Was this doctor "unconventional" enough to lose his license?

**Abstract (summary)**
In a case that many colleagues fear may limit all doctors' latitude to choose among treatments for their patients, the Medical Board of California last August voted to revoke San Francisco internist and allergist Robert J. Sinaiko's license - and to assess him $99,000 for the cost of his own prosecution. The board's charges included gross negligence, excessive prescribing, and unauthorized experimentation on patients. Sinaiko specializes in therapies seldom used by mainstream US allergists - including diet and antifungal medications to treat attention deficit-hyperactivity disorder in children.

**Full Text**

**Headnote**
Widely regarded as a solid, thorough clinician, he nevertheless uses nonstandard treatments. The Medical Board of California is deciding his fate right now.

Even physicians who don't endorse therapies used by Robert J. Sinaiko, a San Francisco internist and allergist strongly defend his right to continue medicine in California. But in a case that many colleagues fear may limit all doctors' latitude to choose among treatments for their patients, the Medical Board of California last August voted to revoke Sinaiko's license-and to assess him $99,000 for the cost of his own prosecution. The board's charges included gross negligence, excessive prescribing, and unauthorized experimentation on patients.

Sinaiko specializes in therapies seldom used by mainstream US allergists-including diet and antifungal medications to treat attention deficit-hyperactivity disorder in children. He has also used enzyme-potentiated desensitization, an allergy treatment method involving low-dose injections of common allergens. EPD and antifungal treatments have each become something of a cause celebre for advocates of alternative medicine. But the medical aspects of the board's case against Sinaiko aren't as melodramatic as the legal skirmish that brought it about: It was sparked by a squabble between the divorced parents of a young boy, in which the father argued that his ex-wife had taken their son to Sinaiko, who used a dangerous drug to treat the boy's hyperactivity The state attorney general's office, which prosecuted the case for the board, also cited Sinaiko's treatment of three other patients, alleging inappropriate prescribing of oral antifungal agents.

Sinaiko was not accused of harming any of these patients. But, in the words of the administrative law judge who decided his case, he had hurt the public by "lending the legitimacy of a physician's reputation to unproven, disproven, and potentially harmful diagnoses and treatments"

Is that enough to warrant lifting a doctor's license? The arguments were complex, and the initial hearings encompassed 26 days, concluding in February 1998. In the end, the judge decided that Sinaiko had overstepped the "appropriate limits of medical practice in California"-and should lose his license.

The board accepted the judge's proposal, but is now reconsidering its decision. A final verdict is expected in July.

"I don't do alternative medicine I'm more of an early adopter"

After earning an undergraduate degree at Brandeis University, Robert Sinaiko graduated from Loyola University Chicago, Stritch School of Medicine, in 1970. He interned at the San Francisco hospital of the US Public Health Service, where he did a residency in internal medicine, then went on to another residency, in allergy and immunology at Kaiser Foundation Hospital in San Francisco. He was board-certified in internal medicine in 1979, and in clinical immunology in 1985. Sinaiko set up solo practice in 1985, and since 1988 has been an assistant clinical professor at the University of California, San Francisco, School of Medicine. He has also conducted research on the enzyme phenolsulfotransferase under the direction of UCSF's Committee on Human Research, in a study funded by SmithKline Beecham.

At Kaiser, Sinaiko worked under Benjamin Feingold, head of the allergy department and a researcher who saw strong connections between diet and behavior. Feingold's dietary treatments are widely known and often tried, but still not generally accepted among physicians. Sinaiko came to share Feingold's interest in the possibilities of diet-based treatments.

He also made a discovery of his own: The behavior problems of a small group of children seemed to be helped by oral antifungals. These included nystatin and an oral form of amphotericin B. Feingold assured Sinaiko that both drugs were safe, and he recommended that Sinaiko continue to see what benefits he could achieve for his Kaiser patients.

"I don't think of myself as doing alternative medicine," says Sinaiko. "I'm more of an early adopter"

In private practice, Sinaiko has continued to focus on the possible roles of diet and fungal colonization in allergies, ADHD, and other conditions. For support, he points to studies published in The Journal of Pediatrics, The Lancet, Archives of Disease in Childhood, and other publications.
Yet when he thinks that an ADHD patient may need Ritalin after all, Sinaiko refers the child to conventional pediatricians. "I decided in medical school, on the advice of one of my favorite professors, that I didn't want to be involved in prescribing Schedule II drugs of any kind:" he says. "I just didn't want to get into the hassle of prescribing drugs that were open to abuse."

"I will ruin him," a former patient vows.

In June 1993, Sinaiko became the defendant in a medical negligence complaint filed on behalf of a former patient, Suzanne Northington. According to court records, the complaint charged, among other allegations, that Sinaiko had treated her "serious symptoms" with "medically unnecessary and contraindicated drugs and antibiotics in the absence of any infection," had failed to diagnose chronic fatigue syndrome, and had "misrepresented medical acceptance of certain types of treatment." The case was dismissed in January 1996. Northington declined to speak with Medical Economics during the preparation of this article, though she did respond later to a draft.

Northington's negligence complaint also alleged that Sinaiko had ignored her "repeated oral and written efforts to advise the doctor of her concerns." According to Trish Miles, Sinaiko's former office assistant, Northington repeatedly phoned the office before her first visit, demanding to speak with Sinaiko. After several visits, Sinaiko declined to treat her further and suggested that she seek a psychological evaluation. Miles says Northington then rescheduled, sometimes several times a day, demanding to speak with the doctor. When Sinaiko stopped returning her calls, Miles says, Northington wrote long letters insisting on an apology and claiming that she had been abandoned.

Miles says Northington also told her that she had filed a complaint with the Medical Board of California. "She said to me, 'I will ruin him,'" Miles recalls. After seeing an early draft of this article, Northington denied making the statement. She also said that she didn't initiate a complaint with the board, but that its investigators did contact her.

The medical board doesn't comment on complaints and investigations. But ultimately, Sinaiko's care of Northington did not become an issue in the board's review of his license. In 1993, however, an inquiry about Sinaiko in another case did.

Ray Sutton, a retired electrician in Concord, CA, questioned the treatment that his ex-wife, Kellie Robison, had obtained for their son, Travis. The boy had been newly diagnosed with mild ADHD, but the Ritalin prescribed by Ray's family physician had caused side effects. "I did not want to go the drug route as the first alternative:" says Robison. Within weeks of the start of the Ritalin, she brought Travis to Sinaiko for an evaluation.

"He was a wonderful doctor," Robison recalls. "He's honest, he takes his time with his patients, and he always examined my son; many doctors don't do that when the child is on drugs:"

Sinaiko recommended dietary controls and amphotericin B by mouth, suspecting from the boy's history that he could have an intestinal fungal colonization. Sinaiko had found the best service and price for the drug in capsule form—a legal though unlabeled use—from a compounding pharmacy in Oregon.

But this regimen wasn't followed long enough to see whether it worked. "When Travis went to his father's for visitation," says Robison, "Ray always fed him pizza—when Ray knew Travis wasn't supposed to be having milk products:" The father, for his part, became alarmed when he looked up amphotericin B in the Physicians' Desk Reference. He found information about intravenous and topical preparations, but nothing that mentioned a capsule.

"That's what blew me away," says Sutton today. "That, and the fact that Travis' capsules were unmarked and unlabeled. And that's when I called the Food and Drug Administration." Though an oral form of amphotericin B has been approved in the US since 1971, the FDA's San Francisco regional office referred the matter to the state medical board, noting that Sutton had said he "will sue FDA if his son dies:"

Sutton also called Sinaiko, who had been trying to get him to come in with Travis to discuss the boy's treatment.

"Dr. Sinaiko," says Sutton, "was very nice and everything, very cordial. But I asked him: 'Where are you getting this from?' When he told me that it was brought in through Canada and Oregon, that sort of got my attention. Why would you bootleg it in, like whiskey, instead of just buying it from the local drugstore? I went full-fledged to stop the medication."

Sutton contacted his son's family physician, Gloria Vreeland, in Pleasant Hill, CA. Vreeland consulted Goodman & Gilman's The Pharmacological Basis of Therapeutics, which notes that "absorption of amphotericin B from the gastrointestinal tract is negligible:" Nevertheless, in a letter she gave to Sutton addressed "To Whom It May Concern," Vreeland cited Goodman & Gilman's statement that more than 80 percent of persons given amphotericin B develop decreased renal function and abnormal urine sediment. Vreeland added "this form of therapy could be considered child endangerment. Please discontinue the use of this medication:" Vreeland also declined to speak with Medical Economics.

Sutton took the letter to family court and got a restraining order against Robison to discontinue Sinaiko's treatment. The judge was at first reluctant to overturn the mother's medical choice, Sutton recalls. But the judge relented when Sutton asked, "Are you going to wait until my son is dead?"

Ray Sutton thought that the matter had ended there, but three years later, in 1996, the California attorney general's office subpoenaed him to testify. Sinaiko would be prosecuted.

At the same time, former patient Suzanne Northington got in touch with Alfredo Terrazas, the deputy attorney general who would prosecute the case. "She contacted me regularly," says Terrazas, "sending me reams and reams of information, most of it off the Internet"

Sinaiko and his staff believe that Northington brought other cases to Terrazas' attention, though she denies doing so. Eventually, three more patient records were combined with the Sutton inquiry—one involving a patient with chemical sensitivities and two involving patients with allergy symptoms.

One of the allergy patients told a Terrazas investigator, well after leaving Sinaiko's care, that he "didn't get any better" from the doctor's therapies. The other was a young man described by the prosecutor as "clearly" suffering from "a psychiatric disorder" He left Sinaiko's practice, moved to an Arizona desert location, and two years later committed suicide.

Any attempt to place blame on Sinaiko for this man's fate constitutes "prosecutorial overreaching," says Deane Hillman, a pulmonologist who is chairman of the Due Process Committee of the Union of American Physicians and Dentists in Sacramento. "Sinaiko hadn't seen the patient for two years, and he wasn't
treat him for psychiatric problems."

His treatments were outside the standard of care

"There's lots of literature on all sides of these issues," says Sinaiko. "The board has to draw a line between quackery and appropriate innovation. Just tell me what the rules are, and I'll live by them." According to most of the prosecution's medical experts, however, Sinaiko's treatments by any measure were outside the standard.

One such expert was Lawrence Diller, a behavioral pediatrician and an assistant clinical professor at the UCSF School of Medicine. He is the author of Running on Ritalin: A Physician Reflects on Children, Society, and Performance in a Pill (Bantam 1998), a critique of the overuse of Ritalin to treat ADHD. In his testimony for the prosecution, Diller said he was unfamiliar with Sinaiko's specific treatments, but unimpressed by the studies Sinaiko cited to support them.

"I do believe Dr. Sinaiko believes in what he's doing," Diller says, "but I think that's tragic. Is it not hurting the patient to use these questionable treatments? Is it not hurting the medical profession? His treatments for ADHD, as ambiguous as the condition is, were outside the standard of care for North American physicians."

Diller acknowledges that he doesn't like some things that are within the standard of care. "If someone were prescribing Ritalin, clonidine, and Prozac to a young child, I'd be extremely uncomfortable with it," he explains. "Yet the trend in child psychiatry these days, supported by work in the journals, is combined pharmacotherapy. But to give a kid amphotericin B for ADHD, orally or not, even though it may do no harm, is not within the standard of care."

Administrative Law Judge Ruth S. Astle, who presided at the hearing, accepted the prosecutor's contention that "amphotericin B was not then, nor is it now, a drug approved for oral administration in a solid pill, capsule, or tablet form by the [FDA] for any medical purpose, and is a dangerous drug as defined by law."

She also accepted the views of the prosecution's expert witnesses and dismissed the defense witnesses-including internist Philip R. Lee, former chancellor of the University of California, San Francisco, professor emeritus at the UCSF School of Medicine, and twice Assistant US Secretary of Health-as of "questionable credibility in that their testimony was not based on generally accepted scientific and medical principles."

Astle concluded that Sinaiko had engaged in "clearly excessive" prescribing of antifungal agents and other medications, over a long period of time and in the absence of objective data to support their use.

The judge's verdict did not assert that Sinaiko's care had directly harmed any patients, but noted that "economic harm" could be inflicted by having patients pay for ineffective therapy that they can't afford, or pay for unproven treatments when the money might be better spent on counseling.

About Sinaiko, Astle concluded: "Even if a practitioner believes in some fringe practices, (s)he must still follow sound medical practice and use good medical judgment. When fringe practices fall below the standard of care and result in repeated negligent acts, gross negligence, and overprescribing, the Board must take disciplinary action." She proposed that Sinaiko be stripped of his license, and the board concurred.

To the criticism that she has no medical background, Astle said recently, "There's nothing magical about medicine, understanding it. The little view of the world that they're asking you to try to understand, you just have to read it, take the dictionary out, and you know what they're talking about."

Prosecutor Terrazas still maintains that amphotericin B is "dangerous per se;" apparently because it requires a prescription. He further maintains, "There isn't any proof that it works, so it's an inappropriate prescription. Physicians can't just take a medicine and say, 'Let's try it.'"

Terrazas, who's been prosecuting Medical Board cases since the early 1980s, explains why he discounted Sinaiko's experts: "The allegations refer to four specific patients. Lee and Blum [public health and preventive medicine specialist Henrik L. Blum, professor emeritus of health, public policy, and planning at UC Berkeley School of Public Health] hadn't reviewed the patient records, and they weren't experts in the issues involved."

Lee agrees that in this case he doesn't qualify as an expert in reading patient charts. "That's a matter of one doctor's judgment vs. another's," he says. "The question is: Did Sinaiko prescribe for experimental use or for a therapeutic purpose? I was convinced, based on my discussions with him, that it was for a therapeutic purpose. Lee also strongly questions a doctor's losing his license based on a nebulous definition of "standard of care." He asks, "What is the standard of care? The board's decision is very, very worrisome."

Lois Salisbury, Sinaiko's wife and president of Children Now, a national children's advocacy group, rallied support for her husband. She alerted the Center for Public Interest Law at the University of San Diego School of Law itself a frequent critic of physicians-which tried to file an amicus curiae brief to protest the board's decision. So did the Union of American Physicians and Dentists. The California Medical Association wrote a strong protest. All such submissions were kept from board members.

Annotated copies of some case documents have been put on the Internet by the Medical Defense Fund of the Progress in Medicine Foundation. Numerous former patients and fellow physicians have donated money on Sinaiko's behalf to his attorney, Richard Turner of Sacramento.

Meanwhile, the CMA is calling for reforms. To get them, it has offered to support the medical board's request that the legislature raise physician license fees to ease the board's strained budget. Proposed reforms include a policy of prosecuting physicians only for a "pattern of care:" not for single incidents; eliminating prosecutors' ability to pick and choose among the board's approved expert witnesses; and prioritizing cases so that the most egregious are prosecuted first.

The CMA is also pushing for the elimination of cost recovery such as the $99,000 from Sinaiko-which it contends discourages prosecutors from bailing out of a bad case and doctors from defending themselves. It would like to see medical board review of longstanding investigations as well. (Sinaiko's case lingered three years before it was prosecuted.)

"Here's a person [Terrazas] who got hold of a case like a dog with a shoe in its mouth, wouldn't let go, and went well beyond what we think was reasonable," says Sandra E. Bressler, CMA director of professional standards and quality of care. "And at that point, the medical board loses control over the case by losing sight of its priorities."

The board has agreed to reconsider its decision to revoke Robert Sinaiko's license, and is currently reviewing all 3,500 pages of hearing transcripts and exhibits.
Today, Sinaiko is still in practice, but years of legal costs have wiped out his children’s college funds and other savings. And he still faces the $99,000 state bill for his prosecution if the decision is sustained. In May of this year, after former patient Suzanne Northington was sent a draft of this article, Sinaiko went to court to request a temporary restraining order against her seeking to prevent telephone calls, faxes, E-mails, and voice-mail messages.

Meanwhile, Travis Sutton, now 15, is currently in good health and taking no medication of any sort. In the complex world of medicine, “somebody has to be making decisions,” Sinaiko says. “Should it be the physician who’s face to face with the patient, who has read the literature, understands the controversies, and is at least in a position to make an intelligent choice for the person he’s treating? Or should it be lawyers and judges who are not trained to make medical decisions at all but are making them anyway?”

Sidebar
What do you think?

Sidebar
Should Robert J. Sinaiko’s medical license be revoked? Cast your vote by visiting our Web site at www.memag.com. You’re also invited to fax your opinion to the editors at 201-722-2688, or send an E-mail to meletters@medec.com.

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