references that we use, textbooks that we use, are Costs of Capital by David Parcelland then the other textbook that we use frequently is Roger Morin's Utility—Regulatory Finance Textbook. (p. 20) |
| Q. | Have you read those four cases [Hope, Bluefield, Pennsylvania Electric, and Munn] which were set out there at the bottom of page 3 of your testimony? |
| A. | Not entirely. |
| Q. | Did you read any of those cases in their entirety? |
| A. | No. |
| Q. | Someone provided you with photocopies of those cases? |
| A. | Yes. |
| Q. | Do you recall whether or not those photocopies have on them any notations or underlining? |
| A. | There may have been some highlighted portions. (pp. 24-25) |
| , | Pennsylvania Supreme Court "expands" and "extends" United States
Supreme Court precedent (pp. 28, 36) |

Are there different forms or types of DCF models? Q. There are different types. (p. 51) Α. And why did you select this particular form of the DCF model? Q. It's been what our department has used for quite some time. (p. 52) A. Have you ever used any other DCF form or types? Q. No À. Are there various ways to make a DCF calculation? Q. A. No. Q. There are not? No. A. 0. There is only one way to make one? A. As far as the formula. (p. 53) And would you agree with me that there is a basic principle in finance which Q. says that the greater the risk, the higher the return requirement? A. Holding all else the same, if there is a larger risk, the investor may expect a higher rate of return. (p. 118) Q. Would it be your testimony that an investor would buy stock with a negative earnings expectation? I can't comment with what an investor would specifically do. A. 0. You don't know. You don't have an opinion on that? No. (p. 121) A.

Testimony of David Murray from March 2004 Aquila Hearing

- Q. Can you access in some fashion, electronically or otherwise, the decisions issued by other state agencies, for example the Kansas Corporation Commission?
- A. If I was inclined to to look at their website, I'm sure I could.
- Q. Have you ever done that? Have you ever looked at any decisions of other Public Utility Commissions or Public Service Commissions and read those decisions where they discussed the authorized returns that they were allowing for the companies under their jurisdictions?
- A. No.
- O. You never have?
- A. No. I have—I have enough stuff to do here as far as doing my economic analysis using the DCF model and the capital asset pricing model. As far as what goes on in the specifics of cases throughout this country, I would be working 24/7 to be able to keep up with that. (pp. 93-94)
- A. [F]or the most part if I'm comfortable with how I arrived at it [DCF analysis], I'm not going to change it.
- Q. What would cause you to change it based on a different result for your comparable companies?
- A. Like I say, if there's <u>an act of God</u> that occurred that caused, you know, unbelievable loss to—that's out of their control.
- Q. To who?
- A. To the utility company. (p. 188)
- Q. Well, what information would show you or convince you that the divisional capital structure of [the divisions] were closer estimates of the actual capital used to serve those customers than the capital structure of [the parent].
- A. Spin them off as a subsidiary and have them issue their own debt.

Staff Response to MGE Motion to Exclude Testimony of David Murray

- MGE has put in front of the Commission "no less than seven financial textbooks in order to parse Staff's rate of return recommendation." (¶ 4)
- "Fundamental justice demands the admission of Mr. Murray's rate of return testimony and recommendation." (¶ 8)

OPC Response to MGE Motion to Exclude Testimony of David Murray

- "Missouri case law holds that these types of allegations are matters that go to the issue of credibility of the witness and the evidentiary weight that the PSC may assign to his opinion; these matters are not determinative of the admissibility of his testimony and the opinions stated in that testimony." (p. 2)
- "The PSC must await the conclusion of the evidence before it can make a factual finding regarding the credibility of the witnesses after it has considered all of the relevant evidence that goes to the issue of rate of return and the credibility of the witnesses presenting evidence on that issue." (p. 8)
- "Questions as to the sources and bases of the expert's opinion affect the weight, rather than the admissibility." (p. 8)
- Federal decisions are only "illustrative." (p. 6)
 - Missouri Supreme Court in State Board of Registration for the Healing Arts v. McDonagh, 123 S.W.3d 146 (2003) holds: federal decisions provide "relevant and useful guidance in interpreting and applying section 490.065."

Murray Is Not An Expert (May 2004 Murray Deposition Testimony)

| Q. | And when you first came to the Commission, in what year was that? | | | | | |
|-------------|--|--|--|--|--|--|
| A. | June of 2000. | | | | | |
| Q. empl | And prior to coming to the Commission in June of 2000, you were loyed by the Department of Insurance; is that correct? | | | | | |
| A. | That's correct. | | | | | |
| Q.
while | And did you have any rate of return testimony that you submitted e employed at the Department of Insurance? | | | | | |
| A. | No, I did not. | | | | | |
| Q.
or w | Did you have any rate—return on equity testimony that you submitted worked on while at that Department of Insurance? | | | | | |
| A. | No. | | | | | |
| Page | e 11, lines 3-17 | | | | | |
| | | | | | | |
| Q.
envi | And the first time you ever used it [DCF modeling] in a practical ronment was when you came to work for the Missouri Staff, right? | | | | | |
| A. | That's correct. | | | | | |
| Page | e 14, lines 7-10 | | | | | |
| Q. | Prior to joining the Missouri Staff, did you ever give any lectures on s of return? | | | | | |

- A. No.
- Q. You ever publish any books dealing with rates of return or return on equity?

A. No.

Page 16, lines 19-24

- Q. And have you published any peer review studies as it relates to rate of return or return on equity?
- A. No.
- Q. Have you consulted with any other staffs at any other commissions in any other jurisdictions as to how they're applying the DCF model in their recommendations regarding rate of return?
- A. No.

Page 17, lines 14-21

- Q. Are you a CPA?
- A. No, I'm not.
- Q. The methodology that you just described [purportedly backing out Panhandle's equity from Southern Union's consolidated balance sheet], does that conform to Generally Accepted Accounting Principles?
- A. I don't know.
- Q. Did you consult with anyone at the Missouri Commission to find out whether your proposed methodology had anything to do with GAAP?

| A. Not specifically with GAAP. I talked about the process that I did with a couple of people. | | | | | | |
|---|--|--|--|--|--|--|
| Page 84, lines 12-22 | | | | | | |
| | | | | | | |
| Q. I'm asking if it turns out that GAAP says your process is completely wrong, would that change your opinion? | | | | | | |
| A. No, because I think this is the equity associated with Panhandle. | | | | | | |
| Q. And you're as sure of that answer as everything else you've put in your testimony, right? | | | | | | |
| A. Yes. | | | | | | |
| Page 86, lines 24-25; page 87, lines 1-6 | | | | | | |
| | | | | | | |
| Q. Have you ever tested the methodologies that you are using to make sure that they comply with the Supreme Court precedents as it relates to expert testimony? | | | | | | |
| A. No, I haven't. | | | | | | |
| Page 47, lines 7-11 | | | | | | |
| | | | | | | |
| Q. Have you ever seen any textbooks that have the selection criteria that you've used in your testimony here to select the comparable companies? | | | | | | |
| A. All these criteria? | | | | | | |
| Q. Yes. | | | | | | |

A. In their entirety? I don't recall specifically anything where it sets out the specific criteria I have here.

Page 56, lines 7-14

Q. Mr Murray, when we were talking about you using the 2002 data and I asked you if the 2003 information was available, would you update your calculations if there were some significant changes, the question is, would you make those adjustments?

A. No.

Page 88, lines 23-25; page 89, lines 1-3

- Q. And would you agree that Dr. Mor—I'm sorry Professor Morin is an expert on regulatory finance?
- A. I believe he's an authoritative figure, that's correct.
- Q. And do you believe Professor Morin to be one of the leading authoritative figures in the country on regulatory finance?
- A. He's one of the most widely quoted, that's correct.

Page 71, lines 19-25; page 72 lines 1-3

Murray Uses "Canned" Testimony (May 2004 Murray Deposition Testimony)

- Q. The first time you submitted testimony as it related to MGE in 2001, do you recall that testimony you submitted?
- A. Yes.
- Q. And you discussed your testimony with Mr. Bible before you submitted it, right?
- A. Yes, I did.
- Q. And Mr. Bible gave you his -- well, somebody at some point gave you the standard testimony, right?
- A. Yes.
- Q. And did someone explain to you when you first got there that this is the standard testimony that we use for each of the rate cases that come before the Commission?
- A. Yes.

Page 10, lines 12-25; page 11 line 1

- Q. And there's some portions of this testimony that you used back in 2001, right?
- A. Yes.
- Q. And there's some portions of this testimony that you know based on prior depositions came from years ago from other witnesses, right?
- A. Yes.

Page 13, lines 21-25; page 14, lines 1-2

- Q. Well, is it safe to say that the person who gave you primary guidance as to how things are done at the Commission when you first arrived was Mr. Bible?
- A. Yes.
- Q. And he was your boss, right?
- A. Yes.
- Q. He's the one that handed you this canned testimony, right?
- A. He handed me some of the testimony that he had done in the previous MGE rate case.
- Q. And he's the one that explained to you how the Staff generally dealt with rate cases, right?
- A. Yes.
- Q. And did he tell you at that time that, prior to joining the Missouri Commission, he had no experience with the regulated industries?
- A. No.

Page 40, lines 6-22

Q. Let me read to you a portion of Mr. Bible's testimony from November 3rd of 2000.

Question: Prior to joining the Missouri Commission in August of 1997, did you have any regulatory experience?

Answer: No.

Had you worked for any companies that had been regulated by the Missouri Commission prior to '97?

Answer: No.

Did Mr. Bible ever explain to you how he came to obtain the canned testimony that's been submitted by the Staff for several years?

A. I don't recall if he did or not.

Page 41, lines 2-14

Q. Have you ever tested the methodologies that you are using to make sure that they comply with the Supreme Court precedents as it relates to expert testimony?

A. No, I haven't.

Page 47, lines 7-11

Professor Morin Rebuttal Testimony

- "A proper application of cost of capital methodologies would give results substantially higher than those that [Murray] obtained. Mr. Murray's overall testimony and recommendations are well outside the mainstream of both financial theory and practice. As such, Mr. Murray's opinion ass to an ROE for MGE is fundamentally unsupported and unreliable. I do not believe that Mr. Murray's testimony can be credited with providing the Commission with any expert analysis that can give it insight in responsibility addressing the ROE issue in this case." (p.5)
- "The average allowed return in the gas utility industry in both the years 2002 and 2003 as reported by Regulatory Research Associates in its most recent quarterly survey of regulatory decisions dated March 2004 was 11% for both years. In the first quarter of 2004, the average authorized ROE is 11.1%. These ROE's exceed by a substantial margin Mr. Murray's recommended ROE of 8.52%-9.52% for MGE, an above average risk utility." (p.10)
- There are some very serious problems with Mr. Murray's approach to DCF growth rates:
 - (1) Inclusion of negative growth rates
 - (2) Use of 2-year old growth rates
 - (3) Unrepresentative and redundant historical growth rates
 - (4) Dividend growth rates

(p. 18)

• "I also conclude that Mr. Murray's recommended 8.52%-9.52% ROE for the Company is well outside the zone of currently authorized rates of return for energy utilities in the United States for his own sample of comparable risk utilities, and would be among the lowest, if not the lowest, in the country, if ever adopted." (p. 41) (emphasis added)

Murray's Use of Improper Methodology

► Proposed Capital Structure is Improper

- Murray improperly attributes Panhandle debt to MGE in complete disregard for the MPSC Order in Case No. GM-2003-0238
 - Even the OPC agrees the cost of Panhandle debt should be excluded from MGE long term debt cost
- OPC offers a hypothetical capital structure alternative reflecting 37% common equity ratio

► Calculation of Return on Equity is Improper

- Murray arbitrarily refused to use the most recent historical data from 2003
 - "Estimates for tomorrow cannot ignore prices of today." (Bluefield Water Works and Improvement Co., v. Public Service Commission of West Virginia, 262 U.S. 679, 691 (1923).
- Murray improperly included negative growth data in his DCF analysis to estimate investor required returns
- Murray admitted that almost all factors he used to select proxy group companies have no relationship to risk
- Murray failed to make proper adjustments to recommended ROE to take into account the higher risk capital structure he attributes to MGE
- Murray refused to consider other jurisdictions' authorized ROE and ROR for proxy group companies as a check on the reasonableness of his recommendations
 - "[T]he return to the equity owner should be commensurate with returns on investments in other enterprises having corresponding risks." Federal Power Comm., et. al. v. Hope Natural Gas Co., 320 U.S. 591, 603 (1944).

Staff's Proposed Capital Structure For MGE is Improper

► Staff's Proposal Fails to Comply with MPSC Order Re: Southern Union Acquiring Panhandle.

....

- Commission, at Staff and Public Counsel's Request, ordered Southern Union to insulate its MGE operating division from Panhandle business. Order in Case No. GM-2003-0238, effective April 6, 2003, at p. 3.
- Staff, Public Counsel, and Southern Union agreed that Southern Union would "exercise its best efforts to insulate MGE from any adverse consequences from its other operations or the activities of any of its affiliates." Stipulation and Agreement, filed March 25, 2003, p.6.
- Staff witness Murray testified that neither Southern Union nor MGE is in violation of any orders or agreements with the MPSC. (Murray Deposition, 5-4-04, p. 19, 61)

► Staff's Capital Structure Improperly Attributes Panhandle Debt and Equity to MGE.

- Panhandle a natural gas pipeline is a business with different business risks, financial risks and capital requirements than MGE, a natural gas distribution company.
- Murray concedes the importance of a business unit-bybusiness unit methodology by focusing on MGE as a standalone business in his calculation of MGE's cost of equity.

• Staff, Public Counsel, and Southern Union agreed that:

"Southern Union will not allow any Panhandle debt to be recourse to them."

"Southern Union will not enter, directly or indirectly, into any "make-well" agreements, or guarantee the notes, debentures, debt obligations or other securities of any Panhandle entity without Commission approval.

"Southern Union will not transfer to [any Panhandle entity] assets necessary and useful in providing service to MGE's Missouri customers without Commission approval.

Stipulation and Agreement, filed March 25, 2003, ¶2, p.6.

Staff's Arbitrary Refusal to Include 2003 Data

Result: ROE Unreasonably Low Due to Exclusion of Current Data

- Murray Used Historical Data to Predict Future Growth
- Murray Refused To Use Most Recent Historical Data
 - o "Estimates for tomorrow cannot ignore prices of today." (Bluefield Water Works and Improvement Co., v. Public Service Commission of West Virginia, 262 U.S. 679, 691 (1923).
- Murray Had 2003 Data Available
- Murray Knew Or Should Have Known 2003 Data Would Significantly Impact ROE
- Murray Testified He Would Not Change His Recommended ROE Even Though He Knew 2003 Data Would Drastically Change His Financial Schedules:
 - Q: If the 2003 information was available and that would drastically change the numbers contained on Schedule 15.2 and forward, would that cause you any pause in changing your recommendations?

A: No.

(Murray Deposition, 5-4-04, p. 81)

o Mr. Murray, when we were talking about you using the 2002 data and I asked you if the 2003 information was available, would you update your calculations if there were some significant changes, the question is would you make those adjustments?

A: No.

(Murray Deposition, 5-4-04, pp. 88-89)

- Murray's Position is Unfounded and Unreasonable
- The 2003 Data Significantly Changes Murray's Financial Projections and Thus His Proposed ROE

Return on Equity Comparison

| Company | Staff DCF
ROE | OPC DCF
ROE | *Actual
2003 ROE | **Current Authorized ROE |
|----------------|------------------|--|---------------------|--------------------------|
| AGL Resources | 8.03% | 10.34% | 14.0% | 10.99% |
| Cascade | 7.70% | 8.76% | 8.6% | 11.75% |
| NJ Resources | 8.94% | ــــــــــــــــــــــــــــــــــــــ | 15.6% | 11.50% |
| Northwest | 7.80% | 8.64% | † 8.5% | 10.20% |
| Peoples Energy | 8.80% | 8.09% | † 12.3% | 11.20% |
| Piedmont | 9.89% | | 11.8% | 11.30% |
| South Jersey | 8.90% | 9.67% | † 12.5% | 11.25% |
| WGL | 6.70% | 8.06% | 14.0% | 10.95% |
| | | | | |

Compare to:

Recommendation

For MGE

Staff: 8.52-9.52%

OPC: 9.01-9.34%

^{*} Source: Value Line March 19, 2004

^{**}Source: C.A. Turner Utility Reports Survey May 2004

⁻⁻Note that current authorized ROE average is 11.1% which is also the average ROE authorized for natural gas distributors by regulatory authorities in the first quarter of calendar year 2004.

^{† 2002} numbers, 2003 not available

<u>Authorized Rate of Return Must Be Reasonable</u> According To U.S. Supreme Court:

- "[T]he fixing of 'just and reasonable' rates, involves a balancing of the investor and the consumer interests." *Federal Power Comm., et. al. v. Hope Natural Gas Co.,* 320 U.S. 591, 603 (1944).
- "[T]he return to the equity owner should be commensurate with returns on investments in other enterprises having corresponding risks." (Id.)
- "That return, moreover, should be sufficient to assure confidence in the financial integrity of the enterprise, so as to maintain its credit and to attract capital." (*Id.*)
- The return should be "reasonably sufficient to assure confidence in the financial soundness of the utility...." (Bluefield Water Works and Improvement Co., v. Public Service Commission of West Virginia, 262 U.S. 679, 693 (1923).
- "A public utility is entitled to such rates as will permit it to earn a return... equal to that generally being made at the same time and in the same general part of the country on investments in other business undertakings which are attended by corresponding risks and uncertainties...." (p. 692)
- The return should be "adequate, under efficient and economical management, to maintain and support [the utility's] credit...." (Id.)