William F. Gutierrez, Bar No. 148668
TAYLOR & GUTIERREZ, LLP
1212 Broadway, the Penthouse
Oakland, CA 94612
(510) 873-8750 tel.
(510) 893-3143 fax

Attorney for *Amicus Curiae*
Association of American Physicians and Surgeons, Inc.

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF SACRAMENTO

ROBERT SINAIKO, M.D., Petitioner, v. MEDICAL BOARD OF CALIFORNIA, Respondent.	No. 99 CS 02275 ***AMICUS CURIAE* BRIEF OF ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, INC. IN SUPPORT OF PETITIONER ROBERT SINAIKO, M.D.** Before: The Honorable Ronald Robie Dept.: 41 File Date: 10/99 Trial Date: Administrative Mandamus

The Association of American Physicians and Surgeons ("AAPS") appears as *amicus curiae* to address the general question: Can the Medical Board of California ("MBC") properly discipline a physician for "unprofessional conduct" under Business & Professions Code section 2234, when the physician in good faith supplements conventional treatment with innovative procedures that find a good faith basis in medical research? Specifically, AAPS challenges the MBC's decision

to discipline Dr. Sinaiko for evaluating in good faith whether his patient L.T.S.'s diagnosed Attention Deficit and Hyperactivity Disorder ("ADHD") was in part caused by allergic processes, where L.T.S. was already taking Ritalin under the care of another doctor and Dr. Sinaiko made no attempt to discontinue that treatment.

This question should have been answered by deferring to the judgment of the treating physician, Dr. Sinaiko. Instead, the MBC labeled Dr. Sinaiko's practices "unprofessional" and revoked his license[1] by measuring his innovations against the average or routine practice--a standard intended in this case to condemn a broad range of medical theories the MBC labels "unscientific," but which, if applied more broadly, will chill the exercise of independent medical judgment by all physicians. The use of this standard lacks any justifiable legal or logical basis and, if left uncorrected, it will stifle advances in the medical community, reduce patients' abilities to make informed choices about their health care and lead to a *reduction* in the quality of health care in the state.

Moreover, the decision of the MBC (the "Decision") wrongfully revokes Dr. Sinaiko's license based on alleged "economic," rather than actual medical harm. Decision at para. 79. This is an arbitrary and capricious basis for de-licensing where negligence is alleged, and must be reversed. The United States Supreme Court has noted that due process operates to "exclude everything that is arbitrary and capricious in legislation affecting the rights of the citizen," including the arbitrary and capricious de-licensing of physicians. Dent v. West Virginia, 129 U.S. 114, 124 (1889). "'When we consider the nature and the theory of our institutions of government, the principles upon which they are supposed to rest,

[1] The order is, however, stayed for 5 years during which time Dr. Sinaiko is subject to expansive

and review the history of their development, we are constrained to conclude that they do not mean to leave room for the play and action of purely personal and arbitrary power.'" Id., quoting Yick Wo v. Hopkins, 118 U.S. 356, 369 (1886). Economic harm is unavoidable in all but gratuitous medical treatments. In the absence of fraud, it should be up to the buyer alone to decide how he or she wishes to spend money, just as in any other commercial context. The economic aspects of medical care should be sorted in the free market, not by a licensing board through the draconian penalty of exclusion of a credentialed physician.

I. The Decision is Flawed in its Total Rejection of Dr. Sinaiko's Methodologies

In its zeal to condemn Dr. Sinaiko, the MBC relies on practitioners who refuse to acknowledge possible merit in Dr. Sinaiko's treatment methodologies and in so doing, the MBC has taken sides—and very possibly the wrong side—in an ongoing medical debate.

Reading such comments in the MBC's Answer as "the evidence…clearly and convincingly, leads to the factual conclusion that petitioner adheres to many of the practices espoused by Clinical Ecologists", at 11:20-22, one cannot help but sense a bit of McCarthyism at work--a witch hunt of sorts trying to find Dr. Sinaiko guilty by association. In fact, although the Decision nowhere mentions clinical ecology or environmental medicine, the MBC devotes a substantial portion of its Answering Brief to building up the theories, only to strike them down as "unscientific in [] concept and unproven as a medical diagnosis." Answer, at pgs. 1-13. To the extent the MBC offers the discussion to provide context, the Court should know the context is incomplete. In truth, at least one court has suggested

probationary terms.

that medical treatment under these theories is proper and, more importantly, to AAPS' knowledge, no Court has ever ruled that treatment pursuant to these theories is negligent. In fact, with respect to the treatment of ADHD, the Federal Government has even suggested that the theories have merit in a small percentage of cases. In this context, the Decision presents an unjustified and *extreme departure* from existing precedent.

A. Case Law Precedent in California Suggests that Investigative Treatment of MCS is Proper

Multiple chemical sensitivities ("MCS"), or clinical ecology as it is sometimes known, is not new to California courts. In Ruth v. Kizer (1992) 8 Cal.App.4th 380, the Department of Health and Human Services disputed its obligation under Medi-Cal to pay for treatment of MCS. Id, at 382-383. The Department's primary argument against the obligation was that "MCS does not exist as a recognized medical diagnosis." Id., at 385.

Then, as now, there were divergent views in the medical community over MCS. The Ruth court noted the Social Security Administration's policy to evaluate, "all of the claimant's symptoms, signs, and laboratory findings…to determine if there is a medically determinable impairment…," id, at pg. 389, fn. 3, as well as the observations of practicing academics that it was "increasingly evident…that there exists a not insignificant minority of patients with MCS" with "recurrent and toxicologically inexplicable symptomatic reactions to quite low levels of common airborne substances." Id. Even skeptics like the California Medical Association recognized that, "certain environmental chemicals and allergens produce well-defined syndromes in humans and some people suffer from illnesses that are not readily diagnosed and for which only supportive therapy exists." Id.

The Ruth Court did not answer the Department's primary question, but instead ruled in the Department's favor because the services were deemed investigative and the record did not substantiate the right to compensation for such services. The court remanded the case for further consideration as to whether the treatment costs should be compensated as investigational services.

Ruth v. Kizer is the last reported decision by a court of this state addressing MCS. There has been no intervening case law precedent or statutory enactments condemning MCS as a diagnosis, or deeming the treatment of patients with symptoms identified with chemical sensitivities to be negligent or improper. Thus, the Court must undertake the anomalous task of upholding an MBC order revoking a doctor's medical license for investigative treatments, the cost of which may be compensable under Medi-Cal according to established case precedence--precedence established at the same time Dr. Sinaiko was providing treatment.[2]

B. The Recognition and Treatment of MCS has Never been Held Negligent by Any Other Court

The MBC did not pursue the associational indictment between Dr. Sinaiko's practices and MCS without reason--the validity of the MCS or related illnesses as diagnoses has been litigated elsewhere. In fact, the MBC's lead expert witness, Dr. Abba I. Terr, is cited in at least eight reported decisions nationwide, invariably as an ardent opponent of MCS.[3]

---

[2] This anomaly is akin to the unresolved dichotomy in the paragraph 77 of the Decision that recognizes MCS-type illnesses are compensable disabilities with various government entities, but disciplines Dr. Sinaiko for pursuing innovative techniques that try to investigate or at least ameliorate the symptoms. The MBC would have those afflicted with these illnesses pour their disability payments into the coffers of psychiatrists, only to have them diagnose that it is "in their heads." That is, until the MBC realizes that because it has ruled these afflictions "do not have a known cause" either mental or physical, Decision at para. 77, it is improper for psychiatrists to be treating it as well. These patients will have no recourse.

[3] See, e.g., Frank v. New York, 972 F.Supp. 130 (ND NY, 1997); Carlin v. Rfe Indus. 1995 U.S. Dist. Lexis 19035 (ND NY, 1995); Schmaltz v. Norfolk & W. Ry., 878 F.Supp.1119 (ND IL,

None of these cases involve doctor discipline, however. In fact, AAPS could not find a single reported case nationwide where a doctor was disciplined for treating patients for MCS or seeking allergen-based explanations for illnesses with unknown or imprecise etiologies. Nor could AAPS find any instance where such actions were found negligent or unprofessional. Rather, the cases invariably deal with the issues in a liability context--where the threshold question is whether the defendant (an insurer, tortfeasor, etc.) is liable to compensate a plaintiff for illnesses the plaintiff ascribed to factors for which the defendant (or its insured) was responsible. In Frank v. New York, supra, 975 F. Supp. 130, for example, the court held inadmissible the testimony of various experts on MCS because the science of MCS' etiology had not yet progressed to the point where it was sufficiently reliable to assist a trier of fact, jury or judge. Id., at pg. 136. Pertinently, the court observed, "the controversy surrounding MCS remains to be 'settled by the methods of science rather than by the methods of litigation.'" Id., quoting Sanderson v. Int'l Flavors, 950 F. Supp. 981, 1002 (ND CA 1996).

The debate continues over MCS because the illnesses are real. Dr. Abba Terr**,** for example, has said the following about claimed sufferers of MCS:

> Their symptoms are absolutely real. I want to make that clear. What they are experiencing is, I don't believe they make it up. I think they are relating exactly how they feel, and they do suffer from it, the concept that it was caused by chemicals is the belief, not the reality of their symptoms.

Bahura v. S.E.W. Investors, supra, 754 A.2d at 938. The Decision of the MBC acknowledges the symptoms are real. Decision, at para. 74. What drives Dr. Terr

---

1995); Burnham v. Rohnert Park, 1992 U.S. Dist. Lexis 8540 (ND CA, 1992); Dwight v. Humana Hospital Alaska, 876 P.2d 1114 (1994); Bahura v. S.E.W. Investors, 754 A.2d 928 (DC, 2000); Fuyat v. Los Alamos Nat'l Lab., 811 P.2d 1313 (NM, 1991); and Skoogfors v. Haverstick-Borthwick Co., 44 P.A. D & C.4th 1. (See Exhibit A attached.)

and similar detractors is they not satisfied with the proof of the theory generated.[4]

These difficulties of proof have plagued MCS proponents in the courts, but the proponents of MCS theory have never before been sanctioned as unprofessional or negligent in their efforts--until now. The MBC has taken the case against MCS to an unprecedented level and it now seeks the imprimatur of this Court for its actions. The Court should reject the MBC's attempt to use its powers to wage a battle against practitioners like Dr. Sinaiko, not only because the MBC has applied a flawed standard that ignores well-established precedence, but also because it denies the right of practitioners to advance their fields. This is a medical dispute that should be resolved with "methods of science," rather than "methods of litigation," as the MBC has sought to do.

C. The Treatment of ADHD is Particularly Controversial Because the Disease Has No Known Cause and the Prevailing Methods of Treating the Disease have Significant Potential Side Effects.

The MBC Decision errs most conspicuously in its indictment of Dr. Sinaiko's treatment of L.T.S. The Decision sets forth in crystal clarity that the dispute over the treatment of L.T.S. arose directly out of a larger custody battle between the parents of L.T.S. Decision, para. 4-25. On the one hand was

[4] AAPS calls the Court's attention to Dr. Terr because, in addition to conflicts noted in the Decision, the tenor and purported certitude of his testimony surpassed all of the other MBC witnesses. While none of the others ascribe to allergen, food or chemical sensitivities explanations for ADHD or other illnesses of unknown etiology, none would unqualifiedly dismiss the theories upon which Dr. Sinaiko based his treatments. Dr. Levin, for example, when asked whether the community of child behavioral or developmental specialists widely accepted the medical concept that associates food molds or other allergic processes with ADHD, responded, "Usually No." Answer, at pg. 55:13-16. In other words, sometime yes. And again, when discussing the establishment's response to these theories, he testified, "They were pretty much broadly dismissed as irrelevant in the diagnosis of ADHD for the overwhelming majority of patients… ." Answer, at pg. 56:1-2. In other words, the theories were not dismissed as irrelevant in a small minority of patients. Similarly, Dr. Miraglia, when discussing the correlation of diet to ADHD testified that, "Most of the studies cited in the Feingold diet have been poorly controlled with too small numbers, …, the predominance of those studies show no effect of diet on behavior. Answer, at pg. 61:21-24. In other words, some of the studies were well controlled and a portion (short of a predominance) showed some effect of diet on behavior.

L.T.S.'s father, who sought conventional treatment, which resulted in L.T.S. being treated with Ritalin. Id. On the other was his mother, who sought from Dr. Sinaiko alternative explanations and treatment for ADHD. The MBC's bias for conventional Ritalin treatment rings clear in the Decision, but that should not have controlled the issue.

To this day, while there are scientific studies suggestive of causes of the disorder in specific cases, no uniform explanation has emerged and the preferred methods of treating ADHD remain controversial. The prevalent use of Ritalin, for example, has been a lightning rod for controversy.

The Physician's Desk Reference ("PDR") describes Ritalin (or methylphenidate hydrochloride) as a "mild central nervous system stimulant" the mode of action of which "is not completely understood." Despite this seemingly benign description, the PDR recognizes that the drug has potentially severe side effects. It cautions that the drug "should not be used in children under six years, since the safety and efficacy have not been established" and that data on the "safety and efficacy of long-term use of Ritalin in children are not yet available." It goes on to cite a whole host of concerns associated with the use of the drug, any one of which would give a parent pause to consider whether their child should be on the drug: nervousness, insomnia, hypersensitivity, skin rash, fever, anorexia, nausea, headache, dizziness, palpitations, visual disturbances, blood pressure and pulse changes, angina, cardiac arrhythmia, convulsions/seizures, abdominal pain and weight loss. In more rare instances, there have been reports of Tourette's Syndrome, Toxic Psychosis and abnormal liver function. See also Vastag, ***Pay Attention: Ritalin Acts Much Like Cocaine***, JAMA 286 (905-06), Aug. 22/29, 2001 ("[T]he drug [Ritalin] acts much like cocaine, albeit cocaine dripped through

molasses.") (citing *J. Neurosci* 2001; 21; RC121); Moll, Hause, Ruther, Rothenberger & Huetter, *Early Methylphenidate Administration to Young Rats Causes a Persistent Reduction in Striatal Dopamine Transporters*, J. Child & Adolescent Psychopharmacology 11(1):15-24, 2001 Spring (observing "long-lasting changes in the development of the central dopammergic system caused by the administration of methylphenidate during early juvenile life").

These are just some of the known potential complications--the unknown, but suspected possible adverse reactions are more troubling. Studies carried out on mice showed possible carcinogenic qualities to the drug and, while specific studies of Ritalin had not yet been conducted, growth suppression has been observed in long-term use of stimulants in children. Finally, there is a definite concern of increased potential for substance abuse. The unknown effects of stimulants like Ritalin led the National Institute of Mental Health ("NIMH"), part of the U.S. Department of Health and Human Services, to observe in February 2000 that there exists "a major gap in our knowledge…on the long-term effects" of such treatments and to undertake a study to seek answers. See Exhibit B; see, also, Cherland, Fitzpatrick, *Psychotic Side Effects of Psychostimulants: a 5-year Review*, Canadian J. of Psychiatry 44(8): 811-13, 1999 Oct. ("Awareness of the potential for psychotic side effects from stimulant medications is important when prescribing for children.").

The MBC overlooks all of these questions about the safety of Ritalin and instead persecutes a doctor for employing a food elimination regimen and allergen-detection protocol that present no credible threat of harm because it claims that there was no basis for his actions. But a simple reference to the NIMH website, www.nimh.nih.gov, shows that even our own federal government

is educating the public to the possibility that Dr. Sinaiko's theories may be correct at least in some cases.

Attached as Exhibit C is a downloaded version of a pamphlet the NIMH now distributes to the public regarding ADHD, which was printed in 1996, three years *after* Dr. Sinaiko ceased treating L.T.S. At page 6, under a section entitled "What Causes ADHD?", the NIMH advises that "since no one knows what causes ADHD, it doesn't help parents" to look for causes. However, it goes on to say,

> Another theory was that refined sugar and food additives make children hyperactive and inattentive. As a result, parents were encouraged to stop serving children foods containing artificial flavorings, preservatives, and sugars. However, this theory, too, came under question. In 1982, the National Institutes of Health (NIH), the Federal agency responsible for biomedical research, held a major scientific conference to discuss the issue. After studying the data, **the scientists concluded that the restricted diet only seemed to help about 5 percent of children with ADHD, mostly either young children or children with food allergies**.

(Emphasis added.) In other words, a restricted diet was found to help about 5 percent of the children in the study, particularly those with food allergies! Perhaps Dr. Terr went too far when he testified that, "As a practicing physician, regardless of specialty, Dr. Sinaiko either knew or should have known that ADHD is a psychiatric condition. In particular as a board certified allergist/immunologist practicing in that specialty, he should have known that ADHD is not an allergic disease." Answer, at 34:25-28; see, also, *Sapira's Art and Science of Bedside Diagnosis*, 2nd Ed. 2000, at 609 ("Some observe that certain children with the diagnosis of ADHD seem to be markedly worse after ingesting food containing excitotoxins such as aspartame (R. Blaylock, personal communication, 1999).") The role of endogenous neurotransmitters as well as exogenous agents is not well

studied. The physician should take a careful history and make meticulous observations, remembering the enjoinder of Hippocrates that the physician should strive to know 'what man is in relation to the articles of food and drink, and to his other occupations, and what are the effects of each of them to every one' (Hippocrates, *On Ancient Medicine*, 20).").

Against this background, the deficiency of the Decision is apparent—it condemns Dr. Sinaiko's methodologies by invoking only one side of a legitimate medical debate and without ever acknowledging that a statistically significant portion of the medical community is in his corner. This approach may be justified if the issues could be sorted with hard proof, but they cannot. The cause of afflictions like ADHD remain a mystery to modern medicine, and none of the "experts" the MBC paraded before administrative law judge could prove otherwise. They were left to sling barbs at Dr. Sinaiko's innovative efforts while hiding behind the mantle of majority practice. It is not the role of the MBC to resolve disputes of this nature--the rule of law should have intervened to avoid this unjust result. It did not because the Decision applies a flawed standard.

II. Dr. Sinaiko's Treatment of L.T.S. was Not Negligent

The MBC's authority to take action against Dr. Sinaiko arises under California Business & Professions Code section 2234. It directs that actions be taken against "any licensee who is charged with unprofessional conduct." Unprofessional conduct is given various non-exclusive definitions, one of which was cited as grounds for discipline against Dr. Sinaiko--repeated negligent acts. Bus. & Prof. Code § 2234, subd. (c).

A. Professional Negligence Cannot Equate to an Evidentiary Standard

The term "negligence" is not defined in Section 2234. Petitioner posits

that the MBC wrongly applied a negligence standard akin to the Kelly-Frye standard and, from a fair read of the Decision and record, there appears to be merit to this claim. The attorney general questioned witnesses in a manner designed to elicit opinions on this standard. See, e.g., Answer at 66:14-16. The MBC invoked the standard in its answer. Id., at 60:27-28. And, perhaps most tellingly, the Decision rejected in toto the opinions of Dr. Sinaiko's experts on the basis they were not qualified to provide testimony on the matters at issue. Decision, at para. 77. If the issue before the administrative law judge was whether reasonable support could be found in medical theory and literature for Dr. Sinaiko's practices, the testimony would have been undeniably relevant and admissible. Only when the question is narrowly defined as what has been widely accepted or generally recognized does the testimony on innovative practices become irrelevant or unqualified.

There is of course no authority for equating negligence with a Kelly-Frye evidentiary standard, and for good reason. While only relevant evidence is admissible in the legal context, Evidence Code §§ 210, 350 and 351, courts are cognizant of the fact that otherwise relevant scientific evidence can give a "misleading aura of certainty," and deserves extra judicial caution; accordingly, such evidence must be barred from consideration when it lacks sufficient indicia of reliability. People v. Kelly, 17 Cal.3d 24 (1976). Courts have applied this rule to bar unproven scientific techniques offered to prove guilt in criminal cases. See People v. Leahy, 8 Cal.4th 587 (1994) (Supreme Court approved a lower court order excluding evidence of unproven horizontal gaze nystagmus field sobriety test used by officer to conclude the defendant was driving under the influence). It has also been applied to preclude expert medical testimony on causation in tort

cases. See Frank v. New York, supra, 972 F.Supp. 130 (court rejected expert testimony that MCS was caused by exposure to pesticides and other agents at State Campus as experts could not state with any certainty cause of MCS).

An exclusionary rule makes eminent sense in those contexts. In Leahy, for example, the defendant's civil liberties were at stake and the People's case rested in large part upon an HGN test that had some supporters, but no proven reliability in the scientific community. A criminal conviction cannot stand on tests that may or may not be correct, when the State is required to prove its case beyond a reasonable doubt. Similarly, a defendant cannot be held liable for a plaintiff's claimed injury when experts cannot reliably identify the source of injury or causation. In these cases, the evidentiary standards ensure a level of certainty that will avoid violence to well-established standards of proof--they do not chart standards of conduct.

To elevate an evidentiary rule into a standard of conduct would do great violence to the advances brought by those endeavoring to establish the reliability of alternative techniques or theories. Take the case of aspirin, for example. In the 5th Century B.C., Hippocrates discovered that a bitter powder made from the bark of a willow tree could ease pain and reduce fever in his patients. The active ingredient in the bark, salicin, eventually was isolated, synthesized and combined with a buffer approximately a century ago to become aspirin. Today, it is perhaps the most widely used drug in the world. See "Aspirin: A New Look at an Old Drug," Ken Flieger, *FDA Consumer*, (Feb. 1994), attached as Exhibit D. Despite its prevalent use, the medical profession to this day does not know precisely how aspirin works. And, until the 1970s, when British pharmacologist, Sir John Vane, discovered through his Nobel Prize-winning research that aspirin achieved some

of its effects by blocking the release of prostaglandins, the medical community could not even a venture a guess. Id. Despite this uncertainty over the drug, its beneficial uses continue to expand as scientists and the medical profession evaluate evidence that suggests it may help prevent cardiovascular disease, control high blood pressure, and prevent some forms of colon cancer and other afflictions. Id.

The medical profession is steeped in the tradition of applying treatments the efficacy of which has been substantiated through empirical data but has not yet garnered widespread support. In fact, it is through this process that many common remedies have gained widespread acceptance. For the MBC to apply a standard of conduct on Dr. Sinaiko, or any other physician, which restricts his practice to treatments that have gained widespread support undercuts the fundamental tenets of professional practice. How far would we have come if we defined negligence or unprofessional conduct as the failure to comport with theories that have been widely accepted or generally recognized? Plainly, rules designed to ensure that scientific theories or techniques are sufficiently reliable for legal certainty are ill-suited for determining whether a professional's actions are reasonable.

B. The Applicable Standard is Whether a Doctor's Actions Were Taken in Good Faith and Were Reasonable Based on all Relevant Circumstances--A Standard Dr. Sinaiko Met

Despite the attention the attorney general gave to the "widely accepted" standard at trial, the MBC makes no attempt to support it in its brief, commenting instead that Dr. Sinaiko was properly found negligent for departing "from the ordinary standard of practice." Answer, at 27:18-24. To the extent this means that a doctor is negligent unless he or she treats patients in conformance with majority

practices, it is difficult to distinguish this argument from the flawed Kelly-Frye analysis discussed above and it should be rejected for the same reason.

Perhaps the MBC relies on Instruction 6.00.1 of the Book of Approved Jury Instructions, 8th Ed., which defines a physician's duties to include the duty "to use the care and skill ordinarily exercised in like cases by reputable members of the profession practicing in the same or similar locality under similar circumstances." But, for the MBC to equate this definition with a rigid obligation to conform to majority practices lacks sound reasoning.

Indeed, even Instruction 6.03 of the same volume defines an exception that is sufficiently broad to practically subsume the rule:

> Where there is more than one recognized method of diagnosis or treatment, and no one of them is used exclusively and uniformly by all practitioners of good standing, a physician is not negligent, if in exercising [his][or][her] judgment, [he][or][she] selects one of the approved methods which later turns out to be a wrong selection, or one not favored by certain other practitioners.

Applying this exception to the case of Dr. Sinaiko renders the Decision improper--Dr. Sinaiko's respected experts would opine, and NIMH report confirms, that Dr. Sinaiko's attempt to diagnose a dietary or allergen cause of ADHD had received recognition in the scientific community and that his methods were used by practitioners in good standing. That he chose to employ these methods of diagnosis, rather than tell L.T.S.'s mother she had no choice but to allow her child to go untreated or accept the troubling side effects of Ritalin, was a matter subject to his sound judgment, regardless of whether Dr. Terr or the anti-MCS crowd disfavors them.

There is no need, however, to invoke exceptions in Dr. Sinaiko's case because his decision to explore alternative explanations for L.T.S.'s ADHD

symptoms was fundamentally not negligent. There is no magical negligence standard that applies solely to medical professionals:

> "[N]egligence is conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm." (Rest.2d Torts, § 282.) Thus, as a general proposition one "is required to exercise the care that a person of ordinary prudence would exercise under the circumstances." [Citations.] Because application of this principle is inherently situational, the amount of care deemed reasonable in any particular case will vary, while at the same time the standard of conduct itself remains constant, i.e., **due care commensurate with the risk posed by the conduct taking into consideration all relevant circumstances**.
>
> * * *
>
> With respect to professionals, their specialized education and training do not serve to impose an increased duty of care but rather are considered additional "circumstances" relevant to an overall assessment of what constitutes "ordinary prudence" in a particular situation. Thus, the standard for professionals is articulated in terms of exercising "the knowledge, skill and care ordinarily possessed and employed by members of the profession in good standing ... ." (Prosser & Keeton, Torts (5th ed. 1984) The Reasonable Person, § 32, p. 187.)

Flowers v. Torrance Memorial Hosp. Med. Center, 8 Cal.4th 992, 997-998 (1994). The focus in any professional negligence action is whether the doctor used due care given the risks posed under the circumstances taking into consideration all relevant circumstances.

The circumstances presented to Dr. Sinaiko at the time he treated L.T.S. included all of the following:

- L.T.S. was already under the care of another physician, who was administering conventional therapy involving Ritalin
- there are many known and unassessed dangers involved in the use of Ritalin that would give any parent cause to be concerned with its continued use if it was not medically necessary
- there was (and is) no generally accepted cause of ADHD in all cases

- Federal agencies responsible for biomedical research had undertaken studies that showed a restricted diet helped about 5 percent of children with ADHD, and particularly cases involving young children or those with food allergies, thereby supporting the conclusion that food allergies could cause or exacerbate the symptoms of ADHD in a small percentage of cases
- undertaking tests to determine whether L.T.S.' diagnosed ADHD was caused or exacerbated by food allergies which could facilitate control of the symptoms had as much as a five percent chance of success
- if he did not try to determine whether L.T.S. fell in the narrow range of cases where ADHD was due in part to food allergies, L.T.S. and his mother would have no choice but to either suffer with the symptoms of the disorder or surrender to stimulant therapy and the risks of severe side effects it presents
- the protocol used to identify whether food-related allergies were involved in L.T.S.' case presented no appreciable risk of harm

Viewed in this context, the conclusion emerges that the only "reasonable" course for Dr. Sinaiko was to try to rule out food allergies as a causative factor in L.T.S.' case. In fact, because the only identified cause of ADHD that had any support in the medical literature at that time was food allergies, the only standard of practice against which Dr. Sinaiko's efforts should have been measured is the standards of practice employed by those trained in identifying food allergen influences on ADHD. Not only did the MBC not employ this standard, it persecuted Dr. Sinaiko through the use of "experts" who either were not aware of or rejected the body of evidence supporting Dr. Sinaiko's methodologies theories in favor of doing nothing--de Tocqueville's tyranny of the majority at work.

One might be tempted to conclude that it is practitioners like Dr. Terr who are negligent for not exploring in their patients whether they fall within the narrow category of cases where diet restrictions provide help. But to follow this path would be folly, because it merely presents the reverse side of the same issue. Just as Dr. Sinaiko should not have been persecuted for his exercise of judgment in employing emerging methodologies, neither should the average practitioner be

held liable for failing to pursue disputed theories.

Where, as here, there is a good faith dispute in the medical community over the merits of a particular methodology or treatment, the propriety of employing or refusing to employ that methodology should be resolved by "methods of science," not "methods of litigation." The MBC utterly failed to acknowledge or apply this accepted standard and the victim in this case was not only Dr. Sinaiko, but also the medical profession and public in general. See NNV v. American Association of Blood Banks, supra, 75 Cal.App.4th 1358, 1387 (where issues are subject to good faith debate in the medical and scientific community, the threat of liability for failure to adhere to prevailing standards could "hinder reconsideration of established standards," "skew scientific and medical debate," and cause reluctance "to recommend a new [preferable] standard that was still subject to debate [that] would not provide the same shield of liability.") None of these results are consistent with the MBC's goals.

III. The MBC Decision Unreasonably And Unconstitutionally Interferes With The Practice of Medicine

The purpose of the State Medical Practice Act (§ 2000 et seq.) is to assure the high quality of medical practice--to keep unqualified persons and those guilty of unprofessional conduct out of the medical profession. Shea v. Board of Medical Examiners, 81 Cal. App. 3d 564, 575 (1978). The Legislature's power to enact the Medical Practice Act or similar laws to protect the safety, health, morals, and general welfare of society is beyond question. Blinder v. Div. of Narcotic Enforcment, 25 Cal.App.3d 174, 179 (1972). It has the right to require

that those licensed to practice medicine be of good moral character, reliable, trustworthy, and not given to deception of the public or to the practice of imposing upon credulous or ignorant persons. Fuller v. Board of Medical Examiners, 14 Cal.App.2d 734, 741-742 (1936). However, because a physician has a vested property right in his or her medical license**,** due process requires that enacted laws not amount to arbitrary or unreasonable interference with the right to practice one's profession. Smith v. Board of Medical Quality Assurance, 202 Cal.App.3d 316, 326 (1988); Doe v. Bolton, 410 U.S. 179 (1973). Further, such laws must be "sufficiently clear to give fair warning of the prohibited conduct." Morrison v. State Board of Ed., 1 Cal.3d 214, 231-232 (1969) (noting at fn. 32 ambiguity in the terms "unprofessional conduct"). The MBC Decision does not meet these standards.

A. **Medical Professionals are Not on Notice that Medical Innovations Equate to Unprofessional Conduct**

Under the MBC's interpretation of the evidentiary record--that there is no scientific basis for Dr. Sinaiko's treatment--the Decision against Dr. Sinaiko amounts to the conclusion that he engaged in unprofessional conduct by failing to treat according to widely accepted practices and instead employing experimental techniques. AAPS is aware of no authority equating medical experimentation with unprofessional conduct. And, in fact, such a conclusion cannot be reconciled with the Human Experimentation Act, California Health & Safety Code § 24171.

In the Human Experimentation Act, the Legislature declares that "medical experimentation on human subjects is vital for the benefit of mankind" and

acknowledges the corresponding "right of individuals to determine what is done to their own bodies." Certainly, medical experimentation can be performed negligently. "There is…a growing need for protection for citizens of the state from unauthorized, needless, hazardous, or **negligently** performed medical experiments on human beings." Cal. Health & Saf. Code § 24171, subd. (d). However, the clear import of the Human Experimentation Act is that medical experimentation is neither negligent, nor unprofessional by itself, and is encouraged so long as the safeguards imposed to protect individual rights (informed consent) are followed. In the face of this statutory scheme, the MBC cannot credibly conclude that medical professionals are on notice that experimentation, or innovative treatment efforts[5], are unprofessional. To hold otherwise would be Constitutionally unjust.

B. The MBC Acts Arbitrarily When It Regulates the Commercial Aspects of Patient Care in the Absence of Fraud

Second, because individuals do have a legislatively and constitutionally recognized right to determine "what is done to their own bodies" with respect to ameliorative treatment, it was arbitrary and unreasonable, and an abuse of state power for the MBC, to discipline a doctor in the absence of injury or at least a credible threat of harm. As discussed more fully below, the MBC Decision offers no credible evidence that Dr. Sinaiko exposed any of his patients to an unreasonable risk of physical harm. Further, AAPS is not aware of any precedent

[5] Dr. Sinaiko apparently did not engage in medical experimentation because the statutory scheme defines the terms to mean "the use of a drug or device…upon a human subject in the practice or research of medicine *in a manner not reasonably related to maintaining or improving the health of*

for the de-licensing of a physician based merely on alleged "economic harm."

It is well-established that "'unprofessional conduct'...must relate to conduct which indicates an unfitness to practice medicine." Shea v. Board of Medical Examiners, supra, 81 Cal. App. 3d 564, 575.

> The concept of "unfitness to practice medicine" must be understood by reference to the qualifications established by the State of California for licensure as a physician and surgeon, and the types of conduct which the Legislature and the courts have defined as grounds for discipline or loss of the professional license. (See, e.g., § 2234 [general definition of "unprofessional conduct"], 2236 [conviction of crime substantially related to the qualifications, functions or duties of a physician as unprofessional conduct], 2238 [conviction of federal or state laws regulating dangerous drugs and controlled substances as unprofessional conduct], 2239 [misuse or abuse of dangerous drugs, controlled substances or alcoholic beverages as unprofessional conduct], 2280 [practice of medicine while under the influence of narcotic drug or alcohol as unprofessional conduct], 2241 [furnishing drugs or controlled substances to an addict as unprofessional conduct], 2253 [procuring, aiding, or abetting an illegal abortion, except as authorized by the Therapeutic Abortion Act (Health & Saf. Code, § 123400 et seq.) as unprofessional conduct], 2271 [false or misleading advertising as unprofessional conduct]; Glover v. Board of Medical Quality Assurance (1991) 231 Cal.App.3d 203, 205-206 [physician's license revoked for repeatedly dispensing potentially lethal doses of prescribed medications for a patient who had attempted and ultimately succeeded at suicide using these medications]; Windham v. Board of Medical Quality Assurance (1980) 104 Cal.App.3d 461, 470 [physician convicted of evading $ 65,000 in taxes subject to discipline]; Shea, supra, 81 Cal.App.3d at pp. 578-579 [physician's license revoked because of improper sexual conduct with four patients, coupled with unwanted treatment without an adequate medical history]; Matanky v. Board of Medical Examiners (1978) 79 Cal.App.3d 293, 304-305 [physician's license revoked because he intentionally submitted several false and fraudulent Medicare claims for purpose of personal gain].)

Thorburn v. Dept. of Corrections, 66 Cal. App. 4th 1284, 1291, 78 Cal. Rptr. 2d 584, 589-90 (1998). The Thorburn Court emphasized a principle equally

---

the subject." Cal. Health & Saf. Code § 24174, subd. (a) (emphasis added). His treatment was reasonably related to maintaining or improving his patients' health.

applicable here: "We must also keep in mind that the statutory definition of 'unprofessional conduct' **must not be given an 'overly broad connotation' if it is to pass constitutional muster**." 66 Cal. App. 4th at 1291, 78 Cal. Rptr. 2d at 590 (emphasis added).

Unquestionably, the MBC can and should protect the public against unscrupulous individuals who under the guise of professional services wrongfully cause economic harm to the public. And the MBC in the past has exercised such powers. See, e.g., Fort v. Board of Medical Quality Assurance, 136 Cal. App. 3d 12 (1st App. Dist. 1982), where the Board disciplined a psychiatrist based on a billing dispute. The Court expressly relied on its finding that the physician "had authorized the false signing of his name to Medi-Cal claims, falsely stating that he had personally provided psychiatric services." Id. at 14.

The Fort decision recognizes the commercial aspect of medical treatment--doctors provide services in exchange for compensation from Medi-Cal, insurers or patients directly. As in other commercial contexts, the state may have a legitimate need to ensure that doctors do not prey upon the vulnerable or gullible by recommending or undertaking treatment for the purpose of defrauding patients or their insurers. But, where there is no evidence of fraud or undue advantage, the state's charge to protect the health and welfare of society is not served by injecting itself into the purely commercial aspects of the patient/doctor commercial relationship. See State Board of Examiners of Florida v. Rogers, 387 So.2d 937 (Fl. 1980); see, also, Cal. Health & Saf. Code §§24176 and 24172, subd. (j), (imposing penalties on doctors for medical experimentation only in the

absence of informed consent, meaning "without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence.").

Most physicians, acting professionally, are vulnerable to charges of economic harm in connection with patients who do not respond to treatment ranging from chemotherapy to prescription drugs. But patients are generally willing to pay the expense for such treatment, even if not as successful as hoped, and the law recognizes their inherent right to make such decisions. The Board should not deny patients that right, and revoke the license of the treating physician, absent a showing of fraud or a threat of substantial medical harm.

C. The MBC Order Improperly Found Dr. Sinaiko Put L.T.S. At Risk By Administering Amphotericin B.

One final point that merits comments is the MBC's determination that Dr. Sinaiko put L.T.S. at risk by administering Amphotericin B. The MBC's Order against Dr. Sinaiko appears to have based its decision to discipline Dr. Sinaiko at least in part for his use of Amphotericin B, in that the order is based on repeated acts of negligence by "Reason of the matters set forth in Findings,…12,…, 14, 15, 16, … ." Decision, at pg. 20, para. 1. Paragraph 12 notes that "Amphotericin B was not then approved for oral administration" by the FDA and "is a dangerous drug as defined by law," though it cites no source for this conclusion. Paragraph 14 refers to the "To whom it may concern" letter of Dr. Vreeland in which she cites comments on the *intravenous* form of the drug in the pharmacological text, Goodman and Gillman, and offers her opinion that "all patients requiring Amphotericin B (injectable) must be hospitalized," and that Dr. Sinaiko's treatment "…**could be considered child endangerment**… ." (Emphasis added.) This basis for the MBC's decision does not stand up to the test of scrutiny.

The task of this court is in reviewing an administrative decision is to apply its independent judgment. Bixby v. Pierno (1971) 4 Cal.3d 130, 143. It must examine the record for errors of law and reweigh the evidence in a limited trial de novo. Ibid., fn. 10. A preponderance of the evidence must support the administrative disposition. Ca. Code Civ. Proc., § 1094.5, subd. (c). "'The reviewing court must consider the entire record . . . and may not isolate only the evidence which supports the board's findings [citation] and thus disregard relevant evidence in the record.'" Steve Rados, Inc. v. California Occupational Saf. & Health Appeals Board (1979) 89 Cal.App.3d 590, 595.

Plainly, whether Amphotericin B *taken orally* presents any significant risk of harm is a subject beyond the knowledge of any layman, and apparently beyond the knowledge of the average practicing physician. There is no evidence in the record to establish that Dr. Vreeland has any demonstrable expertise on the harmful effects of Amphotericin B in its various forms. Thus, her "testimony"--in the form of a "To who it may concern" letter[6]--is incompetent to prove that Amphotericin B is dangerous when administered orally or that Dr. Sinaiko endangered L.T.S. by having him take Amphotericin B. In fact, the proffered comments of Dr. Vreeland reflect that she had no independent opinion on the subject--her comments amounted to no more than a citation to a pharmacological text on the dangers of Amphotericin B given intravenously.

The MBC's Answer cites extensively to the opinions of Abba I. Terr, M.D., in which he too comments on the alleged deleterious effects on intravenous Amphotericin B, again without demonstration of expertise. Answer, at page

[6] The ALJ's reliance on this letter is itself troubling. It is plainly not a medical record and in fact it appears to have been prepared by Dr. Vreeland to assist L.T.S.'s father in a collateral battle related to the custody dispute. It seems clearly barred by the hearsay rule, but even it is not, it is troubling that decision has to rely on this questionable evidence to prove such a pivotal fact.

35:10-28. However, Dr. Terr had to admit safety of the drug when taken orally--"it is virtually not a systemic drug when it's given orally… ." Id., at 35:24. And, the only concern he had with its use required him to embrace the notion that L.T.S. suffered from the exact afflictions that Dr. Terr had categorically rejected. Id., at 35:25-28. It seems that if the MBC invokes evidentiary standards to disqualify the testimony of experts offered by Dr. Sinaiko, it should apply those standards non-discriminatorily. That is, the MBC should have required reliable, scientific evidence that Amphocerin B taken orally presents a significant risk of harm, rather than relying on the untested hypotheses of the MBC's experts.

There is no evidence in the Decision that Amphotericin B taken orally presents a danger. And, in the absence of reliable expert testimony that Amphotericin B presents a risk of harm in this form, the MBC's finding that L.T.S. was put at risk by Dr. Sinaiko, or that Dr. Sinaiko was negligent or engaged in unprofessional conduct on this basis was improper.

IV. Conclusion

The Decision of the Medical Board of California to revoke the license of Dr. Sinaiko presents an extreme departure from existing precedent. By treading so far from accepted standards, the Decision not surprisingly tramples not only the Constitutional rights of Dr. Sinaiko to be apprised of the conduct that will give cause for license revocation, but also on the rights of the public in general to make informed decision about their health care and to be free from arbitrary interference in such rights by the state. The Court should use its right of review to rectify these errors in the MBC Decision.

Respectfully submitted,

TAYLOR & GUTIERREZ LLP

By:

William F. Gutierrez
Attorney for Amicus Curiae
Association of American Physicians
and Surgeons, Inc.