

**IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA
THIRD APPELLATE DISTRICT
DIVISION ONE**

Robert Sinaiko,)	
Petitioner,)	Court of Appeal Case No. C045502
)	
v.)	Trial Court Case No. 99CS02275
)	
Superior Court of the State of)	
California, for the County)	
of Sacramento,)	
Respondent,)	
)	
Medical Board of California,)	
Real Party in Interest)	
_____)	

**ON EXTRAORDINARY WRIT TO THE THIRD DISTRICT COURT
OF APPEAL FROM SACRAMENTO COUNTY SUPERIOR COURT
Before the Honorable Trena Burger-Plavan**

**APPLICATION OF CHILDREN’S ADVOCACY INSTITUTE
FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF
IN SUPPORT OF PETITIONER**

AND

***AMICUS CURIAE* BRIEF OF
CHILDREN’S ADVOCACY INSTITUTE
IN SUPPORT OF PETITIONER**

DEBRA BACK (State Bar No. 204842)
Staff Attorney, Children’s Advocacy Institute
5998 Alcalá Park
San Diego, CA 92110
(619) 260-4806 / (619) 260-4753 (fax)
Attorney for *Amicus Curiae*
Children’s Advocacy Institute

**IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA
THIRD APPELLATE DISTRICT
DIVISION ONE**

Robert Sinaiko,)	
Petitioner,)	Court of Appeal Case No. C045502
)	
v.)	Trial Court Case No. 99CS02275
)	
Superior Court of the State of)	
California, for the County)	
of Sacramento,)	
Respondent,)	
)	
Medical Board of California,)	
Real Party in Interest)	
_____)	

**ON EXTRAORDINARY WRIT TO THE THIRD DISTRICT COURT
OF APPEAL FROM SACRAMENTO COUNTY SUPERIOR COURT
Before the Honorable Trena Burger-Plavan**

**APPLICATION OF CHILDREN’S ADVOCACY INSTITUTE
FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF
IN SUPPORT OF PETITIONER**

AND

***AMICUS CURIAE* BRIEF OF
CHILDREN’S ADVOCACY INSTITUTE
IN SUPPORT OF PETITIONER**

DEBRA BACK (State Bar No. 204842)
Staff Attorney, Children’s Advocacy Institute
5998 Alcalá Park
San Diego, CA 92110
(619) 260-4806 / (619) 260-4753 (fax)
Attorney for *Amicus Curiae*
Children’s Advocacy Institute

Table of Contents

	<i>Page</i>
Table of Authorities	ii
 Application of Children’s Advocacy Institute For Leave to File <i>Amicus Curiae</i> Brief In Support of Petitioner	
The Interest of the Children’s Advocacy Institute	App-1
Purpose of <i>Amicus</i> Submission	App-2
 Children’s Advocacy Institute’s <i>Amicus Curiae</i> Brief In Support of Petitioner	
I. Child ADHD Ritalin Therapy Versus the Alternative Here at Issue	1
II. Expert Testimony Admissibility in Medical Enforcement Cases	16
Conclusion	17

Table of Authorities

Page

California Cases

California Medical Board v. Robert Sinaiko,
Sacramento County Superior Court Case No. 99CS02275 *passim*

Miscellaneous

18:3 American Council on Health and Science Newsletter (1996) . . 2

Peter R. Breggin, M.D. and Ginger Ross Breggin, *The Hazards of Treating "Attention-Deficit/Hyperactivity Disorder" with Methylphenidate (Ritalin)*, JOURNAL OF COLLEGE STUDENT PSYCHOTHERAPY, Vol. 10(2) 1995, pp. 55–72 3

National Institute on Drug Abuse, “*New Research in Animals Reveals Possible Long-Term Effects of Stimulants on Brain and Behavior*,” Press Release (Dec. 8, 2003) at www.drugabuse.gov . . . 5

National Institutes of Health, *Diagnosis and Treatment of Attention Deficit Hyperactivity Disorder*, Consensus Development Conference Statement (Nov. 16–18, 1998), at www.consensus.nih.gov/cons/110/110_statement.htm#5 4. *What* (hereinafter “*NIH Consensus Statement*”). 4, 7

Ritalin: Are We Overmedicating our Kids? Cover Story, Newsweek 1996; 78:50-6 (article written by LynNell Hancock and reported by Pat Wingert and Mary Hager, Claudia Kalb, Karen Springen and Dante Chinni) 5

B. Vastag, “*Pay Attention: Ritalin Acts Much Like Cocaine*,” JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, 286:905–906 (2001) 3, 6

J. Zito, D. Safer, S. dosReis, J. Gardner, M. Boles, F. Lynch, *Trends in the Prescribing of Psychotropic Medications to Preschoolers*, JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, 283:1025–1030 (2000) 3

**IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA
THIRD APPELLATE DISTRICT
DIVISION ONE**

Robert Sinaiko,)	
Petitioner,)	Court of Appeal Case No. C045502
)	
v.)	Trial Court Case No. 99CS02275
)	
Superior Court of the State of)	
California, for the County)	
of Sacramento,)	
Respondent,)	
)	
Medical Board of California,)	
Real Party in Interest)	
_____)	

**ON EXTRAORDINARY WRIT TO THE THIRD DISTRICT COURT
OF APPEAL FROM SACRAMENTO COUNTY SUPERIOR COURT
Before the Honorable Trena Burger-Plavan**

**APPLICATION OF CHILDREN’S ADVOCACY INSTITUTE
FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF
IN SUPPORT OF PETITIONER**

DEBRA BACK (State Bar No. 204842)
Staff Attorney, Children’s Advocacy Institute
5998 Alcalá Park
San Diego, CA 92110
(619) 260-4806 / (619) 260-4753 (fax)
Attorney for *Amicus Curiae*
Children’s Advocacy Institute

1. The Interest of the Children’s Advocacy Institute

The Children's Advocacy Institute (CAI) submits the attached brief as *amicus curiae* in support of the petition for extraordinary writ filed in the above-entitled case, and seeks leave of this Court for consideration as such.¹ The attached brief has been drafted solely by *amicus* CAI and without compensation from any party, and has been served on all parties (proof of service attached).

CAI is an academic center and statewide advocacy group representing the interests of California’s children. Based at the University of San Diego School of Law, CAI’s academic program includes courses and clinical training of USD law students in child advocacy. CAI also engages in legislative and regulatory advocacy, publishes various documents such as the Children’s Regulatory Law Reporter and the annual *California Children’s Budgets*; and litigates on behalf of children. CAI represents children—and only children—in the California Legislature, in the courts, before administrative agencies, and through public education programs. CAI educates policymakers about children’s needs for economic security, adequate nutrition, health care,

¹ The Children’s Advocacy Institute is a sister organization of the University of San Diego Center for Public Interest Law, whose administrative director has recently been appointed Medical Board Enforcement Monitor pursuant to the terms of Business and Professions Code section 2220.1. This letter is submitted by the Children’s Advocacy Institute solely on its own behalf. The University of San Diego, the Center for Public Interest Law, and the Medical Board Enforcement Monitor take no position on this matter.

education, quality child care, and protection from abuse, neglect, and injury. CAI seeks to ensure that children's interests are effectively represented whenever and wherever government makes policy and budget decisions that affect them.

CAI's interest in this case stems from its implications concerning the treatment of children diagnosed with attention-deficit/hyperactive disorder (ADHD), and related concerns. Improving the quality and availability of services and treatments for children with special needs has been part of CAI's mission since its inception in 1989. For example, for the past ten years, CAI has devoted an entire chapter in its annual *California Children's Budget* to Children with Special Needs, including a discussion of the prevalence, causes, and detection of — and responses to — the major types of child disabilities in California (including ADHD). Additionally, CAI's Children's Regulatory Law Reporter regularly summarizes and critiques proposed child-related rulemaking, including regulatory proposals that impact special needs children.

CAI's academic program is funded by the University of San Diego School of Law, and its advocacy program is funded primarily through grants and donations. CAI is not funded by the government or medical provider groups. CAI's perspective is not that of physicians' counsel, nor of the state agency.

Purpose of *Amicus* Submission

The instant case raises important questions concerning the treatment of

children diagnosed with attention-deficit/hyperactive disorder (ADHD) and related concerns. These questions are of special interest to the Children's Advocacy Institute, and have been the subject of thought, research, and advocacy by CAI and its professional staff. Based on its experience and background in the subject matter, CAI believes that it may contribute helpfully to the court's consideration of the difficult issues raised herein.

CAI contends that most of the discussion, citations, and points made in the attached proposed brief will not be presented by either party before this Honorable Court.

Dated: Dec. 16, 2003

Respectfully submitted,

DEBRA BACK (State Bar No. 204842)
Staff Attorney, Children's Advocacy Institute

**IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA
THIRD APPELLATE DISTRICT
DIVISION ONE**

Robert Sinaiko,)	Court of Appeal Case No. C045502
Petitioner,)	
)	
v.)	Trial Court Case No. 99CS02275
)	
Superior Court of the State of)	
California, for the County)	
of Sacramento,)	
Respondent,)	
)	
Medical Board of California,)	
Real Party in Interest)	
_____)	

**ON EXTRAORDINARY WRIT TO THE THIRD DISTRICT COURT
OF APPEAL FROM SACRAMENTO COUNTY SUPERIOR COURT
Before the Honorable Trena Burger-Plavan**

***AMICUS CURIAE* BRIEF OF
CHILDREN’S ADVOCACY INSTITUTE
IN SUPPORT OF PETITIONER**

DEBRA BACK (State Bar No. 204842)
Staff Attorney, Children’s Advocacy Institute
5998 Alcalá Park
San Diego, CA 92110
(619) 260-4806 / (619) 260-4753 (fax)
Attorney for *Amicus Curiae*
Children’s Advocacy Institute

The Children's Advocacy Institute respectfully contends that two factors commend review by this Honorable Court of the trial court's decision.

I.

Child ADHD Ritalin Therapy Versus the Alternative Here at Issue

The instant case centered initially on Dr. Sinaiko's handling of children diagnosed with attention-deficit/hyperactive disorder (ADHD) (especially the case of patient LTS).² In the United States, children diagnosed with ADHD are commonly prescribed Ritalin and other amphetamine or tricyclic drug regimes to control their symptoms.³ The use of these drugs in Western Europe and elsewhere is minimal.⁴ Moreover, the increased reliance on child

² Other issues not addressed in this brief may be beyond the expertise of CAI, and we do not offer an opinion as to other patients or issues.

³ Use of Ritalin (methylphenidate), the drug of choice for treating ADHD, has risen nearly six-fold since 1990. Up to 6% of all school-age American boys are now believed to take Ritalin for ADHD symptoms, which include a short attention span, hyperactivity, and impulsive behavior. This dramatic increase in the use of Ritalin has prompted accusations that the drug is being wildly overprescribed and that the condition it treats does not even exist. See contentions to this effect by Richard Bromfield, Ph.D. (psychologist on the faculty of Harvard Medical School) and the contrary argument of Jerry Wiener, M.D. in 18:3 American Council on Health and Science Newsletter (1996) at www.acsh.org/publications/priorities/0803/pcyes.html.

⁴ CAI does not join the homeopathic advocates who contend that ADHD and attention deficit disorder (ADD) are American pharmaceutical-psychiatric fabrications (see the numerous books, commentary, and contentions arrayed by homeopaths at <http://www.shirleys-wellness-cafe.com/ritalin.htm>). However, a case may be reasonably inferred for their excessive diagnoses as the malady *du jour* based on their vague qualifying criteria, extraordinary increase, and substantial isolation within the United

amphetamine administration is remarkable: Over three million children are now subject to these prescriptions, with the American Medical Association taking note of the increase from 1991 to 1995, and additional extraordinary growth over the last eight years, now reaching over 4 million U.S. children prescribed these powerful amphetamines.⁵ The costs and long-term implications of these common therapies are not fully known,⁶ but developing

States. Similarly, CAI does not reject Ritalin or other similar drug prescriptions for children with serious ADHD or ADD symptoms. Nor did Petitioner Dr. Sinaiko. His position was not to reject Ritalin, but to maintain it and explore eliminating its possible costs by testing for a causative factor that would accomplish a cure, rather than symptom treatment with the addiction and other dangers of amphetamines.

⁵ The Journal of the American Medical Association concluded in 2000 that “[i]n all three data sources, psychotropic medications prescribed for preschoolers increased dramatically between 1991 and 1995. The predominance of medications with off-label (unlabeled) indications calls for prospective community-based, multidimensional outcome studies.” Julie Magno Zito, Ph.D., Daniel J. Safer, M.D., Susan dosReis, Ph.D., James F. Gardner, Sc.M., Myde Boles, Ph.D., Frances Lynch, Ph.D., *Trends in the Prescribing of Psychotropic Medications to Preschoolers*, JAMA, 283:1025–1030 (2000). Note the estimate of 4 to 6 million U.S. children taking Ritalin in JAMA 2001; 286: 905–906.

⁶ “As the National Institute of Mental Health succinctly stated, ‘The long-term effects of stimulants remain in doubt’ (Regier and Leshner, 1992). The FDA-approved information put out by the drug company, Ciba-Geigy, admits ‘long-term effects of Ritalin in children have not been well established’ (Physicians’ Desk Reference, 1994, p. 836). Yet methylphenidate is typically advocated as a long-term treatment.” Peter R. Breggin, M.D. and Ginger Ross Breggin, *The Hazards of Treating “Attention-Deficit/Hyperactivity Disorder” with Methylphenidate (Ritalin)*, JOURNAL OF COLLEGE STUDENT PSYCHOTHERAPY, Vol. 10(2) 1995, pp. 55–72. Even short-term benefits may be somewhat limited: “NIMH further states that studies have demonstrated

evidence suggests legitimate concerns about improper dosage problems⁷ and limited benefits,⁸ as well as a lack of knowledge about long-term impacts.⁹

short-term effects such as reducing ‘class room disturbance’ and improving ‘compliance and sustained attention.’ But it recognizes that the drugs seem ‘less reliable in bringing about associated improvements, at least of an enduring nature, in social-emotional and academic problems, such as antisocial behavior, poor peer and teacher relationships, and school failure.’” *Id.* See www.breggin.com/methylphen.html.

⁷ The National Institutes of Health (NIH), examining Ritalin use for ADHD, concluded that immediate risk is primarily focused on proper dosage, but also warned: “It is well known that psychostimulants have abuse potential. Very high doses of psychostimulants, particularly of amphetamines, may cause central nervous system damage, cardiovascular damage, and hypertension. In addition, high doses have been associated with compulsive behaviors and, in certain vulnerable individuals, movement disorders.” The NIH adds as to the tricyclics: “Drugs used for ADHD other than psychostimulants have their own adverse reactions: tricyclic antidepressants may induce cardiac arrhythmias, bupropion at high doses can cause seizures, and pemoline is associated with liver damage...” National Institutes of Health, *Diagnosis and Treatment of Attention Deficit Hyperactivity Disorder*, Consensus Development Conference Statement (Nov. 16–18, 1998), at www.consensus.nih.gov/cons/110/110_statement.htm#5 4. What (hereinafter “*NIH Consensus Statement*”).

⁸ The National Institutes of Health summarized studies to the late 1990s: “[S]hort-term trials have found beneficial effects on the defining symptoms of ADHD and associated aggressiveness as long as medication is taken. However, stimulant treatments may not ‘normalize’ the entire range of behavior problems, and children under treatment may still manifest a higher level of some behavior problems than normal children. Of concern are the consistent findings that despite the improvement in core symptoms, there is little improvement in academic achievement or social skills.” *Id.*

⁹ The NIH Consensus statement concludes: “The current state of the empirical literature regarding the treatment of ADHD is such that at least five important questions cannot be answered. First, it cannot be determined if the combination of stimulants and psychosocial treatments can improve functioning with reduced dose of stimulants. Second, there are no data on the

CAI is concerned that the trial court's holding will effectively create an irrational rule that may lead to yet greater reliance on Ritalin and other amphetamine administration to children, already at unprecedented levels. It is troubling that this shift in treatment of children diagnosed with ADHD has proceeded without measurement, without double-blind testing, and without any other scientific methodology effectively predicting its long-term implications. The weight of the evidence regarding direct and collateral harm from the current practice of widespread and immediate Ritalin administration is mounting and is reflected in both professional journals and the popular press.¹⁰ Indeed, the opinion trend among experts appears to be shifting to greater caution about the widespread, reflexive use of these drugs.

treatment of ADHD, Inattentive type, which might include a high percentage of girls...Fourth, there is no information on the effects of long-term treatment (treatment lasting more than 1 year), which is indicated in this persistent disorder. Finally, given the evidence about the cognitive problems associated with ADHD, such as deficiencies in working memory and language processing deficits, and the demonstrated ineffectiveness of current treatments in enhancing academic achievement, there is a need for application and development of methods targeted to these weaknesses." *Id.*

¹⁰ Note the front page cover article in Newsweek on March 18, 1996 "Ritalin: Are we Overmedicating Our Kids?" with 24 articles or letters appearing since in that publication; see http://archives.newsbank.com/ar-search/we/Archives?p_action=list&p_topdoc=21. See also, the press release dated December 8, 2003, "New Research in Animals Reveals Possible Long-Term Effects of Stimulants on Brain and Behavior" by the National Institute on Drug Abuse (a component of the National Institutes of Health) at www.drugabuse.gov.

According to a recent study in the Journal of the American Medical Association, the results of positron emission tomography (PET) scans of the brains of 11 healthy men who took various doses of oral Ritalin revealed that a typical Ritalin dose given to children (0.5 mg/kg) blocked 70% of dopamine transporters in the adult subjects. The study suggests that Ritalin has brain effects remarkably similar to cocaine, except that it is an even stronger stimulant.¹¹

Critics of Ritalin contend that one motivation for its prevalence may be traced to pharmaceutical interests promoting its use.¹² Some practitioners allegedly rely on the presumptive prescription of these drugs wherever children present ADD or ADHD symptoms. However, the literature and the record of the instant case confirm that some portion of the ADHD-diagnosed population may well be suffering from allergic reactions to food or related environmental factors. While expert opinion is divided about the incidence of such

¹¹ JAMA 2001; 286: 905–906.

¹² Ritalin is produced by the pharmaceutical giant Ciba-Geigy, which has engaged in aggressive marketing. Other major producers now manufacturing tricyclic drugs compete for the ADHD market. Given the extraordinary profits obtainable from these products and their common Schedule 2 status requiring physician approval, marketing to the medical profession through the numerous incentives commonly employed, and even to the public, is substantial.

ascertainable causes, it is a cognizable percentage.¹³ Petitioner Sinaiko, without advising the cessation of other therapies (including Ritalin), attempted to test possible allergic causes through purportedly non-harmful amphotericin B or nystatin anti-fungal drugs. His stated purpose was to explore the elimination of a possible cause, rather than the suppression of symptoms with a long-term regimen of amphetamines.

The court below agreed with Dr. Sinaiko that the ALJ's criteria for considering expert testimony (the Kelly-Frye test used to admit new scientific evidence such as DNA) is too narrow (*see* discussion under II, below). Accordingly, the court agreed that the ALJ's categorical rejection of all of the

¹³ See the record below, with expert testimony indicating 3%–10% incidence. Note also that the extraordinary breadth and vagueness of the ADHD diagnosis may lead to the inclusion within its parameter of behavioral patterns caused by allergies or other environmental causes. The NIH stated: “Primary care and developmental pediatricians, family practitioners, (child) neurologists, psychologists, and psychiatrists are the providers responsible for assessment, diagnosis, and treatment of most children with ADHD. There is wide variation among types of practitioners with respect to frequency of diagnosis of ADHD. Data indicate that family practitioners diagnose more quickly and prescribe medication more frequently than psychiatrists or pediatricians. This may be due in part to the limited time spent making the diagnosis. Some practitioners invalidly use response to medication as a diagnostic criterion, and primary care practitioners are less likely to recognize comorbid (coexisting) disorders. The quickness with which some practitioners prescribe medications may decrease the likelihood that more educationally relevant interventions will be sought.” See *NIH Consensus Statement*, *supra* note 6.

Petitioner’s expert evidence was improper.¹⁴ And much of that evidence derives from sources deserving substantial weight — composed of esteemed experts in pediatrics and public health, including the former Assistant Secretary of Health of the U.S. Department of Health and Human Services, Phillip Lee, M.D. The court then stated that the proper methodology is to review the testimony of witnesses with on-point expertise, *e.g.*, immunologists, and ascertain whether those opinions and their bases warrant a narrow judgment that the standard of care was breached. The court found as follows: “This is neither the case nor the forum where Respondent (Board) can invalidate an entire medical theory. Nor can Petitioner simply prove that the practices he followed are accepted in a portion of the medical field.” (*See* opinion below at 6.)

The court then noted that the Medical Board’s experts reviewed the particular charts at issue and were more focused in their testimony; *e.g.*, opining specifically that, in the LTS case, administration of amphotericin B was “below the standard of care,” and supporting the Board’s contention that Dr. Sinaiko had failed to use a “step ladder” approach before deciding to so prescribe and violated the standard of care by “quickly bypassing conventionally accepted treatment modalities, commonly used by physicians

¹⁴ Opinion below at 6, noting that the ALJ “found all of those (Petitioner) experts not qualified for the purposes of this hearing.”

in the fields of behavior pediatrics and child psychiatry for the treatment of ADHD such as the stimulants (Ritalin or Dexedrine), et al., and psychological counseling and support....” (*See* opinion below at 2.)

But it is undisputed that Dr. Sinaiko did not stop or advise stopping LTS’ Ritalin therapy. Nor did he in any way impede counseling. Moreover, consider the implications of the “step ladder” approach here posited. It is a ladder that explicitly begins with the “conventionally accepted” modality of amphetamine delivery, which is now revealed to have the same addictive and other brain effects as schedule 1 unlawful (to sell or possess) cocaine (see discussion above). Further, administration of Ritalin or other amphetamines appears to be allowed without clear dosage or time limitation, notwithstanding the evidence cited briefly above. And indeed, children now face an entire childhood of powerful chemical interventions of Ritalin or tricyclics or what the ALJ termed “more recent drugs” such as Clonidine and Bupropion. CAI does not dispute that such drugs may well be appropriate in certain cases, but notes that they are not backed by double-blind, long-term studies of child impact, and are not entirely benign; recent evidence from the most mainstream of sources is alarming, but is not considered germane by the trial court’s analysis.

The court below remarked that LTS has a mild case of ADHD, implying that the extreme remedy of amphotericin B was not indicated. But

there is a legitimate view that the “step ladder” here posited is backwards. Perhaps the first step should be counseling or psychotherapy in conjunction with examination of possible organic causes, including allergens. The prescription of dangerous, addictive, and chemistry-altering amphetamines and tricyclics should be a middle or high step on the ladder, not the first step. It is troubling that LTS has such a mild case of ADHD that he cannot be tested for a possible fungal/allergic cause, but can be administered significant amphetamines without comment as to dosage, period, or long-term effect.

Most important, the trial court below framed the entire issue as the violation of the “standard of care” in failing to proceed with an antifungal test until after the other “steps” had been traversed. According to this new standard, physicians are not to test for allergic causes (through amphotericin or nystatin antifungal treatment) until after Ritalin, then counseling. Since both occurred here (Ritalin and counseling were prescribed), the implication is that other steps may be required. What are those steps? CAI agrees that if there were a specific, reliable test for an allergic cause, it would certainly be advisable. But that is not indicated by the record below. Testing for allergic causes appears to be a trial and error process. In fact, physicians commonly ask patients to try a treatment and see if it works (ranging from “drink lots of liquid” or “stop drinking” to “lose weight”). Physicians commonly try prescription drugs to simply see if they solve the problem (a substantial part

of antibiotics administration is so based). If it works, the treatment result confirms the hypothesis.

The underlying issue here is whether amphotericin B is “dangerous,” because the degree of danger informs the judgment here at issue. One properly weighs that degree against: (1) the danger presented by the illness; (2) the likelihood of beneficial effect; and (3) the effects and benefits of alternative treatments. The record is virtually devoid of convincing evidence that amphotericin B in its oral form is dangerous as administered by Dr. Sinaiko. If there were such evidence, CAI would be the first to condemn its use. But where is it? It is not dangerous based on problems with an injectable form not here relevant, nor merely because it was at one time an “off-label” use that physicians are permitted, nor that it is schedule listed — Ritalin is schedule listed. If the danger of the oral antifungals exceeds or approaches the dangers presented by the illness or by the alternative remedies (particularly if those remedies were *curative*), the standard of care issue would be easy. But that is not the case here.

What the Board has done, and the trial court confirmed, is to take sides in a dispute between “conventional” amphetamine and related drug administration and a search for a cure that will succeed in fewer than 10%, perhaps 3% of the cases, but will have a substantial advantage over both the illness and the “conventional” symptom-attacking remedy, and which has

minimal, even trivial downside.

The trial court stated that the issue can be decided narrowly, and that it concerns only LTS. But the power of the Board does not require a *stare decisis* published opinion to have broad effect. No reasonable practitioner will risk his or her livelihood to test for any allergen (or other cause) for an ADHD child given the medical policy here enunciated. And so many questions regarding treatment of children with ADHD are left unanswered: Is it limited to amphotericin B or nystatin? Why? The “step ladder” is referred to, but what is it? As stated, it is amphetamines or tricyclics without limitation, or counseling. Exactly what warrants exploration of an allergy-based cause? How can it be explored without risk even if common antifungals like amphotericin B or nystatin yield possible license revocation? Without guidance or indication of Board approval, what practitioner dare risk anything other than the stated and approved first ladder step of prescribing Ritalin or other amphetamines, with counseling?

This case occurs in the context of no evidence of patient harm or patient complaint. CAI agrees with the Board that potential danger is sufficient and actual harm is not required, but the lack of such harm in the record, combined with the alleged lack of risk from the therapies proffered (*i.e.*, antifungal treatment, *et al.*) is relevant in the evaluation of a standard of care offense. In the context of ADHD, it is unclear how the physician can test a thesis of an

addressable cause by any method.

CAI contends that at least as to the LTS matter, the medical community may sometimes divide into groups, each defending the *modus operandi* it has found effective and believes to be, *ipso facto*, the “standard of care.” Each believes that every patient deserves nothing less than the approach he or she has found successful. Sometimes such opinion is based on scientific examination and double-blind test findings, but more often it is based on less reliable factors. CAI acknowledges that some of this expert certitude is driven by the often irresponsible claims of “alternative medicine” practitioners who foreswear the scientific method for anecdotal, faith-based, or sometimes bizarre therapies. But the questions raised by the LTS matter do not fall into this category.

The adherents of drug administration to ADHD children as the virtually exclusive medical treatment are ascendant in some circles. But there is a legitimate conflict between schools of thought as to when antifungal or other alternatives are appropriately tried. Choosing between those alternatives is not practical via the trial court’s focused, narrow approach of giving almost exclusive weight to the three Board experts and ignoring the experts of Dr. Sinaiko because they focused less on an examination of the child’s chart, which in this case does not provide the answers sought. Testimony concerning off-label use of amphotericin, its record, the nature of ADHD, the implications

of Ritalin and related facts, medical policy concerning off-label drugs are all inextricably part of a standard of care judgment as to LTS and other children with ADHD. The trial court below essentially repeated the error of the ALJ he condemned. The court conceded that the Board and ALJ were wrong in limiting or disregarding the testimony of the petitioner's experts under the Kelly-Frye test because the nature of weighing a standard of practice violation does not call for such a limited criterion. Then the court cited the testimony of the three Board experts that the standard of care was breached, without considering the arguments and factors urged by Petitioner Sinaiko's experts. The court had its own threshold of exclusion: admit, but disregard. The "narrow question" approach does not work in the condemnation of a medical practice or approach backed by the force of license revocation.

CAI contends that the decision here at issue (when to use antifungals) is best made in a rulemaking context. Such a procedure means that lines are drawn in advance, not *post hoc* through a disciplinary action. Rulemaking provides guidance. As argued above, the current holding will mean that other physicians may not seek other therapies to Ritalin as did Dr. Sinaiko, as it does not inform anyone when and where such alternatives are permitted. The adjudication alternative throws a cloud over the approach taken by the physician even where all concerned may possibly concede their merit, especially given the "step ladder" elements here posited and that implicitly

exclude other alternatives. Even a conservative approach can raise a risk of professional ruin where no elements of the “step ladder” are identified warranting use. With rulemaking, the Board does not merely say “no,” but explains when “yes” is indicated.

Such rulemaking also has a related advantage. The record in an adjudication is created by the parties. One may be dominated by several experts with a particular mindset and tied to a particular modality of treatment. The other party may be focused only on the accusation applicable to him and may be limited in resources. In contrast, a rulemaking allows the decision maker to hear from a wide range of interested parties. It allows for the considered measurement of the nature of ADHD, its long-term implications, the health implications of Ritalin and related drug administration over prolonged periods, the nature and track record of alternatives, and the creation of a rule of practice that is clear and minimizes unintended consequences.

While the Board must often proceed by adjudication, particularly where harm has occurred or is imminent, rulemaking has clear advantages. The same factors that commend a rulemaking approach here gravitate against the trial court’s decision to narrow the proceeding to a simplistic review of the few experts who have reviewed LTS’s chart.

II. Expert Testimony Admissibility in Medical Enforcement Cases

The Medical Board has adopted the position that the admissibility of all expert testimony in medical discipline cases must meet the Kelly-Frye test. That test is designed to limit new scientific indicators of guilt in criminal cases to methods that meet strict standards of reliability. The ALJ applied that test to effectively foreclose consideration of the Petitioner's expert testimony. As CAI argued above, an enforcement action of the kind here at issue has broad policy implications and properly considers testimony well beyond the standards applicable to DNA or fingerprint identification in criminal proceedings. As noted above, the trial court rejected that narrow criteria for the admissibility of expert testimony, but then disregarded that same testimony as irrelevant. As discussed above, CAI disagrees as to the latter judgment. But the trial court's rejection of the Kelly-Frye test is important where it at least allows the admission of relevant testimony. The "law of the [Sinaiko] case" is that Kelly-Frye does not apply to expert testimony. The position of the Board and the ALJ on the Office of Administrative Hearings' (OAH) Medical Quality Review Panel is that it does apply. The Board and the ALJs deciding these cases are free to continue Kelly-Frye application unless and until an appellate court decides otherwise.

The clarification of the proper standard for expert testimony admissibility is of no small import. It permeates quality of care cases — for

the Medical Board, and for many of the other 250 state agencies engaged in disciplinary enforcement. The extremely limited basis for admissibility extant from agencies and affirmed by OAH will not be assuredly corrected without published clarification from this Honorable Court. Because of its crucial procedural significance in all such cases, and the confusion attending the contradiction between the trial court's view and the Board and OAH view, a failure of such clarification may portend confusion as to expert testimony admissibility, and widespread error in these proceedings below.

From CAI's perspective, unless the trial court's holding on this point is upheld as effective law, expert testimony of the sort highly important in the instant Ritalin debate — or similar controversies involving child health policy — may be barred as inadmissible on a threshold basis.

CONCLUSION

Based on the foregoing, CAI respectfully asks this Honorable Court to review the case below in order to clarify the points discussed above.

Dated: Dec. 16, 2003

Respectfully submitted,

/s/

DEBRA BACK¹⁵ (State Bar No. 204842)
Staff Attorney, Children's Advocacy Institute

¹⁵ Pursuant to Cal. Rules of Ct., Rule 14(c)(1), I certify that this brief and application, including footnotes, consists of 5,433 words.