

Exh. 21

February 10, 1995

Food and Drug Branch

FEB 15 1995

Carl Costella  
Department of Public Health  
Complaints Unit  
185 Berry Street  
Suite 260  
San Francisco, CA 94107

**RECEIVED**  
MEDICAL BOARD OF CA

FEB 24 1995

NOVATO DISTRICT OFFICE

In re: Consumer Complaint against a San Francisco Allergist, Dr. Robert J. Sinaiko, for abuse and misuse of non-FDA approved homeopathic allergy injection treatment, Enzyme Potentiator Desensitization (EPD) in ways that have damaged and defrauded hundreds of Bay Area patients

Dear Mr. Costella:

I am a former patient of a San Francisco allergist and clinical ecologist, Dr. Robert Sinaiko, who practices at 450 Sutter Street, Suite 1124, San Francisco, CA 94108, phone (415) 788-2099. I wish to file a formal complaint against him for damages that many of his patients have suffered from an experimental treatment he gave them. It is called EPD or Enzyme Potentiator Desensitization.

I am writing on behalf of a large group of his patients who sustained injury from his EPD treatment. I was also critically injured by this same doctor, although a different drug was involved. Nevertheless, I am very familiar with the negligent practices of this doctor, and therefore, feel qualified to file this complaint with the Department of Public Health (DPH).

We patients wish to alert the DPH to what Dr. Sinaiko is doing. We believe he is doing extraordinary harm to large numbers of his patients with EPD, and hope the DPH will take urgent action to stop his use of EPD before more people are harmed.

EPD is under the FDA's legal domain, because the FDA reportedly granted Dr. Sinaiko a "license" to use EPD in his practice about 4 years ago. However, the FDA is apparently not aware of the medical damages he has caused through abuse and misuse of the drug, as well as the misrepresentations he has made to patients about its success rate.

However, because this case involves such large numbers of Bay Area patients, and involves both medical care and pharmaceutical issues, we were told by attorneys to file a complaint with the Department of Public Health as well. We assume that the DPH might have authority to stop this doctor from conducting these destructive experiments on his patients -- and might be able to respond and take action in this case quicker and faster than the FDA in Maryland could. The FDA is a large and understaffed bureaucracy which might take many months to even begin an investigation into this case.

It is important to note that our complaint involves not only our concern about a dangerous doctor using a drug inappropriately, but also the issue of FRAUD. Patients believe they were misled and deceived by Dr. Sinaiko about the efficacy

EXHIBIT B

of EPD. We believe he deliberately defrauded his patients because he stood to gain financially from administering the drug to large numbers of them. He gave patients falsified and exaggerated data on his "success rate" with EPD as a way of inducing them to try the experimental drug.

I am submitting the information about Dr. Sinaiko to you under pseudonym, and request that the DPH respect my wish to remain anonymous. I fear that if Dr. Sinaiko finds out I reported him to the DPH, he could "retaliate" against me in some way. I have a husband and children to protect and cannot afford to have a problem with him.

In short, our complaints about Dr. Sinaiko's administration of EPD include:

1. The majority of patients report that they have received absolutely no medical benefits at all from his EPD injections.

2. He has harmed a significant number of patients with EPD injections.

According to other allergists, this occurred because he did not follow proper procedures, or did not have the skills and background necessary to administer it. Damages reported include increases in allergic reactions, more severe allergies and chemical sensitivities, severe infections, triggering new medical problems in patients with autoimmune disease, and exacerbation of underlying immune system diseases. These patients report that EPD has caused permanent damage to their health.

3. Almost all Sinaiko patients receive EPD, even high risk patients and even those for whom there is no medical necessity for the treatments.

We were shocked to learn that Sinaiko gives EPD to almost every patient who walks in his door, regardless of what their underlying disease and risk factors may be. He is totally indiscriminate in choosing which patients get the controversial treatment. He will give it to virtually anyone. This is why so many patients have been damaged by the drug — they were not the right candidates for the treatment in the first place.

4. Dr. Sinaiko is persuading patients to use EPD by exaggerating its benefits, claiming it will "cure them of all their allergies".

He has claimed to many patients that he has a 65% to 80% success rate, which they believe is deceptive, false and misleading data. We have met very few patients who felt they were helped by EPD. Certainly, 80% of his patients have not been cured of their allergies by EPD! We believe his deceptive claims are for the purpose of luring patients into taking his high priced injections.

5. Dr. Sinaiko is charging exorbitant fees for the EPD injections.

The amount of money charged — \$250 to \$350 per injection — is vastly out

of proportion to the dubious -- usually nonexistent -- medical benefits they receive. He tells patients they must take the injections for 5 or 6 years for a total cost of \$8,700 to \$10,000, not including his consultation fees.

6. We feel his primary motive in treating hundreds of patients with EPD is the profit motive - not medical integrity.

Dr. Sinaiko, is profiting tremendously from an unproven, untested, experimental drug. He is making a huge amount of money from EPD, considering the high fees he receives for each injection, multiplied by the large volume of patients who receive the treatment.

### Background Facts on EPD

The FDA has granted about 17 allergists in the U.S. some limited rights to use EPD in their practice. I'm sure the DPH knows all about EPD, but for your convenience, I would like to give you some background on this controversial treatment. I did extensive research on EPD, after learning that many Sinaiko patients had been injured by it, and therefore, would like to share my information with you:

As the DPH knows, EPD was first developed in Europe, and has been used by allergists there, although most "European FDA equivalents" have not approved it. The EPD product is manufactured in Europe, mainly England and Italy. It cannot be manufactured in the U.S., since no drug company would waste their time manufacturing a pharmaceutical which the FDA has not approved.

Dr. Sinaiko and other EPD allergists are importing their EPD supplies from McEwen Laboratories in Henley, England. The president of the EPD company, Dr. Len McEwen also works at St. Mary's Hospital in London, England. Dr. Sinaiko buys \$10,000 worth per month (a huge amount) from McEwen Laboratories. Sinaiko is reportedly McEwen's largest American customer and consumer of EPD.

EPD is a homeopathic remedy that consists of dozens of different allergens, plus enzymes and other additives, that are injected into the patient over a long period of time. Dr. Sinaiko gives each patient 5 EPD injections per year for 5 or 6 years, and charges them \$350 for the first injection, \$250 for later injections. The total cost of EPD for a Sinaiko patient could run as high as \$8,750, for 5 years of injections alone. But that's not all. On top of that, patients must pay Dr. Sinaiko's office fee, which is \$350.00 per hour.

Dr. Sinaiko is the only allergist in San Francisco using EPD, and one of only two in California.

Prominent academic allergists from University of California and Stanford University Schools of Medicine told me that they do not believe EPD is a viable allergy treatment. In most cases, they claim, EPD simply does not work and the patient is simply wasting his money. In other cases, medical damages can result

if the wrong dosage is given, if too many injections are given, if too few are given, or if proper procedures are not followed.

The problem is, however, that the treatment is so new and experimental that no doctor really knows what those proper procedures are. The professors warned me that any allergist using EPD was just "making wild guesses" about dosage, number of injections, and other patient risk factors. They further claimed that there is absolutely no data available on EPD in the U.S., and that no clinical trials have been done on EPD at any American university or research institute.

#### Background on Dr. Robert Sinaiko

Dr. Sinaiko is a highly controversial clinical ecologist who is known in San Francisco medical circles for his "alternative, holistic treatment" of allergies and immune disorders, and for using experimental therapies that are not accepted by 99% of the medical community. But despite his "holistic orientation", he uses traditional pharmaceuticals extensively, and has been widely criticized for his abuse of prescription drugs, i.e., for prescribing 6 to 12 drugs simultaneously, and for prescribing drugs (antifungals, antibiotics, thyroid hormone) without medical indication. He has also been criticized for not carrying out proper diagnostic tests before prescribing excessive levels of drugs.

He is the former partner of Dr. Joseph McGovern, a clinical ecologist who had his license revoked by the California Medical Board in 1986 after he injured a number of patients with controversial allergy treatments. Dr. Sinaiko took over McGovern's clinical ecology practice when Dr. McGovern lost his medical license. Ironically, Dr. McGovern and Dr. Sinaiko later had a "falling out" because Dr. McGovern was concerned that Dr. Sinaiko's allergy practices were "too radical and irresponsible."

Dr. Sinaiko himself is today under investigation by the California Medical Board (at the Novato district office) for medical malpractice and sexual misconduct. The Medical Board's investigation of him apparently involves several different cases. I base this assumption on the fact that 3 other patients told me they had filed complaints against him. In addition, I know of at least 7 other patients planning to file formal complaints against Sinaiko with the Medical Board in the next two months, most of them in reference to damages from EPD.

Dr. Sinaiko is also currently the defendant in a medical malpractice lawsuit, in which he is being sued for Fraud, Medical Negligence, Sexual Misconduct, Spoliation of Evidence and Medical Records, and Abandonment of Care during a Medical Emergency.

A group of former Sinaiko patients -- approximately 25-40 persons -- are planning to file a Joint Petition-Complaint to the California Medical Board in support of disciplinary action against his license. This petition will probably not be ready for many months -- possibly not till mid 1995. Some of these patients are considering a class action (multi-patient) lawsuit against him, although no definitive plans have been made yet.

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Lastly, one EPD doctor is trying to get Sinaiko's EPD practice halted because he is concerned about reports of patient injury. He has personally treated many of Sinaiko's EPD failure cases. He claims that patient injury is caused by Sinaiko's refusal to follow proper EPD procedures. He is recruiting other doctors and patients to join in his campaign to stop Sinaiko. This physician has also contacted McEwen Laboratories and recommended that McEwen refuse to sell Sinaiko any more EPD.

This development is very revealing because it shows that even alternative, holistic doctors who believe in EPD think that Sinaiko is a dangerous doctor whose EPD practice should be stopped before he harms more patients.

Sinaiko apparently got some sort of "approval" from the FDA to use EPD around 1991. The FDA gave him authorization to conduct a clinical trial of EPD in his office. Yet Sinaiko has absolutely NO research background whatsoever. He has never conducted a controlled clinical trial at a university or academic medical institution. He has never published a scholarly article in his life. He enjoys neither prominence nor prestige as a medical scientist. Dr. Sinaiko is mainly known in San Francisco as a controversial, yet highly commercial doctor who charges the highest rates in town for his "new age medicine."

The DPH should take special note of the following: Two sources told me that Sinaiko had illegally provided EPD supplies to two doctors who did not have FDA approval to use it. One of them was Vincent Marinkovich, a Palo Alto, CA doctor. Another was a doctor in Los Angeles, whose name I do not currently have, but which I could get, if the DPH wanted to know who he is. A former Sinaiko patient named James Hawkins of Tucson, Arizona knows the name of this Los Angeles doctor.

It is not clear to me whether Sinaiko illegally supplied EPD to the two unauthorized doctors only a few times in past years, OR whether he is currently providing them with EPD supplies on a regular basis. What is important is that he has broken the law in giving his own EPD supplies to these non-FDA approved doctors - who did not have FDA authorization to use EPD in their own practices.

#### Sinaiko's use of Enzyme Potentiator Desensitization (EPD).

According to what we have learned, Sinaiko's current practice is devoted almost exclusively to EPD. It is extremely unusual for an allergist to use one treatment so excessively in his practice, but Sinaiko is doing just that. He has treated hundreds of patients with it in the past 4 years. Despite the risks & unknowns of a new treatment, Sinaiko gives it to anyone, regardless of what their underlying risk factors may be. He even gives it to people who could not possibly benefit from it.

An example of this malpractice is a patient who went to Sinaiko with only one minor food allergy. Even though his allergy problem was very mild, Sinaiko gave him dozens of EPD injections. The poor man ended up developing allergies

to dozens of foods. He is now a severely allergic person, allergic to all the substances that were in the EPD mixture.

If the DPH were to examine his medical files -- perhaps in conjunction with the Medical Board -- the above allegations would be confirmed. His medical records would reveal all the hundreds of patients who have received EPD since 1991, and also show how little prior diagnostic testing he did before beginning EPD treatment. The files would show that he gave the drug to patients without medical necessity, as well as to high risk patients.

Sinaiko makes many, many exalted claims about EPD to patients. He tells them that it will "cure them of their allergies, cure chronic fatigue syndrome, and cure environmental illness, cure chemical sensitivities, and cure many other autoimmune and immune system diseases." If asked, he would probably deny this, but patients claim this is what he told them. Desperate for help, many sick patients are easy prey for a doctor promising a cure for all their ills. They fall for it, not realizing he is using them as guinea pigs and in fact, cannot cure them of their diseases with EPD.

One patient said Sinaiko claimed a 65% cure rate with EPD, another said Sinaiko claimed an 80% cure rate, still another said he claimed a 55% cure rate. These are pretty high percentages for a treatment that UCSF academic allergists claim is "totally experimental and unproven in clinical trials, and which does not work at all in the majority of known cases."

Sinaiko's patients feel duped by his EPD treatment. They feel he deliberately misled them about its miraculous benefits, and that he was motivated by profit, not by medical integrity. They are resentful, because they dished out thousands of dollars for a bogus cure that was at best, ineffective, and at worst, dangerous. Patients now believe that Sinaiko's "cure rate" claims were phony or fabricated, and were designed solely to induce patients to buy his high priced treatments.

For example, one patient became suspicious about Sinaiko's claims of a high success rate and therefore, asked him to supply her with the name of a patient who had truly been "cured of her allergies with EPD". Sinaiko gave her the name of a patient he said was "his best example of an EPD success story". The patient called the woman and was surprised when the woman told her she was confused and uncertain about whether EPD had helped her at all. The patient found it revealing that even Sinaiko's best references for EPD were not able to claim any real benefits from it.

Most important, if EPD is really as miraculous a cure for allergies as Sinaiko claims it is, then why has The New England Journal of Medicine or some other respected medical journal not published the results of his amazing clinical trial? Obviously, because EPD is NOT the miracle cure Sinaiko claims it is. No respected medical journal sees any legitimacy in Sinaiko's EPD claims. Prominent academic allergists also don't believe Sinaiko's claims of a high success rate.

I must inform the DPH that Dr. Sinaiko has each patient sign a waiver of responsibility form, which supposedly outlines some of the risks of EPD. However, the patients claim that what he told them orally was different from what the fine print said in the release form. Obviously, with this waiver, he has tried to absolve himself of any legal liability, and will probably claim to the DPH that the form "fully warned them" of the risks of EPD. However, patients still feel they were defrauded by him because of the false data and facts about EPD he gave them orally in consultation. They further believe that recommending the treatment to patients who don't need it and who can't benefit from it was a form of fraud he perpetrated for his own financial gain.

To summarize, Dr. Sinaiko's abusive use of EPD has raised several disturbing issues about this drug:

(1) There has been no legitimate academic medical research done on it in the U.S. It's an untested, unproven medication that does not have the approval, either of the FDA or of the academic allergy establishment. Since no clinical trials have ever been done on EPD in the U.S., the success/failure ratio is unknown, as are risk factors and side effects. Furthermore, proper procedures have not yet been established. Thus, no doctor really knows how to administer EPD properly.

One allergist stated that EPD might be a legitimate treatment one day in the distant future, but only after legitimate clinical trials have been done and only after academic researchers have established proper procedures for administering it. But other allergists admonished that today's EPD treatment is risky because no pharmaceutical research has been done to develop the right chemical formulation. Medical science also has not established which types of patients should receive it, who is at risk, and what the contra-indications are.

(2) EPD reportedly doesn't work in the majority of cases. As previously stated, academic allergists say that EPD is "a waste of the patient's money. In the majority of cases, it is absolutely useless, ineffective. It is not a "cure-all, for allergies."

They claim that the failure/no-effect rate for EPD is in the range of 70% to 80%. It's no wonder that the FDA has not approved EPD for use in the United States.

(3) EPD, in some cases, actually harms patients. Since the treatment is so new and untested, doctors like Sinaiko make repeated mistakes in the way they administer it. Sinaiko is forced to make wild guesses as to what dosage is appropriate, how often it should be given, etc. With no guidelines established, Sinaiko has to keep trying different methods until he hits upon one that works - in short, he is using his patients as guinea pigs. Yet these patients are not aware that Sinaiko is operating in the dark -- they assume he is qualified to administer the drug. Given these factors, it is no wonder that so many Sinaiko patients have had serious side effects.

Most of the cases of severe damage occurred in the 1991-93 period when Sinaiko was just beginning to use EPD and didn't know what he was doing. But even in

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1995, Sinaiko is continuing to inflict medical injury with EPD. I know of several current cases where patients are complaining that their health has deteriorated since they began EPD treatment.

Dr. Sinaiko treats large numbers of patients with EPD who have no allergies at all -- just "Environmental Illness". "EI" is a controversial syndrome which 95% of all allergists believe to be a behavioral or psychiatric disorder, not a true immune system disorder. Most allergists believe that EI patients are not suffering from true allergies at all. It is the EI patients who have been damaged the most from Dr. Sinaiko's EPD therapy. The highest failure rate has come from EI patients. Perhaps EPD caused medical damages in these patients because they had no allergic disorder to begin with, and thus, their bodies could not tolerate the high doses of potent allergens in the EPD injection.

Truly, many patients have been harmed by EPD. But one person is benefitting tremendously from the treatment: Dr. Sinaiko. If anyone bothered to investigate the prices he pays for his EPD supplies, they would discover that he is making huge profits on it. His markup is enormous. That's why he gives it to so many patients. The more patients he gives the treatment to, the more money he makes. It's no wonder he gives it to such a large volume of patients!

It strikes me as insidious that Sinaiko, a mere commercial clinician, is profiting enormously from conducting an unmonitored clinical trial in his office. Yet university medical researchers do not make huge personal profits off of running clinical trials! Should the DPH, the FDA and the Medical Board allow Dr. Sinaiko to reap huge profits on a purely experimental clinical trial with an unproven medication? Could the profit motive not skew Sinaiko's clinical data or cause him to be less-than-objective in his reporting of treatment results?

The DPH should seriously question Dr. Sinaiko's motives. For example, he treats patients with EPD for extended periods -- 5 to 6 years. Is this really because the drug needs 5 years to work, or is it because long-term treatment benefits Dr. Sinaiko financially? The fees he charges for the injections, AND the hefty office fees he collects from long-term patient relationships both provide him with enormous fee income.

EPD seems to have been beneficial to Dr. Sinaiko's lifestyle also. Right at the time he started using EPD in his practice, he cut back his office hours from 4 days a week to 2-1/2 days a week, and increased his hourly fee from \$150 to \$350. Patients then noticed that his office stopped keeping regular hours, and would often shut down at 3 or 4 in the afternoon -- even though his stated business hours were 9 to 5. He began to be unavailable and absent for long periods of time. A patient asked his nurse why he was gone so much, and she claimed he was traveling on vacations.

There are many explanations as to why Sinaiko suddenly cut back his hours, and we can only speculate as to the reason. But one obvious explanation might be that Dr. Sinaiko was making so much money from EPD that he no longer needed to work regular hours to earn his living. His high EPD income was allowing him to

work just a couple of days a week -- as well as giving him plenty of money to go on lots of vacations.

Here is a patient anecdote that might explain why Sinaiko was able to go on so many vacations. This patient reported that every time she went to his office, there would be huge crowds of patients lined up waiting to get their EPD injections. She reasoned that, if there were this many people getting EPD injections in a single hour, there must be a tremendous number of patients getting EPD injections in a full day. She then multiplied his EPD and office fees times the number of patients she had observed per hour and was shocked to realize that his daily income was around \$11,000 per day!

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As I told you at the beginning of this letter, I know of many other patients who have been harmed by Dr. Sinaiko's EPD therapy. I have not used their names in this letter because I do not have permission to release their names. However, many of them will probably contact the DPH on their own. If they do not, then I will ask them to get in touch with you. In some cases, they may permit me to give you their names and phone numbers, and you can contact them directly for their testimony about Dr. Sinaiko's use of EPD.

Also, you might want to contact the California Medical Board, which is currently investigating Sinaiko for medical malpractice in several cases. It is the Novato office (not the main office in Sacramento, CA) that is conducting the Sinaiko investigation; contact Noelle Holloway, Medical Board of California, 371 Bel Marin Keys Blvd, Suite 220, Novato, CA 94949, phone (415) 352-1197.

The FDA has also received complaints from patients about EPD, but I believe the complaints were just filed in the past few weeks. We assume the FDA will also investigate the case, although as previously stated, we expect it will take them a long time to get around to it. At any rate, you might want to interface with the FDA about this case as well.

As far as myself is concerned, I am not willing to release my true name, but I am willing to discuss the case over the phone with you. I will call you in the near future and ask you if you need further information or help from me. My greatest contribution might lie in connecting you with other patients who have been damaged by his EPD. As long as my family's safety is not jeopardized and I am assured anonymity, I am happy to cooperate with the DPH. I and many other patients feel this doctor is truly incompetent and misguided and believe the FDA should not be allowing him to use EPD.

Lastly, I know a doctor who might be an excellent source of information for the DPH on Dr. Sinaiko:

Dr. Abba Terr — This physician has known Dr. Sinaiko for years and is very well informed about Sinaiko's "alternative medical practices." Terr is a prominent and well respected allergist who is a senior professor of medicine at Stanford

University. His wife is the respected psychiatrist, Lenore Terr. He might well be a source of patient names for you, and has reportedly treated many of Sinaiko's former patients. He would be an excellent doctor to review this case for you, in terms of being able to judge Sinaiko's competency. Dr. Terr would surely be a very cooperative source who could give you leads on who to contact (i.e., doctors) to get names of other EPD patients harmed by Dr. Sinaiko.

Phone: 415-433-7800, San Francisco, CA

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So what does one conclude about Dr. Sinaiko? We patients believe that he is exploiting patients with his EPD therapy. Patients are initially seduced by him into believing this "alternative allergy treatment" is effective and scientifically valid. Sadly, they find out too late that 99.99% of all doctors disagree with Sinaiko's EPD procedures and theories. Only later, after all the harm is done, do they find out that EPD is not what Sinaiko claimed it was. They are just \$8700 poorer for having fallen for his deceptive medical claims. This has happened in dozens of cases. It is terrible how unprotected his patients really are! They have no one to tell them how deluded he is until it is too late.

EPD exploits the patient because it is exorbitantly expensive, yet it does not offer any medical benefits to the vast majority of patients, and is even medically damaging to some. The treatments benefit only one person: Robert Sinaiko, who gets richer and richer the more he prescribes them.

All the information I gave you in this letter is based on what honest and reliable sources told me about Dr. Sinaiko. I cannot, however, guarantee that every single detail is correct. I am merely telling you what they told me. The information is for the purpose of helping the DPH so that it will have the evidence it needs to take action against this doctor. But all the information in this letter will have to be checked out to insure its accuracy.

I hope this letter has been helpful. It was very time consuming to have to write all this to the DPH, but I am doing so only because all of us patients want to see something done about Dr. Sinaiko. In our opinion, Dr. Robert Sinaiko is an incompetent, negligent, dangerous and possibly dishonest doctor who should not be allowed to administer an experimental treatment like EPD.

If I get any further information about him, I will write you again, under the same pseudonym. And, although I am not willing to release my name, I am willing to talk over the phone with you so that you may ask me questions. I may be able to assist your investigation by providing you with patient names or other information about this doctor.

I will plan to phone you in the next few weeks after you have had a chance to review the information in this letter. Thank you sincerely for your attention

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to our consumer complaint. I hope it has been helpful.

Sincerely,

Samantha Simon