Appendix #382

Petition for Administrative Writ of Mandate to Review Administrative Decision

[*Code Civ. Proc. § 1094.5*]

SUPERIOR COURT OF CALIFORNIA,
COUNTY OF LOS ANGELES

DAVID K. CUNDIFF, MD,	)	
Petitioner,	)	CASE NO. 27-2009-197832
vs.	)	OAH No. 2009090479
THE MEDICAL BOARD OF CALIFORNIA,	)	PETITION FOR WRIT OF MANDATE
Respondent.	)	Date: May 24, 2010
	)	Time: 12:00 pm
	)	Los Angeles County

Petitioner respectfully represents:

1. DAVID K. CUNDIFF, MD

2. Respondent is the Medical Board of the State of California, an administrative agency in the Department of Consumer Affairs.

3. Under *Sections 2220 et seq. of the Business and Professions Code*, the Respondent has discretion to determine whether a ground exists for suspension or revocation of a physician's and surgeon's certificate, and particularly whether a petition for the reinstatement of a medical license shall be granted. Pursuant to *Section 2230 of the Business and Professions Code* and *Sections 11500-11528 of the Government Code*, the Board is required to hold a hearing and take evidence in its proceedings for the determination of those facts.

4. On January 14, 2010, at 320 West Fourth Street Room 630, Los Angeles, California, Petitioner attended a hearing held to receive evidence on the issue whether a ground exists for the reinstatement of the Petitioner's physician's and surgeon's certificate which was revoked on September 11, 2000. On April 28, 2010, Petitioner received the Respondent's decision and order denying reinstatement of the medical certificate on the ground that Petitioner failed to provide sufficient evidence of rehabilitation to merit reinstatement. Petitioner submitted a petition for reconsideration of the court's Proposed Decision to deny license reinstatement which the Respondent denied.

5. The Respondent's decision and order are invalid for the following reasons [*Code Civ. Proc. § 1094.5(b)*]:

(1) At the hearing, Petitioner tried to offer evidence that was barred but should have been admitted, as Petitioner alleges more particularly hereinafter.

(2) The hearing officer's principle conclusion, adopted by the Respondent, was, "Saliently, if faced with the same situation today, Petitioner would essentially not act differently. Such a steadfast position, in light of the factual findings and conclusions in the underlying proceeding, leads to the conclusion that the public would not be safe if Claimant's license were reinstated. His writing and research efforts and his letters of support do not lessen or modify this conclusion" (pg 5, LEGAL CONCLUSION #5). The evidence received at the hearing does not support these findings, as Petitioner alleges more particularly hereinafter.

(3) The decision is not supported by the findings resulting from the administrative hearing [*see Code Civ. Proc. § 1094.5(b)*], because license reinstatement was denied entirely based on a single controversial medical opinion held by the Petitioner, as Petitioner alleges more particularly hereinafter.

6. A verbatim transcript of the record of the hearing, containing the evidence received, is attached hereto as Exhibit A and made a part hereof. Relevant evidence supporting the petitioner's rehabilitation was inappropriately barred, the documents and testimony in evidence does not support the finding that the petitioner is not rehabilitated, and the findings do not support the decision to deny license reinstatement for the following reasons:

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(1) After 25 years of medical practice with no prior medical board discipline, the Petitioner's actions in a single case resulted in the revocation of his medical license. In 1998, the Petitioner stopped anticoagulant medications on day five of hospitalization in a patient with deep venous thrombosis (a clot in a leg vein) out of concern about the risk of serious or fatal bleeding. Unfortunately, the patient later died of pulmonary emboli (clots in the lungs).

(2) While treating patients with deep venous thromboses with anticoagulant medications was indisputably the standard of care in 1998 at the time of the case at issue, anticoagulant treatment of deep venous thrombosis patients is no longer the undisputed worldwide or Los Angeles County community standard of care. The barred evidence was in the form of the testimony by the Petitioner, an acknowledged expert in anticoagulation medicine, supported by Petitioner's exhibits N, O, P, and Q that were entered into evidence. The hearing officer ruled that the testimony explaining the salient points of the admitted exhibits was not admissible, because it was an attempt to relitigate the original case.

As opposed to focusing on the issue in the original case—whether the patient was alcoholic and, therefore, unsuitable for anticoagulant treatment—the Petitioner's research and publications involved the evidence basis for anticoagulation treatment for deep venous thrombosis, pulmonary emboli, and 28 other medical indications generally. As such, the testimony should have been admitted as demonstrating rehabilitation and should have factored into the Decision.

(3) The Petitioner is also an expert in the field at issue (anticoagulation medicine) as established by documents admitted into evidence (Exhibits L, N, O, P, Q) and further delineated by Petitioner's testimony about his credentials as an expert in anticoagulation medicine (i.e., certification by American Board of Internal Medicine, subspecialty certification in the American Board of Hematology, three years practice as a staff hematologist in the LA County + USC Medical Center Hematology Department, and publication of multiple articles on the evidence-basis of anticoagulation for prophylaxis and treatment of 30 medical conditions in peer-reviewed medical journals, including Exhibits N – Q (transcript pg. 72 line 10 to pg 88 line 22). The court admitted into evidence the testimony and documentation presented to establish the Petitioner as an expert in anticoagulation medicine.

(4) Testifying as an expert witness in his own behalf, the Petitioner presented evidence that the standard of care in the 1998 case at issue (treating people with deep venous thrombosis with anticoagulant medications for three months) is inappropriate in general, not just because of the particular circumstances of the patient at issue (i.e., alcoholism). Petitioner attempted to testify about his articles, published in the peer-reviewed medical literature, showing that anticoagulants should no longer be used for deep venous thrombosis. Those articles demonstrated that anticoagulants increase the risk of death compared with non-steroidal anti-inflammatory drug treatment or no medication (Exhibits N and Q). No expert in anticoagulation medicine has rebutted the methodology, data analysis, or conclusions of these articles that are published in peer-reviewed medical journals.

(5) (FACTUAL FINDING #2) "…In support of his petition, Petitioner attempted to present evidence and argue that the facts upon which his revocation was based were faulty. Petitioner was not allowed to present such evidence or argue on that basis. (See Legal Conclusion 6.) Petitioner further contended that he has engaged in sufficient rehabilitative acts to warrant reinstatement."
(FACTUAL FINDING #3) "The Attorney General contended reinstatement was inappropriate because Petitioner failed to provide adequate evidence of rehabilitation."

The Petitioner did try to present evidence that the star witness against him in the original hearing committed perjury regarding the patient's alcohol consumption on which the case hung, because anticoagulants are contraindicated in alcoholics. This evidence was barred by res judicata, and we are not in this appeal contesting that ruling.

In part, the Petitioner's rehabilitative acts involved researching and publishing articles challenging the evidence-basis for anticoagulant drug treatment for deep venous thrombosis and 29 other FDA approved and off-label medical indications generally. In addition, the Petitioner presented three books on a variety of

medical topics, numerous articles published in peer-reviewed medical journals, and six letters from licensed physicians attesting to the value of the Petitioner's scholarship since the medical license was revoked. Two of the letters were from chief editors of prominent medical journals. The court's finding adopted by the Respondent that the Petitioner's research publications involved relitigating the original ALH ruling ignored the evidence presented of the Petitioner's rehabilitative scholarship in the field of anticoagulation medicine generally and in other areas of medical research.

By the submission of exhibits N – Q into evidence, providing expert testimony—although much abbreviated by the court—and the six physician declarations under penalty of perjury (Exhibits 4 – 9) of the Petitioner's scholarship since the revocation of his license; the Petitioner has met the burden of proof for evidence of adequate rehabilitation.

Neither the Attorney General nor the Respondent presented evidence that the Petitioner's medical research and publications had been vetted and found lacking by their experts in the highly technical areas of scholarship in which the Petitioner preformed his rehabilitation. The Attorney General's unsupported opinion on this crucial matter should not equate to a FACTUAL FINDING.

(6) (FACTUAL FINDING #9) "… In his testimony at the instant hearing, Petitioner clarified that the only thing he might do differently is that he would not start the patient on anticoagulant therapy in the first place."

The Petitioner's rehabilitative research and publications focused in part on the relationship of discontinuing anticoagulants to the subsequent occurrence of fatal pulmonary emboli. Petitioner's Exhibit O, published in a peer-reviewed medical journal, shows that the discontinuation of anticoagulants leads to an increased risk of thromboses including fatal ones due to increased tendency to clot over the next several weeks ("rebound hypercoagulability").

Petitioner testified (pg 96 line 11 – pg 98 line 25) that this research lead him to change his opinion about the optimal treatment of a future patient with deep venous thrombosis. Petitioner now believes that the patient at issue died because of rebound clotting due to the Petitioner's starting and then stopping the anticoagulants. Instead of beginning anticoagulant medications and then stopping them on day five as happened in the case at issue, the Petitioner testified that he would not begin anticoagulant medication at all. The Petitioner does not dispute that it is medically likely that the discontinuation of the anticoagulants caused the pulmonary embolism that resulted in the patient's death. However, the distinction between rebound hypercoagulability in causing the fatal embolism versus the absence of anticoagulation altogether is crucial to determining the optimal treatment of deep venous thrombosis in future cases.

The Respondent did not seek expert consultation to evaluate the scientific basis of Petitioner's opinion that rebound hypercoagulability rather than the failure to continue an anticoagulant drug for three months caused the patient's death.

(7) (FACTUAL FINDING #7d) "The evidence in the underlying proceeding further established that Petitioner's decision to discontinue the Heparin and Coumadin was an extreme departure from the standard of care and constituted gross negligence and incompetence."

A single incidence of malpractice involving a medical judgment call in a 25 year clinical career is rarely a cause for the revocation of a medical license, especially since only two anticoagulation medicine expert witnesses testified at the original hearing and the Petitioner's expert witness testified that, because of the clinical circumstances, stopping the anticoagulants was within the standard of care. This finding does not support the decision that the Petitioner's license reinstatement should be denied.

(8) (FACTUAL FINDING #8) "In his Petition, Petitioner asserts that his decision to discontinue the anticoagulants was based on his belief that the patient was an alcoholic and that according to the Physician's Desk Reference, and the Warfarin package insert, alcoholism is a contraindication to warfarin therapy. At the instant hearing, Petitioner made several attempts to explain his actions in 1998. More specifically, he attempted to submit evidence to establish that several facts upon which findings were made

in the underlying hearing were inaccurate, and evidence of research to establish that his actions in 1998 were, at least arguably, within the standard of care. The ALJ did not allow such evidence. (See Legal Conclusion 6.)"

See '(5)' above.

(9) (FACTUAL FINDING #7c) "The evidence in the underlying proceeding established that it was medically likely that the discontinuation of the anticoagulants caused the pulmonary embolism that resulted in the patient's death."

See '(6)' above.

(10) (FACTUAL FINDING #10) "…he has researched and written about anticoagulation and the standard of care, as it relates generally to the issues in the underlying proceeding..."

The issue in the underlying proceeding was whether the patient had a contraindication to the use of anticoagulant drugs such that the standard of care was not to use them. While the underlying case stimulated The Petitioner to study the evidence-basis for anticoagulants in the treatment of deep venous thrombosis, he originally had no intent to challenge anticoagulant therapy as the standard of care generally. Through conducting a survey of physician practices in treating patients with deep venous thrombosis, he discovered evidence that anticoagulant treatment as the standard of care for this condition is flawed and that anticoagulant treatment tends to increase rather than decrease the risk of deaths. None of Petitioners many peer-reviewed publications on the evidence-basis of anticoagulant treatment for deep venous thrombosis or 29 other medical indications relate in any way to the clinical issues of the patient in the underlying proceeding other than that the patient had a deep venous thrombosis.

(11) LEGAL CONCLUSION (#5 above (2)) disregards the Petitioner's testimony and admitted evidence. It presupposes the following three conditions that are not supported by the evidence or the FACTUAL FINDINGS:

- The medical standard of care for treatment of deep venous thrombosis patients in 1998 (i.e., to prescribe anticoagulant medications for a three month duration) is still the case in 2010.
- The Petitioner's testimony that, if he were confronted in 2010 with a patient with the same clinical circumstances as the 1998 deep venous thrombosis patient, his recommended treatment, although different from his clinical management of the 1998 patient, would still be expected to lead to the patient's death by pulmonary emboli.
- For the Petitioner's medical license to be reinstated the Petitioner had to testify that he made a medical error in stopping anticoagulants on day five in 1998 rather than continuing warfarin for three months; without that admission no other evidence of rehabilitation would be sufficient.

(12) Despite the fact that the court accepted the Petitioner's documentation and testimony establishing the Petitioner's expertise in anticoagulation medicine, the court allowed the Petitioner to give only cursory testimony about the contents of the relevant exhibits in evidence (Exhibits N – Q), for instance, saying, 'The specifics of the findings, for example, and the methodology used to conduct that research and make that paper, I would sustain objections to the relevance of that just because, again, I don't want to go into the substance of what you found necessarily. I want to know your actions. So research and writing an article is fine, good information for the Board to know. The specifics of your findings is information that I would sustain as irrelevant to this proceeding; okay?'(Pg 77 line 24 – pg 78 line 9) The court did not allow into evidence Petitioner's full explanation of how his research, peer-reviewed article publications, and lack of rebuttals to them determined his all important changed opinion about how he would treat a future patient with deep venous thrombosis. These documents challenge the standard of care for treatment of deep venous thrombosis that was undisputedly in effect in 1998. These articles are the reason that anticoagulation treatment is not the undisputed standard of care in the medical community in 2010. While the court stated that he would read (Exhibits N—Q) before rendering a Proposed Decision (pg 88 lines 11- 16 : "I'm going to look at the titles. I'm going to look at what's provided by the abstract. And understand that I'm going to sustain the objection. It's not needed to read the conclusions of the information that is in the document, and I will read that document"), no mention was made of the content

of those exhibits or to the Petitioner's testimony about the basis of his changed opinion of optimal deep venous thrombosis treatment in the Proposed Decision.

(13) Petitioner objected to the court's ruling forbidding him to refer to his research and published articles to fully explain his all important changed opinion concerning the optimal treatment of patients with deep venous thrombosis treatment (Pg. 78 line 19-20)—the opinion on which the court based its ruling in the case.

(14) The Respondent adopted the court's Proposed Decision and denied Petitioner's 'Petition for Reconsideration of the Proposed Decision' without commenting on the relevant exhibits in evidence (N – Q) or the abbreviated testimony of the Petitioner regarding the basis of his changed medical opinion in the case at issue.

(15) In 2010, a medical malpractice case could not be successfully brought against a physician who treated a patient with deep venous thrombosis without anticoagulants, because the Petitioner's articles (Exhibits N – Q) are in the peer-reviewed medical literature and are unrebutted by any anticoagulation medicine authorities. Therefore, Petitioner's articles would be admissible into evidence to defend any future physician treating any deep venous thrombosis patient without anticoagulants. This was not the case in 2000.

(16) Neither the court nor the Respondent could have evaluated Petitioner's highly technical medical research documents (Exhibits N – Q) without consulting experts in the fields of hematology and evidence-based medicine.

(17) The deputy attorney general failed to call any impartial specialists in hematology and evidence-based medicine to testify about the validity (or lack of validity) of Petitioner's expert testimony about his anticoagulation treatment research findings which led to his changed medical opinion about the optimal treatment for a patient with identical clinical circumstances as the patient at issue in the original hearing. That failure to provide appropriate professional analysis of the Petitioner's expert testimony and documentation alone should have been reason for the court to rule in favor of the Petitioner.

(18) Respondent likewise failed to retain impartial specialists in hematology and evidence-based medicine to provide expert consultation about the validity (or lack of validity) of Petitioner's changed medical opinion as evidenced in Exhibits N – Q on which the entire case hung.

(19) The issue of whether treatment with anticoagulant drugs should be considered the standard of care for patients with deep venous thrombosis and pulmonary emboli is of public health importance, because 1,017-3,525 people in the USA bleed to death each year due to anticoagulant medications (Exhibit N).

(20) The public health is also impacted by patients at risk for deep venous thrombosis and pulmonary emboli being treated with anticoagulants, because they are at increased risk of death from pulmonary emboli due to rebound hypercoagulation in the two months after stopping anticoagulant medications compared with such patients not prescribed anticoagulants. An estimated 5,000 patients per year in the USA die of rebound clotting (Exhibits P and Q). Indeed, the patient at issue most likely died of pulmonary emboli caused by rebound hypercoagulation due to the five day course of anticoagulants.

(21) Exhibits N – Q have made Petitioner's challenge to the supposed benefit to patients of anticoagulants for treatment of deep venous thrombosis is widely known among anticoagulation researchers worldwide, yet no anticoagulation researcher has issued a rebuttal and defended anticoagulants for this medical indication. Virtually all anticoagulation researchers except for the Petitioner are funded by anticoagulant producing drug companies and dependent to some degree on that funding for their academic medicine careers. Petitioner alleges that financial conflicts of interest in the field of anticoagulation medicine account for the lack of response of anticoagulation researchers to the Petitioner's challenges. Proper evaluation by impartial experts in hematology and evidence-based medicine can not only facilitate justice in the Petitioner's license reinstatement case, but it can also facilitate the transparent analysis of the Petitioner's published articles by drug regulators and impartial experts in evidence-based medicine. Given

the large number of bleeding and rebound hypercoagulability deaths due to anticoagulants for deep venous thrombosis, the public health would be served by the Respondent's hearing the case itself

(22) At one point in the Petitioner's testimony (Pg 36 line 3 – 8), the court said, '……what the Medical Board is interested in knowing about you is what actions you've taken since your discipline to show them and demonstrate rehabilitation. That doesn't require you to provide mea culpas to the Board if you feel that you didn't do anything wrong...'

However, the court's Proposed Decision hung entirely on the Petitioner's not providing 'mea culpas'. Aside from the fact that neither the court nor the Respondent engaged expert consultation and testimony to properly determine whether the Petitioner's changed medical opinion about the optimal treatment for deep venous thrombosis is or is not in accordance with the standard of care in 2010, a single erroneous opinion should not make the Petitioner ineligible for medical license reinstatement. Top medical experts have disagreed with each other frequently about optimal medical treatments in challenging clinical situations.

(23) Qualified medical experts often differ about the value of tests and treatments including anticoagulation treatments. Given the lack of uniformity of medical opinions, many medical experts advocate systematic reviews of the medical literature as the best source of evidence to guide clinical decisions and determine standards of care. As a result of ongoing debate among experts and of the publication of new systematic reviews, standards of care change over time. For example, one study (*Ann Intern Med.* August 21, 2007;147(4):224-233) tracked 100 recommendations for evidence-based "best practices guidelines" based on systematic reviews of the medical literature published in prestigious medical journals. Within 5 1/2 years, half were no longer considered valid. Peer-reviewed medical journals published the Petitioner's three systematic reviews of the medical literature on anticoagulation prophylaxis and treatment topics (Exhibits N, O, and Q), finding many best practices guidelines in anticoagulation medicine invalid.

(24) The Respondent adopted the court's ruling that the Petitioner's changed opinion about deep venous thrombosis treatment was erroneous without evaluating Exhibits N – Q. The Respondent tacitly concurred that holding that single erroneous medical opinion makes the Petitioner ineligible for medical license reinstatement. This is a failure to exercise discretion.

8. Petitioner meets all of the qualifications for a physician's and surgeon's certificate established by law. Petitioner duly applied in 1977 for a physician's and surgeon's certificate, in compliance with all statutes and administrative regulations governing the application. Petitioner applied for the reinstatement of the revoked medical license on March 3, 2009.

WHEREFORE, Petitioner prays judgment as follows:

(1) for an alternative writ of mandate directing Respondent to set aside its order of April 22, 2010, denying the reinstatement of Petitioner's physician's and surgeon's certificate, and to itself hold a hearing (Section 11517, Government Code (option #3, i.e., decide the case itself upon the record, including the transcript with the introduction of new evidence) to reconsider whether Petitioner is entitled to receive a physician's and surgeon's certificate as applied for or in the alternative to show cause why a peremptory writ of mandate to the same effect should not be issued.

Attorney representing the Petitioner to be determined before the hearing.

VERIFICATION

I, David K. Cundiff, am the Petitioner in the above-entitled proceeding. I have read the foregoing petition and know the contents thereof. The same is true of my own knowledge except as to those matters which are therein alleged on information and belief, and as to those matters, I believe it to be true.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.
May 24, 2010

_____ [*signature*]

Appendix #382

SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF LOS ANGELES

Supporting Petition for Writ of Administrative Mandamus [Code Civ. Proc. §§ 1094.5]

David K. Cundiff Petitioner, vs. California Medical Board Respondent, Attorney General Edmund G. Brown, Jr. Deputy Attorney General Klint McKay Real Party in Interest.	)))))))))))	NO. 27-2009-197832 OAH No. 2009090479 MEMORANDUM OF POINTS AND AUTHORITIES [*Code Civ. Proc. §§ 1094.5*(; *Cal. Rules of Ct., Rule 8.486*)] Date submitted : May 24, 2010 Time: 4:00 pm Location: 320 West Fourth Street, Room 630 Los Angeles, CA 90013 Judge: Daniel Juarez Date Action Filed: April 22, 2010 Hearing Date: pending

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A WRIT OF MANDATE SHOULD ISSUE TO COMPEL RESPONDENT TO RECONSIDER PETITIONER'S DENIAL OF MEDICAL LICENSE REINSTATEMENT BY FULLY EVALUATING EVIDENCE OF REHABILITATION SUBMITTED BY THE PETITIONER, BECAUSE RESPONDENT'S FAILURE TO DO SO CONSTITUTES AN ABUSE OF DISCRETION, AND PETITIONER IS BENEFICIALLY INTERESTED AND HAS NO PLAIN, SPEEDY, AND ADEQUATE REMEDY IN THE ORDINARY COURSE OF LAW.

California Code of Regulations, title 16, section 1360.2 states in pertinent part:

When considering a petition for reinstatement of a license, certificate or permit holder…the division or panel shall evaluate evidence of rehabilitation submitted by the petitioner considering the following criteria:

a) The nature and severity of the act(s)…under consideration as grounds for denial.

e) Evidence, if any, of rehabilitation submitted by the applicant.

Administrative mandate proceedings are governed by *Code Civ. Proc. § 1094.5*.

The Petitioner alleges that the California Medical Board's adjudicatory decision represented a prejudicial abuse of discretion [*Code Civ. Proc. § 1094.5(b)*]. Abuse of discretion may be established by showing any of the following [*Code Civ. Proc. § 1094.5(b)*]:

- The agency failed to proceed in the manner required by law.
- The agency's order or decision is not supported by the findings.
- The agency's findings are not supported by the evidence.

The Petitioner alleges that the Board's decision is not supported by the findings and that its findings are not supported by the evidence. Supplemental points and authorities will be presented before the hearing.