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# Hastings Women's Law Journal



*"If you're gonna go out on a limb, you might as well grow your own tree."*

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## SUBMISSIONS

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## The Criminalization of Medicinal Marijuana

*The Hastings Women's Law Journal Symposium, "The Resurgence of Herbal Remedies: Controlling Access to Herbal Supplements and Medicinal Marijuana," was held at Hastings College of the Law on February 6, 1999. Following are the Symposium speeches given during Panel II, "Criminalization of Medicinal Marijuana." Hastings Women's Law Journal staff edited for clarity, researched and added footnotes to the text of the speeches. The Journal wishes to thank Sarah L. Ream for her editorial work, and Christopher Leung, Karolyn Plummer, Samantha Rajaram, Penelope Shaner-Gaffney and Claudia Spielman for their work on the footnotes.*

### STEVEN HEILIG, MODERATOR<sup>1</sup>

Hello, my name is Steve Heilig, I'm the moderator today probably because I am somewhat of the spokesperson for the local medical association. I was very involved in both the political lobbying around Proposition 215<sup>2</sup>

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1. Steven Heilig served as the moderator for Panel II of the Symposium. Steven Heilig is currently Director of Public Health and Education for the San Francisco Medical Society. He is also co-founder and Director of the Bay Area Network of Ethics Committee, a professional educational and policy making association.

2. Proposition 215, effective November 6, 1996, added section 11362.5 to the California Health and Safety Code, as follows:

(a) This section shall be known and may be cited as the Compassionate Use Act of 1996.

(b)(1) The people of the State of California hereby find and declare that the purposes of the Compassionate Use Act of 1996 are as follows:

(A) To ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief.

(B) To ensure that patients and their primary caregivers who obtain and use marijuana for medical purposes upon the recommendation of a physician are not subject to criminal prosecution or sanction.

and then trying to implement it initially when it was first passed and everybody was scrambling to figure out what medical marijuana was all about. Let me start with a little story, a true story. The other day on Haight Street, which is my neighborhood, I was handed a little orange flyer which said: "Announcing under new management San Francisco Patient and Caregiver's Health Center. Medical marijuana everyday 3:00 to 7:00 p.m. Holistic massage Saturday and Sunday 3:00 to 7:00 p.m. A hassle free safe medical cannabis facility. \$5.00 off first order with this coupon."

So we had, until it was shut down by authorities, very close to where we are today a "buyer's club" that is no longer in existence. I was interested to see this flyer because apparently the closed facility is operating under new management. I was coming up from San Francisco General Hospital from a meeting Thursday, I was in the neighborhood and so I thought I would stop by. I had the coupon even. So, I parked and ran the gauntlet of people purveying all sorts of chemicals dangerous or otherwise, ranging from heroin and syringes to alcohol and tobacco, and came to this little storefront. The fellow looked at me through the cage that locked the door and then buzzed me in, thought I looked all right I guess. Then I was welcomed in through the glass door and sat down in a big cloud of smoke. I started to get a second-hand buzz as it were, as I tried to see what I could get there—what did I need to do? The guy just handed me some forms and said, "Fill these out." But then he looked at me, and unfortunately he "made me," as they say in the business and said, "I know you from somewhere and you don't want this."

But anyway, what we have now is this legally and medically questionable gray area that has been heightened ever since Proposition 215. The main irony of Proposition 215 is that it made things a lot less clear in some ways about what is legal to do regarding marijuana in a medical and clini-

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(C) To encourage the federal and state governments to implement a plan to provide for the safe and affordable distribution of marijuana to all patients in medical need of marijuana.

(2) Nothing in this section shall be construed to supersede legislation prohibiting persons from engaging in conduct that endangers others, nor to condone the diversion of marijuana for non-medical purposes.

(c) Notwithstanding any other provision of law, no physician in this state shall be punished, or denied any right or privilege, for having recommended marijuana to a patient for medical purposes.

(d) Section 11357, relating to the possession of marijuana, and Section 11358, relating to the cultivation of marijuana, shall not apply to a patient, or to a patient's primary caregiver, who possesses or cultivates marijuana for the personal medical purposes of the patient upon the written or oral recommendation or approval of a physician.

(e) For purposes of this section, "primary caregiver" means the individual designated by the person exempted under this section who has consistently assumed responsibility for the housing, health, or safety of that person.

CAL. HEALTH & SAFETY CODE §1132.5 (West 2000).

cal setting. A lot of doctors I have talked with through the years have said that they are much more reluctant to talk about, or recommend, marijuana, for whatever symptoms, than they were before it became supposedly legal in this state. These questions are some of the things you are going to hear about today. Is there really a medical use for the drug? It depends on who you ask. If you ask our drug czar he'll say that it's "Cheech and Chong" medicine and there is no use for it. And is it legal? Well, if you ask some people at the federal level, they'll say, "No, under no circumstances." Some people at the state will tell you, "Either way, depends on who's in office."

So, we have quite a gray area, interestingly it's all about a plant first mentioned in written history 5,000 years ago. Chinese and Indian texts talked about it for various medicinal uses. Nowadays you have the same debate. You have some, like longtime marijuana activist Dennis Peron,<sup>3</sup> who was one of the authors of Proposition 215 and has now retired to his farm up in Humboldt County, saying that all marijuana use is medicinal and anybody who smokes this stuff is doing it to medicate themselves for some reason. On the other hand, you have people who would say there is no legitimate medicinal use.

I'm not going into those questions because we have people here who are going to go into those questions in somewhat more depth and better than I could. We're going to hear the medical side of this first and I'm very glad that Dr. Donald Abrams is here. I want you to know that if you could have anybody come to talk about this, he is the only person in this country right now who now has actual approved legitimate research underway.

Before medical marijuana became a big issue though, he was already very well known. I can assure you he's neither Cheech nor Chong; he is a full professor of medicine at the University of California, and has co-run the AIDS program at San Francisco General, which if you ask anybody in the know there is no place better in the world to go if you want treatment for HIV. He has also run an organization called the Community Consortium which has brought together AIDS clinicians of all different types to conduct research and do various projects that have been very well respected and well known all over the world in that field. So, Dr. Abrams is first going to tell us about the real medical story of marijuana.

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3. Dennis Peron is a Vietnam Veteran, author of Proposition 215 and founder of the San Francisco Cannabis Cultivators Club that distributed medicinal marijuana to people with AIDS-related diseases, cancer, multiple sclerosis and other painful afflictions. See Rick DeVecchio, *Pot Club Plea—'Morally Not Guilty,'* S.F. CHRON., Oct. 30, 1996, at A13; see also CALIFORNIANS FOR COMPASSIONATE USE, *Medical Marijuana Resources* (visited Mar. 10, 2000) <<http://www.marijuana.org/peron57.html>>.

DR. DONALD ABRAMS<sup>4</sup>

Thank you, I don't know if I'll do all of that but, as Steve mentioned, marijuana has been used for a millennium in treatment of diseases, and was first introduced into Western medicine in the 1840s by a Dr. W. B. O'Shaughnessy<sup>5</sup> in the British Isles. He said that marijuana had many properties against pain, inflammation. It was anti-spasmodic, anti-seizure, an everything sort of drug. With such a broad array of activity, people could be concerned it might be akin to snake oil or something that is not real.

Marijuana use began to drop, or cannabis as it was known, began to drop off at the beginning of the 1900's when actual agents that could do all of these other indications against pain and helping people sleep became available for the first time, as well as aspirin and syringes. So our ability to treat was expanded and the use of cannabis declined. In 1937 the Federal Government imposed the Marijuana Tax Act<sup>6</sup> which imposed a dollar an ounce tax on people using marijuana for medicinal purposes and a hundred dollars an ounce tax for people using marijuana for recreational purposes.

Interestingly, the American Medical Association at the time was virtually alone in opposing this Act because they thought there was no evidence that marijuana was harmful as a medicine, and that this Act would impede further research into the therapeutic benefits. In 1970 marijuana was classified as a Schedule I substance in the Controlled Substance Act,<sup>7</sup> along with drugs such as heroin, LSD, amphetamines, etc. So, that's where marijuana has been, requiring a special license to be prescribed. But again, the medical utilization of marijuana has declined and really disappeared to nothing.

Clinical research of the effectiveness of marijuana in various conditions is very poor. Most of the studies were done in the 1960's and 70's, before we had the availability of the technology that we have today. We

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4. Dr. Donald Abrams received his M.D. from Stanford University. He is currently Assistant Director of the AIDS Program at San Francisco General Hospital, and Chairman of the Community Consortium (the Bay Area's community-based HIV clinical trials organization). Dr. Abrams has performed extensive cancer and AIDS research, teaching and clinical practice for the past twenty years. He is currently involved in the only federally approved study researching the potential medicinal benefits of marijuana inhalation for AIDS patients.

5. William Brooke O'Shaughnessy, *On the Preparations of the Indian Hemp, or Gunjay*, reprinted in MARIJUANA: MEDICAL PAPERS, 1839-1972 3 (Tod H. Mikuriya ed., Medi-Comp Press 1973). Dr. O'Shaughnessy was Assistant-Surgeon, and Professor of Chemistry at the Medical College of Calcutta and an early proponent of medicinal marijuana. *See id.*

6. Marihuana Tax Act of 1937, Pub. L. No. 75-238, ch. 553, 50 Stat. 551 (1937), repealed by Internal Revenue Code Act of 1939, ch. 4, 53 Stat. 1. A nearly exact copy of the 1937 Act was resurrected in 1939 and codified as 26 U.S.C. § 2593(a). In 1954, it was renumbered as Section 4744(a). The Marihuana Tax Act was ultimately repealed by the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, § 1101(b)(3)(A), 84 Stat. 1236, 1292 (1970) (codified at 21 U.S.C. §§ 801 *et seq.*)

7. 21 U.S.C. § 812(a); *see generally id.* §§ 801-971 (1981).

found ourselves in San Francisco in a unique situation. My group, The Community Consortium, does what is called community-based clinical trials. One of the things that inspires us to do clinical trials is if patients are using something in the community we want to know if it works or not.

We did this with inhaled Pentamidine,<sup>8</sup> a treatment to prevent the AIDS pneumonia that was very popular in the early 1980's. People were using it; we had no idea if it worked, so we established a clinical trial. We found out it worked, got published as a lead article in the *New England Journal of Medicine*,<sup>9</sup> and it also led to the FDA approving this as a mechanism to prevent this pneumonia.

In the beginning of the 1990's we found ourselves in a similar situation. Patients were telling us that smoking marijuana was helpful to them, particularly patients who were suffering from the AIDS wasting syndrome.<sup>10</sup> In the mid-80's, an extract of marijuana, Delta-9-THC (the main psychoactive component) became available as a prescribed drug—Marinol<sup>®</sup> (or dronabinol).<sup>11</sup> Marijuana itself has more than three hundred compounds but the single most psychoactive ingredient, Delta-9-THC, a Schedule II substance, was licensed and became a prescribable drug. This was approved originally in the mid-80's for treating nausea and vomiting secondary to chemotherapy.<sup>12</sup> In 1992, the indication was expanded for Marinol<sup>®</sup> to include treating patients with the AIDS wasting syndrome and it was moved to Schedule III.<sup>13</sup>

Now, many of you look a little too young to remember AIDS six or seven years ago, but it was a different disease then. Many patients died of this wasting syndrome where they developed loss of appetite and nausea. They could not eat, and they became skeletal and wasted away. Patients were getting the benefit of increased appetite, decreased pain and decreased depression if they were smoking marijuana.

Everybody said, "Why do you need to smoke marijuana when we have

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8. Pentamidine is an antibiotic used in the treatment of pneumocystis carinii. See THE PHYSICIAN'S DESK REFERENCE FAMILY GUIDE TO PRESCRIPTION DRUGS 845 (David W. Sifton et al. eds., 1993).

9. See G.S. Leoung et al., *Aerosolized Pentamidine for Prophylaxis Against Pneumocystis Carinii Pneumonia—the San Francisco Community Prophylaxis Trial*, 323 NEW ENG. J. MED. 769 (1990).

10. See CURRENT MEDICAL DIAGNOSIS AND TREATMENT 1271 (Lawrence M. Tierney, Jr. et al. eds., 39th ed. 2000) (defining AIDS wasting syndrome as decreased appetite and weight loss in AIDS patient suffering from anorexia, nausea, vomiting, nutritional malabsorption and/or heightened metabolic rate).

11. Marinol<sup>®</sup> is a brand name and Dronabinol is the generic name for an anti-nausea and appetite stimulant medication. See H. WINTER GRIFFITH, COMPLETE GUIDE TO PRESCRIPTION AND NON-PRESCRIPTION DRUGS 334 (1999).

12. See Schedules of Controlled Substances: Rescheduling of the Food and Drug Administration Approved Product Containing Synthetic Dronabinol, 64 Fed. Reg. 35928, 35928 (1999) (to be codified at 21 C.F.R. §§ 1308, 1312).

13. See *id.*

this pill available?" Again, the pill is a single compound, Delta-9-THC, and marijuana itself is composed of over 300 different substances. I also do some traditional Chinese medicine studies and people say you cannot get the same benefit from a traditional Chinese herb that has been dried and extracted and put into a pill. It has to be the whole herb, and it has to be made into a tea or a concoction or a decoction.

Similarly, our patients said, "Delta-9-THC or Marinol<sup>®</sup> is not the same as marijuana plus, I cannot control the effect if I swallow the pill as well as if I smoke it." And, in fact, if you look at the pharmacokinetics if you swallow THC as a pill, it is not very well absorbed from the stomach. The peak concentration is slowly reached and it lasts for a much longer time. When you smoke it, the THC comes in very quickly and disappears more rapidly. Also, when taken by mouth, one of the breakdown products of Delta-9-THC is an 11-hydroxy product, also a psychoactive agent. So, people who take the pill orally often complain that they are more zonked than if they smoked.

For all these reasons, patients were turning to marijuana and turning to the buyers' clubs. The Community Consortium felt that it was our obligation to look at what our patients were doing and to study it to see: (1) if it was safe and (2) if it might in fact be effective. So, in 1992, we began to develop a clinical trial to look at marijuana compared to Marinol<sup>®</sup> in patients with the AIDS wasting syndrome. We planned the trial in collaboration with the FDA because I needed to get a special Investigational New Drug number from the FDA to do this work.

The study was approved by the UCSF Institutional Review Board, and, because we were dealing with a controlled substance in California, it also had to be approved by the Research Advisory Panel of California, or the C-RAP. The C-RAP also approved our study and my next step was to get my Schedule I license so that I could prescribe the marijuana in this study.

At the time we were working with a collaborator who had made a connection with a Dutch marijuana grower who grows marijuana for medicinal purposes. He was going to give us three different strengths of marijuana for the study as well as \$50,000 to conduct a forty-patient clinical trial. I sent off my application to the the Drug Enforcement Administration (DEA), to get my Schedule I license in April of 1994, and I didn't hear anything from them directly. A few months later, the FDA told me, "Donald, the DEA is not going to give you a Schedule I license, because they are not in favor of you importing marijuana across international borders from the Dutch grower." That sounded reasonable and I said, "Well, do you have any other ideas?" They said, "Seek a domestic source." I said, "Well, do you have any clues on who that would be?" They said, "Go to NIDA, the National Institute on Drug Abuse, because they supply marijuana for people doing clinical trials." That's true, but NIDA supplies marijuana mainly for people who are trying to show that it does bad things to people's

lungs, chromosomes, motivation, etc., and they had never really been asked to supply marijuana for a study that may show that it has a benefit.

Our trial was designed to give patients in an outpatient setting either Marinol<sup>®</sup> or three different strengths of inhaled marijuana to see if they gained weight or increased their appetite, and also to see what happened to their immune systems. We were going to look at hormone levels, because there is a concern that marijuana could decrease testosterone levels in men and testosterone is important for building lean body mass.

So, we were going to do a pretty good study I thought. I wound up sending it to Dr. Alan I. Leshner, the Director of the National Institute on Drug Abuse, in August of 1994, asking for 5.7 kilograms of NIDA's marijuana. NIDA was rather slow to respond to me. An investigative reporter in San Francisco called them in January 1995. She got somebody to answer the phone saying, "Oh no, we have no intention of providing marijuana for a study that may show that it has a medical benefit." Four months later, I got my official response from Dr. Leshner. He said he was sorry he could not approve this study, and he could not give the marijuana for the study because it was not scientific. Again, it had previously been approved by the FDA, the University of California Institutional Review Board, as well as the C-RAP, but he felt that it was not scientific. We were told, ultimately, that if we produced a study that got favorable peer review, Dr. Leshner would reconsider providing us with marijuana from NIDA. Being in academic medicine long enough, I knew favorable peer review meant "send it off to the National Institutes of Health as a grant application."

So, one of the concerns that NIDA had is they did not want us giving marijuana to outpatients. How did we know they were going to smoke it and not share it? What if they got into a car accident, etc., etc.? They also were concerned that if we were looking at weight gain we had no way of knowing if people changed their caloric intake. We took all this to mean that we should put our patients someplace where we could monitor them. At San Francisco General Hospital, we have a General Clinical Research Center, or GCRC, where patients can be housed. They get all their food provided for them and made by dietitians who know how many calories are in everything; everything is weighed and measured. We could also monitor them smoking marijuana. So, we redesigned our study.

In the second study that we submitted, we were going to have fifteen patients admitted for fifteen days to the GCRC; two fifteen day periods separated by a three-week washout. During one time, the patients would smoke marijuana, and during the other time, they would smoke marijuana from which the THC had been removed, inert or placebo marijuana. During the study we would measure everything. We were going to measure their caloric intake, their energy expenditure, their weight, their body composition and also look at the impact on the AIDS virus level in their bloodstreams, their immune systems, their hormones, their neuropsychiatric

testing and their lungs. We were going to measure everything.

We were just looking for a grade; when you submit a grant to the Government you need a priority score. Some of them are fundable, some of them are not. All we needed was a number. We submitted this grant in May 1996, and we were very confident that this was a much better submission.

Two days after the large Dennis Peron buyers' club (Cannabis Buyers' Club) was closed in August 1996, I got a little rip-and-tear envelope from the Government saying that they received my grant. Unfortunately, they reviewed it but they were not going to give it a score, which meant that they felt that it was not worthy of scoring. We were somewhat dismayed at this, because we thought this was a much better proposal. They said, "Wait for a few months until you get your review sheets from the reviewer." Again, the media started calling me and saying, "Donald, this surely must be political." And I said, "No, no, no, this is science. This is a review by my peers. At the National Institutes of Health, they put together these committees to review the grants, and it's not politics at all. This is scientific and there must have been something wrong with the grant."

When I got the reviewers' comments two out of the three reviewers said, "We don't understand why they would consider studying such a toxic substance." The third reviewer said, "Aren't you concerned that if patients smoked marijuana in the setting of AIDS wasting that they may develop high blood fat levels and hardening of the arteries?" Now patients usually did not live long enough to have these concerns, so I was sort of shocked that this was a so-called peer review estimation.

I went to my executive board, our scientific advisory committee and our community advisory forum at the Community Consortium and said, "Should we continue this, because this is now five, six years I've been working on this? I have a life. I do other things. Maybe we should stop here." They said, "Donald, they tell us 11,000 of our patients are smoking marijuana, and they are obtaining it from the buyers' clubs. We need to know if it is safe and effective."

Well, a lot of things have happened in the past few years in AIDS treatment. The biggest are the cocktails, or the protease inhibitor containing regimens. These drugs are very sensitive to metabolism by the liver. They require one of the liver enzymes, and many other drugs interact with that system so you can lower or raise the level of the protease inhibitors in the bloodstream, which will either make them less effective or perhaps more toxic. Interestingly, the cannabinoids are metabolized by the same enzyme system. So, in 1997, a little light bulb went on in my head and I said, "What we will do now is show them safety. We will submit a grant that will look for drug interactions between protease inhibitors and cannabis. We are going to look to see if smoking or swallowing THC impacts on the level of the AIDS drugs in patients' blood streams."

We designed another study where patients would be housed, again, in our GCRC for twenty-five days. They would be assigned either to smoke a marijuana cigarette three times a day before meals, take a Marinol<sup>®</sup> pill or take a Marinol<sup>®</sup> placebo. By having a placebo arm we can determine whether there is any impact of cannabis at all. And, by having smoked versus oral, we can tell whether there is a difference in this interaction, should it exist, if people smoke cannabis or swallow it.

Again, we submitted a grant to the Government asking for \$1 million. Many things had happened in the political side of this, including General McCaffrey's statement, after Proposition 215 was passed, saying that doctors in California and Arizona should not talk to patients about marijuana.<sup>14</sup> This really organized medicine, I think, for the first time to say, "You can't tell us what to do." People got angry. The NIH put together a Blue Ribbon panel to study the question of medical marijuana, although the results of that panel were not made public for six months after the panel's deliberations. Their conclusion was that more research was necessary. Many people were calling for more research, including the editors of the *New England Journal of Medicine*, and we just happened to be there again with this new proposal which the Government actually liked. So in August 1997, they gave us a very good score, sent us \$1 million and 1,400 marijuana cigarettes.

So, we have now begun, as Steve mentioned, the first federally-sanctioned clinical trial of medical marijuana in the country. I just met with Dr. Leshner who came out and visited us and was very happy. He told me another study had been approved to look at glaucoma and, I think, multiple sclerosis. But we are now halfway done with our study and, hopefully, we will have results by the end of the year. Again, the end points that we are looking at in this study are safety. We are looking at the levels of the protease inhibitor in the bloodstream, the levels of the virus, impact on the immune system and the impact on hormones.

We are also looking at efficacy. We are not going to enroll sixty-four patients and fail to see if it increases their appetite, increases their weight and changes their body composition (i.e., do they put on fat or do they put on lean muscle mass?). Again, it has been a struggle. I always said if the science outlives the politics, eventually, we may, in fact, be able to do this study. I am really pleased and delighted to be conducting this study. It is a very important clinical trial. We hope that if we do show safety, and perhaps if there is some efficacy of the smoked marijuana, that we will be able to continue on and do a series of studies looking at the impact of marijuana in patients with HIV both on appetite and nausea, and also on pain relief, particularly of the peripheral neuropathy, or painful feet, that our patients

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14. See *Conant v. McCaffrey*, 172 F.R.D. 681, 688 (N.D. Cal. 1997).

get. This condition often requires treatment with morphine and other very strong analgesics.

Colleagues at the University of California, San Francisco in the neurology program have discovered that THC has specific effects against neuropathic pain which opiates do not have. So, in fact, there could be a time where people might use cannabis as a pain relief agent before moving on to stronger addictive narcotic agents. I think we are at a very exciting time in the history of the use of these agents. The Institute of Medicine also did a one-year study of medical marijuana, commissioned by General McCaffrey, our drug czar, despite the fact that they did one in 1982, and concluded more research was necessary. This one-year study was just completed,<sup>15</sup> and I understand that it appeared on a web page today.<sup>16</sup> The results of the one-year study are that more research is necessary. So, we are here to tell you that research is being done and I look forward to the rest of the panel's discussion. Thank you.

#### STEVE HEILIG, MODERATOR

Thank you Dr. Abrams. So everybody was saying research was indicated, and it's finally underway. It takes time, though, and as you also heard between the lines there, it is hard to keep 'pure' science pure when you are talking about something like marijuana. So, in the interim, while we are waiting for the research, the implementation and interpretation of the status of marijuana for medical purposes in California is still very much in the hands of attorneys, politicians and those who are charged with interpreting and implementing the law. So, we are going to turn now to attorneys. The first one is Dan Abrahamson, the legal director for the Lindesmith Center. The Lindesmith Center has an office here in San Francisco and is basically a drug policy think tank and action group. They really try to raise the level of debate about drug policy in the states. I met Dan when Proposition 215 passed and he was very interested in having some educational forums on this and being involved in the implementation. So, he is intimately close to, at least in San Francisco and elsewhere, what this really means, and is trying to, in a logical sense, implement Proposition 215.

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15. See MARIJUANA AND MEDICINE: ASSESSING THE SCIENCE BASE (Janet E. Joy et al., eds., 1999).

16. See National Academy Press, *Marijuana and Medicine, Assessing the Science Base* (visited Mar. 21, 2000) <<http://www.nap.edu/catalog/6376.html>>.

DANIEL ABRAHAMSON<sup>17</sup>

Thank you, Steve. I want to add a few points to the history of medical marijuana that Dr. Abrams set out. Then, I will provide a rough overview of where things stand with respect to the legality of medical marijuana in California and in other states around the country, as well as some of the legal interplay between the federal and state governments.

Dr. Abrams noted that marijuana has been used for medical purposes for almost 5,000 years. It appeared in the 1764 English dispensatory, which was the pharmacopoeia in England in the 1700's. Over the last hundred years or so, there has been basic research on medical marijuana, but the research has not reached the level of sophistication of which we are capable today. Nonetheless, several high-level commissions, in this and other countries, have examined marijuana and their conclusions should not be ignored. One of the first was the LaGuardia Commission<sup>18</sup> composed of scientists, doctors, a corrections commissioner and public health experts who were appointed in 1938 following the passage of the Marijuana Tax Act of 1937—the wellspring of the federal government's war on marijuana. The LaGuardia Commission presented its detailed findings in 1944 and concluded that marijuana use does not cause crime, antisocial behavior or lead to an acquired tolerance of the drug. Nevertheless, the conclusions of the LaGuardia Commission, although still valid today, were swept under the rug so that the federal government could intensify its war on marijuana.

In 1970, as Dr. Abrams noted, marijuana was assigned to Schedule I of the federal Controlled Substances Act.<sup>19</sup> That meant that in the eyes of the federal government, marijuana had a high potential for abuse and no accepted medical use. One year later, in 1971, President Richard Nixon appointed the National Commission on Marihuana and Drug Abuse, also known as the Shafer Commission.<sup>20</sup> Nixon appointed this commission thinking that this panel of his hand-picked experts would conclude once-and-for-all that—counter to the claims of the Woodstock generation—marijuana was a dangerous substance, and sanction the continued war on marijuana and its users. The Shafer Commission proved a disappointment to the President and in 1972 recommended that marijuana use be “depoliti-

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17. Daniel Abrahamson received his J.D. from New York University Law School. He is currently Director of Legal Affairs for The Lindesmith Center in San Francisco, a policy research institute founded in 1994 as a project of the Open Society Institute that focuses on broadening the debate on drug policy and related issues. Additional information about the Center can be found at <<http://www.lindesmith.org>>.

18. See L. Grinspoon & J. Bakalar, *MARIJUANA THE FORBIDDEN MEDICINE* 11 (1993). Grinspoon and Bakalar's book explains how New York's Mayor LaGuardia appointed a committee of scientists in 1938 to study the medical, sociological and psychological aspects of marijuana use in New York. See *id.*

19. 21 U.S.C. § 801 et seq.

20. See *MARIJUANA: A SIGNAL OF MISUNDERSTANDING, FIRST REPORT OF THE NATIONAL COMMISSION ON MARIJUANA AND DRUG ABUSE* (1972).

cized, deglamorized and decriminalized."<sup>21</sup>

Between 1970 and the mid-1980's, thirty-five states in this country passed laws permitting physicians to prescribe marijuana to patients. Most of those laws lay dormant on the books. Nonetheless, the majority of states in one way or another, at one time or another, officially recognized the medical efficacy of marijuana. In 1976, Robert Randall, a glaucoma patient, successfully petitioned the federal government to obtain medical marijuana for his disease under an experimental drug treatment protocol.<sup>22</sup> Subsequently, thirty more patients received permission from the feds to receive marijuana to treat their illnesses, ranging from cancer, to painful bone and degenerative disorders, to HIV/AIDS. The marijuana was grown on federal land in Mississippi, by federal marijuana farmers, rolled up into the cigarettes that Dr. Abrams referred to and sent through the federal mail to patients around the country. Despite the program's apparent success, in the late 1980's the Bush administration stopped admitting new patients to the medical marijuana program, declaring that the program sent the wrong message to the public, especially children. This is a central refrain of the federal War on Drugs, and in particular, the war on marijuana. In fact, it is the very response offered by the federal government to the passage of Proposition 215 by the voters of California in November 1996.

Proposition 215, also known as the Compassionate Use Act, is a short law—only about one-half page long.<sup>23</sup> On its face, it is not very complex or detailed. Indeed, it is pretty straightforward. It provides that patients suffering from serious illnesses, who have a recommendation from a California physician stating that marijuana might be beneficial to their health, can legally grow or possess medical marijuana or have a caregiver grow or obtain marijuana for them. Also, doctors who recommend marijuana to their patients in the course of their care are not in violation of state law. In passing Proposition 215, California voters were not legalizing marijuana. Rather, they were simply saying, "We are not going to use our limited law enforcement resources to pursue sick people who benefit medically by using marijuana, or arrest the persons who are trying to help these patients get well."

In other words, California voters decided to take a 'baby step' back from the larger War on Drugs. In so doing, Californians were not changing or bucking federal law. Federal law prohibits marijuana use and Proposition 215 does not alter that fact. Californians merely chose not to devote their limited resources to enforcing the federal war against marijuana when

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21. RICHARD J. BONNIE & CHARLES H. WHITEBREAD II, *THE MARIJUANA CONVICTION: A HISTORY OF MARIJUANA PROHIBITION IN THE UNITED STATES* xi (1999); *see also* LYNN ZIMMER & JOHN P. MORGAN, *MARIJUANA MYTHS, MARIJUANA FACTS* 7-9 (1997).

22. *See* MARIJUANA, *MEDICINE AND THE LAW* 27-28 (Robert C. Randall ed., 1988).

23. *See* CAL. HEALTH & SAFETY CODE § 11362.5 (West 2000).

that war was waged against the sick and dying. So, for the law students in the audience, you see that the passage of Proposition 215 did not create a conflict with federal law.

Now, the federal government did not like the message it felt was sent by Proposition 215. However, absent a direct conflict of laws, the federal government could not sue California and have Proposition 215 declared unconstitutional under the Supremacy Clause. Officials in Washington, D.C. thought long and hard about how to put an end to the Compassionate Use Act before other states enacted similar measures. In all their brilliance, the Beltway bureaucrats decided to wage a war on the doctors of California. On December 30, 1996, in a press conference in our nation's capitol, Attorney General Janet Reno, Secretary of Health and Human Services, Donna Shalala, Director of the Office of National Drug Control Policy, General Barry McCaffrey (our "Drug Czar"), and Tom Constantine, Administrator of the Drug Enforcement Administration, announced to the television cameras that any physician in California who recommended marijuana to a sick or dying patient could be punished under federal law.<sup>24</sup> Specifically, they threatened physicians with the revocation of their federal license to prescribe controlled substances medicine, revocation of their contracts with Medicaid so they cannot get reimbursed with federal monies, and/or prosecution under federal law. Any one of these sanctions could put a doctor out of business. That was the federal government's response to Proposition 215.

As Dr. Abrams suggested, and I think as Alice Mead will discuss further, doctors in California were outraged that federal officials (none of whom were physicians) were telling them what they could and could not tell their patients. The American Civil Liberties Union, a San Francisco law firm and The Lindesmith Center, agreed to represent California's physicians and patients in a class action suit against the federal government to vindicate their First Amendment rights. The class was headed up by a group of leading physicians specializing, primarily, in oncology and HIV/AIDS and several prominent patients who used medical marijuana pursuant to a doctor's recommendation. We went to court in January 1997, and in April 1997, Federal District Court Judge Fern Smith ruled that the federal government likely had violated the First Amendment in threatening the doctors.<sup>25</sup> The court proceeded to issue first a temporary restraining order and then a preliminary injunction against the government, enjoining government officials from threatening or punishing physicians for recommending marijuana to certain classes of patients.<sup>26</sup> The case, *Conant v.*

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24. See 62 Fed. Reg. 6164 (1997). See also Tim Golden, *Doctors are Focus of Plan Fight New Drug Laws*, N.Y. TIMES, Dec. 23, 1996 at A10.

25. See *Conant v. McCaffrey*, 172 F.R.D. 681, 687 (N.D. Cal. 1997).

26. See *id.*

*McCaffrey*, continues to be litigated towards a permanent injunction as we sit here today.<sup>27</sup>

There are complicated issues still to be resolved. Judge Smith said that doctors should be able to speak openly with their patients, but she also stated that doctors cannot aid and abet patients in obtaining marijuana because that would be illegal under federal law. But what does it mean for a doctor to "aid and abet" a patient in obtaining marijuana? For reasons I'll briefly discuss, that is a gray area that needs to be clarified.

Steve Heilig, in his opening remarks, discussed the new medical marijuana dispensary on Market Street, a few blocks from the law school. I think it is useful to spend a moment talking about what these so-called "buyers' clubs" probably *cannot* do in light of Judge Smith's ruling that doctors cannot "aid and abet" patients in obtaining marijuana. Cannabis buyers' clubs operate in order to insure that legitimate patients can safely obtain medical-grade supplies of the medicine recommended by their physician. The best way for these dispensaries to accomplish this laudable goal is to ensure that their clientele are *bona fide* patients—that they are seriously ill, are being treated by a doctor and that their doctor recommends marijuana for their medical use. Can the person in charge of dispensing medicine at the buyers' club pick up the phone and call the doctor to confirm that the person in front of them is a patient in need of marijuana? Or that the patient is using an appropriate amount of marijuana? Or that the patient is ingesting it in an appropriate manner given their medical condition (e.g., drinking it in a tea versus eating it in a brownie)? As a lawyer, I find myself in the uncomfortable position of telling the clubs, "No, you may not pick up the phone and call that doctor, even if doing so enables you to run a tighter ship and better serve your clients." Similarly, I feel compelled to counsel physicians that they risk violating federal law if they have good reason to know or believe that saying or writing something for a patient will likely facilitate that patient's acquisition of marijuana. We are now wandering in that gray area of aiding and abetting a federal crime.

In short, the federal government is driving a wedge between doctors' ability to inform their patients about what might help them, and the ability of patients to obtain the treatment that their doctors recommend where that treatment involves marijuana. To be sure, there are other difficulties with Proposition 215. Vernon Grigg will speak more about the day-to-day enforcement issues surrounding the law for patients, prosecutors and cops on the beat. But let me conclude with a post-Proposition 215 update.

Proposition 215 remains the law in California. And to the consternation of the federal government, other states are following suit. A few months ago Alaska, Washington, Oregon and Nevada passed medical

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27. As of March 2000, the parties were litigating disputes related to issues of discovery.

marijuana laws.<sup>28</sup> Unlike Proposition 215 which was quite short, the initiatives in these other states were quite detailed in many respects, and provided much more guidance to patients, doctors and state officials. The laws set out more clearly what medical conditions qualify a patient for marijuana. Some of the laws establish registries where state health agencies will verify the patient's status and issue photo I.D. cards to patients who can then prove to law enforcement officials that they are legitimate users of medical marijuana. The laws also set forth permissible amounts of marijuana that patients can lawfully possess. Additionally, the laws establish a "preponderance of the evidence" standard, such that if patients are caught with more marijuana than what is allowed under those states' laws, patients are able to assert an affirmative defense and introduce evidence showing that the additional marijuana is medically justified.

There was also a medical marijuana initiative placed on the November 3, 1998, ballot in the District of Columbia.<sup>29</sup> In response, Republican Congressman Bob Barr of Georgia added an amendment to the federal budget which provided that no federal money could be used in any way to advance medical marijuana or to decriminalize marijuana.<sup>30</sup> Because D.C. is utterly dependent on federal money, this amendment sought to nullify the D.C. initiative. Although it would cost only \$7.23 to push the button to tabulate the D.C. ballot results, the federal government refused to pay the money, and it refused to accept offers by others to pay it. All because the voters of D.C. might 'send the wrong message' if they voted to decriminalize medical marijuana. The ACLU again went to federal court, suing the federal government for deprivation of First Amendment rights of the D.C. electorate.<sup>31</sup> The battle continues.

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28. See ALASKA STAT. § 17.37.030 (Michie 1999); 1999 OR. LAWS 825; WASH. REV. CODE § 69.51.040 (1999). Maine's initiative is the most recently adopted. See *Medical Marijuana: Maine Approves Initiative*, AM. HEALTH LINE, Nov. 4, 1999. Voters in Nevada will decide on their initiative in November 2000. See Mike Kalil, *Legality of medical marijuana addressed*, LAS VEGAS REV. J., Feb. 20, 2000, at 1B.

29. *Washington to Vote On Marijuana Use*, N.Y. TIMES, Sept. 18, 1998, at A26

30. Omnibus Consolidated Appropriations Bill of 1998, Pub. L. No. 105-277, § 171, 112 Stat. 2681-150 (1998).

None of the funds contained in [the District of Columbia Appropriations Act] may be used to conduct any ballot initiative which seeks to legalize or otherwise reduce penalties associated with the possession, use, or distribution of any schedule I substance under the Controlled Substances Act . . . or any tetrahydrocannabinols derivative.

*Id.*

31. In September 1999, the federal district court ruled that the Barr Amendment does not prevent the Board from computing and certifying the results of the referendum on Initiative 59. See *Turner v. District of Columbia Bd. Of Elections & Ethics*, 77 F. Supp. 2d 25 (D.C. 1999). The votes were counted and the initiative was approved 69 percent to 31 percent. See Bill Miller & Spencer Hsu, *Results Are Out: Marijuana Initiative Passes*, WASH. POST, Sept 21, 1999, at A1.

## STEVEN HEILIG, MODERATOR

Thank you Dan. Now we are going to hear from two people who have the unenviable task of trying to interpret this in terms of enforcement. Vernon Grigg is head of the narcotics division here in the San Francisco's D.A. office. He is a graduate of Yale Law School and is going to tell us what it is like to try to figure out how to interpret this great gray area that we are hearing about today.

VERNON GRIGG<sup>32</sup>

Good afternoon, I am the managing attorney of the narcotics unit for the San Francisco District Attorney's Office, and I can be really brief. It sucks to try to interpret this law. I am not going to kid you, it really does. I think speaking to the law students in the group, one of the things that I can say to you is that this law is a model on what happens when clear lines are not drawn, and when efficiencies and other considerations are not taken into account when drafting legislation.

The thing is a mess; it really is. It leaves so many subjective decisions along the way—determinations that have very severe implications for people's lives. In many cases, the people who are making these decisions are not necessarily qualified to be making assessments regarding whether or not it is reasonable for a person to possess a certain quantity of marijuana, whether or not someone really is a caregiver and things of that nature. It falls on our desk, because we are responsible for all the local prosecution of narcotics cases. We are ultimately the ones who decide whether or not you are going to face the power of the state in court trying to put you in jail. With that by way of a preface, let me begin with a description of what our experience has been like.

First of all, District Attorney Terence Hallinan has long been a supporter of medicinal marijuana, from the very earliest stages of proposed legislation. During his time on the Board of Supervisors, he was in favor of the seriously ill having access to medicinal marijuana. It was with some great anticipation that the results of Proposition 215 came in positively and we thought, "Okay, this is good because it will put medicine in the hands of sick people," or at least that was the thought. Very quickly we learned just how complicated this whole thing can become.

Throughout our office we are presented with approximately 1,000 cases a month to make prosecution decisions regarding a range of violations, from heroin sales in the South of Market area to marijuana sales in the Mission. Needless to say, efficiency matters. When you are going

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32. Vernon Grigg received his J.D. from Yale Law School. He is currently an Assistant District Attorney and Head of the Narcotics Division at the San Francisco District Attorney's Office.

through those kinds of numbers, you have to know what is legal and what is illegal conduct. When you have to stop and study in great depth exactly what is going on and try to figure out whether or not it is a violation of the law, it can really encumber the system. When there is a charge in front of you of a person who was caught in his car with some marijuana and he has his I.D. card, and he says "I'm a medicinal user," you look at the circumstances, and you make your charging decision. That is easy.

The more difficult case is when you are awakened at 3:00 a.m. You have twenty or thirty law enforcement officers at a location wanting a search warrant based upon their belief that there is marijuana cultivation going on inside. There may be some evidence that the location is involved in some way, or has asserted itself to be involved, in the provision of medicinal marijuana. I think that can illustrate just how people not necessarily well qualified to make determinations have to make decisions regarding whether law enforcement goes in, seizes the plants and arrests people. There are always dangers both to law enforcement and to the people inside residences when there is a forcible entry, so, you sort it out in the morning, or you find some other way to decompress the crisis and you deal with it all the next day. You make your decisions and you try to move on.

One of the things that complicates matters for us is that we can talk about medicine, we can talk about how to fix this law, but the reality is that marijuana in this country is a tremendously profitable business. Marijuana generates tremendous revenue. Medicinal marijuana is a subset that, hopefully, will not become imbued with the same kind of economics as illicit marijuana. The prohibition on marijuana has driven marijuana prices and profit margin so high that I have talked to crack cocaine dealers who stopped selling crack cocaine and started selling marijuana. They say it is a lot safer to sell marijuana, the penalties are not as severe and the profits are higher. Rather than selling to crack addicts and people on the street, with the accompanying dangers and hassles, a dealer can sell marijuana. In the illicit, non-medicinal marijuana market, many of the users tend to be affluent and can be functional. Marijuana, except at the highest levels, is not characterized by a whole lot of violence surrounding its trafficking. So dealers can make more money and live longer selling marijuana than they can selling crack.

The amount of money involved raises other issues that complicate the medicinal marijuana analysis: issues of security, issues of supply and access, whether or not it should be on a for-profit or not-for-profit basis if it is for medicinal use. Let me draw a scenario so it is easier for you to go through this with me. Let us assume that law enforcement gets a report of water leaking through a ceiling. A landlord goes in to try to find out why water is leaking into an apartment. He has reason to believe they are cultivating marijuana upstairs and that the hydroponics system is leaking, so he calls the police.



Now, sometimes in San Francisco that call to the police is motivated by the fact that the tenant growing marijuana upstairs has been there for ten years and is paying \$550.00 a month for rent, and the landlord wants him out. So we have to always be very careful not to be used to settle landlord-tenant disputes. If someone grows two plants of marijuana, and the landlord goes in there and says, "He is cultivating drugs, and he is going to get my place seized. We want him out." That, of course, opens up the rental property.

But let's say it is actually a substantial operation, 100-250 plants, and the police show up. They look inside and see bright glowing lights. They subpoena the PG&E bills and find out that the guy has been using \$1,000 worth of electricity every month. They can smell it through some air vents and apply for a search warrant. They get the search warrant and go in there. It is peaceful. They take all the plants; they take everything. They come down, and they charge a case. The person comes in the next day and says, "Ah, I am a caregiver." The caregiver designation is one of the most tricky, thorny, unclear areas that we have to deal with. We are really not in the business of prosecuting sick people who are legitimate users and who are just using marijuana; we are just not interested in that.

It is the sellers that we are interested in. Because there is so much in marijuana, and the illicit market is so large and well-developed, we must then determine the terms on which they are selling, to whom they sell, what kind of money they make, what kind of money they are investing, their historical involvement with medicinal marijuana and the provision of medicine, and so on and so forth. You get into a myriad of aspects of the person's "operation"—financial, medical and so on. We must ask, for example, "What kind of proof do you have? Who are you a caregiver for?" And it can be very difficult to make a decision—very difficult to know for sure, because in many cases, you have a hybrid operation. You can have someone who provides medical marijuana to sick people, but also sells some on the side to whoever wants to buy it.

You also have situations where people sell marijuana to people who eventually sell it on Haight Street and then donate marijuana to clubs to provide cover. They can say, "I give X amount every month to these clubs so you can't come after me." Sometimes what they are giving away is not of the same quality as what they are selling. They are giving away the stuff that is not as good. It is a very muddled and difficult task to determine whether or not someone's primary focus is profit in the illicit market, or whether or not it is medicinal provision. Then the question arises of why should it be his primary purpose? That is an arbitrary distinction. Likewise, what if his primary purpose is medicinal marijuana and a little tiny teensy side purpose is making some money? That is criminal conduct too, and it is our job to decide what is criminal conduct and what is worthy of prosecution.

So the point of the matter is there are no standards. Everything is gray with this law from start to finish, and that makes it really difficult now. We are trying to implement it in a common sense, humane manner designed to effectuate the purpose of the will of the voters. Terence Hallinan is very clear: 80% of San Franciscans voted for medicinal marijuana, 69% of those people who went to the polls on Proposition 215 voted for medicinal marijuana.<sup>33</sup> We wanted to bring that reality to San Francisco, but without any definite, hard standards it is very hard.

So, that is just the case of the privateer, someone who is in their apartment growing some marijuana. They are giving some away or selling some. Should they just cover expenses, or should they make a profit? Some will argue that pharmaceutical companies make a profit, so why shouldn't someone who grows marijuana make a profit? Then you have the club situation. The Court of Appeals has said that the club model is not what was contemplated by Proposition 215.<sup>34</sup> This was the basis upon which the Market Street clubs had to close.

The law seems to contemplate almost a family farm. It contemplates that an individual who is sick will be out there in his backyard cultivating his own marijuana. That is completely unrealistic, particularly someplace like in the City and County of San Francisco. So again, you have drafting problems, perhaps unavoidable, that inhibit the ability of law enforcement to really make this law meaningful.

However, we are trying to improve upon that. Just last week I attended a meeting with Bill Lockyer and a number of other law enforcement people from throughout the state to try to figure out what is to be done about Proposition 215. The people around the table were from both ends of the spectrum—people with pending cases for cultivating marijuana and people prosecuting them on behalf of the Attorney's General office. It is the hope of law enforcement and state officials that some kind of rational interpretation can be brought to bear on the law, and that we can figure out how and what to do. I am going to close on that, and I look forward to your questions, because I think therein we can target exactly what it is that you want to go into. If you are going to have a supply of medicinal marijuana, the most important factors to be considered are: (1) Where is it going to come from? (2) Under whose authority is it going to be regulated? Regulation has to be a part of it, given the profit that is available on the illicit market. So, with that, I will sit down, and we will hear from some of the other speakers.

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33. See Sabin Russell, *Federal Judge Orders Closure Of Pot Clubs*, S.F. CHRON., May 15, 1998, at A19 (stating that the initiative passed by an 8 to 1 ratio in San Francisco).

34. See *People ex rel. Lungren v. Peron*, 59 Cal. App. 4th 1383, 1392 (1997).

## STEVE HEILIG, MODERATOR

We are going to hear a little bit more from the law enforcement side from Robert Elsberg, who reminded me that we debated each other during the campaign about Proposition 215. He has been the president of the state's Narcotic Officers Association and is senior special agent in that bureau. So, I expect he may focus a little bit more on the issues of the entire state in trying to again interpret what is a very gray area.

ROBERT ELSBERG<sup>35</sup>

Let me clear up a little bit, actually I have two titles. I am here today representing the California Narcotic Officers Association (CNOA), where about 7,000 police officers represent the federal government, state government and local government. We are all out working for law enforcement agencies throughout the year arresting people that are illicitly growing, selling and manufacturing drugs for illicit purposes. Our primary role is actually to put on training for peace officers. But because it is very hard to specialize training in this very narrow topic, at the same time we have been very legislatively active.

I face a unique situation. My boss a few weeks ago was Dan Lundgren, and my boss today is Bill Lockyer. So, those of you who know these people know that they are totally different people, and they have different ideas about what we should be doing in this state. I do work for the California Attorney General and am a special agent in charge of the California Bureau of Narcotic Enforcement which encompasses about nine counties in the Bay Area. But, I am here today to speak about CNOA because I am not sure what Bill Lockyer would say about medicinal marijuana, just like I am not sure about everything that Dan Lundgren might have said about marijuana.

We clearly are here to suppress drugs, enforce the state and federal laws and put people that put other people on drugs in jail. We have a big drug problem in this country, and we have a big problem in this state. We probably have been called the capital of the problem more often than any other state in the nation for many of the drugs that are illicitly sold are produced in this county. We really care about preventing illicit drugs from getting onto the street. Marijuana was a topic we did not deal with a whole lot a few years ago and today, I think I spend probably 50% of my time talking on this one subject.

First of all, let's just talk about the law. It has been argued or discussed

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35. Robert Elsberg is Senior Special Agent in Charge of the Bureau of Narcotic Enforcement at the California Department of Justice. As past President and Executive Board Member of the California Narcotic Officer's Association, he served as a legislative chairperson against Proposition 215. Mr. Elsberg has thirty years of law enforcement experience at the Attorney General's office.

how gray the area is, but I am not sure you all know exactly how gray it is. The way that the law was drafted, you only need a verbal recommendation. It does not say that you even have to see your doctor but you could possibly get a recommendation over the telephone or by some other means. It is a recommendation. It does not say how old you have to be to get this recommendation. You could be a kid; you could be an adult. If you were to go to a doctor for a prescription other than marijuana you would be looked at and prescribed something. For your treatment you would probably have to go back again and you would get a certain amount of the drug to last for a certain amount of time.

Not with this law. With this law you basically are on your own. You grow your own, you grow as much as you want, you use as much as you want, no one tells you when to quit using this drug, you can use it for the rest of your life. These are some of the problems that we in the Narcotic Officers Association had with this particular law. This law was so broad that here we are trying to prevent marijuana from getting to our kids, from getting out for illicit purposes, and this law was broadening the availability and the exposure. Now, with the more abundant amount of marijuana there could even be a reduction in prices of marijuana.

There is a program each year called CAMP (Campaign Against Marijuana Planting). Every year during the marijuana season, teams go out and raid the gardens primarily in Humboldt, Del Norte and Mendocino counties, but also throughout the state. Since Proposition 215 was passed, the seizures have been in record numbers. They have never been bigger than they are today. Clearly, Proposition 215 is having that kind of impact on growing and it is not all going for medicine. So, CNOA is very concerned about this whole issue. We are not trying to be doctors; we know nothing about medicine. There may be a few who do but most of us do not. We are not scientists, and we are not here to tell you it is not a medicine because we honestly do not know. But, we are here to try to prevent marijuana from getting to people on the street for illicit purposes. We support, which is kind of hard for some people to believe because they thought we were against everything, but we really do support research, and we were one of the few groups last year that was with Senator John Vasoncellos actually supporting a bill<sup>36</sup> to try to do more studies for marijuana as a medicine. Unfortunately, the bill never made it through.

One of the problems that we see is a clear tension between the federal and state laws. Before we were born, there were all kinds of leeches that were used to cure everything. We have things that are medicine now, like cocaine. I mean it went through the system and became a medicine. Now, we have something called marijuana and it is having trouble getting

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36. See The Marijuana Research Act of 1999; S.B. 847, 1999-2000 Sess. (Cal. 1999).

through the system to be shown that it is a safe and effective substance that can be a medicine. We would like to see that cleared up but, until it is, we oppose marijuana being used by anyone for any purpose. It is a violation of federal law.

If I go out on the street with a federal agent and we find somebody with a lot of marijuana, the federal government can arrest that person and then prosecute in federal court. We, state officers, would go to the District Attorney to see if we could file charges. Obviously, if there was a rebuttal presumption and the defendant could show the marijuana was for medical purposes, he or she would not be convicted of the offense. We have cannabis buyer's clubs all over the state, and we were laughing there is one out here on Mission Street. Now that's a joke. We basically have a Court of Appeals decision holding that a cannabis buyer's club is not a caregiver. So, we have people out there now actually violating the law; and we have people that are very sensitive to the fact that there are some sick people out there that may be getting some good benefits from this substance, and we do not want to disturb the cart.

But, in essence, this whole thing is not going away. It is not going to get any better until we do the research. Once we do the research, it is our recommendation that if it is proven to be safe and effective that we treat marijuana just like any other substance, and we make it a controlled substance Schedule II, III or IV. Then a doctor can legally prescribe the substance just as he now does for any other sickness. A doctor could then feel comfortable writing a prescription for marijuana to treat something, but again that is not the way it is now.

So we have a big fight between various factions and we are spending a lot of the federal, state and local taxpayers' time, the workers' time and the politicians' time. We are just slowly starting to find and make some progress through work such as Dr. Abrams' scientific studies. I think we all want to see this thing come to an end, but I do not think any of us want to see these open businesses selling to everybody and anybody. All they have to do is walk in and pick up their pot. These are profit-making ventures. We have evidence from several cases that we have worked on that even if they do not charge for the marijuana, they charge other types of fees so even if the marijuana is free they are making money in a different way.

I do not want to be repetitious, but, by and large, I think that both sides of the counter here are on the same page regarding wanting to put this thing to rest, wanting to do the scientific studies, wanting to finally determine once and for all if marijuana is safe and effective. We would like both the federal and state governments to be on the same page and to treat marijuana just like any other medicine. Then patients would not have to worry about how to get marijuana or how to grow it. They could just have it delivered to their doors, or they could go to the local pharmacy. Thank you.

## STEVEN HEILIG, MODERATOR

As has been mentioned in addition to law enforcement having difficulty in interpreting what they can and cannot do in California in regard to medicinal marijuana, physicians in California obviously have a lot of uncertainty as well. Alice Mead is legal counsel with the California Medical Association. I have worked with her on all kinds of issues through the years and know that there is probably no one better to give a summary on exactly what the official line of what attorneys should be telling physicians regarding what they should or should not do. Keep in mind that what physicians really want to do is practice medicine and they do not want to get into court for any reason if possible, including for talking about medical marijuana.

ALICE MEAD<sup>37</sup>

Thank you, I'm glad to be here today. It seems like I have spent a lot of my time talking about medical marijuana for the last few years. I represent the California Medical Association (CMA) which has about 30,000 practicing physicians. We are the largest state medical association in the country, and I have handled this issue because I specialize in the area of end-of-life care. So, it seemed appropriate for me to examine medical marijuana since so many people who appear to benefit from the use of marijuana are unfortunately in an end-of-life disease situation.

Proposition 215 posed a terrible dilemma for organized medicine. CMA did not support Proposition 215 because as you have learned from the other speakers, organized medicine is very committed to the scientific process. We are committed to clinical trials like Dr. Abrams'. The way a new drug is introduced into the population is through such clinical trials where safety and then efficacy are demonstrated and the FDA gives its approval. We were very concerned that this was the introduction essentially of a new drug, despite its honorable lineage. It had not gone through that scientific process, so it was being introduced by popular fiat. We were concerned that this would set a somewhat dangerous precedent for the future if other initiatives could be enacted by the people that allow untested drugs to be used at the state level.

We want to see hard clinical evidence that something is safe and efficacious. Physicians want to benefit their patients, but they do not want to give or recommend something that may be a nullity. It may not actually help the patient, it may give them false hope that they are going to be benefited, or it may have some undesirable effect on this particular medical

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37. Alice Mead received her J.D. from University of Santa Clara School of Law, and her L.L.M. from Yale Law School. She is currently legal counsel for the California Medical Association.

condition or this particular patient. Physicians certainly do not want to prescribe something that might be contaminated, where the dosage is not controlled, or where the source is not regulated.

For all these reasons CMA did not support Proposition 215, although it knew that there were many physicians who were discussing medical marijuana with their patients and who had determined that, in their professional opinion, it might be helpful for those patients. We have consistently supported further research in the area, and our policy has become a bit broader over the last few years, to the point where we do support a "limited distribution to appropriate patients by closely regulated sources." However, we have not exactly identified what those sources should be if they are not pharmacies. We think that the structure of distribution by cannabis clubs is somewhat dangerous. Some dispensaries were run very professionally, and the quality of the cannabis was probably consistent and good. Others, however, were not. Institutions that are not under any single supervisory authority, or not even under local authority, run the risk of inadvertently providing contaminated material to patients.

So, we wanted further research, and we applauded Dr. Abrams' work. We sent a letter in his support to the federal government.<sup>38</sup> It was not lost on CMA that there have been political obstacles to the research being conducted. We see that it is a double bind, but nevertheless, the research has not been conducted—that is still the bottom line. We would like to diminish those obstacles. For example, why should Dr. Abrams have to submit a grant proposal just because he wanted to use NIDA marijuana, which is not even of very good quality. Its THC content is not very high, and it does not give him a choice of different THC contents. Why should he have to use it, just because he uses their marijuana? Why shouldn't he be able to import it from some reliable source somewhere else? Why should he have to seek funding from NIH? Those seem to us to be an unreasonable obstacles, and I think the AMA has written a letter to NIDA suggesting that there should

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38. CMA also recently wrote a letter of support to the federal government on behalf of the work of GW Pharmaceuticals, Ltd., a small pharmaceutical company founded by a British physician, Dr. Geoffrey Guy. GW is dedicated to the research and development of non-smoked delivery mechanisms (including a sublingual spray and inhaler) that will be used to deliver pharmaceutical-quality whole cannabis extracts. GW will provide standardized dosages of known and reproducible compositions, that are designed to meet the rigorous scientific standards applicable to pharmaceutical products. Its approach was endorsed by the Institute of Medicine's 1999 report on cannabis, *Marijuana and Medicine: Assessing the Science Base*, and has been enthusiastically received by the federal Drug Enforcement Administration and Director McCaffrey's office. GW hopes to make prescription medicine available to patients within 3-4 years in this country. CMA in its letter stated that the GW approach "will address the concerns of both health care providers—many of who do not believe that a medicine should be smoked—and patients—who desire the ability to titrate their dosages to achieve therapeutic effect." Letter from John C. Lewin, MD to the Honorable Barry R. McCaffrey, September 20, 1999; see also *U.K. Medicinal Cannabis Project* (visited Mar. 24, 2000) <<http://www.medicinal-cannabis.org>>.

be no need.<sup>39</sup> The grant application process is basically an added obstacle over and above the FDA approval process, and FDA approval should be sufficient to require NIDA to provide marijuana to a researcher. So, we definitely oppose these additional obstacles that seem to us to be more politically motivated than anything else. FDA approval should have been sufficient to allow Dr. Abrams to have obtained marijuana from essentially whatever legal and reliable source he could find.

Now, having said that we did not support Proposition 215 for all the reasons discussed above about the scientific process, and that we support further research, CMA still believes that physicians ought to be able to talk to their patients now and have full physician-patient discussions about whatever the physician thinks might be beneficial to the patient. We were disturbed when Barry McCaffrey, Director of the Office of National Drug Central Policy, came out with his statement about going after doctors who recommended marijuana.<sup>40</sup> We thought, "They cannot mean that doctors can't talk with patients. They surely can't mean that. They know about the First Amendment too."

We applauded the lawsuit that was filed, but we did not join it because we simply could not believe that the federal government meant what it appeared to be saying. We contacted Director McCaffrey and talked at great length with his office. We said, "You surely do not mean that there cannot be full physician-patient discussions. This is protected by the First Amendment. This is what physicians do." They said, "That's right. They can have discussions but they cannot take any additional steps for the purpose of assisting the patient in getting marijuana because that is aiding and abetting, and that is not protected by the First Amendment." We said, "We agree. We think they can have full professional discussions in a bona fide physician-patient relationship." We went home and wrote extensive guidelines for physicians about what we thought they could do and say and what they could not do, including making confirmations to buyer's clubs, because that was taking the "next step". If a physician writes a letter or has a telephone conversation with a buyer's club, the question may be asked, "Why did you tell that buyer's club that the patient is your patient?" If the physician tells the buyer's club that he or she recommended marijuana or

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39. On May 21, 1999, the Department of Health and Human Services (HHS) announced a change in this policy. HHS stated that, effective December 1, 1999, HHS would allow research-grade marijuana to be made available, on a cost-reimbursement basis, for approved research projects other than those directly submitted to and reviewed by NIH through the regular grant approval process. See Richard Sisk, *U.S. to Deal Reefer But It'll Only Sell for Research Use*, DAILY NEWS (New York, N.Y.), May 22, 1999, at 2. In theory, at least, research that is not funded by NIH may qualify for and receive research-grade marijuana. However, Dr. Ethan Russo, the first researcher to seek research marijuana under this new policy, was turned down, despite the fact that his protocol had already been approved by the FDA.

40. See Michael Pollan, *The Pot Proposition*, N.Y. TIMES, July 20, 1997, at 23.

that the patient has a serious disease, what is the only credible answer—to assist the patient in getting marijuana? So, that runs the risk of crossing over the line to aiding and abetting.

We did not recommend that physicians do that, but we were specific about all the things that physicians could do. We believed on the basis of our conversation with McCaffrey's office that there could be a full patient-physician discussion, and the physician could share any anecdotal experiences of other patients similarly situated. Obviously, there were not clinical trials but there was anecdotal evidence that could be shared, including whatever possible benefits and risks the physician could share. The physician could even say, "In your case it might be worth a try." That is a recommendation. We said that the physician should write all that in the medical record. This is what doctors normally do when they have on their physician hats. They have a full physician-patient discussion and record it in the medical record. And, that is what they should do in this context. The guidelines were distributed. But, in the courtroom during the First Amendment litigation, the federal government said they would not subscribe to these guidelines. We were dismayed because we thought we had agreement from the federal government.

Unfortunately, the lawsuit is continuing and the federal government is continuing to fight. All we can surmise is that they think physicians cannot have full physician-patient discussions, and that these are not protected by the First Amendment. Otherwise, I assume some sort of reasonable settlement would have been reached, and that is very disturbing. If there were another unapproved substance such as St. John's Wort, a full discussion and recommendation would be allowed. Physicians should be able to discuss these options with patients and share whatever information, knowledge or experience they have without fear of some kind of retribution.

I fear that even if the lawsuit is ultimately successful and a permanent injunction is issued, if the injunction looks anything like the preliminary injunction, physicians will be able to discuss or recommend marijuana, but they will not be allowed to aid and abet.<sup>41</sup> The many questions I have re-

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41. However, a recent Ninth Circuit panel decision may have expanded the assistance that physicians and others can lawfully give to certain medical marijuana patients. In the course of an appeal in a civil lawsuit brought by the federal government in an attempt to close a number of the clubs, the Court stated that, despite the federal Controlled Substances Act, the clubs could legally dispense marijuana to patients who meet the criteria for "medical necessity." The concept of medical necessity applies to patients who (1) have serious medical conditions for whom the use of cannabis is necessary in order to treat or alleviate those conditions of their symptoms; (2) will suffer harm if they are denied cannabis; and (3) have no legal alternatives to cannabis for effective treatment of their medical conditions because they have tried other alternatives and have found that they are ineffective, or that they result in intolerable side effects. *See* U.S. v. Oakland Cannabis Buyers' Cooperative, 190 F.3d 1109, 1114 (9th Cir. 1999). The federal government has sought rehearing and rehearing en banc. CMA filed an amicus brief in support of the panel's ruling on medical neces-

ceived from physicians have centered around where the line is drawn. Unfortunately, as lawyers are always saying, it is not clear. Physicians are very uncomfortable with that, because their entire practices are at stake. So, despite the preliminary injunction, I get calls from different counties where physicians are reluctant to have any discussions at all about marijuana or to write anything in the medical record. Additionally, I have had conversations with cannabis clubs about why the physician cannot confirm that the patients are real patients, and that is a legitimate concern. If a cannabis club wants to be run as professionally as possible, it wants to be sure that it is distributing to genuine patients. They want to be sure they have real physicians with real recommendations, but how do they find that out?

We did think of a reasonable solution. Under state law, patients have the right to get access to their medical records. They can go into the office and say, "Physician/Nurse/ Receptionist, I want a copy of my medical record or part of it." The patients have a right to get a copy. So we said, on the one hand, physicians should have full discussions. Physicians should document those discussions in the medical record, including the statement about how marijuana might be worth a try. Then, if the patient comes in and gets a copy of the medical record, that is the patient's business. The patient has done so unilaterally, exercising his or her rights under state law. What the patient does with that medical record, including going to a cannabis club, is up to the patient and does not involve the physician. We thought that would work nicely, and I think in some places it does work reasonably well. However, some cannabis clubs are still concerned that there is a possibility of a patient forging a medical record. It is difficult to come up with the perfect solution that can protect all parties in that case.<sup>42</sup>

A few other areas have also been problematic. For example, the Medical Board, which has a disciplinary power over physicians, has issued some uncertain guidelines which say that the Board will not pursue a physician if the physician treated marijuana like a standard drug, did a good faith prior exam of the patient, is not over-prescribing, got informed consent of the patient and demonstrated in the medical record the basis of his or her recommendation. Well, how do you get informed consent from the patient? There have not been clinical trials, so the risks for any particular medical condition are sort of unknown. How does a physician establish a scientific basis for his/her recommendation in the medical record so the Medical Board will be satisfied that this was a reasonable recommendation? What

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sity.

42. During the first half of 1999, Attorney General Bill Lockyer established a Task Force of Medical Marijuana. See Maura Dolan & Mary Curtius, *Medical Need a Factor in Pot Cases*, L.A. TIMES, Sept. 14, 1999, at A1. The Task Force, of which CMA was an active member, developed legislation, carried by Senator John Vasconcellos (S.B. 848) to try to implement Proposition 215 in a way that would protect bona fide patients from unnecessary and onerous prosecution. That legislation failed because of lack of support from Governor Davis. See *id.*

scientific literature can physicians point to?

I have gotten those questions across my desk, and it is difficult for physicians to know how to protect their practices if they want to make a recommendation. As part of the informed consent process, do they need to warn the patient that there is no protection for the patient under federal law, and that the patient might still be prosecuted? Indeed, in some counties the patient might even be prosecuted under state law. I cannot tell you how many requests for assistance I have received from patients with recommendations in counties where supposedly they were told, "We do not apply that law here."

Doctors are not really accustomed to having to make those kinds of warnings to patients. If a physician fails to make a warning to a patient and the patient gets prosecuted or the patient has an untoward reaction that nobody would have known of because there were no clinical trials, is the physician covered by malpractice insurance? I have spoken with some malpractice carriers and they said, "That is a really good question. We do not know if we would provide coverage. We might provide a defense with reservation." I know of at least one case where the Medical Board is looking at a physician who made several recommendations for conditions that are specifically spelled out in Proposition 215. So, the medical profession is very sympathetic to the needs of patients who have serious medical conditions. We are currently in a state of such uncertainty on so many fronts that we need a way of ironing this out so that all parties are protected and physicians are able to help their patients in the way they are at least reasonably accustomed and which provides protection to everyone involved. Thank you.

#### STEVEN HEILIG, MODERATOR

Thank you Alice. I should mention I actually brought a handout that is the official position of the San Francisco Medical Society<sup>43</sup> on what physicians can do and what model they should follow and actually it's very close to what Alice has outlined in terms of what we call the "medical records" model. On the other side is a little editorial I wrote in the *Chronicle* called *When Newt Gingrich Spoke Out For Medical Pot*<sup>44</sup> that you might find interesting. We come now to Marsha Cohen who is a professor at Hastings and also has been the head of the State Board of Pharmacy. Thus, she straddles these various worlds, and we have saved her for last because she is going to tell us how to solve all of the problems that have been detailed here by the other speakers.

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43. Steve Heilig, *MEDICAL MARIJUANA UPDATE: Legal Developments and Practical Considerations*, 70 S.F. MED. 11 (1997).

44. Steve Heilig, *When Newt Gingrich spoke out for medical pot*, S.F. EXAMINER, May 12, 1997, at A23.

MARSHA COHEN<sup>45</sup>

Thank you, I am not going to solve these problems by myself. I need some political involvement here. Mr. Grigg said the thing is a mess. Of course, it is a mess—it was passed by initiative. That is not an unusual problem with the initiative process, because if something is put in an initiative, you do not have to solve all the logical problems that a legislature might look at.

Many people in this state were disappointed when they woke up the day after election day and marijuana, at least for medical purposes, was not really legal in California. As I was fond of telling the press at the time, medicinal marijuana would not be legal in California unless we were also to secede from the union. Federal law in this area could not be cancelled by our initiative, however well intentioned. The other aspect of federal law that the initiative did not cancel, and that has not been talked about very much, although it has been touched upon today, is the authority possessed by the Food and Drug Administration to determine which substances that are intended to cure or ameliorate human disease are safe and effective for their intended purposes, and thus may be legally distributed as drugs. States cannot choose to distribute as a drug or approve as a drug something which the federal government does not approve of. There were lawsuits up to the Supreme Court of the United States on this issue a number of years ago in the 70's on a substance called laetril which was a purported cancer cure.<sup>46</sup>

As you know from hearing other people, marijuana has not been approved for sale as a human drug, except in the form of Marinol<sup>®</sup> which is considered marijuana itself. Marinol<sup>®</sup> is a Schedule I controlled substance. Someone mentioned that Schedule I controlled substances are dangerous. Actually, the legal definition of a Schedule I drug is a drug for which there is a high potential for abuse, no currently accepted medical use in treatment in the United States and a lack of accepted safety for use under medical supervision. The federal government and, in particular, the Drug Enforcement Administration, has brought this mess upon itself. It is a very expensive legal dilemma we are in because everybody is spending money on lawyers and we have a whole bunch of states involved; five I believe.

So, we have a bunch of states which are defying the federal government. Of course, all of their laws will fall to federal law as our has, but

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45. Marsha Cohen received her J.D. from Harvard Law School. She currently teaches health law as a professor at Hastings College of the Law, and lectures for the Pharmacy Program at the University of California, San Francisco. Previously she participated on a review panel for the Department of Health Education and Welfare that investigated the FDA's approval of new drugs, and later served as president of the California State Board of Pharmacy for two terms.

46. See generally *United States v. Rutherford*, 442 U.S. 544 (1979).

conservative medical opinion has favored reclassifying marijuana from Schedule I into Schedule II. The editors of the *New England Journal of Medicine*, certainly no radicals, editorialized about this in January of 1997.<sup>47</sup> The definition of a Schedule II drug<sup>48</sup> is one where there is a high potential for abuse, a currently accepted medical use and abuse may lead to severe psychological or physical dependence. A rescheduling petition for marijuana was filed in 1972.<sup>49</sup> It was not denied until the early 1990s. Judicial review upheld the DEA's decision in 1994.<sup>50</sup> A new petition has been filed and was cited in Judge Breyer's opinion in one of the pot club scrimmages. The new petition was referred to the Secretary of Health and Human Services at the end of 1997, according to that Breyer opinion.<sup>51</sup>

In order to prove that there is a currently accepted medical use to re-schedule a drug from Schedule I to Schedule II, you must be able to get the drug to test it. You need the drug so that you can prove that there is, in fact, a legitimate medical use. And, as you heard from Dr. Abrams, the federal government has been less than cooperative in making marijuana available for this testing, although it is totally obvious that it ought to be tested to determine whether it is appropriate for the various conditions for which it appears to provide at least systematic relief. It is only clinical testing that can distinguish between people's observations that a drug is helping and real proof, due to the serious placebo effect with any drug.

Controlled clinical studies are needed. Those studies also need to decide what are the appropriate dosages, what are the contra-indications, for whom the drug would be dangerous and what drug interactions exist. All of these considerations are important for the approval of a drug and for its safe use; but until it is tested, there is no way to move it from Schedule I to Schedule II. If marijuana is determined to be safe and effective, and again they approved Marinol<sup>®</sup> which suggests that there is safe and effective use, it should be made available like every other medication—by a prescription from a licensed prescriber that would then be filled at a pharmacy by a licensed pharmacist.

I have been involved with pharmacists, as you know, and pharmacists are important players in the drug distribution scene. As with other prescription drugs, although the doctor chooses the drug, the pharmacists are there to make sure that the drug is appropriate. They check interactions with other drugs the patient may be taking. Allowing one drug to be dis-

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47. Jerome P. Kassirer, *Editorial: Federal Foolishness and Marijuana*, 336 NEW ENG. J. MED. 336, 336 (1997).

48. See 21 U.S.C. § 812(b)(2)(1994).

49. See *Alliance For Cannabis Therapeutics v. Drug Enforcement Admin.*, 15 F.3d 1131, 1133 (D.C. Cir. 1994).

50. See generally *id.*

51. See *United States v. Cannabis Cultivators Club*, 5 F. Supp. 2d 1082, 1105 (N.D. Cal. 1998).

pensed outside of the system without the protection these professionals provide seems to make absolutely no sense. The problem is, how do we get from this expensive mess to a proper determination of marijuana's medical use, appropriate review by the Food & Drug Administration and then, if it is approved, to rescheduling?

I doubt that this stalemate will be broken anytime soon by federal initiative, although on November 5, 1998, the Drug Enforcement Administration (DEA) published in the Federal Register a proposal to change the scheduling of Marinol<sup>®</sup> from Schedule II down to Schedule III, which is very interesting.<sup>52</sup> It is also interesting that in that document they say they are re-evaluating Marinol<sup>®</sup> at the request of the Assistant Secretary for Health. The DEA added that they are not asking to move marijuana from Schedule I down; they made sure that their proposal has no impact on that. Although, obviously, they ought to be related scientifically.

I am hoping that California's new political leadership will be willing to invest some of its time and talent and the state's time, talent and energy to getting rid of this stalemate. I would like to see Governor Davis and Attorney General Lockyer say to the federal government, "We will commit state government resources to supervising the testing of marijuana for legitimate medical purposes and settle this matter in return for a couple of guarantees for some cooperation by the federal government."

Obviously, the first thing the feds have to do is assure access to adequate supplies of marijuana for that testing, or give California permission to cultivate marijuana for that single purpose. Also, I would like them to agree to do the testing. Then, if the FDA is willing to admit or to approve a "New Drug Application" (NDA) for marijuana for some medical purposes, and the DEA would agree to reschedule marijuana, rather than saying, "You reschedule, then we will get the NDA's out there." I also hope they would ask the FDA to cooperate in reviewing the design of the clinical tests before they are run to assure that the resources the state would invest in this whole process are not wasted. In return, the state government would make the further commitment that once medical marijuana was available in pharmacies, of course it would not just be California but throughout the nation, the leadership in California would introduce legislation with the purpose of returning California law and marijuana to conformity with federal law. In other words, we will go to the legislature to reverse the loop-hole which Proposition 215 put into our drug laws in return for getting true medical marijuana.

You might wonder where the drug companies are, because there is money to be made here. However, marijuana is a generic product, and the

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52. See Schedule of Controlled Substances: Rescheduling of Synthetic Dronabinol (Martinol<sup>®</sup>); Tetrahydrocannabinol in Sesame oil and Encapsulated in Soft Gelatin Capsules) From Schedule II to Schedule III, 63 Fed. Reg. 59751 (proposed Nov. 5, 1998).

drug companies cannot get patents. The companies get their patents before they even get their INDs.<sup>53</sup> Their investigational new drug information is out there because they do not want anyone to jump in ahead of them in the patent office. They want their intellectual property protection before they move forward so they have a period of time when they have exclusive rights to the product. Because it is a generic product, and also a very controversial product, the major drug companies have not been willing to support the testing needed to determine the safety and efficacy of marijuana.

This, of course, presents a problem for the state, but frankly there are philanthropists who have been plowing in huge amounts of money to get an initiative passed. If so, they might be willing to support the testing of the drug so that no more initiatives would be necessary. It would seem that California could certainly look into doing this. We have a lot of California institutions with the talent to conduct the necessary clinical tests; we have Dr. Abrams, and we have the school of pharmacy at UCSF, which is the premier pharmacy school in the nation and has some drug testing capacities. Drug companies might be interested in other methods of administration, given the serious health problems incident to smoking any substance.

Testing should obviously include other methods of administration that circumvent the digestive system such as nasal sprays and skin patches. I understand there some small entrepreneurial drug companies that are looking into this, and private firms might support testing of that nature as the resulting products might well be eligible for patent protection. Obviously, lots of money and energy have been spent on trying to decide what is legal here. I think we need to appeal to Governor Davis and Attorney General Lockyer to make a pitch to their friends in Washington. At least now we have a state government that has broken bread with the federal government. California and the federal government's mutual resources could be better diverted to a far more productive task; namely, trying to determine whether medical marijuana ought to take its place in the medical armamentarium along with many other substances that are far more dangerous than marijuana but also provide relief from human suffering. Thank you.

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53. IND, investigational new drug, is a phase in the process of FDA approval for new drugs. At this stage the drug may be used on humans, not for treatment but for investigation. See PETER HUTT & RICHARD MERRILL, *FOOD & DRUG LAW*, 513-16 (1991).