MARIJUANA AND MEDICINE: THE NEED FOR A SCIENCE-BASED APPROACH

HEARING

BEFORE THE

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

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MARIJUANA AND MEDICINE: THE NEED FOR A SCIENCE-BASED APPROACH

THURSDAY, APRIL 1, 2004

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:30 p.m., in room 2154, Rayburn Office Building, Hon. Mark Souder (chairman of the subcommittee) presiding.

Present: Representatives Souder, Cummings, Carter, Sanchez, and Norton.

Staff present: J. Marc Wheat, staff director and chief counsel; Nicholas Coleman, professional staff member and counsel; Roland Foster, professional staff member; Nicole Garrett, clerk; Tony Haywood, minority counsel; Cecelia Morton, minority office manager; and Ricky Choi, minority intern.

Mr. SOUDER. The subcommittee will now come to order.

Good afternoon, and thank you all for coming. This hearing will address the highly controversial topic, the use of marijuana for so-called medical purposes.

In recent years, a large and well-funded pro-drug movement has succeeded in convincing many Americans that marijuana is a true medicine to be used in treating a wide variety of illnesses. Unable to change the Federal laws, however, these pro-drug activists turned to the State referendum process and succeeded in passing a number of medical marijuana initiatives. This has set up a direct conflict between Federal and State law, and put into sharp focus the competing scientific claims about the value of marijuana and its components as medicine.

Marijuana was once used as a folk remedy in many primitive cultures. And even in the 19th century, it was frequently used by some American doctors, much as alcohol, cocaine and heroin were once also used by doctors. By the 20th century, however, its use by legitimate medical practitioners had dwindled, while its illegitimate use as a recreational use had risen.

The drug was finally banned as a medicine in the 1930's. Beginning in the 1970's, however, individuals began reporting anecdotal evidence that marijuana might have medically beneficial uses, most notably in suppressing the nausea associated with cancer chemotherapy. Today, the evidence is still essentially anecdotal, but many people take it as a fact that marijuana is a proven medicine. One of the main purposes of this hearing is to examine that claim.

At present, the evidence in favor of marijuana's utility as a medicine remains anecdotal and unproven. An Institute of Medicine study published in 1999 reviewed the available evidence and concluded that at best, marijuana might be used as a last resort for those suffering from extreme conditions. This report is repeatedly cited by the pro-marijuana movement as proof that marijuana is safe for medical use. In fact, the report stressed that smoking marijuana is not a safe medical delivery device and exposes patients to a significant number of harmful substances.

In contrast to its supposed medical benefits, the negative health effects of marijuana are well known and have been proven in scientific studies. Among other things, the drug is addictive, impairs brain function and when smoked greatly, increases the risk of lung cancer. The respiratory problems associated with smoking any substance makes the use of marijuana cigarettes as medicine highly problematic. Indeed, no modern medicine is smoked.

It is quite possible, however, that some components of marijuana may have legitimate medical uses. Indeed, the Institute of Medicine report so often erroneously cited as support for smoked marijuana actually stated that, "If there is any future for marijuana as a medicine, it lies in its isolated components, the cannabinoids, and their synthetic derivatives." Interestingly, the Federal Government has already approved a marijuana derivative called Marinol, but rarely do the pro-marijuana advocates mention this. The Federal Government has also approved further studies of the potential use of marijuana or marijuana derivatives as medicine.

However, in the United Kingdom a pharmaceutical company has applied for a license to market an inhalant form of marijuana called Sativex. Thus, the real debate is not over whether marijuana could be used as medicine, the debate is over the most scientifically safe and effective way the components of marijuana may be used as medicine. The responsibility for ensuring that any drug, whether derived from marijuana or not, is safe and effective has been entrusted to the U.S. Food and Drug Administration [FDA].

Under Federal law, the FDA must review, test and approve each medicine and determine what conditions or diseases may be used to treat and at what dosage level. The FDA continues to monitor each drug, making sure that it is manufactured and marketed properly and that unforeseen side effects do not jeopardize the public health. State laws purporting to legalize marijuana for medicinal purposes bypass these important safeguards.

California and Oregon have adopted the most wide reaching such laws. They allow anyone to use, possess and even grow his own marijuana provided he obtains the written recommendation of a doctor. Few if any restrictions are placed on what conditions marijuana may be used to treat, virtually no restrictions are placed on the content, potency or purity of such medical marijuana.

The laws adopted in California, Oregon and other States are extremely open-ended. California law even allows marijuana to be used for migraine headaches. This has led to a number of uses of marijuana as medicine that I believe to be highly questionable. For example, one of our witnesses, Dr. Phillip Leveque, has personally written recommendations for over 4,000 people to use marijuana. Another of our witnesses, Dr. Claudia Jensen, has recommended

that teenagers use marijuana for the treatment of psychiatric conditions like attention deficit disorder [ADD]. Only a small percentage of medical marijuana users in California and Oregon have actually used the drug to treat the conditions for which it was publicly promoted, namely, the nausea associated with chemotherapy and AIDS-wasting syndrome.

In Oregon, statistics kept by the State medical marijuana program indicate that well over half the registered patients use the drug simply for pain, while less than half of them use it for nausea, glaucoma or conditions related to cancer or multiple sclerosis. In San Mateo, CA, a study of AIDS patients showed that only 28 percent of the patients who used marijuana did so even to relieve pain. Over half used it to relieve anxiety or depression, and a third used it for recreational purposes.

This raises one of the key questions we must address today. If we are going to treat marijuana as a medicine, will we subject it to the same health and safety regulations that apply to other medicines? We do not allow patients to grow their own opium poppies to make painkillers like morphine, oxycontin or even heroin with just a doctor's recommendation. We do not allow people to manufacture their own psychiatric drugs like Prozac or Xanax to treat headaches.

Why then should we authorize people to grow their own marijuana when the potential for abuse is high and there is little or no scientific evidence that it can actually treat all the illnesses and conditions? Why should we abandon the regulatory process that ensures that drugs are manufactured at the right potency level and contaminant free? Why should we stop the oversight that makes sure drugs are being administered in the right dosage and in the safest manner? Our witnesses today will try to answer those and other key questions from a wide variety of perspectives.

We welcome back Dr. Nora Volkow, Director of the National Institute on Drug Abuse [NIDA], at the National Institutes of Health, the Federal agency with the greatest expertise on the health effects of marijuana and other drugs. Representing the key Federal agency with responsibility for regulating medical drugs, we also welcome back Dr. Robert Meyer, Director of FDA's Office of Drug Evaluation II, Center for Drug Evaluation and Research. Here to discuss the process of applying for a Federal license to grow marijuana for research purposes, we are joined by Ms. Patricia Good, Chief of the Liaison and Policy Section at the DEA's Office of Diversion Control.

We are also pleased to welcome two representatives of State medical boards that have been forced to attempt to regulate the use of marijuana by doctors, Dr. James D. Scott, a member of the Oregon Board of Medical Examiners, and Ms. Joan Jerzak, chief of enforcement for the Medical Board of California.

We are also joined by two advocates of the use of marijuana as medicine, Dr. Jensen and Mr. Robert Kampia, of the Marijuana Policy Project. I am grateful in particular to Dr. Jensen for her willingness to come and testify about her controversial medical practices, and I hope, anticipate a frank and open discussion with her.

Dr. Leveque apparently will not be able to be here, although he did not inform the committee, so if he shows up we will include him in the second panel.

Finally, we are pleased to welcome Dr. Robert DuPont of the Institute for Behavior and Health, Inc., an expert on marijuana and drug abuse and former head of NIDA.

We thank everyone for taking the time to join us today and I look forward to all of your testimony.

[The prepared statement of Hon. Mark E. Souder follows:]

Opening Statement
Chairman Mark Souder

"Marijuana and Medicine: The Need For A Science-Based Approach"

Subcommittee on Criminal Justice, Drug Policy, and Human Resources
Committee on Government Reform

April 1, 2004

Good morning, and thank you all for coming. This hearing will address a highly controversial topic: the use of marijuana for so-called "medical" purposes. In recent years, a large and well-funded pro-drug movement has succeeded in convincing many Americans that marijuana is a true "medicine," to be used in treating a wide variety of illnesses. Unable to change the federal laws, however, these pro-drug activists turned to the state referendum process, and succeeded in passing a number of "medical marijuana" initiatives. This has set up a direct conflict between federal and state law, and put into sharp focus the competing scientific claims about the value of marijuana (and its components) as "medicine."

Marijuana was once used as a folk remedy in many primitive cultures, and even in the 19th century was frequently used by some American doctors (much as alcohol, cocaine and heroin were once so used). By the 20th century, however, its use by legitimate medical practitioners had dwindled, while its illegitimate use as a "recreational" drug had risen. The drug was finally banned as a medicine in the 1930's. Beginning in the 1970's, however, individuals began reporting anecdotal evidence that marijuana might have some medically beneficial uses, most notably in suppressing the nausea associated with cancer chemotherapy. Today, the evidence is still essentially anecdotal, but many people take it as a "fact" that

marijuana is a proven medicine. One of the main purposes of this hearing is to examine that claim.

At present, the evidence in favor of marijuana's utility as a medicine remains anecdotal and unproven. An Institute of Medicine study published in 1999 reviewed the available evidence and concluded that, at best, marijuana might be used as a last resort for those suffering from extreme conditions. This report is repeatedly cited by the pro-marijuana movement as "proof" that marijuana is safe for medical use. In fact, the report stressed that smoking marijuana is not a safe medical delivery device and exposes patients to a significant number of harmful substances.

In contrast to its supposed medical benefits, the negative health effects of marijuana are well-known and have been proven in scientific studies: among other things, the drug is addictive, impairs brain function, and when smoked greatly increases the risk of lung cancer. The respiratory problems associated with smoking any substance make the use of marijuana cigarettes as "medicine" highly problematic; indeed, no other modern medicine is smoked.

It is quite possible, however, that some components of marijuana may have legitimate medical uses. Indeed, the Institute of Medicine report so often erroneously cited as supporting smoked marijuana actually stated that "if there is any future of marijuana as a medicine, it lies in its isolated components, the cannabinoids and their synthetic derivatives." Interestingly, the federal government has already approved a marijuana derivative called Marinol – but rarely do the pro-marijuana advocates mention this. The federal government has also approved further studies of the potential use of marijuana or marijuana derivatives as medicine. Moreover, in the United Kingdom a pharmaceutical company has applied for a license to market an inhalant form of marijuana called Sativex. Thus, the real debate is not over whether marijuana could be used as medicine; the debate is over the most scientifically safe and effective way that components of marijuana may be used as medicine.

The responsibility for ensuring that any drug – whether derived from marijuana or not – is safe and effective has been entrusted to the U.S. Food and Drug Administration (FDA). Under federal law, the

FDA must review, test and approve each medicine, and determine what conditions or diseases each drug may be used to treat, and at what dosage level. The FDA continues to monitor each drug, making sure that it is manufactured and marketed properly, and that unforeseen side effects do not jeopardize the public health.

State laws purporting to legalize marijuana for medical purposes bypass these important safeguards. California and Oregon have adopted the most wide-reaching such laws. They allow anyone to use, possess, and even grow his own marijuana, provided he obtains the written "recommendation" of a doctor. Few, if any, restrictions are placed on what conditions marijuana may be used to treat; virtually no restrictions are placed on the content, potency or purity of such "medical" marijuana.

The laws adopted in California, Oregon and other states are extremely open-ended; California law even allows marijuana to be used for migraine headaches. This has led to a number of uses of marijuana as "medicine" that I believe to be highly questionable. For example, one of our witnesses, Dr. Phillip Leveque, has personally written recommendations for over 4,000 people to use marijuana. Another of our witnesses, Dr. Claudia Jensen, has recommended that teenagers use marijuana for the treatment of psychiatric conditions like attention deficit disorder (ADD). Only a small percentage of "medical" marijuana users in California and Oregon have actually used the drug to treat the conditions for which it was publicly promoted, namely the nausea associated with chemotherapy and "AIDS wasting syndrome." In Oregon, statistics kept by the state medical marijuana program indicate that well over half of the registered "patients" use the drug simply for "pain," while less than half use it for nausea, glaucoma, or conditions related to cancer or multiple sclerosis. In San Mateo, California a study of AIDS patients showed that only 28 percent of the patients who used marijuana did so even to relieve pain; over half used it to relieve "anxiety" or "depression," and a third used it for "recreational" purposes.

This raises one of the key questions we must address today: if we are going to treat marijuana as a medicine, will we subject it to the same health and safety regulations that apply to other medicines? We do not allow patients to grow their own opium poppies to make

painkillers like morphine, Oxycontin and even heroin with just a "doctor's recommendation." We do not allow people to manufacture their own psychiatric drugs like Prozac or Xanax to treat headaches. Why, then, should we authorize people to "grow their own" marijuana, when the potential for abuse is high and there is little or no scientific evidence that it can actually treat all of these illnesses and conditions? Why should we abandon the regulatory process that ensures that drugs are manufactured at the right potency level and contaminant-free? Why should we stop the oversight that makes sure that drugs are being administered in the right dosage and in the safest manner?

Our witnesses today will try to answer those and other key questions, from a wide variety of perspectives. We welcome back Dr. Nora Volkow, Director of the National Institute on Drug Abuse (NIDA) at the National Institutes of Health, the federal agency with the greatest expertise on the health effects of marijuana and other drugs. Representing the key federal agency with the responsibility for regulating medical drugs, we also welcome back Dr. Robert Meyer, Director of the FDA's Office of Drug Evaluation II, Center for Drug Evaluation and Research. Here to discuss the process of applying for a federal license to grow marijuana for research purposes, we are joined by Ms. Patricia Goode, Chief of the Liaison and Policy Section at the DEA's Office of Diversion Control.

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Mr. SOUDER. Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman.

The possession and sale of marijuana has been illegal under Federal law since 1937 when Congress passed the Marijuana Tax Act. Prior to that time, however, Americans could legally purchase at least 27 medicines containing marijuana, many of them manufactured by reputable pharmaceutical firms that remain in existence today.

In 1970, Congress passed the Controlled Substance Act, classifying all illegal and prescription drugs according to five schedules. Marijuana was and remains classified as a Schedule I substance, meaning that it has a high potential for abuse, has no currently accepted medical use and treatment in the United States, and cannot be used in an acceptably safe manner under medical supervision. Possession and sale of Schedule I substances are generally prohibited and punishable by Federal criminal statutes. Clinical trials involving Schedule I and other controlled substances are permitted, subject to the approval of the Food and Drug Administration.

The Controlled Substances Act allows for the reclassification of substances on the basis of new evidence of their safety and efficacy. Along with other Federal law enforcement agencies, the Drug Enforcement Administration enforces Federal anti-drug laws and the DEA also is responsible for approving applications by research institutions to cultivate marijuana in bulk for research purposes.

Changes in the law have not altered the perception or belief of many Americans who continue to believe that marijuana has medical or medicinal benefits and that it should be legally available for the treatment of various conditions and ailments. Beginning in the 1990's, numerous States, California and Oregon prominent among them, passed legislation or ballot initiatives legalizing medical marijuana, resulting in a conflict in those States between State law and the Controlled Substances Act.

In 2001, the Supreme Court ruled that California's Medical Marijuana Law, Proposition 215, did not create a valid defense to a Federal prosecution for marijuana possession on the basis of medical necessity. Still, Proposition 215 remains on the books and medical marijuana remains legal as a matter of State law.

Federal law enforcement agencies have asserted their authority to enforce the Federal prohibition by conducting raids on medical marijuana distribution centers and private homes in medical marijuana States. Further complicating the matter, a 2003 ruling by the Supreme Court affirmed the right of physicians under the first amendment to recommend marijuana for their patients free of Government censorship. A few physicians have earned notoriety for prescribing marijuana for a wide range of ailments ranging from pain and wasting associated with cancer and HIV-AIDS to depression and attention deficit disorder.

Meanwhile, research has confirmed the efficacy of the synthetic marijuana drug, Marinol, which is classified separate from natural marijuana on Schedule III, rather, on the Controlled Substances Act. As of 1999, the bulk of the scientific literature as evaluated by the Institute of Medicine in a prominent study appears not to support the use of smoked marijuana as a medicine, except in a

small number of unusual cases. The IOM recommended, however, that additional scientific research should be undertaken to determine the potential benefits of marijuana and marijuana-derived drugs.

Our witnesses represent a wide range of perspectives and will attempt to help the subcommittee to sift through the competing claims regarding the efficacy or potential efficacy of marijuana and marijuana-derived medicines, as well as the harms that accompany marijuana use and the public health implications of State medical marijuana laws. Hopefully they will shed new light on the current state of research within and beyond the United States, including recent developments in the United Kingdom, where a drug company has submitted an application to market an inhalant form of marijuana to treat a variety of symptoms and conditions.

I look forward to the hearing today and I yield back. Thank you, Mr. Chairman.

Mr. SOUDER. Mr. Carter, do you have any opening comments? Ms. Norton.

Ms. NORTON. Thank you, Mr. Chairman.

I'm not going to be able to stay to hear the testimony, but I did want to come and say I appreciate your having this hearing and the range of witnesses that you have invited to testify. Because it is the absence of Federal leadership that I think is why many States move ahead on their own to try to at least make medicinal marijuana available. Of course, occasionally there are prosecutions, but not a great many, because the Federal authority obviously understands where they are most needed when it comes to the prosecution of our drug laws.

I would think, though, that the fact that we have 8 to 10 States moving ahead to legalize medical marijuana would have caused far more vigorous Federal research and leadership than we have seen thus far. This city was one of the several cities that had simply moved forward on its own, not because the council or the legislative body for the District of Columbia decided that medicinal marijuana was something that the people of the District of Columbia should have, but because the people of the District of Columbia voted to allow medical marijuana in this city in Initiative 59. That of course, that provision of course, was remanded by the Congress of the United States, as it has not been able to do in any of the States, which have proposed similar laws, and shouldn't be able to do to a local law here.

In any case, the point of Initiative 59 should be understood. There was no elected official that put it on the ballot, there was no official body that put it on the ballot. An AIDS victim collected the signatures and put the matter on the ballot. That AIDS victim has since died. Essentially what he was seeking was the use, the legal use of medical marijuana to alleviate some of his own AIDS symptoms.

I must say that there were some organizations and individuals seeking legalization of marijuana for its own sake that morphed into the District all of a sudden, but it should be said that this proposition emanated from a patient, and was approved by the residents of the District of Columbia and had nothing to do with the legalization of marijuana itself. The people of the District of Co-

lumbia have been very clear that they want the two to be distinguished.

My own sense is that young people should lay off the entire set of controlled substances, whether they are very harmful or terribly harmful, from marijuana to heroin, or for that matter, and by the way, heroin has become increasingly popular with young middle class students. And for that matter they should lay off alcohol, which is perhaps the drug of choice for young people in college today. So you don't find me saying any of these things are good for you, or because you're young and foolish, go right ahead.

When it comes to medical marijuana, we are about a serious matter and one that frankly, I think our Government could have found the answer one way or the other to long before now. But the greatest objection I have is not about this medical controversy. Most people with AIDS today are not going to seek medical marijuana. This is not a raging controversy in the country.

Do you know what is a raging controversy in the country? It is putting young people in jail for smoking pot. Wherever you stand on these matters, it doesn't seem to me that we ought to ruin a kid's life by giving him a record for smoking pot, and to the credit of most of the States of the United States, they understand that. There are very few such arrests made, nevertheless, as it stands, it is on the books that way, and you can get yourself a prosecutor who will in fact enforce it that way, particularly if you don't happen to be an empowered part of this society, which brings me to the next point.

The Congress of the United States has gone so far as to say you can't get educational grants if you've been put in jail for—sorry, if you have a record of any kind for smoking pot. Do you know who that falls on? Middle class white kids don't very often have records for smoking pot. But if you live in drug infested parts of the inner city where you're surrounded by drugs from the moment you hit the streets as a kid, it is probably the case that you will smoke something before you go to college.

The notion of denying Pell Grants and denying therefore a college education to kids who happen to live in a drug culture, no matter how drug free they are today, is the real crime to me. While this is an important hearing, because it's way past time for the Federal Government to in fact straighten out this matter, the state-of-the-art research could have been done by now, so that we lay this matter to rest, there are far more serious matters affecting controlled substances that deserve our attention.

Thank you.

Mr. SOUDER. Thank you.

A couple of things for the record. I think it needs to be said that the Ninth Circuit ruled and the Supreme Court didn't review, which is a little different than the Supreme Court making the decision. We're not going to debate the preemption law today, because the Supreme Court has already ruled on preemption. In fact, we fought a civil war over preemption. States do not have the right to pass laws contrary to Federal law any more than the States have referendums to pass and support slavery. We fought a war and said, Federal law prevails. You don't have the right of nullification. Now, how we enforce those is another question.

One other thing on the record. As the author of an amendment, I did not, Congress did not pass a law that said if you had a drug conviction you couldn't get a Pell Grant or a loan. Congress passed a law that said if you have a Pell Grant you will lose it. The Clinton administration interpreted it and the Bush administration falsely continued that interpretation, which we are about to repeal in the Higher Ed Act.

Also before we start, I want to take a point of personal privilege, because today is the last day for a long time member of my staff, Nicole Garrett. She came to us highly recommended from the California Department of Justice, Bureau of Narcotic Enforcement, where she had worked on California's growing problem of clandestine meth labs.

I hired her as a junior staffer the first week of June 2002, and promoted her to clerk of the Subcommittee on Criminal Justice, Drug Policy and Human Resources on July 28th of that year. Since then she has been ably and efficiently handling the logistics and follow-through that has been required for 36 congressional hearings in Washington and across America. She has also made invaluable contributions to our policy work on extradition and other criminal justice issues, and as our subcommittee's primary public relations staffer, was always both pleasant and effective.

Her work on this subcommittee, the California Department of Justice, Bureau of Narcotics Enforcement, the San Jose Police Department and her volunteer work with the concerns of police survivors does great honor to the memory of her father, Sergeant George Garrett, who was head of the Redwood City Police Department's narcotics detail. He was killed in the line of duty on May 8, 1981.

Nicole, I have been impressed by your dedication to making this country a better place and wanted to say so on the record. I wish you and your family all the best as you return to California, and we will miss you very much.

[Applause.]

Mr. SOUDER. Now I would like to ask unanimous consent that all Members have 5 legislative days to submit written statements and questions for the hearing record, and that any answers to written questions provided by the witnesses also be included in the record. Without objection, it is so ordered.

I also ask unanimous consent that all exhibits, documents and other materials referred to by Members and witnesses may be included in the hearing record, and that all Members be permitted to revise and extend their remarks. Without objection, it is so ordered.

Our first panel, if you'll stand and raise your right hands, I'll administer the oath.

[Witnesses sworn.]

Mr. SOUDER. Let the record show that each of the witnesses has answered in the affirmative.

I want to welcome Dr. Volkow back, and you are recognized for 5 minutes.

STATEMENTS OF NORA D. VOLKOW, M.D., DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT J. MEYER, M.D., DIRECTOR, OFFICE OF DRUG EVALUATION II, CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND PATRICIA GOOD, CHIEF, LIAISON AND POLICY SECTION, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION

Dr. VOLKOW. Good afternoon, Chairman Souder and members of the subcommittee. I am pleased to be here with my colleagues, Dr. Robert Meyer from FDA and Patricia Good from DEA.

I would like to focus my comments today on the tremendous progress that the National Institute on Drug Abuse has made in the past 16 years to inform us about marijuana and its health consequences. Fact No. 1, marijuana has been and continues to be the No. 1 illegal drug in this country. Fact No. 2, marijuana is not a benign drug. It has many adverse health and social consequences, including the often overlooked fact that marijuana can lead to addiction.

Of the 21 million people who reported using marijuana in 2001, more than 2 million met the diagnostic criteria for marijuana addiction. More people are addicted to marijuana than to heroin, cocaine and all the other illicit drugs put together. It is also bringing more people to our emergency rooms. There has been a 164 percent increase in emergency room visits involving marijuana since 1995.

Moreover, a recent study found that early exposure to marijuana increased the likelihood of a life filled with drug and addiction problems. Another study found that those who have engaged in a lifetime of heavy marijuana use report an overall dissatisfaction with their mental and physical health, as well as their life achievements. These data provide a glimpse of the impact this drug has on our society.

Marijuana disrupts memory, attention, judgment and other cognitive functions. It can impair motor coordination, time perception and balance, and its likely to contribute significantly to motor vehicle accidents. Basically, marijuana can affect almost every organ and system in the body, including the immune system, the heart and the lungs. Because marijuana is typically rolled into a cigarette, or joint, and smoked, it has many carcinogenic chemicals. It can also increase the likelihood of some cancers.

Marijuana itself is not just a single drug. It consists of dry leaves from the hemp plant, cannabis sativa, and it contains more than 400 chemicals. Delta–9-tetrahydrocannabinol [THC] is the primary ingredient in marijuana that causes the intoxicating effects, or high.

While researchers were investigating why marijuana is abused and how it affects the brain, they discovered a new neural transmitter system. They found the brain has specific sites where marijuana binds, called cannabinoid receptors. Many of these receptors are found in the brain areas related to pleasure, motivation, memory and movement coordination. Recently, a second type of cannabinoid receptor was discovered, and this cannabinoid recep-

tor, which is outside the brain, is involved in immune function and in pain perception.

The discovery of these endogenous cannabinoid systems is now allowing scientists and pharmaceutical companies to develop some very useful medications, not just for drug abuse, but for a wide variety of medical conditions, including chronic pain, obesity, smoking and alcoholism, among others.

In addition to pursuing promising new compounds, the Department of Health and Human Services has also responded to the recommendations made by the NIH and the Institute of Medicine reports. Both reports concluded that further research into the potential medical uses of marijuana is justified. NIH has been open to receiving research proposals on this topic, and those that are deemed meritorious by the peer review process are considered for funding.

One current NIH study is looking at the effects of oral THC and smoked marijuana on appetite, weight gain and other behavioral and performance measures in HIV infected patients. To maximize research opportunities, HHS created a mechanism to provide research grade marijuana on a reimbursable basis to non-federally funded researchers. Currently, there are 17 protocols from a California State funded research center that have been approved. The protocols are for a range of medical conditions, including pain, spasticity, nausea and HIV infection. These represent a substantial increase in scientifically valid research studies involving marijuana.

This research, coupled with the recent discovery of the cannabinoid system and the tremendous science advances that have followed are leading us to a wealth of new opportunities for the development of useful non-addictive cannabinoid based medications for a variety of health conditions. To conclude, the scientific evidence is clear, marijuana is an addictive substance that has adverse health and behavioral consequences. It is also true that the cannabinoid system through which marijuana asserts its effects offers a wide range of potential therapeutic applications. However, cannabinoid medications are being developed that optimize the therapeutic properties and minimize adverse effects.

Thank you, and I will be happy to respond to any questions you may have.

[The prepared statement of Dr. Volkow follows:]

Testimony
Before the House Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy and Human Resources
United States House of Representatives

Marijuana and Medicine: The Need for a Science-Based Approach

Statement of
Nora D. Volkow, M.D.
Director

National Institute on Drug Abuse
National Institutes of Health,
U.S. Department of Health and Human Services

For Release on Delivery

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Room 2154, Rayburn
House Office Building

Chairman Souder and Members of the Subcommittee, thank you for inviting the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health, to participate in this important hearing. As the world's largest supporter of biomedical research on drug abuse and addiction, we have learned much about the behavioral and health effects of marijuana over the past 15 years. Additionally, we have a greater understanding of how marijuana and other drugs of abuse affect the brain. I am pleased to be here with my colleagues to present what the science has taught us about marijuana, the health consequences associated with its use, as well as to briefly describe the role that NIDA and the Department play in supporting research on the potential medical uses for marijuana and its constituents.

MARIJUANA OVERVIEW

I would like to begin this afternoon by providing a quick overview of our Nation's most commonly used illicit drug, marijuana. As we all know, marijuana is not a new drug. It has been around and used for thousands of years. In fact, more than 95 million Americans (40 percent) age 12 and older have tried marijuana at least once, according to the 2002 National Survey on Drug Use and Health (NSDUH). In 2000, among the 1.5 million adult substance abuse treatment admissions (age 18 or older), 154,400 were admitted as primary marijuana abusers.

Marijuana is also not just a single drug—it is a mixture of dried flowering leaves from the hemp plant cannabis sativa. It contains more than 400 chemicals. Over 60 of these chemicals are referred to as cannabinoids. Delta-9-tetrahydrocannabinol or (THC) is the main psychoactive cannabinoid or ingredient in marijuana and the one that causes intoxication.

Scientists have learned a great deal about how THC acts in the brain to produce its many effects. When someone smokes marijuana, THC rapidly passes from the lungs into the bloodstream, which carries the chemical to organs throughout the body, including the brain. In the brain, THC connects to specific sites called *cannabinoid receptors* on nerve cells and thereby influences the activity of those cells. Some brain areas have many cannabinoid receptors; others have few or none. Most cannabinoid receptors are found in the parts of the brain that influence pleasure, memory, thought, concentration, sensory and time perception, and coordinated movement. Recently researchers have also found that cannabinoid receptors are found outside the brain. The newly discovered cannabinoid 2 receptors, for example, are found mostly in areas associated with immune function.

HEALTH EFFECTS OF MARIJUANA

There are numerous deleterious health consequences associated with short and long-term marijuana use, including the possibility of becoming addicted. During the period of intoxication, marijuana disrupts short-term memory, attention, judgment, as well as other cognitive functions. In addition, marijuana has also been shown to impair coordination and balance, and can increase an individual's heart rate. Longer lasting cognitive deficits have been reported in heavy marijuana users, although these have been shown to be reversible following a period of sustained abstinence. New research published last year shows that those who engage in a lifetime of heavy marijuana use reported an overall dissatisfaction with their mental and physical health as well as their life achievement.

Recently we have learned that there is in fact a marijuana withdrawal syndrome that can last several days to a week following abstinence. This syndrome is characterized by increased anxiety, increased drug craving, sleep difficulties, and decreased appetite. It is very similar to the withdrawal that many users report after abstaining from nicotine and may explain why quitting marijuana can be difficult for some.

New research is also showing us that marijuana can affect almost every organ in the body, from the central nervous system to the cardiovascular, endocrine, respiratory/pulmonary, and immune systems. Because marijuana is typically rolled into a cigarette or "joint" and smoked, it has been shown to greatly impact the respiratory system and increases the likelihood of some cancers. Marijuana users typically inhale more deeply and hold their breath longer than tobacco smokers do, exposing them to the 50 percent to 70 percent more carcinogenic hydrocarbons than tobacco smoke has. Also, animal studies show us that THC can impair the immune system's ability to fight off infectious diseases thus increasing the likelihood of adverse health consequences. In humans however, the overall effect on the immune system is not clear. One clinical study on short-term exposure (21 day) to marijuana cigarettes in HIV-infected adults who were on a stable antiretroviral regimen did not find an effect of marijuana on the immune system in this population. Whether marijuana exerts significant immune effects when administered over long periods of time has not been studied.

Also, we are finding that early exposure to marijuana is associated with an increased likelihood of a lifetime of subsequent drug problems. A study, published last year in the Journal of the American Medical Association of over 300 fraternal and identical twin pairs, who differed on whether or not they used marijuana before the age of 17, found that those who had used marijuana early had elevated rates of other drug use and drug problems later on, compared to their twin who did not use marijuana before age 17.

Finally, there are also some known subtle effects associated with children born to mothers who used marijuana frequently while pregnant. An ongoing longitudinal study that has been investigating the consequences of prenatal exposure to marijuana, for example, recently published results in this now

adolescent aged population and found that prenatal exposure was associated with worse performance on tasks that required visual memory, analysis, and integration.

RESEARCH ON MEDICAL USES OF MARIJUANA:

TWO SIGNIFICANT REPORTS BY THE NIH AND IOM

Marijuana is currently listed as a Schedule I drug. Schedule I under the Controlled Substances Act means that the drug has a high potential for abuse and that there is no current accepted medical use in the United States. However, there continue to be claims about the potential medical uses of marijuana, particularly smoked marijuana. THC, the main active ingredient in marijuana, produces effects that can be useful for treating several medical conditions. Several early studies supported by NIH to examine claims, for example, that marijuana relieved the nausea and vomiting accompanying cancer chemotherapy, have in fact led to the FDA approval of a synthetic form of oral THC for nausea associated with cancer chemotherapy. More recently, the FDA has approved oral THC for treatment of AIDS wasting.

There have been at least two exhaustive and comprehensive reports written in the past decade regarding the medical potential of marijuana by the National Institutes of Health (NIH) and the Institute of Medicine (IOM). In February 1997, the NIH convened a panel of eight non-federal experts in fields such as cancer treatment, infectious diseases, neurology, and opthalmology for a two-day meeting to examine the extant research on the medical uses of marijuana and its active constituents, primarily THC. In 1999, the Office of National Drug Control Policy commissioned the IOM to do an exhaustive study as well. "Marijuana and Medicine: Assessing the Science Base" was published in 1999.

Both reports found that there are too few scientific studies to determine marijuana's therapeutic utility, but that research is justified into marijuana's use for certain conditions or diseases including

pain, neurological and movement disorders, nausea in patients who are undergoing chemotherapy for cancer, and loss of appetite and weight (cachexia) related to AIDS.

The reports noted that there is greater promise in purifying the active constituents of marijuana and developing alternate delivery systems, such as inhalers, rather than studying smoked marijuana. The reports also noted that alternative FDA-approved medications already exist for treatment of the majority of proposed uses of smoked marijuana. For example, synthetic oral forms of THC, the major active ingredient in marijuana, have been approved by the FDA for use by patients undergoing chemotherapy and by patients with AIDS.

FACILITATING RESEARCH ON THE MEDICAL USES OF MARIJUANA

Additional research on the possible medical uses of marijuana and its constituents has continued since these reports were issued. The NIH has continued to accept proposals to investigate potential therapeutic uses of marijuana through its peer review process, and those that are scientifically meritorious have been considered for funding. Since the Reports by the IOM and NIH have been written, there have been two studies that have been supported by the NIH. One study looked at the effects of smoked marijuana on HIV levels and appetite and reducing weight loss associated with HIV-related wasting syndrome. Another ongoing study is looking at the effects of THC (smoked marijuana and oral) in individuals who have the human immunodeficiency virus infection (HIV+) with unintended weight loss (<90 percent body cell mass/height). In addition to studying food intake and body composition, they are also studying mood and physical symptoms (e.g. nausea stomach pain), psychomotor task performance and sleep to determine the specificity of the drug effects on food intake in relation to other behaviors.

In May 1999, the Department announced it would create a new mechanism to provide research-grade marijuana not only for NIH-funded research but also for scientifically valid research that is funded by other sources. A multi-agency Public Health Service (PHS) committee now reviews non-NIH funded studies and assesses them both for scientific quality and the likelihood that they will yield data on possible benefits.

After the PHS committee approves a study, the researcher applies for an Investigational New Drug Application (IND) from the FDA and must also obtain a DEA registration number for Schedule I substances. When these are obtained, NIH provides research-grade marijuana for the project on a reimbursable basis (researchers reimburse NIDA's contractor for the costs of growing and producing the research-grade marijuana). Since NIDA's inception in 1974, it has been the administrator of a contract to grow marijuana for research purposes on behalf of the US government. In this way, NIH is able to produce and supply research-grade marijuana for a variety of clinical studies that would not otherwise be possible.

Most of the research approved by the PHS committee so far is sponsored by the Center for Medicinal Cannabis Research at the University of California in San Diego, a state funded research center. Currently there are 17 pre-clinical or clinical studies that have been approved by HHS for this Center. Topics to be covered include cannabis for spasticity/tremors in multiple sclerosis patients, sleep disorders, CD4 immunity in AIDS, and for neuropathic pain. This represents a substantial increase in scientifically valid research studies involving marijuana.

THE PROMISE OF RESEARCH

Researchers have made much progress in the past 15 years in understanding how marijuana exerts its effects. In fact, the support of basic research on marijuana led to the discovery of the endogenous cannabinoid system. Since 1988, scientists have discovered two major classes of

cannabinoid receptors, one that is mostly found in the brain, "CB1," and "CB2,"which is not in the central nervous system and is predominantly found on immune system cells. This cannabinoid system is involved in a number of physiological functions, including pain regulation, appetite, movement and motor function, memory, as well as its role in marijuana's abuse liability and addiction.

These breakthroughs have led to research advances and medicinal developments at a rapid pace. The presence of this newly discovered receptor system in the brain circuitry controlling learning and memory is yielding new insights into how marijuana disrupts memory traces. Additionally, recent research shows that there are connections between the cannabinoid system and the neuronal processes connected with relapse to cocaine abuse, lending further support to the commonality in the brain processes mediating addiction.

The discovery and characterization of the cannabinoid receptors has allowed scientists to begin to develop potential medications to treat a variety of ailments, including obesity, pain, and addictive disorders. In 1994, researchers produced the first CB1-specific cannabinoid receptor antagonist, SR141716, (now called Rimonabant) which is able to block THC's ability to activate the CB1 receptor. Preclinical and clinical research suggests that Rimonabant blocks the subjective high elicited by marijuana and may also be useful in preventing relapse to other drug use. Two large clinical trials supported by the pharmaceutical industry also have found that Rimonabant may help people lose weight and stop smoking.

Today marijuana-related research continues to yield valuable insights into the effects of THC on critical brain functions, such as cognition and memory, the role of the drug's receptor system in addiction and relapse, as well as insights into the treatment of marijuana addiction and the potential role of cannabinoid-based medications in treating a variety of medical conditions. Finally, these insights are

leading us to an overall greater understanding of neurobiology, memory, and immunity. They also provide us with proven strategies that can be employed to help us elucidate other systems.

CONCLUSION

Marijuana is not a benign drug. It is illegal and has significant adverse health and social consequences associated with its use. Given the fairly recent discovery of the endogenous cannabinoid system and the tremendous science advances that followed, the development of useful cannabinoid-based medicines is an important area of investigation that should prove fruitful for a variety of health conditions. However, the use of smoked marijuana as a medicine is problematic due to its adverse health consequences and the inherent difficulties with respect to accurate dosing and the purity of the formulation. Approval for the use of marijuana, or perhaps more importantly purified compounds based upon the chemicals found in marijuana, as therapeutic agents must show substantial evidence of effectiveness and show the product is safe under the conditions of use in the proposed labeling. Safe, in this context, means that the benefits of the drug appear to outweigh its risks.

Thank you for allowing me to share this information with you. I will be happy to answer any questions you may have.

Mr. SOUDER. Thank you very much.

Dr. Meyer, thank you for coming to our subcommittee again, and please go ahead with your testimony.

Dr. MEYER. Good afternoon, Mr. Chairman and members of the subcommittee. I'm Dr. Robert Meyer, Director of the Office of Drug Evaluation II at FDA's Center for Drug Evaluation and Research.

I'm pleased to be here today with my colleagues from NIDA and DEA. FDA appreciates the opportunity to discuss the need for a science based approach to evaluating the merits of marijuana for medical purposes. Marijuana, botanical marijuana is not an approved drug.

Let me first speak about the drug approval process. FDA's primary mission for over 90 years has been to promote and protect the public health under the authority of the Federal Food, Drug and Cosmetic Act and the Public Health Service Act. The FD&C Act requires that new drugs be shown to be safe and effective before being marketed in this country. A new drug may not be distributed in interstate commerce until a sponsor, usually a drug manufacturer, has submitted and FDA has approved a new drug application or a biologic license application for that product.

For approval, an NDA or BLA must contain substantial scientific evidence that demonstrates the safety and effectiveness of the drug for its intended use. The first step a sponsor usually must take to obtain approval for a new drug is to test the drug in animals for toxicity. The sponsor submits these data, along with proposed studies, the qualifications of its investigators and assurances of informed consent and protection of the rights and safety of the human subject to the FDA in the form of an investigational new drug application [IND]. FDA reviews the IND for assurance that the proposed studies, generally referred to as clinical trials, do not place human subjects at unreasonable risk of harm. FDA also verifies that there are adequate assurances of informed consent in human subject protection.

At that point, the first of three phases of studies in humans can begin. Phase I studies primarily focus on the safety of the drug in humans. Phase II studies are clinical studies involving a limited number of subjects to explore the effectiveness of the drug for a particular indication over a range of doses and to determine short term common side effects. The next step is to conduct phase III studies involving up to several thousands subjects. These studies firmly establish efficacy for a particular indication, and also provide further safety data.

Once the phase III trials are completed, the sponsor may submit the results of all the relevant testing to the FDA in the form of an NDA. FDA's reviewers review the application to determine if the sponsor's data in fact show the drug is both safe and effective. The drug's manufacturing processes are also evaluated to make sure the drug can be produced consistently with high quality.

Results of controlled clinical trials, which form the core of an NDA or BLA are the basis for evidence based medicine. These trials allow physicians and patients to use therapies with a clear understanding of their benefits and risks, and in some cases, form the basis for strong public health recommendations.

Let me now turn to the topic of marijuana. I want to repeat, botanical marijuana is not approved for any indication in the United States. Pursuant to the Food, Drug and Cosmetic Act, FDA is responsible for the approval and marketing of drugs for medical use, including controlled substances. DEA is the lead Federal agency responsible for regulating controlled substances and enforcing the Controlled Substance Act [CSA]. The CSA separates controlled substances into five schedules, depending upon their approved medical use and abuse potential.

Schedule I controlled substances, such as marijuana, are those deemed not to have any legitimate medical use, as well as a high potential for abuse. The primary responsibility for enforcement of CSA again resides with the DEA. The criminal penalties related to Schedule I controlled substances are far greater under the CSA than those available under the Food, Drug and Cosmetic Act for the distribution of an unapproved drug.

FDA regulates marijuana when it is being investigated for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals. Much of that research is focused currently on smoked marijuana. However, due to the inherent toxicities of smoking, it is likely that any future approvals would not be of smoked botanical marijuana. Indeed, the Institute of Medicine has recommended that clinical trials be conducted with the goal of developing safe delivery systems.

To date, FDA has approved two drugs, Marinol and Cesamet, for therapeutic use in the United States, both of which contain active ingredients related to those present in botanical marijuana. As approved drugs, these products have been through FDA's rigorous approval process and have been determined to be safe and effective.

In conclusion, when a drug treatment goes through the FDA drug approval process, solid clinical data are obtained and scientifically based assessment of the risks and benefits of the investigational drug is made. Upon FDA approval for marketing, patients who need the medication could have confidence that the approved medication will be both safe and effective. Without this rigorous scientific evaluation, benefits and safety remain uncertain.

However, FDA will continue to be receptive to sound, scientifically based research into medical uses of botanical marijuana and its derivative cannabinoids.

I would like to thank the subcommittee again for this opportunity to testify on this important issue, and I would be happy to take any questions the members of the subcommittee may have. Thank you.

[The prepared statement of Dr. Meyer follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

STATEMENT OF

ROBERT J. MEYER, M.D.

DIRECTOR

OFFICE OF DRUG EVALUATION II
CENTER FOR DRUG EVALUATION AND RESEARCH
FOOD AND DRUG ADMINISTRATION
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY, AND HUMAN RESOURCES

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

APRIL 1, 2004

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good afternoon, Mr. Chairman and Members of the Subcommittee. I am Dr. Robert Meyer, Director of the Office of Drug Evaluation II at the Food and Drug Administration's (FDA or the Agency), Center for Drug Evaluation and Research (CDER). I am pleased to be here today with my colleague, Dr. Nora Volkow, Director of the National Institute on Drug Abuse (NIDA). FDA appreciates the opportunity to discuss the need for a science-based approach to evaluating the merits of marijuana for medicinal purposes.

In my testimony today, I will first describe the FDA drug approval process. Second, I will clarify FDA's role in facilitating the objective evaluation of the potential merits of cannabinoids for medical uses as well as FDA's role with respect to enforcement efforts relating to Schedule I Controlled Substances such as marijuana.

FDA APPROVAL PROCESS

FDA's primary mission for over 90 years has been to promote and protect the public health, under the authority of the Federal Food, Drug, and Cosmetic (FD&C) Act and the Public Health Service Act. These statutes were enacted and amended, in part, in response to public health tragedies resulting from the sale to, and use by, an unsuspecting public of unsafe and ineffective products sold as medicines and medical devices. The FD&C Act requires that new drugs be shown to be safe and effective before being marketed in this country.

The single most important public health provision in these statutes is the requirement that a person wishing to sell to the public a product to prevent, cure or mitigate illness or injury must first prove that such product is safe, and actually does what the vendor claims it does. This statutory provision affords patients the most effective protection against untested and unproven products.

A new drug or biologic (referred to in this statement as a drug) may not be distributed in interstate commerce (except for clinical studies under an investigational new drug application) until a sponsor, usually the drug manufacturer, has submitted and FDA has approved a new drug application (NDA) or a biologics license application (BLA) for the product. For approval, an NDA or BLA must contain sufficient scientific evidence demonstrating the safety and effectiveness of the drug for its intended uses.

The evidence of safety and effectiveness usually is obtained through controlled clinical trials. The disciplined, systematic, scientific conduct of such trials is the most effective and certain means of obtaining the data that document safety and efficacy of a drug and how to use the new product so that it will have the most beneficial effect.

A. INVESTIGATIONAL NEW DRUG APPLICATION PROCESS

The first step a sponsor usually must take to obtain approval for a new drug is to test the drug in animals for toxicity. The sponsor then takes that animal testing data, along with additional information about the drug's composition and manufacturing, and develops a plan for testing the drug in humans. The sponsor submits these data, along with proposed studies, the qualifications of the investigators who will conduct the clinical studies, and assurances of informed consent

and protection of the rights and safety of the human subjects, to FDA in the form of an investigational new drug application (IND).

FDA reviews the IND for assurance that the proposed studies, generally referred to as clinical trials, do not place human subjects at unreasonable risk of harm. FDA also verifies that there are adequate assurances of informed consent and human subject protection. At that point the first of three phases of study in humans can begin. Phase I studies primarily focus on the safety of the drug in humans. Phase I studies carefully assess how to safely administer and dose the drug with an emphasis on evaluation of the toxic manifestations of the therapy, how the body distributes and degrades the drug, and how side effects relate to dose. Phase I studies typically include fewer than 100 healthy volunteers or subjects.

Phase II studies are clinical studies to explore the effectiveness of the drug for a particular indication over a range of doses and to determine common short-term side effects. Phase.II studies typically involve a few hundred subjects. Once Phase II studies are successfully completed, the drug's sponsor has learned much about the drug's appropriate dosing and its apparent safety and effectiveness. The next step is to conduct Phase III studies involving up to several thousand subjects. These studies establish efficacy for a particular indication, examine additional uses, may provide further safety data including long-term experience, and consider additional population subsets, dose response, etc. FDA strongly encourages sponsors to work closely with the Agency in planning definitive Phase III clinical trials to help assure that the trials are designed to have the greatest likelihood of producing results sufficient to provide adequate data and permit the Agency to make appropriate decisions about the safety and efficacy of the product.

Once Phase III trials are completed, the sponsor submits the results of all the relevant testing to FDA in the form of an NDA. FDA's medical officers, chemists, statisticians, and pharmacologists review the application to determine if the sponsor's data in fact show that the drug is both safe and effective. The drug's manufacturing process is evaluated to confirm that the product can be produced consistently with high quality. It is common to allow subjects in Phase II and III studies to continue on a therapy if it seems to be providing benefit. This practice provides long-term safety information at an early stage in this process. At present, there are literally thousands of clinical trials ongoing, involving hundreds of thousands of subjects. There are over 15,000 active INDs for drugs, therapeutic biologics, and biologics filed with the Agency.

Results of controlled clinical trials are the basis of evidence-based medicine. These allow physicians and patients to use therapies with a clear understanding of their benefits and risks and, in some cases, a basis for strong public health recommendations for treatments.

Clinical trials also have saved us from unwanted public health consequences. For example, when azidothymidine (AZT) was the only approved AIDS treatment, dideoxycytidine (ddC) was made available under treatment-IND for the several years while clinical trials were underway. These trials were to assess whether ddC was superior to AZT or if it was effective for patients intolerant of AZT. Although the product, ddC, could cause permanent, sometimes severe nerve damage, there was great demand for early access to the product. It was even manufactured by sources other than the company (probably by amateur chemists) and this "bathtub" ddC was made available through buyers clubs when the demand exceeded the sponsor's supply. FDA

acted with the sponsor, the buyers clubs, patient advocates, and investigators to make more of the drug available and get the illicit, poorly manufactured product off the market.

What did the ddC clinical trials show? In a head-to-head comparison versus AZT as initial therapy, an independent data safety monitoring board stopped the trial early because the death rate in the ddC group was at least twice higher than in the AZT group. For patients intolerant to AZT, a clinical trial compared switching to ddC versus dideoxyinosine (ddI). In this study the trend was that ddC had superior survival to ddI. Later studies showed that ddC in combination with AZT had superior survival to AZT alone. Each of these studies involved hundreds of patients and was essential to determining where ddC improved survival and where it did not. Although some of the early access uses were later found to be poor choices, physicians considered it reasonable at the time to provide the drug while the question was still being answered. The important point is that patients are only well served by early access when the controlled clinical trials proceed in parallel with early access.

A second example that illustrates the importance of conducting clinical trials is the recently announced results of the Women's Health Initiative (WHI) study of estrogen and progesterone in treating post-menopausal women conducted by the National Institutes of Health. This large (more than 16,000 women), scientifically rigorous clinical trial was done to confirm the widely held belief that estrogen/progesterone therapy in post-menopausal women would significantly reduce the risk of cardiovascular events, such as heart attacks and strokes. There was also some hope that this post-menopausal therapy might lessen the onset of Alzheimer's disease. These widely held beliefs were based on scientific evidence that was not from clinical trials, such as

epidemiology. On the strengths of these beliefs, post-menopausal hormone therapy was very widely used and growing in popularity.

The WHI trial or post-menopausal estrogen/progesterone preceded but was stopped early due to an excess of harm in women taking these drugs compared to placebo. Surprisingly and importantly, women given the active drugs were more likely to suffer heart attacks and strokes and appeared to be more likely to develop dementia. This study not only failed to prove the widely held notion that this therapy was good for preventing these types of occurrences, but actually confirmed harm. These important results have led to significant changes in the use of post-menopausal hormones.

FDA sometimes uncovers individuals who do not comply with statutory and regulatory drug approval requirements. This puts patients at risk of using unproven products and also denies to all patients the knowledge of whether the untested therapies may actually work. Distribution of unproven products and subsequent widespread use combined with little accountability or liability reduces the incentive for manufacturers and health care practitioners to conduct studies of safety and effectiveness. We constantly work to find ways to make safe and effective products available to patients as quickly and efficiently as possible, consistent with the protections established in the law. It is essential to preserve the system of controlled clinical trials that provides the information necessary to make the final determination on the safety and effectiveness of unapproved products. The two concepts, the protection of public health and making available treatments for individuals, can and must co-exist.

B. HUMAN SUBJECT PROTECTION

The FD&C Act and its implementing regulations are one part of a complex system of safeguards designed to protect human subjects. Each participant in a research effort -- the company that sponsors the research, the clinical investigator who conducts the research, and the Institutional Review Board (IRB) is obliged to protect the interests of the people who are taking part in the experiments. FDA's responsibility is to see that the safeguards are met. FDA monitors the activities of research sponsors, researchers, IRBs and others involved in the trial. We take very seriously our role to protect people enrolled in clinical trials.

The sponsors of research -- usually, manufacturers or academic bodies, but sometimes individual physicians -- must select well-qualified clinical investigators, design scientifically- sound protocols, make sure that the research is properly conducted, and make certain that the clinical investigators conduct the research in compliance with all pertinent regulations, including requirements for obtaining informed consent and review by an IRB. The primary regulatory obligations of the clinical investigator are to: 1) conduct or supervise the study; 2) conduct the study according to the approved protocol or research plan; 3) ensure that the study is reviewed and approved by an IRB that is constituted and functioning according to FDA and other Federal requirements; 4) obtain informed consent; 5) maintain adequate and accurate records of study observations (including adverse reactions); 6) administer the drug only to subjects under the investigator's personal supervision or under the supervision of a sub-investigator responsible to the investigator; 7) report to the sponsor adverse experiences that occur in the course of the investigation; and 8) promptly report to the IRB all unanticipated problems involving risks to humans or others.

The core of FDA's informed consent regulations, Title 21, Code of Federal Regulations (CFR) Part 50, is that the clinical investigator must generally obtain the informed consent of a human subject or his/her legally authorized representative before any FDA-regulated research can be conducted. The researcher has to make sure that, whenever possible, the study participants fully understand the potential risks and benefits of the experiment before the experiment begins. The information provided must be in a language understandable to the subject, and must not require the subject to waive any legal rights, or release those conducting the study from liability for negligence. The clinical investigator must tell the human subjects important information about the study and its potential consequences so that the person can decide whether to be in the experiment. The entire informed consent process involves giving the subject all the information concerning the study that he or she would reasonably want to know, ensuring that the subject has comprehended this information, and obtaining the subject's written consent to participate.

An IRB is a group (consisting of experts and lay persons) formally designated to review, approve the initiation of, and periodically review the progress of, research involving human subjects. The primary function of IRBs is to protect the rights and welfare of the people who are in trials. FDA's regulations, 21 CFR Part 56, contain the general standards for the composition, operation, and responsibility of an IRB that reviews clinical investigations submitted to FDA under sections 505(i), and 520(g) of the FD&C Act. IRBs must scrutinize and approve each of the clinical trials that are conducted on FDA-regulated products in this country each year. IRBs must develop and follow procedures for their initial and continuing review of the trials. Among other requirements, IRBs must make sure that the risks to subjects are minimized and do not outweigh the anticipated study benefits, that the selection of participants is equitable, that there are adequate plans to monitor data gathered in the trial and provisions to protect the privacy of

subjects and the confidentiality of data. The IRB has the authority to approve, modify, or disapprove a clinical trial. The IRB must approve the informed consent form that will be used. If the researchers fail to adhere to IRB requirements, the IRB has the authority and the responsibility to take appropriate steps, which may include termination of the trial. The IRB is required to conduct continuing review of ongoing research at intervals appropriate to the degree of risk, but not less than once per year. It also has the authority to observe or have a third party observe the consent process and the research.

IRBs are currently not required to register with FDA nor inform FDA when they begin reviewing studies. However, FDA performs on-site inspections of IRBs that review research involving products that FDA regulates, including IRBs in academic institutions and hospitals as well as those independent from where the research will be conducted. The primary focus of FDA's IRB Program is the protection of the rights and welfare of research subjects, rather than validating the data obtained from research.

Marijuana

FDA has not approved marijuana for medical use in the United States. Despite its status as an unapproved new drug, there has been considerable interest in its use for the treatment of a number of conditions, including glaucoma, AIDS wasting, neuropathic pain, treatment of spasticity associated with multiple sclerosis, and chemotherapy-induced nausea. Under the Controlled Substances Act (CSA) Congress listed marijuana in Schedule I. Schedule I substances have a very high potential for abuse, no accepted medical use in the United States, and lack accepted safety data for use under medical supervision. Schedule I substances can still be the subject of an IND; however, the conditions for its use are more restrictive.

Pursuant to the FD&C Act, FDA is responsible for the approval and marketing of drugs for medical use, including controlled substances. DEA is the lead Federal agency responsible for regulating controlled substances and enforcing the CSA. The CSA separates controlled substances into five schedules, depending upon their approved medical use and abuse potential. Unlike Schedule I controlled substances, Schedule II substances are approved for medical use, although they also have a very high potential for abuse. Schedules III, IV, and V include those controlled substances that have been approved for medical use, but whose potential for abuse is diminished.

FDA's Office of Criminal Investigations (OCI) is responsible for managing and conducting the Agency's criminal investigations. As a part of its duties, OCI has worked closely with DEA on a number of criminal investigations involving the illegal sale, use, and diversion of controlled substances including controlled substances sold over the Internet. OCI's close working relationship with DEA and local law enforcement agencies has led to many successful criminal cases involving controlled substances. FDA cooperates with DEA and other state and Federal agencies. OCI is often requested by these entities to provide assistance. Both OCI and DEA have worked together in the past to utilize the full range of regulatory and administrative tools available to them to pursue cases involving controlled substances. However, the primary responsibility for enforcing the CSA resides with DEA, and, FDA generally defers to DEA on criminal enforcement efforts related to Schedule I controlled substances. The criminal penalties related to Schedule I controlled substances are far greater under the CSA than those available under the FD&C Act for the distribution of an unapproved new drug.

The Department of Health and Human Services (HHS) and FDA support the medical research community who intend to study marijuana in scientifically valid investigations and well-controlled clinical trials, in-line with the FDA's drug approval process. HHS and FDA recognize the need for objective evaluations of the potential merits of cannabinoids for medical uses. If the scientific community discovers a positive benefit, HHS also recognizes the need to stimulate development of alternative, safer dosage forms. In February 1997, an NIH-sponsored workshop analyzed available scientific information and concluded that "in order to evaluate various hypotheses concerning the potential utility of marijuana in various therapeutic areas, more and better studies would be needed."

In March 1999, the Institute of Medicine (IOM) issued a detailed report that supports the absolute need for evidence-based research into the effects of marijuana and cannabinoid components of marijuana, for patients with specific disease conditions. The IOM report also emphasized that smoked marijuana is a crude drug delivery system that exposes patients to a significant number of harmful substances and that "if there is any future of marijuana as a medicine, it lies in its isolated components, the cannabinoids and their synthetic derivatives." As such, the IOM recommended that clinical trials should be conducted with the goal of developing safe delivery systems.

In May 1999, HHS released "*Guidance on Procedures for the Provision of Marijuana for Medical Research*," a document intended to provide the medical research community who intend to study marijuana in scientifically valid investigations and well-controlled clinical trials on HHS procedures for providing research-grade marijuana to sponsors.

The HHS guidance is intended to facilitate the research needed to evaluate pending public health questions regarding marijuana by making research-grade marijuana available for well-designed studies on a cost-reimbursable basis. The focus of this HHS program is the support of quality research for the development of clinically meaningful data regarding marijuana. An appropriate scientific study of a drug requires, among other things, that the drug used in the research must have a consistent and predictable potency, must be free of contamination, and must be available in sufficient amounts to support the needs of the study. NIDA allocates resources to cultivate a grade of marijuana that is suitable for research purposes. The HHS Guidance outlines the procedures for obtaining research-grade marijuana including: 1) the researcher must make an inquiry to NIDA to determine the availability and costs of marijuana, and NIDA has to determine that marijuana is available to support the study; 2) researchers who propose to conduct investigations in humans must proceed through the FDA process for filing an IND application: and 3) all researchers must obtain from DEA registration to conduct research using a Schedule I controlled substance.

FDA regulates smoked marijuana, a botanical product, when it is being investigated for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals, as a drug, under the FD&C Act. Botanicals include herbal products made from leaves, as well as products made from roots, stems, seeds, pollen or any other part of a plant. Botanical products pose some issues that are unique to this class of product, including the problem of lot-to-lot consistency. These unpurified products, which may be either from a single plant source or from a combination of different plant substances,

often exert their reported effects through mechanisms that are either unknown or undefined. For these reasons, the exact chemical nature of these products may not be known. In addition, issues of strength, potency, shelf life, dosing and toxicity monitoring need to be addressed. If a product varies greatly, as can occur with botanicals, it is critical to obtain lot-to-lot product consistency. Without this it is difficult to determine if the product is causing the change in a patient's condition, or the change is related to some other factor. Because of the problems associated with obtaining lot-to-lot consistency with botanical marijuana, it is not surprising that IOM recommended that clinical trials should be conducted with the goal of developing safe delivery systems.

HHS performed a scientific and medical evaluation of marijuana in 2001 and concluded with a recommendation to DEA that marijuana should remain in Schedule I pursuant to section 201(b) of the CSA. HHS's scientific and medical evaluation and scheduling recommendation can be found at Volume 66, *Federal Register* page 20038 (April 18, 2001). After receiving an HHS evaluation and recommendation, DEA is responsible for scheduling substances and as noted previously, has primary responsibility for the regulation and distribution of Schedule I substances.

FDA Approval of Safer Dosage Forms of Cannabinoids

FDA has approved two drugs, Marinol and Cesamet, for therapeutic uses in the U.S., which contain active ingredients that are present in botanical marijuana. On May 31, 1985, FDA approved Marinol Capsules, manufactured by Unimed, for nausea and vomiting associated with cancer chemotherapy inpatients that had failed to respond adequately to conventional antiemetic

treatments. Marinol Capsules include the active ingredient dronabinol, a synthetic delta-9-tetrahydrocannabinol or THC, which is considered the psychoactive component of marijuana. On December 22, 1992, FDA approved Marinol Capsules for the treatment of anorexia associated with weight loss in patients with AIDS. Although FDA approved Cesamet Capsules for the treatment of nausea and vomiting associated with chemotherapy on December 26, 1985, this product was never marketed in the U.S. Cesamet Capsules contain nabilone as the active ingredient, a synthetic cannabinoid. Nabilone is not naturally occurring and not derived from marijuana, as is THC.

These products have been through FDA's rigorous approval process and have been determined to be safe and effective for their respective indications. It is only through the FDA drug approval process that solid clinical data can be obtained and a scientifically based assessment of the risks and benefits of an investigational drug is made. Upon FDA approval for marketing, consumers who need the medication can have confidence that the approved medication will be safe and effective.

CONCLUSION

Having access to a drug or medical treatment, without knowing how to use it or even if it is effective, does not benefit anyone. Simply having access, without having safety, efficacy, and adequate use information does not help patients. FDA has and will continue to use its IND and other expanded access programs to provide patients freedom to choose investigational medical treatments while reasonably ensuring safety, informed choice, and systematic data collection that allows us to review drug applications.

FDA will continue to be receptive to sound, scientifically based research into the medicinal uses of botanical marijuana and other cannabinoids. FDA will continue to facilitate the work of manufacturers interested in bringing to the market safe and effective products.

I would like to thank the Subcommittee again for the opportunity to testify today on this important issue. I would be happy, at this time, to answer any questions Members of the Subcommittee may have.

Mr. SOUDER. Thank you very much. Ms. Good.

Ms. GOOD. Chairman Souder, Congressman Cummings and distinguished members of the panel, I appreciate your invitation to testify today regarding the process that would need to be gone through for someone to obtain a DEA registration under the Controlled Substances Act [CSA], to grow marijuana for scientific research. While I cannot discuss any specific pending applications or discuss hypothetical situations, I'm pleased to explain the general process.

In the United States, anyone who wishes to cultivate marijuana to supply scientific requirements would have to obtain a bulk manufacturer registration from the Drug Enforcement Administration. The statutory basis for considering applicants is contained in Title 21, U.S. Code Section 823(a), and these considerations are applied to anyone who wishes to apply to manufacture a substance in Schedules I or II of the Controlled Substance Act.

The Attorney General, and subsequently the DEA, is empowered to register those whose applications are consistent with the public interest and are in compliance with various U.S. treaty obligations. The statute sets out six factors that DEA shall consider when determining whether or not to grant an application, and considering whether it's in the public interest. First is DEA's ability to maintain effective controls against diversion of the substance in question to make sure it does not get into other than legitimate medical scientific research or industrial channels. This is done by limiting the number of bulk manufacturers to that number necessary to produce an adequate and uninterrupted supply of marijuana or any other substance under adequately competitive conditions for legitimate medical, scientific and research purposes.

We must also consider the applicant's compliance with State and local law, the applicant's ability to promote technical advances in the art of manufacturing controlled substances and in the development of new substances. DEA must also consider any conviction record that the applicant may have under State or Federal law related to the manufacture, distribution or dispensing of controlled substances. We must also consider the applicant's past experience in the manufacture of controlled substances and the existence of effective controls by that applicant to prevent diversion. And finally, DEA must consider any other factor which is relevant to and consistent with the public interest.

In order to determine whether a proposed applicant would be consistent with U.S. treaty obligations as the law requires, we must consider the requirements of the Single Convention on Narcotic Drugs of 1961 and the Convention on Psychotropic Substances of 1971. Among the basic principles of these treaties is that the cultivation of marijuana should be limited to the number of producers who can provide an adequate supply to meet the country's legitimate medical, scientific and research needs. Congress has expressly incorporated this principle into the CSA.

The DEA regulations provide more detailed information on the process of obtaining registration to bulk manufacture bulk marijuana. This is contained in chapter 21 of the Code of Federal Regulations, Section 1301.33. Briefly, an applicant wishing to cultivate marijuana for scientific studies or to bulk manufacture any class of

a Schedule I drug, for that matter, is required to submit a DEA Form 225, an application for registration, along with the appropriate fee.

Upon receipt of that application, assuming it is completed in its entirety, DEA publishes a notice of application in the Federal Register. This notice identifies the applicant as well as the controlled substances they are wishing to apply to handle. And a copy of that notice is provided to every other bulk manufacturer who handles that same class of drug. By regulation, all those other manufacturers have 60 days to file written comments or objections to the proposed registration of this new applicant by filing notice with the DEA administrator.

At the same time, DEA conducts an investigation of the applicant to determine the information necessary to satisfy the six public interest factors I described previously. DEA takes into consideration any comments or objections filed on behalf of the other registered manufacturers in that same class of drug, as well as information gathered during the investigation in making its decision on whether or not the applicant in question would be consistent with the public interest.

In general, if no comments or objections are filed and the results of the investigation conclude that the registration is consistent with the public interest and that all U.S. obligations under international treaties have not been contravened, then the applicant will be approved and a notice of registration will be published in the Federal Register.

If DEA seeks to deny registration, it must serve the applicant with an order to show cause, which provides that applicant with an opportunity for a hearing in accordance with the Administrative Procedures Act. Any applicant whose application is denied is then entitled to seek review of that decision through the U.S. Court of Appeals.

In conclusion, DEA will carefully consider any application for registration as a bulk manufacturer of marijuana consistent with the relevant statutory criteria. Mr. Chairman, thank you for the opportunity to testify today, and I will be happy to answer any questions.

[The prepared statement of Ms. Good follows:]

Statement of
Patricia Good
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Drug Enforcement Administration

Before the

House Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy and Human Resources

April 1, 2004

"Marijuana and Medicine: The Need for a Science-Based Approach"

Chairman Souder, Congressman Cummings, and distinguished members of the Subcommittee, I appreciate your invitation to testify today on the process of applying for a registration under the Controlled Substances Act (CSA) to grow marijuana for scientific research. While I cannot discuss specific pending applications or apply the relevant factors to hypotheticals, I am pleased to explain the general process.

Bulk Manufacturing of Marijuana Registration Application Considerations

In the United States, those that wish to cultivate marijuana to supply scientific requirements must obtain a bulk manufacturing registration from the Drug Enforcement Administration (DEA). The statutory basis for considering such applicants is contained in Title 21, United States Code, Section 823(a); these considerations are given to all those that wish to manufacture a substance controlled in Schedule I or II of the Controlled Substances Act. Briefly, the Attorney General, who has subsequently re-delegated this function to the Administrator and Deputy Administrator of the DEA, is empowered to register those whose applications are consistent with the public interest and United States' obligations under various international treaties.

The statute sets out six factors that the DEA shall consider to determine whether granting the application is in the public interest. The first factor is DEA's ability to maintain effective controls against diversion of the substance(s) into other than legitimate medical, scientific, research or industrial channels by limiting the number of bulk manufacturers to the number of establishments necessary to produce an adequate and uninterrupted supply of marijuana under adequately competitive conditions for legitimate medical, scientific, and research purposes. The second factor is the applicant's compliance with applicable State and local law. The third factor is the applicant's ability to promote the technical advances in the art of manufacturing controlled substances and the development of new substances. As a fourth factor, the DEA must consider any conviction record of the applicant under both Federal and State laws relating to the manufacture, distribution, and dispensing of controlled substances. The fifth factor is the applicant's past experience in the manufacture of controlled substances and the existence in the establishment of effective controls against diversion. Finally, the sixth factor allows the DEA to consider any other factors which are relevant to and consistent with the public interest.

International Treaty Considerations

In order to determine whether the proposed application would be consistent with United States treaty obligations, as section 823(a) requires, the primary treaty obligations that DEA must take into account are those under the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971. Among the basic principles of these treaties is that the cultivation of marijuana (along with opium poppy and coca leaves) should be limited to the minimum number of producers who can provide an adequate supply to meet the country's legitimate medical, scientific, and research needs. Congress expressly incorporated this principle in subsection 823(a)(1).

Bulk Manufacturing of Marijuana Registration Process

The DEA regulations provide more detailed information on the process required for obtaining a registration to bulk manufacture marijuana, as set forth in Chapter 21, Code of Federal Regulations, Section 1301.33 (21 C.F.R. § 1301.33). Briefly, applicants wishing to cultivate marijuana for scientific studies, or bulk manufacture any basic class in Schedule I for that matter, are required to submit Form DEA-225 "Application for Registration" along with the appropriate registration fee. Upon receipt of a completed application, the DEA publishes a notice of application in the Federal Register. This Notice identifies the applicant as well as the controlled substance for which the applicant has applied to manufacture. Simultaneously, a copy of the Notice is sent to each bulk manufacturer of that same controlled substance as well as the applicants. By regulation, such manufacturers and applicants have 60 days to file written comments on or objections to the proposed registration with the Administrator.

The DEA concurrently conducts an investigation of the applicant in order to obtain the information necessary to make determinations consistent with the six public interest factors previously mentioned (21 U.S.C. § 823(a)).

The DEA takes into consideration any comments or objections filed on behalf of other registered manufacturers of the same controlled substance or applicants therefore as well as the information gained during the investigation in making its decision as to whether the registration of the applicant is consistent with the public interest. In general, if no comments or objections are filed with the DEA and if the results of the investigation conclude that the registration is consistent with the public interest and that U.S. obligations under international treaties have not been contravened, then the application will be approved and a Notice of Registration is published in the Federal Register.

If the DEA seeks to deny an application for registration it must serve the applicant with an order to show cause, which provides the applicant with an opportunity for a hearing in accordance with the Administrative Procedure Act, as set forth in 21 U.S.C. section 824(c). Any applicant whose application is denied is entitled to seek review of the decision in the United States Court of Appeals, as provided in 21 U.S.C. section 877.

Conclusion

The DEA will carefully consider any application for registration as a bulk manufacturer of marijuana consistent with the relevant statutory and regulatory criteria.

Mr. Chairman, thank you for the opportunity to testify here today. I will be happy to answer any questions you may have on this process.

Mr. SOUDER. Thank you very much.

Dr. Meyer, I wanted to ask you a few questions. If the pharmaceutical companies wish to bring a new or even existing medical product to market and chose to bypass the FDA approval process by using valid initiatives or State legislative approval, would FDA take any action? If so, what would it be? For example, if a company tried to pass a State referendum allowing oxycontin to be recommended by a doctor for any condition whatsoever, what action would FDA take?

Dr. MEYER. Actually, Mr. Chairman, I'm having a little trouble hearing you, but I believe I did hear the question.

I don't think I can speculate on what the FDA action would be. I'm more of a scientific-medical expert than I am a legal expert. So I'd hate to speculate on that.

Mr. SOUDER. Let me ask you this question, then. Would you think it's fairly safe to say that the FDA would not approve of pharmaceutical companies avoiding the Federal FDA guidelines through State referendums to introduce new drugs?

Dr. MEYER. I think you could certainly point to instances where the FDA has acted in such circumstances.

Mr. SOUDER. Would that not call into some degree the whole question of having an FDA and a scientific process that you described so thoroughly? What would be the point of having you and others do all this research if it can just be done by referendum?

Dr. MEYER. Right. Again, I don't want to talk about speculation here, but I think FDA certainly strongly feels that the FD&C Act and our actions under that are protective of public health and the right way to develop drugs.

Mr. SOUDER. One of our concerns is that this whole so-called medicinal marijuana movement has implied that marijuana is medicinal, and as Dr. Volkow has pointed out, there are 200 ingredients marijuana, just like heroin and cocaine and other narcotics that are dangerous, with sub-ingredients that can be used and harnessed in certain ways to help with certain conditions, but that FDA has been virtually absent in the debate over the medical value of marijuana use.

The reason FDA was established and is funded by Congress is to make sure that such confusion in fact does not exist. Will the FDA now consider issuing warning letters to all States, localities and sellers of marijuana, explaining that botanical marijuana has not been approved by the FDA for medical use and cannot be advertised as such, as you would do in other things? In fact, it was just announced in the Washington Post you're investigating walnuts.

The question is, why hasn't this been more aggressively handled by FDA, and will it consider imposing appropriate penalties on those that continue to illegally promote this dangerous drug as medicine? We're not even talking about, at this point, the clinics. We're talking about those who advertise it as medicine without FDA approval. It is, if nothing else, false advertising.

Dr. MEYER. Let me answer that in two ways, Mr. Chairman. First, within the last couple of years, the FDA has given a consultation to the DEA on the status of marijuana as far as where it should be scheduled. We agreed that it should remain on Sched-

ule I under the Controlled Substance Act and should therefore be controlled. It should be enforced as a Schedule I product, meaning it has no known medical use and has substantial possibility for abuse.

The second thing is, I believe part of your question was directed to the FDA in written form recently. I believe that preparation for answering is underway, and I will defer to that written answer for that.

Mr. SOUDER. I understand that when we bring a researcher in, you're not necessarily making the political policy level decisions. But it has been a frustrating process because we read that the FDA is cracking down on other things. By the way, I feel compelled to make this comment. We had one of our most appalling hearings in Florida on oxycontin just recently, with the sweeping number of deaths there in Florida.

We have a similar problem in Indiana. No. 1, it just exploded through a bunch of bank robberies, a bunch of kids, the abuse of a legal drug. As I understood Ms. Good's comment, one of the first criteria is, can this be controlled and managed. What we learned at that hearing is the No. 1 cause of narcotics deaths in the United States are from legal, approved drugs that were supposed to be in this category of things that we were managing. It's going to be pretty hard to convince a lot of us that in fact, there can be a management process for controlled drugs.

I'll go a second round here. Let me yield to Ms. Sanchez next.

Ms. SANCHEZ. I thank the chairman. At this time, I actually have no questions for the first panel.

Mr. SOUDER. OK, so I'm going to go on. I wanted to move to Dr. Volkow, what do you think, you went through the research, you isolated pretty clearly what we're trying to find out in the subcomponents of marijuana, where we might find some things to help some people. This, however, has been seized upon by some to try to falsely imply that marijuana itself is safe.

What do you think are the best ways we can try to balance this very difficult problem that we're having with oxycontin, with heroin, with other types of derivatives, the opioids, if we find some medical things that can be treated through very controlled usage that then give the impression that the narcotic itself is somehow safe? How can we more aggressively show through the Federal Government health divisions that marijuana is actually very dangerous? You've outlined a whole series of things, not only including gateway, but impacts on individuals and addiction and other things.

Dr. VOLKOW. Yes, and this of course is a difficult proposition, particularly I think in the case of opiates, the drugs you are referring to, because we are faced now with the No. 2 illegal drugs in this country are prescription compounds. These are opiates, analgesics, after marijuana. And that includes kids and elderly people.

And these are drugs that are being prescribed by physicians that have very good therapeutic applications but somehow are being diverted and abused and leading to addiction and high levels of toxicity. So the No. 1 issue I think is extremely important, we know from research that one of the best strategies to combat drug addic-

tion is prevention. And one of the best ways of addressing prevention is education.

So in order to educate people, you have to have information. That's one of the aspects that is very, very relevant. In the case of marijuana, there have been extensive studies conducted to determine the effects of toxicity of marijuana. There are many studies that have shown that it is adverse, but there are also other studies that have shown it's not adverse. This has led to controversy.

As new technologies become available and studies become more rigorous, we're starting to get extremely interesting information documenting in fact that marijuana is not benign. There is clear evidence to suggest that. So our responsibility, the way that I view it, is to generate that knowledge such that the data will speak for itself. It doesn't become, I think this is a benign drug. It is the data that are going to state.

And I mentioned two studies, because I think they are quite impressive in what they are telling us, the one showing identical twins, the ones that started taking marijuana before age 17, had significantly higher problems with drug abuse and addiction. These were identical twins, with the same genetics. And another study showing that chronic use of marijuana, and it wasn't whether you are not remembering or memorizing, led to significantly poorer performance in life as assessed by how much money you make, as assessed by years of education, as assessed by how happy you are.

So to summarize, the way we do this is through prevention. The way that we do it is via education: education of lay public, education of policymakers, education of physicians. It's education across the different levels of society.

Mr. SOUDER. How would you, both Dr. Volkow and Dr. Meyer, if in balancing the good and the risks, if smoking tobacco, cigarettes, turned out to reduce obesity, would either of you recommend smoking tobacco to reduce obesity?

Why would that even be a discussion matter in marijuana, or how do you balance the countervailing forces? Because tobacco harms an individual, shortens their life, but doesn't have an impact on other people. You don't, for example, wreck a car and kill somebody while you're high on tobacco. So the argument that it shortens somebody's life actually has less impact on other people's life, unless we find more data on second hand smoke, which we're rapidly developing. That's another question.

But I'm curious even why things like obesity and other things would come up, unless it would be isolated from the dangerous addiction, and whether in fact if cigarette smoking was shown to reduce obesity, as many people think it does, whether you would approve it on those grounds.

Dr. VOLKOW. I think that's one of those answers that's very simple. No, you would not approve smoking for things like obesity, because to start with, the risk associated with smoking would be much worse than those associated with obesity, No. 1.

No. 2, there are many alternatives, even if in fact it was shown, and it hasn't been shown that nicotine is an effective treatment for obesity. But even if it were, for matter of argument, there are ways of delivering nicotine that do not have the adverse consequences of smoking a cigarette. So why would you want to promote a delivery

system that you know is harmful, when you can actually deliver the same pharmacological agent in a safe way that also minimizes its addictive potential?

Because one of the things that we've learned through the past few years in science is that the effects of a drug are very much modified by the way that you take it. So when you take a drug smoking, that's the route of administration that assures you the higher likelihood of abuse and addictiveness. It has to do with the rapidity with which it gets to the brain and the concentration it reaches.

So when you are smoking marijuana, the effects are going to be very different than when you take it orally. The same thing with nicotine, when you smoke nicotine, the effects are very different than that from a patch. And that dramatically modifies the addictive liability. So even with marijuana, changing the route of administration has a significant effect.

But with marijuana, a step further is, as we are recommending, there are multiple elements to marijuana. So you can now dissect them and optimize a compound that will have the properties you want without the other untoward effects. That's why we have science. And that's why we're investing in institutes like NIDA, in order to be able to develop compounds that are safer and can help people.

Dr. MEYER. I think from my standpoint, I would state that the safety and risk, as opposed to the efficacy, is wholly dependent on what situation you're talking about. I agree with the comments that Dr. Volkow made about smoking and weight loss. So there may be, and I'm not saying there are, but there may be circumstances where a smoked drug such as marijuana in very limited circumstances could be found to be overall safe and effective for something in a patient where perhaps they are quite terminal, for instance.

But I agree very much, and said in my oral testimony, that I think while smoked marijuana may be an expedient way to begin research looking for effects that it's my belief that any approval, just as Marinol was approved, it's an oral dosage form, any approval down the road from this kind of research will likely be some other dosage form than smoked marijuana.

Mr. SOUDER. So for example, if nicotine, a component of tobacco, I'm not arguing that it is, but if nicotine had a side benefit such as, who knows, if you break out cigarettes and the components inside a tobacco cigarette, maybe we'd find certain things that have certain usages. But let's say nicotine did and you took it in pill form. Do you think it would be justified to then refer to cigarettes that are smoked as medical cigarettes?

This is part of the political problem we're having here. You're saying there can be side things in the chemicals in marijuana, if it's taken in pill form. But then people refer to it as medical marijuana, whereas we have other things that if we take the chemicals and components out, we would never let advocates say that it's medical cigarettes because you could get something out of it, or medical heroin because you can get something out of it. And why isn't that false marketing and false labeling, and why aren't you speaking out against it more aggressively in the public arena that

this is not medical? It is a component inside it, just as there are components inside all kinds of things that are terribly unhealthy. Then we come up with other names for them, but we don't call the primary drug, when it's dangerous, medical.

That's the baffling thing here, which suggests a much broader agenda than a health agenda.

Dr. MEYER. Again, I think from the FDA perspective, we have within the last few years gone ahead and again said that we felt that marijuana is an appropriate Schedule I controlled substance, that it has no known medical benefit at this point, and that it does have that high abuse potential. So I think between that and the fact that we're clearly on record today and otherwise saying that it is not approved for any medical use.

Mr. SOUDER. So there is no medical marijuana from the FDA's perspective? There are components within it that can be used in Marinol or other alternatives.

We were having a discussion a little bit earlier about what are other alternatives to marijuana to treat some conditions? Marinol is one alternative.

Dr. VOLKOW. There are conditions that have been brought forward in terms of research, apart from the issue of nausea and vomiting from cancer, and increasing appetite of people that have cachexia, that is they are not hungry, like with HIV or cancer. There are other indications that are actually being investigated, particularly funded through California. And that is pain that comes from the peripheral nerves. And marijuana appears to be effective on those grounds.

One of the things that's interesting is that research has found that there are two cannabinoid receptors, one is in the brain and the other one is on the outside. And it is the cannabinoid receptors outside the brain that are responsible for this pain killing. So the pharmaceuticals are now developing these compounds that don't go into the brain, so they are not going to be addictive, that actually have very, very promising analgesic effects, with none of the untoward effects of the drug. Because if you actually even look at the patients that are getting marijuana or even Marinol, they complain of sedation. That's not desirable for a lot of people.

So if you can treat pain without having the person sleepy all day long, very effectively, with no psychoactive effects, if this doesn't change your mental state, believe me, you'll have a much more powerful medication. So that's for the pain.

The other one that is being promoted is glaucoma, high pressure of the eye. There the stories are controversial, because while cannabinoids effectively decrease the pressure in the eye, they also decrease blood pressure, so there is concern that ultimately may not be beneficial to protect the eye. So the effects there of cannabinoids are not so good, but in terms of the ones that are used for marijuana, nausea and vomiting, there are several compounds that are now available. Cachexia, and that's the one that Marinol appears to be useful in patients, and the one analgesia, which is absolutely fascinating.

Now, there's one other area of research of developing drugs that antagonize the systems that are activated by marijuana. Those are

the ones that are being targeted for obesity, those are the ones that are begin targeted for smoking and for alcoholism.

Dr. MEYER. And from the FDA perspective, I would say that for the majority of the indications that Dr. Volkow just spoke to, there are many pharmaceuticals approved. In fact, Marinol is not particularly widespread in its use, because there are alternatives. It's approved both as anti-nausea for chemotherapy patients and for cachexia or for weight loss in the setting of AIDS. And there are a variety of drugs in other modalities that seem to be preferable for many patients.

That said, I think that there certainly are patients who do not seem to respond even to the best of our pharmaceutical armamentarium. And I can understand where patients would want to see further research. But I think until we have research that shows that any cannabinoid or marijuana itself is safe and effective for these indications, as an agency we really can't say anything other than that we know these other drugs that are approved for these purposes work.

Mr. SOUDER. Did you have any questions?

Ms. SANCHEZ. No, thank you.

Mr. SOUDER. Let me see if I can summarize this. I'm not known for being neutral on this issue, I'm very outspoken on the narcotics issue, so I don't want to misstate this. But there are literally millions of people across America who have the impression that the Federal Government doesn't care or respond to people with AIDS or cancer who are in terrible pain; that we're so obsessed with the drug war in the United States, we don't care about that, we're more concerned theoretically with locking people up because we have this obsession with marijuana.

Let me see if I understand your positions correctly. And I'm going to try to say it precisely, because you were both pretty precise. You do not believe that marijuana is medical, but there are components and chemicals in marijuana that you are actively researching in both agencies. There are products that have been developed from those chemicals that are helping treat the parts of different illnesses that some people have used the arguments for marijuana to treat.

And that Marinol, even as I understood it earlier, that we always heard did not help in nausea cases, has been improved, and that while it may not treat all cases, you are continuing to try to make it more effective. And that in the minds of both your agencies, marijuana itself is not medical, but it does have components that you will continue to research. You have continued to have breakthroughs and we are continuing to improve the health of the United States. Is that a fair statement? Is there anything I misspoke or overstated?

Dr. MEYER. I think just from the agency standpoint, I would say that we do not have the evidence to say that marijuana has a legitimate, safe and effective use.

Mr. SOUDER. Components within it can be used in other products when not smoked.

Dr. MEYER. Well, certainly one component is approved, Marinol, which is the delta–9-THC. But I guess from my standpoint then, if there was to be a medical use for marijuana or any of these other

components, apart from delta–9-THC, we feel there would be much more research needed to both explore the efficacy and to document the safety.

Mr. SOUDER. And it wouldn't be marijuana.

Dr. MEYER. Pardon?

Mr. SOUDER. It wouldn't be marijuana. It would be some component inside the marijuana.

Dr. MEYER. Well, again, I think there are inherent toxicities to smoking anything, and, my best guess as a physician is that it would likely be a dosage form other than marijuana or a route of administration other than smoking, certainly.

Mr. SOUDER. But it probably, even if it was in dosage form, have all 200 chemicals. Did you say there were 200 chemicals?

Dr. VOLKOW. 400.

Mr. SOUDER. 400; 400 chemicals probably wouldn't be in it, because you would be isolating what you're treating, is that correct, Dr. Volkow?

Dr. VOLKOW. Yes. Ideally of course you want to get as pure a medication as you can to minimize side effects. Under certain instances, combinations appear to be better than just a single one. But there are very rare indications where that has been shown.

Mr. SOUDER. May I ask you to clarify that statement? In other words, you could take a component of marijuana and maybe find another one somewhere else that wasn't even in marijuana to combine with something that you found inside marijuana to make a more effective pill?

Dr. VOLKOW. Correct. And there are naturally occurring compounds that, for example, in the case of the amphetamines, which we use to treat children with ADHD. They're are actually two components to it, and it has been shown that both of them exert slightly different effects. So that's one of the elements. But correct. And the main component that is believed to act in marijuana is the delta–9-THC. But there is evidence that others are having effects, but much less so.

Having said that, I do think there's an element that is relevant in terms of research on marijuana and potential medical applications. It has helped us in certain instances to identify areas where we say, marijuana, for example, has these analgesic effects. Then we do the research and say, what are the mechanisms by which marijuana led to that analgesia, and then try to identify what the mechanisms are, and target compounds that go directly to it. But that's a different perspective. That was the research that led to it. But we use it in order to get better interventions.

Mr. SOUDER. Dr. Meyer.

Dr. MEYER. I just felt I needed to be clear on this issue. FDA does not have an inherent bias against botanical products. If botanical products are developed correctly and shown to be safe and effective, even though they contain a variety of substances, many of which may be known, some of which may be unknown, but if those are properly approved and shown to be safe and effective, we would approve a botanical product.

Mr. SOUDER. Do you have any smoked product that you have approved?

Dr. MEYER. I don't believe so, no.

Mr. SOUDER. Anything else you want to add before we conclude the panel?

Thank you all for coming. We appreciate your testimony.

If the next panel will come forward, and remain standing. The next panel is Dr. James Scott, board member of the Oregon Board of Medical Examiners; Ms. Joan Jerzak, chief of enforcement, Medical Board of California; Dr. Claudia Jensen, Ventura, CA; Mr. Robert Kampia, executive director of the Marijuana Policy Project; Dr. Robert DuPont, Institute for Behavior and Health, of Rockville, MD.

I will need to have you each stand and raise your right hands.

[Witnesses sworn.]

Mr. SOUDER. Let the record show that each of the witnesses responded in the affirmative, and we'll start with Dr. Scott.

STATEMENTS OF JAMES D. SCOTT, M.D., MEMBER AND PAST CHAIR, OREGON BOARD OF MEDICAL EXAMINERS; JOAN JERZAK, CHIEF OF ENFORCEMENT, MEDICAL BOARD OF CALIFORNIA; CLAUDIA JENSEN, M.D., VENTURA, CA; ROB KAMPIA, EXECUTIVE DIRECTOR, MARIJUANA POLICY PROJECT; AND ROBERT L. DUPONT, M.D., PRESIDENT, INSTITUTE FOR BEHAVIOR AND HEALTH

Dr. SCOTT. Mr. Chairman and members of the committee, I thank you for the opportunity to be here today.

My name is Dr. James D. Scott, I'm an otolaryngologist, which is more easily known as an ear-nose-throat physician. I have practiced medicine in Roseburg, OR since 1971.

I am a member of the Oregon Board of Medical Examiners and past Chair. The Oregon Board of Medical Examiners was created by the State legislature in 1889 to regulate the practice of medicine. The Board's mission is to protect the health, safety and welfare of the Oregon citizens by regulating the practice of medicine in a manner that promotes quality care.

The Board is governed by and enforces the Oregon Medical Practices Act, and Oregon related administrative rules. The Board conducts investigations, imposes disciplinary actions and supports rehabilitation, education and research to further its legislative mandate to protect the citizens of Oregon.

In 1998, Oregon voters adopted the Oregon Medical Marijuana Act. This act creates an exception to State criminal laws by permitting certain individuals to possess, produce and use small amounts of marijuana which may mitigate a disabling medical condition. The Oregon Health Services Division was assigned the rulemaking authority necessary for the implementation and administration of this act.

To qualify for protection provided by the law, the patient must apply for or have a registry identification card. To obtain this card, the patient is required to have written documentation from the attending physician that the patient has a qualifying disabling medical condition. Attending physician means a physician licensed under the Oregon Medical Practice Act, who has the responsibility, the primary responsibility for the care and treatment of a person diagnosed with a disabling medical condition.

The Board of Medical Examiners is responsible for verifying that physicians are licensed to practice in Oregon with no restrictions that would legally prevent them from signing an attending physician statement regarding medical marijuana. The Oregon medical marijuana program requests such verification from the BME licensing and investigative staff.

No one representing the Oregon Board of Medical Examiners is prepared to give any testimony regarding any scientific or medicinal value of marijuana or any sociopolitical issues regarding marijuana. These issues are beyond our jurisdiction. Our Board's role is to ensure that marijuana is recommended for medicinal use through the same practice of medicine as any other controlled substance. In Oregon, physicians are required to verify patients' identities, review previous patient medical records, collect current histories, perform thorough, in-person physical examinations, reach diagnosis and recommend treatment plans. We also recommend discussion with patients regarding the benefits and risks of such treatment plans.

Physicians are required to have complete, accurate patient records. Our Board has disciplined an Oregon physician who signed attending physician statements for the use of medical marijuana without following the aforementioned procedures. The Board makes no distinction between medical marijuana and any other controlled substance. Physicians have been and will continue to be investigated and disciplined for inappropriate prescribing of all controlled substances regardless of the nature of the drugs in question.

The Oregon Board of Medical Examiners has made no policy statement formally or informally on the use of marijuana for medical purposes. The State's voters and the legislature approved medical use of marijuana without the approval of the U.S. Food and Drug Administration, which has stringent requirements for scientific testing, approval, manufacture and dispensing of legal drugs. The people of Oregon have determined through the process of law that using marijuana for medicinal purposes is part of the standard of care for the State's doctors. The Board of Medical Examiners is responsible for seeing that all standards of care under Oregon law are strictly and fairly enforced.

Thank you very much. I'd be happy to answer questions.

[The prepared statement of Dr. Scott follows:]

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REGARDING MEDICAL MARIJUANA AND OREGON STATE LAW
Before the United States House of Representatives
Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy and Human Resources
Rep. Mark E. Souder, Chair
APRIL 1, 2004

TESTIMONY of James D. Scott, M.D., Roseburg, Ore.
Member and Past Chair, Oregon Board of Medical Examiners

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The Board is governed by, and enforces, the Oregon Medical Practice Act (Oregon Revised Statutes [ORS] Chapter 677) and related Oregon Administrative Rules (OAR Chapter 847). The Board conducts investigations, imposes disciplinary actions and supports rehabilitation, education and research to further its legislative mandate to protect the citizens of Oregon.

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To qualify for protection provided by the law, the patient must have applied for or have a Registry Identification Card. To obtain this card, the patient is required to have **written documentation** from the attending physician, stating that the patient has a qualifying disabling medical condition. "Attending physician" means a physician, licensed under the Oregon Medical Practice Act, who has primary responsibility for the care and treatment of a person diagnosed with a debilitating medical condition.

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FOR IMMEDIATE RELEASE

MARCH 4, 2004

CONTACT: Kathleen Haley
(503) 229-5770

MEDICAL BOARD SUSPENDS LEVEQUE'S LICENSE TO PRACTICE

PORTLAND – The Oregon Board of Medical Examiners (BME) today suspended the license of a Molalla osteopathic physician on the grounds that he poses an imminent risk to public health and safety.

The Board removed Phillip Leveque, D.O. from practice because of his continued violation of an April 2002 order, according to Kathleen Haley, BME executive director. Haley said that any physician statements signed by Leveque under the Oregon Medical Marijuana Program (OMMP) after Thursday, March 4, 2004 will be invalid.

She said the suspension, by unanimous vote of a majority of the Board, was the latest action in 20 years of dealings between the board and Leveque. "The Board suspended Dr. Leveque's license because he has not complied with a stipulated order he signed in April 2002," Haley explained. "That order was crafted as part of an agreement between the board and Dr. Leveque.

Haley said that "expert opinions" of the Board's medical consultants indicate Dr. Leveque is "grossly negligent" in his evaluations of certain patients for the medical marijuana program, and jeopardized the health and safety of his patients.

The Board in 2002 revoked Leveque's medical license, but stayed the revocation and placed Leveque on probation for 10 years, under certain terms and conditions. In signing the 2002 order, Leveque agreed not to sign attending physician statements under the Oregon Medical Marijuana Program without first meeting certain conditions.

Those conditions included making in-person contacts with patients, verifying patient identities, reviewing previous patient medical records and conduct thorough patient histories and physical examinations. In 2002 Leveque also was ordered to provide written treatment plans and keep appropriate medical records for each patient.

"By continuing to issue statements for medical marijuana without meeting the conditions of his probation, Dr. Leveque has violated not only a Board of Medical Examiners order, but also the trust of the Board and of the citizens of the state of Oregon," Haley said.

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Mr. SOUDER. Thank you for your testimony. We'll now move to Ms. Jerzak.

Ms. JERZAK. Chairman Souder and members of the subcommittee, my name is Joan Jerzak, I'm the chief of enforcement for the Medical Board of California, which is a sworn law enforcement position.

Our enforcement program currently employs 90 investigators and supervisors statewide. The Board is legislatively mandated to protect the health care of consumers through the proper licensing and regulations of physicians and surgeons and through the vigorous, objective enforcement of the Medical Practice Act. The Board licenses and regulates more than 115,000 physicians.

Thank you for the opportunity to speak to you regarding the use of medicinal marijuana as a treatment modality from California's perspective. Although the subcommittee is looking at science based medicine and studies on medicinal marijuana, I've been asked to comment on how California physicians deal with medicinal marijuana and its health related impact on patients from the perspective of a regulatory agency.

The Compassionate Use Act of 1996 was passed by California voters through the initiative process and became law in November 1996. The main thrust of the act was to allow seriously ill Californians to obtain and use marijuana for medicinal purposes where such use is deemed appropriate and has been recognized by a physician. The act provides that marijuana may be used by patients for a wide variety of medical conditions, and envisions that the physician will serve as a gatekeeper to ensure that users are indeed patients whose health would benefit from the use of marijuana.

Since 1996, the Board has investigated a small number of physicians who have had complaints filed against them questioning their recommendation for medicinal marijuana. To put this into perspective, the Board receives approximately 12,000 complaints each year. After completion of the triage process, approximately 2,000 complaints are assigned to an investigator. Complaints are received from a wide variety of sources and impact all facets of the practice of medicine. They include quality of medical care, sexual misconduct, substance abuse, unlicensed practice, physical or mental impairment, and an assortment of other issues, including improper prescribing or handling of controlled substances.

Of the physicians the Board has investigated for medicinal marijuana related issues, four cases were closed, one case remains in the investigative stage, and the other four cases resulted in charges being filed. In those four cases where charges were filed, the medical experts were not critical that marijuana was recommended but rather they were critical of the overall care and treatment provided by the physicians and that there was not a good faith prior exam or medical indication, the records were inadequate, or there was failure to obtain proper informed consent. The Board does not pursue disciplinary action against physicians merely for recommending medicinal marijuana.

Physicians in California have expressed concern as to what their role is with regard to medicinal marijuana and the Board's view of physicians who are involved in issuing recommendations. The

Board has taken a proactive approach to educating physicians on the required protocol prior to recommending the medicinal use of marijuana.

After the act passed, the Board published an informational article in its January 1997 newsletter clarifying the role of the physician under the law. The Board was clear in its expectations that any physician who recommends the use of marijuana by a patient should have arrived at that decision in accordance with generally accepted medical standards, which include a history and physical examination, development of a treatment plan, provision of informed consent, periodic review of the treatment and proper recordkeeping. In July 2003, the Board published another article discussing a physician's choice to use medicinal marijuana as a treatment for patients, and the legality of that choice at the State versus the Federal level.

The immunity provision in the California Act does not extend to violations of Federal statute, and for that reason, physicians recommending marijuana know that they may be vulnerable to action by the Federal Government. As you know, the traditional medical model flows from the presentation of ideas that lead to new, emerging medicine. These typically include studies with positive trial outcomes and physicians are introduced to these new methods through educational settings and through ongoing review of medical journals.

In contrast, alternative medical modalities, such as medicinal marijuana, are typically consumer driven, whereby the consumers find out about a particular modality or treatment and they ask their practitioner about it. Physicians must ensure the recommendation is in fact appropriate for a particular patient and that their recommendation for marijuana has been arrived at in a manner which is consistent with the standards of practice for physicians in all other contexts.

To date, no court cases have overturned California's Compassionate Use Act, and in October 2003 the U.S. Ninth Circuit Court of Appeals produced a ruling that first amendment freedom of speech allowed physicians to legally discuss medicinal marijuana with their patients, and this decision was upheld by the U.S. Supreme Court.

Again, thank you for allowing me, on behalf of the State of California, to share this information with you.

Mr. SOUDER. By the way, once again, it was declined to be reviewed by the Supreme Court, which is different. It was not overturned, which is different than being upheld.

Ms. JERZAK. I'm sorry.

Mr. SOUDER. Dr. Jensen.

Dr. JENSEN. Hi. Good afternoon, Congressman Souder and members of the committee. I'm very grateful to be here today.

I wanted to just tell you what I've learned about Cannabis indica and Cannabis sativa, which is also known as medical marijuana. I'm a 49 year old mother of two teenage daughters. I've been a pediatrician for 23 years. I trained at University of Arkansas and I did my residency training at U.C. Irvine Medical Center. I have worked 12 years as a managed care physician, staff model HMO doctor and since 1996, in private practice. I also currently work in

a small community based clinic servicing primarily Spanish speaking patient population.

I was not an advocate of using medical marijuana; however, I was forced into taking responsibility for caring for some patients a few years ago because of the suffering that I saw. They were patients with no money and were unable to seek the aid of some other physicians because they had transportation difficulties. So I called the Medical Board and I asked for some guidance on how to do this, and found that there really weren't systems set up to help physicians yet.

But I elected to go ahead and try and help these people anyway. And since then, I have found that this is one of the most fascinating and challenging fields of medicine that I have ever been involved in. I have learned so much and I have seen so much that I felt compelled to come and talk to you about it today, and I greatly appreciate your asking me to come.

In specific, you asked me about treating children with attention deficit hyperactivity disorder. To make it clear, I have only two patients in my practice that have used cannabis for that problem as children. Both of their parents came to me and asked me to help their kids. Both of those children had very, very serious functional problems in school. One of them was also a social deviant to some level. He was unable to stay in a normal classroom and he had very serious anger management issues. Not quite on the level of Columbine, but he had trouble at home and at school in maintaining his behavior.

He had been tried on all of the usual drugs that we use to treat for ADD, which basically are the amphetamines. I find it very concerning that we treat adolescents, who have authority issue problems, with drugs that cause them to have mood swings and irritability and loss of appetite, which affects their nutritional status, reduces their ability to sleep properly and are well known to cause seizures, can trigger mental illness, etc., albeit small numbers of people are affected negatively by the amphetamines, but there are some.

There are other drugs to use for ADD, but they are off label. They have not been studied in children, for example, Welbutrin, and then some of the anti-depressants. It says very clearly in the PDR nothing about treating children with ADD with those drugs, and yet physicians over the years do that. In this country, we spent over $1 billion annually on giving kids drugs for ADD.

Now, in doing research for this presentation, I discovered that Americans have spent billions of dollars on medical marijuana. You stated in your papers that in 1999, Americans spent $10.6 billion buying marijuana. My feeling is that money should be diverted out of the black market, it should not be funneled into criminal sources, it should be diverted into health care management systems, teach physicians, give the regulatory boards the tools that they need to be able to do it properly, have the money funneled into public health systems and use cannabis as a medication under the guidance of physicians rather than the free for all that it is now.

It is clearly not regulated, the American people are not obeying the Federal Government, and I really feel that with what you're

doing today, perhaps we can rectify this. I am here to answer any questions that you have that I could, which might facilitate that process.

[The prepared statement of Dr. Jensen follows:]

Testimony of Claudia Jensen, M.D.
for the House Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy and Human Resources

Marijuana and Medicine:
The Need for a Science Based Approach

April 1, 2004

I am very grateful for the opportunity to submit my written testimony to the Members of the Subcommittee of the Committee on Government Reform. Thank-you. I am also thankful for the opportunity to have five minutes of oral presentation time. I apologize for the summarized nature of this report as I was invited to speak on March 16, 2004 and have had minimal time to prepare. I pray Members of the Subcommittee as well as the Committee on Government Reform will read the enclosed information with the intention of considering actual social reform.

I am a 49 year old mother of two teenage daughters, and a Physician educated at the University of Arkansas for both undergraduate and medical schools. I studied Pediatrics at the University of California at Irvine, completing my Internship and Residency training in 1981. I have a total of 23 years working as a Pediatrician, first as an HMO physician with Cigna HealthPlans, then in private practice in Ventura, CA.[1]

I currently work two days a week in a small community clinic servicing a poor patient population, three days a week in my own private office and I teach first year medical students one day a week at the University of Southern California Keck School of Medicine. I have always had a reputation for being a patient advocate since the very beginning of my training.

Congressman Souder has asked me to discuss my "practice" of recommending "marijuana" for use by "dozens of patients, including children with ADD.[2]" This "practice" is a direct consequence of California's passing of the Compassionate Use Act of 1996[3] (Health and Safety Code 11362.5, also known as Proposition 215) and my compliance with the law as determined by State of California[4] and the United States Supreme Court.[5] The people of the State of California, as well as a majority of Americans[6] believe marijuana should be available to patients who are ill or in pain. Contrary to popular opinion and scientific fact, it is the position of the Government of the

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[1] Jensen, Claudia, M.D., Curriculum Vitae, 2004.
[2] Invitation to speak to the Subcommittee on Criminal Justice, Drug Policy and Human Resources, March 16, 2004.
[3] Health and Safety Code 11362.5, entire text.
[4] State of California, Senate Bill 420.
[5] Conant v. McCaffrey, No. C97-00139 WHA, subsequent Ninth Circuit Court of Appeals Decision and Supreme Court refusal to hear the appeal.
[6] Stein, Joel, "The Politics of Pot", Time, November 4, 2002, page 57.

United States of America that there are no known medicinal uses for marijuana[7]. Consequently, marijuana has been classified as a drug as dangerous as heroin and LSD. This is clearly contrary to the truth. At this time, while Americans are dying overseas and at home in the service of protecting democracy, it is even more critical for the American people to have faith in the information being disseminated by government. Enclosed in this testimony are references to corroborating documents refuting the position of the Drug Enforcement Administration, the official watchdog of American Physicians and the medications they prescribe, and an agency under the guardianship of this committee. (A full copy of all of the references will be provided to Chairman Souder upon my arrival at the Hearing.)

AN ABBREVIATED HISTORY OF CANNABIS

"Marijuana" is a term used to describe the plants *Cannabis sativa* and *Cannabis indica.* Cannabis has been used as a medication for over five thousand years. "The first evidence of the medicinal use of cannabis is an herbal published during the reign of the Chinese Emperor Chen Nung five thousand years ago. It was recommended for malaria, constipation, rheumatic pains, 'absentmindedness,' and 'female disorders.'"[8] Marijuana was also recommended for "senile insomnia", analgesia, as a sleep inducer (hypnotic), in the treatment of gastric ulcers, morphine addiction, migraine headaches, tic douloureux, depression, and epilepsy.[9] "The first Western physician to take an interest in cannabis as a medicine was W. B. O'Shaughnessy, a young professor at the Medical College of Calcutta, who had observed its use in India."[10] Dr. O'Shaughnessy studied cannabis in India, then introduced the medication to European and American physicians. It was listed in the "United States Dispensatory" in 1854. By 1860, American doctors used cannabis to treat a multitude of medical problems "including tetanus, neuralgia, dysmenorrhea (painful menstruation), convulsions, the pain of rheumatism and childbirth, asthma, post-partum psychosis, gonorrhea, and chronic bronchitis. As a hypnotic (sleep-inducing drug) he compared it to opium"..."The whole effect of hemp being less violent, and producing a more natural sleep."[11]

Cannabis was readily dispensed by U.S. pharmacies until after passage of the Marihuana Tax Act of 1937, a strictly political shuffle motivated by Harry Anslinger under the Federal Bureau of Narcotics. Anslinger's campaign was orchestrated through an aggressive, but largely hysterical media campaign.[12] During Congressional hearings to decide the fate of cannabis as a medication, a spokesman from the American Medical Association, W. C. Woodward, M.D., J.D. noted, "It has surprised me, however, that the

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[7] US.GOV website, House of Representatives, Committee on Government Reform, Subcommittee on Criminal Justice, Drug Policy and Human Resources, News, "Chairman Souder wants you to know that Marijuana is not Medicine" plus related links.
[8] Grinspoon, Lester, M.D., Bakalar, James B., Marihuana, the Forbidden Medicine, Yale University Press, New Haven and London, 1997, page 3.
[9] Ibid., page 6.
[10] Ibid., page 4.
[11] Ibid., page 5.
[12] Ibid., pages 7-8.

facts on which these statements have been based have not been brought before this committee by competent primary evidence."[13] From the very beginning, the choice to ignore the medical therapeutics of cannabis was politically motivated, not based on truth.

In 1970, during a period of great upheaval in America, Congress passed the Comprehensive Drug Abuse Prevention and Control Act (also called the Controlled Substances Act), which placed cannabis in a category called "Schedule I." Schedule I drugs "have no known medicinal use" by definition.[14] Clearly, this was not scientifically based as evidenced by 5000 years of a longitudinal outcome-based folk medicine "study" (i.e. people from all over the world have been using cannabis for medicine after 5000 years of observation of how it works.) Nonetheless, cannabis became illegal with the passage of both these Acts, neither of which was based on scientific facts.

Subsequent to the Controlled Substances Act, several patients applied for special permission to use cannabis to relieve pain and suffering. As there was, indeed, evidence to support the use of cannabis as a medication, Federal drug agencies granted "Investigational New Drug" permits to patients to use marijuana medicinally. The Federal Government took over the dispensing,[15] of marijuana to several sick people and established a cannabis farm in Mississippi. Today there are seven Americans who continue to receive prescriptions of marijuana from the U.S. Government sent to them in the U.S. Mail.

In 1988, Francis L. Young, J.D., and Administrative Law Judge for the Drug Enforcement Administration reviewed the medical literature on Cannabis. "Based upon the foregoing facts and reasoning, the administrative law judge concludes that the provisions of the Act permit and require the transfer of marijuana from Schedule I to Schedule II. The Judge realizes that strong emotions are aroused on both sides of any discussion concerning the use of marijuana. Nonetheless it is essential for this Agency, and its Administrator, calmly and dispassionately to review the evidence of record, correctly apply the law, and act accordingly."[16] He *ordered* the DEA to change the classification of Cannabis such that patients could gain legal access through their physicians. The DEA disobeyed Judge Young and ignored his order. There were no enforcement measures available to force the DEA to comply.

The Compassionate Use Act of California ("Proposition 215") was passed in 1996. In it, patients who are "seriously ill Californians" are given the right to seek their physician's approval to use cannabis to aid in the treatment of their illnesses. Since passage of the act, much legislation has ensued. California lawmakers subsequently put into law a corollary to the Compassionate Use Act. Senate Bill 420 provides for systems to aid Law Enforcement in the compliance with California Law H&S Code Section 11362.5. Additional litigation resulted in a decision protecting patients and physicians from

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[13] Ibid., page 9.
[14] Op. cit.,
[15] "Medical Pot Users Win Key Ruling",
[16] United States Department of Justice Drug Enforcement Administration, Docket No. 86-22, September 6, 1988

interference in their relationships. The Supreme Court of the United States of America has upheld the right of autonomy in this matter for both patients[17] and physicians[18].

Although it is the Law, and although the Law has been supported by the Supreme Court, many enforcement measures have been meted out on both patients and physicians to try to prevent them from complying with California State Law. Many patients have lost their medicine and been subjected to criminal prosecution. William Eidelman, M.D. lost his license to practice medicine. Miriam ("Molly") Fry, M.D. lost her right to write prescriptions for antibiotics and everything else. The grandfather of the Medical Marijuana movement, Tod Mikuriya, M.D., was investigated at great length by the Medical Board of California and subsequently fined $75,000 for his care of medical marijuana patients.[19] Although no patient has complained to the Medical Board about my medical care, I am also under investigation for my care of three patients.

Many physicians who have medical marijuana patients in their practices are currently under investigation although the Medical Board of California's policy clearly states physicians are not to be unduly harassed: "The Board seeks to provide greater guidance to physicians to enable them to participate appropriately in the implementation of Proposition 215, while meeting their professional and ethical obligations under the relevant standard of care. Adherence to such guidance by both physicians and Medical Board enforcement staff will ensure that physicians are not investigated merely because they have issued recommendations for marijuana use to patients. Investigations must be based on information received by the Board which provides a reasonable basis to believe that the physician is not adhering to acceptable medical practice standards when making the recommendation."[20]

In fact, the Medical Board of California has not lived up to its own standards. Not only are the doctors being investigated, frequently without just cause, but physicians have benefited from no guidance from the Medical Board, whatsoever. Physicians evaluate whether a patient is ill and determine if the risk/ benefit ratio of using any medication warrants condoning the patient's use of the drug or not. Examining risk/ benefit ratios in the care of patients is exactly what physicians have been trained to do. It's our job.

Instead of trusting licensed physicians to make educated decisions regarding patient care, the Medical Board depends on its enforcement branch to attend to the physicians who care for medical marijuana patients. No physicians with the Medical Board of California have any experience or training in the management of this highly complex patient population. The care of Medical Marijuana patients is a specialty and requires much greater skills in many areas than does the traditional practice of medicine. The physicians of the California Cannabis Research Medical Group[21] have carved out

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[17] "Court Accepts Medical Pot Use", Los Angeles Times, July 19, 2002.
[18] "Medical Pot Use Given a Boost", Los Angeles Times, December 17, 2003.
[19] Ventura County Star, "Doctor could lose license over marijuana", July 14, 2003.
[20] Medical Board of California, Action Report, www.medbd.ca.gov, July, 2003.
[21] Gardner, Fred, O'Shaughnessy's, Journal of the California Cannabis Research Medical Group, "Cannabis Specialists Agree on Health History Questionnaire," Spring, 2004, page 2.

accepted Practice Guidelines, but they would greatly benefit from a cooperative relationship with the Medical Board rather than the current adversarial relationship. Doctors in the State of California are afraid to learn about how to use cannabis. In the eight years since passage of the Compassionate Use Act, only two educational programs for physicians have been presented.[22],[23]

Books have been written on the details of the history of cannabis. They are filled with facts, data, mystery, descriptions of maltreatment and calls for governmental reform. More and more literature is being published annually. Scientific studies documenting the safety and efficacy of "cannabinoids" (cannabis compounds) are being published (mostly in extra-American journals) with increasing frequency. The "medical marijuana movement" has evolved from a "grass roots" endeavor to become a progressively better organized demand for social reform. In the absence of a totalitarian government, the Medical Marijuana Movement will continue to flourish because its premise is exposing the misrepresentations about cannabis in the pursuit of compassion for sick people.

THE SCIENCE OF CANNABIS AS A MEDICATION

Even the government of the United States of America has documented the safety and efficacy of cannabis compounds in the treatment of chronic pain, neurological and movement disorders, nausea and vomiting, Glaucoma, appetite stimulation/ cachexia,[24] Wasting Syndrome, spasticity, Multiple Sclerosis, Tourette's Syndrome, Epilepsy, and Alzheimer's Disease.[25] A thorough review of the Institute of Medicine Report (a partial text is included in references) and the National Institutes of Health Report (included in references) clearly identify medicinal uses for marijuana sprinkled among the disclaimers about how it would be nice to do more research.

"Since oral delta-9 *THC has some analgesic activity*, it is highly likely that smoked marijuana has some analgesic activity in some kinds of clinical pain,"[26] is a direct quote from the NIH report. That's it. There is the science in review by a group of analysts who are clearly not part of the Medical Marijuana Movement. That statement alone warrants an order to the Drug Enforcement Administration to correct the mistake of labeling cannabis "without medical benefit". But, in fact, the entire report documents repeatedly that cannabis compounds in all formulations have medicinal benefit.

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[22] "Cannabis Therapy: Science, Medicine and the Law", University of California at San Francisco, San Francisco, CA, June 10, 2000.
[23] "Perspectives on the Clinical Application of *Cannabis Sativa* and *Cannabis Indica*", University of Southern California Keck School of Medicine, Los Angeles, CA, February 13, 2004.
[24] Ad Hoc Group of Experts, NIH.GOV, "Workshop on the Medical Utility of Marijuana. Report to the Director, National Institutes of Health", February 19-20, 1997, pages 1-30.
[25] Joy, Janet E., Watson, Stanley J., Jr. Benson, John A., Jr., Editors, Marijuana and Medicine Assessing the Science Base, Institute of Medicine, National Academy Press, Washington, D.C., 2003, http:books.nap.edu/catalog/6376.html, pages 137-191.
[26] Ibid., page 19 ("Analgesia: 2. What are the major unanswered scientific questions?")

"In conclusion, the available evidence from animal and human studies indicates that cannabinoids can have a substantial analgesic effect."[27] The IOM Report clearly refutes the position of the DEA in classifying Cannabis as a Schedule I drug. At the very worst, Cannabis should be included in the Schedule II classification (known medicinal uses with high abuse potential) along with cocaine and amphetamines.

In addition to the U.S. Government funded reports, a panoply of books have been written on the medical efficacy of cannabinoids. Of the many, I use Dr. Grinspoon's, Dr. Earleywine's and Dr. Russo's the most.[28,29,30]. (Dr. Earleywine has provided a copy of his book for the Committee.) Lynn Zimmer, Ph.D. and John P. Morgan, M.D.have published an excellent evaluation of the myths about marijuana.[31] Even the most cursory perusal of these texts reveals the great depth of science behind the use of cannabinoids in medicine.

Also available to review to discover the details about pharmacology, biochemistry, clinical uses and safety/ efficacy profiles of cannabinoids are *hundreds* of published scientific articles. I ran a literature search through the library at the University of Southern California Keck School of Medicine and printed hundreds of pages of recent studies documenting many therapeutic trials documenting the effectiveness of cannabis. I have attached a few as addenda to this testimony.

One article from the German literature, describes the "endogenous cannabis receptors" in the human body.[32] That is, human nerve cells and immune cells have pockets of tissue, like keyholes to a lock, whose sole responsibility is to bind to cannabis compounds. This discovery resulted in a search for an "endogenous" key-like compound produced by the body to plug in to those little locks. The discovery of the "endocannabinoid" (cannabis-like compounds produced in the body naturally), *Anandamide* has led researchers on a further quest to develop synthetic cannabinoids for use in medicine. There are over 483 natural compounds in the cannabis plant, with more than 66 "cannabinoids" (a distinctive class of compounds found only in the cannabis plant). Many cannabinoids function like delta-9 THC (tetrahydrocannabinol) to some degree. Many do not.

Perhaps the most important reason to value the use of cannabis as a medication is because of the testimonials from American citizens who have personally witnessed relief from suffering because of the ability to use cannabis as a medication.[33] We tend to undermine

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[27] Op. cit., Joy, Janet E., page 145.
[28] Op. cit., Grinspoon.
[29] Earleywine, Mitch, Ph.D., Understanding Marijuana A New Look at the Scientific Evidence, Oxford University Press, Oxford, New York, 2002, pages 1-317.
[30] Russo, Ethan, M.D., Grotenhermen, Franjo, M.D., Editors, Cannabis and Cannabinoids Pharmacology, Toxicology, and Therapeutic Potential, The Haworth Integrative Healing Press, New York, London, Oxford, 2002, pages 1-427.
[31] Zimmer, Lynn, Ph.D., Morgan, John P., M.D., Marijuana Myths Marijuana Facts, The Lindesmith Center, New York, San Francisco, 1997, pages 1-233.
[32] Pertwee, R. G., Forsch Komplementarmed, "Cannabis and Cannabinoids: Pharmacology and Rationale for Clinical Use", 1999;6 (suppl 3):12-15.
[33] CBS News, "Recipe for Trouble", CBSNEWS.com, March 7, 2002 12:21:49, pages 1-2.

these stories as "anecdotal", suggesting that a single patient's experiences are not that critical to care about. Many prefer to pretend these patients are merely lying, or manufacturing statements so that they can "get high." As a physician with twenty-three years experience caring for the sick and suffering, I find this attitude disrespectful and un-Christian (I beg forgiveness from those who are offended by my religious orientation.) If there is just one person who is truly benefited from the use of cannabis, it should not be denied to them. It is clearly inhumane and a violation of that poor soul's "right to life, liberty and the pursuit of happiness" to be forbidden access to *any medication* that can relieve his/her torment.

CANNABIS AND ATTENTION DEFICIT DISORDER (ADD)

Attention Deficit Disorder is a neuropsychiatric disorder which affects 3-7% of American children and 3-4% of adults.[34] ADD has three subtypes: Inattentive, Hyperactive and Combined. Patients with ADD or its partner ADHD (Attention Deficit Hyperactivity Disorder) have difficulty with the executive management of their ability to attend to tasks. They frequently and inappropriately have difficulty focusing, listening attentively, completing homework and projects, organizing tasks and activities. Many are forgetful ("absentminded" in archaic terminology), impatient, fidgety, overly active, talkative, intrusional and have difficulty in engaging in quiet play.

There are multiple variations on the syndrome, but approximately 70% of people who suffer from ADD also experience other neuropsychiatric problems, including mood disorders (15-75%) especially depression, antisocial disorders (23-64%) including oppositional-defiant behavior disorder, anxiety (8-30%), and learning disabilities (6-92%.)[35] ADD/ ADHD can be an extremely debilitating problem and generates untold cost to society. Studies suggest incarcerated criminals have a disproportionate incidence of ADD/ ADHD, up to 40% in some studies.[36]

From my experience, it is the adolescents who seem to be having the greatest difficulty in coping with ADD. A teenager with difficulty focusing, listening attentively, completing homework and projects, organizing tasks and activities who is also forgetful ("absentminded"), impatient, fidgety, overly active, talkative, intrusional and has difficulty in engaging in quiet play is likely to have social and academic problems. This is particularly true if the adolescent also experienced life events resulting in him/ her having a poor self image. Adolescents with mood disorders (15-75%) especially depression, antisocial disorders (23-64%) including oppositional-defiant behavior

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[34] Brown, Thomas E., Ph.D., "Recognizing ADHD: Neurobiology, Symptoms, and Treatment, New Approaches to ADHD: Addressing Patient Needs From a Whole-life Perspective, Pragmaton Office of Medical Education supported by an unrestricted education grant from Eli Lilly and Company, 2001, page 3.
[35] Spencer, Thomas J., M.D., "ADHD in Children and Adults: Diagnosis and Comorbidity Issues", New Approaches to ADHD: Addressing Patient Needs From a Whole-life Perspective, Pragmaton Office of Medical Education supported by an unrestricted education grant from Eli Lilly and Company, 2001, page 13.
[36] McCallon, M.D., T. Dwaine, "If He Outgrew It, What Is He Doing in My Prison?", http://add.org/images2/prison.htm, March 25, 2004, pages 1-3.

disorder, anxiety (8-50%), and learning disabilities (6-92%) can be dangerous. ADD ADHD can be an extremely debilitating problem and generates untold cost to society.

Patients with ADD/ ADHD frequently need medication to be able to function normally in society. Unfortunately, amphetamines are the most commonly used drugs to treat ADD in the United States today. Amphetamines can have very undesirable side effects. They can contribute to increased seizure activity, mental illness, cachexia and malnutrition, insomnia and severe behavior disorders. Only 70% of children with ADD respond well to amphetamines, anyway. The use of amphetamines in already emotionally impaired and academically challenged adolescents is not the best idea. Yet, Americans spend more than a billion of dollars every year buying legal amphetamines for their children who have ADD.

The more amphetamines we sell in the U.S., the more amphetamines we need to manufacture. The more amphetamines we manufacture, the more amphetamines can leak into the black market. Amphetamines in the black market fund crime. And they are addictive. Amphetamine users crave more and more drug. Amphetamine abuse is a serious problem in America, and we should limit amphetamine manufacture and distribution, *especially* for use in children and adolescents.

The other legal drugs used to treat ADD are helpful in many patients, but they all have side effects in some people. Actually, the other five of the nine drugs used to treat ADD in this country haven't even been scientifically tested to find out if they are effective treatments for ADD in children.[38,39] These are drugs for depression and high blood pressure, and they all have bad side effects in some people. Yet, doctors all over America write prescriptions for depression and high blood pressure medications to treat ADD in children. Even though those drugs have not been tested scientifically, if they do help the child, it is not uncommon to use a drug "off label"[40] I support the physician's right to be able to try them.

Although not all adolescents with ADD become violent while taking amphetamines, enough are emotionally impaired to warrant having a medication available, like cannabis, whose specific side effect is to make adolescents more peaceful. We really don't need another Columbine. With the help of knowledgeable physicians, adolescents who are suffering with ADD can have access to a medication that can help them function more normally in society while at the same time helping them to be more tranquil rather than more agitated, sleepless, irritable and anorexic. Because all medicines used to treat ADD have side effects, even cannabis, it is better to use any medication only if it is truly necessary; and only under the guidance of an *experienced* physician. Of all the drugs used to treat ADD, cannabis has the least number of serious side effects.[41],[38]

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[37] Op. cit., Spencer, Thomas J., M.D., page 13.
[38] Op. cit., Brown, Thomas E., page 14.
[39] Thomson's Physician's Desk Reference, Fifty-eighth Editions, 2004, multiple pages.
[40] Thomson's Physician's Desk Reference, Fifty-eighth Editions, 2004, Page 3295 under "General Information."
[41] Physician's Desk Reference for Herbal Medicines, First Edition, Medical Economics Company, New Jersey, 1998, pages 712-714.

There are hundreds of case reports of patients who report improvement of their ADHD with Cannabis.[42] There is evidence in the laboratory to show cannabinoids are effective in treating rats with ADHD.[43] We need more research to define which routes of administration (oral seems preferable clinically), dosing, strain types to use, etc. Unfortunately, no pharmaceutical companies are motivated to spend the money on research and the United States Government has a monopoly on the available (poor quality) marijuana and research permits.

THE PROBLEM DEFINED

The problem of using Cannabis as a medication is not an issue of morality. It is immoral to deprive sick people of any medication that can help them.[44]

The real problem with allowing patients to use Cannabis as a medication is *economics*.

If Cannabis were approved for use in just the ADD/ ADHD market alone, it could significantly impact the $1 Billion a year sales[45] for traditional ADD/ ADHD pharmaceuticals. Why would anyone want to give their child an expensive pill (averages about $100 a month)[46] with unacceptable side effects if s/he could just go into the backyard, pick a few leaves off a plant and make a tea for him/ her instead? Multiply those numbers by the tens of medical diagnoses that are effectively treated by Cannabis (for example chronic pain, which is a much bigger business than the treatment of ADD; or Glaucoma, or Multiple Sclerosis, etc) and it is easy to see the pharmaceutical industry would suffer beyond calculation.

We currently have the most expensive pharmaceuticals in the world, largely because American citizens are funding the research and development of new drugs. What company would want to invest the money in R & D if the expected revenues could be diminished by a plant able to be grown in the backyard? It's a serious and real problem. Of course, some companies would adapt. For example, Eli Lilly Pharmaceuticals manufactured a Tincture of Cannabis in the 1920's.[47] Perhaps Lilly would be wise to begin R & D in Cannabinoids to try to beat the foreign markets (e.g. GW Pharmaceuticals in Great Britain.) Perhaps Lilly's $575 million profit in the fourth

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[38] See 38 above.

[42] Gardner, Fred, "Which Conditions are Californians Actually Treating With Cannabis?", O'Shaughnessy's, Journal of the California Cannabis Research Medical Group, Summer, 2003.

[43] Adriani, Walter, et.al., "The spontaneously hypertensive-rat as an animal model of ADHD: evidence for impulsive and non-impulsive subpopulations," Neuroscience and Biobehavioral Reviews, 27 (2003(pages 639-651

[44] Clark, Peter A., "The Ethics of Medical Marijuana: Government Restrictions vs. Medical Necessity", Journal of Public Health Policy, (2001?), Volume 21, Number 1, pages 40-60.

[45] Attention Deficit Disorder Help Center, "Drug Concerta, Atomoxetine, Metadate CD, Ritalin LA, Focalin; The New Meds.", http://www.add-adhd-help-center.com/newsletters/newsletter_31dec02.htm.

[46] Jensen, Claudia, M.D., Telephone survey of local pharmacies, 2004.

[47] See photograph of Tincture of Cannabis and letter from Parke-Davis dated June 19, 1968.

quarter, 2001[48] and other annual profits could be invested in less risky business (although pharmaceuticals don't appear to be too risky at this time. If Cannabis stays off the market, pharmaceuticals are more secure.)

Two other American traditions would suffer if Cannabis were reclassified as (at worst) a Schedule II drug. It is highly likely Americans who could use Cannabis more would use alcohol and tobacco less. Most Cannabis users I have interviewed are not daily alcohol or tobacco consumers; and this seems to be a consensus among the Physicians who actually manage Medical Marijuana patients. Rarely do patients use other illicit drugs, although most of them have a history of having tried other drugs in their lifetimes.

But the real economic catastrophe to be expected if Cannabis is reclassified would be to the Law Enforcement and Judicial branches of government. "According to ONDCP, the $18.822 Billion spent by the federal government on the drug war in 2002 breaks down as follows:..."

"...Domestic Law Enforcement: $9.513 Billion (50.5% of total)
Interdiction: $2.074 Billion (11.0% of total)
International: $1.098 Billion (5.8% of total)
In other words, $12.686 Billion in 2002 was directed to supply reduction, i.e. law enforcement (67.4% of total.)"[49]

"Nearly eight cents of every dollar spent by State and local governments in 1999 was for justice activities."[50] And, as long as Cannabis is classified Schedule I, the Federal Government will be forced to continue to spend money on investigating, arresting, prosecuting, incarcerating, and "rehabilitating" medical marijuana users. The marijuana smokers of America (some 4.2% of the population, and the numbers actually rose since the "War on Drugs" has begun) will continue to funnel $10.6 billion annually into the black market to buy marijuana.[51] That is, *10.6 Billion Dollars* are spent funding criminals selling marijuana in this country, and the American people are paying it.

CONCLUSION: What Should We Do?

Tell the truth. Cannabis does not fit into the category "no known medicinal use."

Enforcement procedures should be implemented to carry out Judge Young's 1988 orders to the Drug Enforcement Administration. Marijuana should actually be rescheduled as

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[48] "Prozac's slippage cuts Lilly's earnings", The Indianapolis Star, January 25, 2002, http://www.indystar.com/library/factfiles/business/companies/lilly/stories/2002_0125.html, page 1.
[49] Office of National Drug Control Policy, "National Drug Control Strategy: FY 2003 Budget Summary" (Washington, DC: Office of the President, February 2002), Table 2, page 6 as reported by Drug War Facts at http://www.drugwarfacts.org/marijuan.htm.
[50] Gifford, Sidra Lea, US Department of Justice, Bureau of Justice Statistics, Justice Expenditure and Employment in the United States, 1999 (Washington, DC: US Department of Justice, February, 2002), page 4 as reported by Drug War Facts at http://www.drugwarfacts.org/marijuan.htm.
[51] "Changing the Way Americans Think About Marijuana Talking Points", http://reform.house.gov/CJDPHR/News/DocumentSingle.aspx?DocumentID=1692 plus attachments.

Schedule III because of its safety profile, but Schedule II would be more honest than what it is now.

Research grants should be awarded to investigators with the intention of producing studies to define how to use cannabis effectively.

Systems should be developed to divert the $10.6 billion Americans spend on marijuana annually into Public Health, Law Enforcement (to guard the crops and distribution), American farmers (to grow the medicine), to Pharmaceutical Industries to promote research and development on smoke-less delivery forms, and to the tobacco giants to manage the smoked products. The American farmers employed should preferably have previous experience in the cultivation and processing of Cannabis as the "medicine" being produced at the Mississippi farm reportedly is embarrassingly low quality. All of the funds could be administered through a "Tax Stamp" system which could feasibly generate $0.50 per gram of Cannabis sold.

We as a nation should value the truth about marijuana. It is the only compassionate thing to do. When law enforcement is freed from mercilessly targeting sick people, it can focus on hard drugs, like methamphetamine and cocaine.

The truth is: Americans should never have to be afraid of the law if they need a medication to relieve pain and suffering.

Thank God in California the law protects patients from being punished for using a medication that helps them. Thank God that the Supreme Court Justices of the United States of America have their eyes open to the truth. I pray that the Committee on Government Reform will take action. Please ask them to do so.

Mr. SOUDER. Thanks, and as I said at the beginning, your full statement will be in the record as well.

Dr. JENSEN. Thank you.

Mr. SOUDER. Mr. Kampia, good to see you again.

Mr. KAMPIA. Thank you, Mr. Chairman, and thank you in particular to Congresswoman Sanchez, who has been such a strong supporter of the medical marijuana patients who are suffering in California.

I'm Rob Kampia, I'm executive director of the Marijuana Policy Project, which is the largest marijuana policy reform organization in the United States. There has been ample research that shows that marijuana is both safe and effective. It's safer than most prescription medicines, it's safer than aspirin, and it's certainly medically efficacious. Patients with MS, AIDS, cancer, chronic pain, have all benefited from marijuana, and the Institute of Medicine, of course, reviewed all that 5 years ago now for the Congress and for the drug czar.

That said, I will admit that there are insufficient studies to prove to the FDA that marijuana should be approved as a prescription medicine. There are political reasons for this. One is that the Department of Health and Human Services issued guidelines which makes it more difficult to research marijuana than to research any other drug on the planet. It's more difficult to research marijuana than ecstasy, LSD, or any newly developed pharmaceutical. So that has a chilling effect on research.

In addition, the DEA has been obstructionist again. Currently, the University of Massachusetts is trying to get DEA permission to grow privately grown, privately funded marijuana up in Massachusetts for the purpose of studying it. After 3 years of waiting, the DEA still has not given them an answer. So consequently, because there is no private source of marijuana in this country, no private sector industry is actually going to go and try to spend money, because you can't get a privately produced drug approved by the FDA if you can't get hold of the drug.

So there's a big political problem, and because of this, it could be years, if ever, before the FDA would approve marijuana as a prescription medicine.

Now, this hearing purports to be about science, and yet I find that hard to believe. This Congress in general and the chairman in particular are not exactly bound by science in their statements. To give you some examples, Chairman Souder here criticized the State medical marijuana laws today as if it's some new discovery. Yet a couple years ago he asked GAO to do a comprehensive study of what's going on in the medical marijuana States. I just read this last night again, and I say this study came down on our side. You must not have liked it, perhaps you didn't read it.

But most of the laws are working just fine, most of the patients are not abusing, the vast majority of the doctors are not abusing. In fact, GAO said that only 1 to 3 percent of the physicians were recommending medical marijuana in these States, and those who are recommending, 82 percent of these physicians made only one or two recommendations. So the vast majority are the people who are actually abiding by the program correctly, but yet in your scientific inquiry you invited Dr. Leveque, who is literally the only

physician in Oregon to have written an inordinate number of recommendations. It seems highly biased.

Two, you wonder what impact medical marijuana has on these patients, given that it hasn't gone through the FDA, but yet you didn't invite any patients to speak today. You could have invited Richard Brookheiser, senior editor of the National Review, who could have told you about his medical marijuana use. You could have invited Lyn Nofsinger from the Reagan administration, who would have told you about his daughter's use. The Federal Government is currently mailing marijuana regularly to seven patients across the country, and yet those seven patients who are currently legally using the Federal Government's marijuana, they were not invited to testify.

Yet another example is on the House floor a year ago. You said, Mr. Chairman, "It does not help sick people. There are no generally recognized health benefits to smoking marijuana." It is generally recognized. The American Nurses Association, the American Public Health Association, the American Academy of Family Physicians and dozens and dozens and dozens of other organizations recognize marijuana's medical value. This information is in the written testimony I've provided. So what you said on the House floor was false.

Also on the House floor you said that you met with officials from the Netherlands and they said, supposedly, that they rejected the use of smoked marijuana for so-called medical purposes. I don't believe you. Holland is currently allowing physicians to prescribe marijuana and patients are currently picking it up at pharmacies. It hardly seems to me that the Dutch oppose medical marijuana.

Unfortunately, this is not a scientific issue, but a political issue. Therefore, because of the obstruction of science, we are moving forward politically. We are going to keep passing State bills and State initiatives until a majority of the States cry out to the Federal Government to fix the Federal problem.

In closing, I want to quote the DEA's own administrative law judge in 1988. He said, "Marijuana in its natural form is one of the safest therapeutically active substances known. The provisions of the Controlled Substances Act permit and require the transfer of marijuana from Schedule I to Schedule II. It would be unreasonable, arbitrary and capricious for DEA to continue to stand between those sufferers and the benefits of this substance."

I agree with the DEA and, Mr. Souder, to the extent that you are not helping research go forward and to the extent that you continue to oppose our legislative efforts, your position on medical marijuana is in fact, as the DEA said, unreasonable, arbitrary and capricious. Thank you.

[The prepared statement of Mr. Kampia follows:]

Testimony of Mr. Rob Kampia
Executive Director, Marijuana Policy Project

Before the Government Reform Committee's Subcommittee on
Criminal Justice, Drug Policy, and Human Resources
April 1, 2004

Introduction

Thank you Chairman Souder, Ranking Member Cummings, and the other distinguished members of this subcommittee. My name is Rob Kampia, and I am executive director of the Marijuana Policy Project, the largest organization in the United States that is solely dedicated to ending marijuana prohibition. The Marijuana Policy Project has 15,000 dues-paying members and -- as of today -- nearly 70,000 e-mail subscribers. (MPP's e-mail list is currently growing at the rate of 1,000 new names per day.)

The Marijuana Policy Project works to minimize the harm associated with marijuana -- both the consumption of marijuana and the laws that are intended to prohibit such use. MPP believes that the greatest harm associated with marijuana is imprisonment.

The threat of imprisonment is especially dangerous and harmful when the individuals in question are seriously ill patients who use marijuana -- with the approval of their physicians -- to alleviate severe nausea, pain, muscle spasticity, and other debilitating medical conditions.

But today's hearing is not designed to debate the moral implications of throwing cancer patients in prison when their doctors have agreed that marijuana is the best therapeutic option for them. Today we are here to talk about the science of medical marijuana.

With respect to the title of this hearing, "Marijuana and Medicine: The Need for a Science-Based Approach," I would like to say upfront that the Marijuana Policy Project welcomes a "science-based approach" to this subject. In fact, we would celebrate such an approach because it would undoubtedly bring an end to the unnecessary and immoral federal attacks on doctors, patients, and caregivers who are acting legally under state law.

Unfortunately, current federal policies are not based on science; rather, they are based on myths and lies. Worse yet,

the federal government is currently blocking scientific inquiry into the therapeutic benefits of marijuana. This collusion in support of delusion is an outrage and must be stopped. State medical marijuana laws must be respected, and research into the therapeutic benefits of marijuana must be allowed to proceed expeditiously.

The medical benefits of marijuana are widely recognized.

Opponents of medical marijuana claim that marijuana has no medical benefits. The chairman of this subcommittee gave a typical demonstration of this tactic in July 2003 during a debate on the House floor. During that debate he said that marijuana "does not help sick people. ... There are no generally recognized health benefits to smoking marijuana."

The chairman, and those who agree with him, could not be more wrong.

The appropriate starting point for demonstrating the inaccuracy of the chairman's claim is a 1999 report by the National Academy of Sciences' Institute of Medicine entitled, "Marijuana and Medicine: Assessing the Science Base." This study was commissioned by the White House Office of National Drug Control Policy and directly addressed the question of smoked marijuana. It concluded in a section entitled "Use of Smoked Marijuana": "It will likely be many years before a safe and effective cannabinoid delivery system, such as an inhaler, is available for patients. In the meantime, there are patients with debilitating symptoms for whom ***smoked*** marijuana might provide relief." (Please see two attachments.) The Principal Investigator of this study added at the news conference at which the report was released, "[W]e concluded that there are some limited circumstances in which we recommend ***smoking*** marijuana for medical uses." It is unfortunate that the authors of this study are not here to testify today.

The recognition of marijuana's medical benefits goes well beyond the Institute of Medicine. For those familiar with the scheduling of controlled substances, marijuana is a Schedule I drug, which is defined as having "no currently accepted medical use," while Schedule II drugs are defined as having a "currently accepted medical use." Therefore, anyone who suggests that marijuana should not be a Schedule I drug believes that it has generally recognized health benefits. With this in mind, let's review what some medical professionals say about marijuana.

An editorial in the New England Journal of Medicine -- while calling the federal war on medical marijuana patients "misguided, heavy-handed, and inhumane" -- suggested that the government "should change marijuana's status from that of a Schedule I drug to a Schedule II drug and regulate it accordingly." (Attached.)

In June 2003, the 2.6 million-member American Nurses Association passed a resolution supporting the rescheduling of marijuana out of Schedule I. (Attached.)

The American Public Health Association, the oldest and largest organization of health professionals in the world, "overwhelmingly" adopted a resolution (attached) concluding, "marijuana was wrongfully placed in Schedule I." In this resolution, the APHA noted that marijuana has been reported to be effective in (1) reducing the intraocular pressure caused by glaucoma, (2) reducing the nausea and vomiting associated with chemotherapy, (3) stimulating the appetite of patients living with AIDS and suffering from wasting syndrome, (4) controlling the spasticity that is associated with spinal cord injuries and multiple sclerosis, (5) decreasing the suffering from chronic pain, and (6) controlling seizures associated with seizure disorders.

Even non-political government officials have supported the rescheduling of marijuana. In 1988, the DEA's chief administrative law judge, Francis L. Young, ruled: "Marijuana, in its natural form, is one of the safest therapeutically active substances known ... [T]he provisions of the [Controlled Substances] Act permit and require the transfer of marijuana from Schedule I to Schedule II. It would be unreasonable, arbitrary and capricious for DEA to continue to stand between those sufferers and the benefits of this substance." (See attached excerpts with link to full document.)

The Marijuana Policy Project has compiled a list of more than 100 organizations with favorable positions on medical marijuana. (Attached.)

The federal government is blocking research on marijuana.

It is disturbing that some members of Congress are unwilling to acknowledge the overwhelming evidence that marijuana has recognized medical uses. But it is even more offensive that these members of Congress sit idly as the executive branch of the federal government blocks research into the therapeutic

benefits of marijuana. If this subcommittee is truly interested in a science-based approach to marijuana's therapeutic uses, it should use its authority and influence to help remove the barriers to this research.

Here are some examples of how the federal government has impeded research on the therapeutic benefits of marijuana:

In December 1999, the U.S. Department of Health and Human Services (HHS) established guidelines that researchers must follow if they wish to study the therapeutic benefits of marijuana. These guidelines place a much greater burden on medical marijuana researchers than on drug companies that develop and study newly synthesized pharmaceuticals. For example, HHS's guidelines require marijuana research protocols to undergo a review by an ad hoc, marijuana-specific panel within HHS, which is in addition to FDA approval of the protocols. This is an unnecessary and cumbersome hurdle that pharmaceutical companies do not face. Medical marijuana researchers should not receive special treatment, but they should receive equal and fair treatment. In November 1999, more than 30 U.S. representatives sent a letter to HHS Secretary Donna Shalala, urging her to promulgate guidelines that would simply treat marijuana research like research on any other drug. (Attached.)

Second, the National Institute on Drug Abuse currently has a monopoly on the cultivation of marijuana for research in the United States. Unfortunately, NIDA's marijuana is only available for research, not for prescriptive use. Therefore, how could a pharmaceutical company be expected to invest millions of dollars in researching a product that it could not eventually sell on the market? Can you imagine any private firm conducting research under these conditions? Moreover, there have been many complaints about the quality of NIDA's marijuana. Five U.S. representatives sent a letter to the DEA (attached) in support of an alternative source of research-grade marijuana, expressing concerns such as those described in this paragraph.

Finally, the Drug Enforcement Administration has played its own important role in blocking medical marijuana research. For nearly three years, the DEA has delayed action on an application from the University of Massachusetts for a license to cultivate marijuana for federally approved research. (A summary of the initial efforts to receive this license -- and the application itself -- are attached.) In fact, the comment period on this application closed more than six months ago. Yet the DEA still

has not approved or rejected this application. The proposed production facility is needed because -- as described above -- NIDA's monopoly is preventing effective research from moving forward. Significantly, the regulations governing this application process direct the DEA to provide for "adequate competition" in the production of Schedule I and II drugs. Massachusetts Senators John Kerry and Edward Kennedy wrote a letter to the DEA (attached) in October 2003 underscoring this point and urging the agency to approve the application.

As a final point, it should be noted that the DEA -- according to federal regulations -- should only be concerned with the possible diversion of marijuana by the University of Massachusetts. So far, there is no indication that such a concern exists. Instead, a letter from the DEA to the University (attached) indicated that the DEA's primary objection to the University's application was that NIDA's supply of marijuana was sufficient. This subcommittee should inform the DEA that this should not be a consideration in its decision on the University of Amherst's application.

Opposition to medical marijuana is based on lies and myths.

As noted, there is almost no way that a science-based approach can lead to the conclusion that marijuana -- even smoked marijuana -- is not medicine. The opposition to medical marijuana isn't based on science, but rather lies and myths that are refutable by indisputable facts.

The lead mythmakers with respect to medical marijuana are the officials at ONDCP. Here are a couple of good examples, both taken from a column by ONDCP Deputy Director Andrea Barthwell, published in the Chicago Tribune on February 17, 2004. (Text attached.)

The first is related to Marinol, the prescription drug that contains a synthetic version of one of the active ingredients in marijuana -- THC. Barthwell wrote that "marijuana advocates refuse to acknowledge Marinol as a viable option. Interestingly enough, the only property that Marinol lacks is the ability to create a 'high'."

Barthwell's assertions about Marinol are false. First, Marinol most certainly produces a high. This is stated clearly in the Physician's Desk Reference (attached). In the list of adverse reactions on page 3326, the very first entry is "a cannabinoid dose-related 'high'." This high is enough of a

concern that the PDR warns, "Patients receiving treatment with Marinol should be specifically warned not to drive, operate machinery or engage in any hazardous activity until it is established that they are able to tolerate the drug and perform such tasks safely."

And, to contradict another of Barthwell's claims, natural marijuana has at least two properties that Marinol lacks: Rapid onset of action, and superior control over dosage. As noted in the article, "Therapeutic Potential of Cannabis," in the May 2003 issue of The Lancet Neurology, "Oral administration is probably the least satisfactory route for cannabis." The journal noted that the oral route "makes dose titration more difficult and therefore increases the potential for adverse psychoactive effects." Barthwell got the science exactly backwards.

The second myth Barthwell propounded in her op-ed is the claim that allowing seriously ill patients to use medical marijuana somehow increases teenage marijuana use. In fact, research has shown otherwise. In California, marijuana use by teens was rising until the 1996 passage of Proposition 215, the medical marijuana law. After that law took effect, teen marijuana use in California dropped dramatically over the next six years -- as much as 40% in some age groups -- as you can see in the attached graph, taken from the official California Student Survey. A special analysis commissioned by the California state government found absolutely no evidence that Prop. 215 had increased teen marijuana use.

Both of Barthwell's myths were refuted in a recent op-ed in the Providence Journal by former U.S. Surgeon General Joycelyn Elders. (Attached.) She also addressed some other common myths, such as "Marijuana is too dangerous to be medicine. It's bad for the immune system, endangering AIDS and cancer patients," and "Smoke is not medicine. No real medicine is smoked." With respect to the latter myth, Dr. Elders offered the following:

"The truth: Marijuana does not need to be smoked. Some patients prefer to eat it, while those who need the fast action and dose control provided by inhalation can avoid the hazards of smoke through simple devices called vaporizers. For many who need only a small amount -- like cancer patients simply trying to get through a few months of chemotherapy -- the risks of smoking are minor."

Regarding the claim that marijuana is too dangerous to be a

medicine, it is interesting to note that there has never been a death attributed to an overdose of marijuana. Clearly, most prescription drugs are far more dangerous than marijuana. Even over-the-counter drugs like aspirin and Tylenol cause numerous overdose deaths each year. (See attachment.)

Since we are accustomed to responding to misconceptions about medical marijuana, the Marijuana Policy Project has prepared factual responses to 33 common challenges to marijuana's therapeutic uses. These responses can be found in the attached document, "Effective Arguments for Medical Marijuana Advocates." Anyone opposed to the medical use of marijuana should read this document before arguing publicly against its use in the future.

This hearing is a witch hunt, not a quest for knowledge.

The goal of this subcommittee, under its current leadership, is not to adopt a true scientific approach to the subject of marijuana. If that were the case, the authors of the Institute of Medicine report and physicians and patients from the eight medical marijuana states would have been invited. Or a representative from the American Nurses Association. Or a representative from the American Public Health Association.

No, the clear goal of the current chairman is to expend federal funds in a fruitless quest to find evidence that supports his own baseless belief. For example, the panel I'm speaking on is composed of representatives from two state boards that are currently investigating possible wrongdoing under state medical marijuana laws, even though no wrongdoing has been established. The chairman also invited two physicians whose activities have come into question, while ignoring the thousands of physicians who have recommended marijuana to their patients under state law without controversy. Finally, the chairman invited Mr. DuPont, whose value as a witness seems to be that he is one of the leading medical marijuana mythmakers.

But this is not the first time Chairman Souder has expended government funds to "expose" medical marijuana. In June 2001, Chairman Souder requested, on behalf of the subcommittee, that the General Accounting Office investigate state medical marijuana programs. At taxpayer expense, the GAO traveled to Alaska, California, Hawaii, and Oregon to carry out this request.

When this lengthy report was completed in November 2002, it contained few, if any, controversial findings. The researchers

commented generally on the small number of patients who are registered, and the paucity of doctors who are recommending marijuana as a treatment option. Even the law-enforcement officials interviewed for the report seemed to be unfazed by state medical marijuana laws.

Most of the 37 selected law enforcement organizations interviewed in the report "indicated that medical marijuana laws had had little impact on their law enforcement activities for a variety of reasons." Nearly two-thirds of these law enforcement officials did not believe that "the introduction of medical marijuana laws have, or could make it, more difficult to pursue or prosecute some marijuana cases." And nearly three-quarters of these officials denied that "there has been a general softening in public attitude toward marijuana or public perception that marijuana is no longer illegal."

Conclusion

In sum, the Marijuana Policy Project strongly supports a science-based approach to medical marijuana. We hope that Chairman Souder eventually abandons his reliance on myths and lies, stops the federal witch hunt for medical marijuana patients and doctors, and embraces an approach that is based on science.

CAPITAL GUYS

In Washington, DC, the Marijuana Policy Project is helping to pave the way for sensible marijuana laws.

by Dan Skye

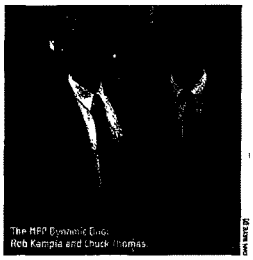
WASHINGTON—They were both star students at Penn State University. Rob Kampia majored in engineering science. Chuck Thomas majored in psychology and graduated summa cum laude.

But before his senior year, Kampia was busted for growing marijuana for personal use and served 90 days in jail, an event that dramatically changed the direction of his life. Though he eventually finished his degree and was even elected student-body president—after getting kicked out of school for a year—his time in jail eroded his interest in engineering. His focus shifted to changing the laws against pot.

Meanwhile, Thomas performed independent study in criminology, and discovered that virtually all experts in the field agreed that the stepped-up war on marijuana under Presidents Ronald Reagan and George H.W. Bush was causing severe social damage. Thomas admits to being a vocal individual—one who speaks his mind freely—and soon he found himself acting as a virtual campus clearinghouse for the legal scoop on marijuana.

But he also witnessed the insidious campaign waged on those unlucky enough to get busted for pot—those forced to "narc out" friends in order to escape harsh prison sentences. Thomas saw one such arrestee get caught in the bind and commit suicide. Events like these caused him to abandon plans for a career in psychology and pursue a path of marijuana-policy reform.

Since their college days, both Kampia and Thomas have worked exclusively to change marijuana policy. They are now in their early thirties and run the Marijuana Policy Project, which they



The MPP Dynamic Duo: Rob Kampia and Chuck Thomas.

CHRIS WOLFE (2)

"The harmful effects of marijuana prohibition far outweigh any harm that marijuana could do."

founded in '95, out of the nation's capital. MPP works out of a snug suite of offices just a short walk from Capitol Hill and its streamlined, but ever-growing budget (provided by private donors and foundations) has been maximized to the point where it has become the largest member-based marijuana-policy organization.

Whereas NORML deals with individual pot-smokers' rights, offering legal assistance and advice on passing drug tests, Thomas and Kampia say, MPP's aim is to get directly involved with state lawmakers to craft legislation that can actually survive the harrowing journeys through legislatures. Hawaii's success in creating a workable medical-marijuana policy owes much to MPP's work over a four-year period, in which they provided marijuana literature to the media and kept lawmakers consistently informed. Kampia and Thomas claim that Maryland, Minnesota and Massachusetts have made promising overtures toward a saner marijuana policy as well.

Kampia says that MPP's overriding aim is to make clear just how damaging the Drug War has become. "The harmful effects of marijuana prohibition far outweigh any harm that marijuana could do. The wasted tax dollars, the time that police could use more fruitfully, the pain of prison to families—this is what people can understand if it's presented correctly."

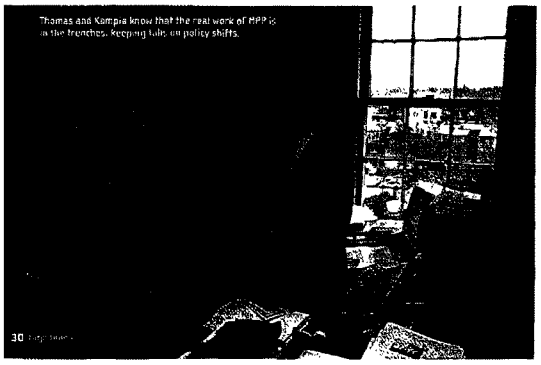
MPP relentlessly flogs the media, always ensuring that the best research on cannabis be presented to counter the propaganda of the government. "We show up," says Thomas. "We want our viewpoint heard." And, it's one that can be generally agreed on by any thinking person: Patients who are told by their doctors to use marijuana shouldn't be arrested or prosecuted.

The hardworking duo can point to a number of high points as far as scoring with the media. One of their outstanding moments came when the Institute of Medicine released its report on marijuana in March of 1999. The study, which was commissioned by the White House Office of National Drug Control Policy, was excerpted by MPP and highlighted the many favorable insights the report made, considerably dampening the impact former Drug Czar Barry McCaffrey expected to make. In fact, the *New York Times*, the *Washington Post* and *USA Today* all led stories on the report with Thomas' quotes, not McCaffrey's.

But Kampia and Thomas know that their real work is on the phone, on the internet, in the trenches, keeping tabs on policy shifts in state and federal governments, and maintaining clear communication lines with the principals involved where marijuana bills gain momentum. MPP has also just released a comprehensive state-by-state report on medical-marijuana laws, with all the information activists need for getting the ball rolling in their state.

As for the federal laws regarding medical cannabis that supersede state law, Thomas is optimistic: "During the campaign, Bush indicated that he thought medical marijuana should be treated as a states' rights issue. We will we be hard at work over the next couple of years to make sure his administration follows through."

To join MPP or to obtain a copy of the state-by-state medical-marijuana report, check out: MPP.org



Thomas and Kampia know that the real work of MPP is in the trenches, keeping tabs on policy shifts.

Information

IN THE COURT OF COMMON PLEAS OF CENTRE COUNTY

Criminal Division

COMMONWEALTH OF PENNSYLVANIA

vs.

ROBERT KAMPIA

Defendant

Criminal Action, 19 89 — 334

THE DISTRICT ATTORNEY of Centre County by this information charges that on or about the twentieth day of April 19 89 ROBERT KAMPIA

the Defendant(s) above named, in the County of Centre, did

Count 1. possess a small amount of Marijuana, a Schedule I non-narcotic controlled substance only for personal use; possess a small amount with the intent to distribute it but not to sell it; or distribute a small amount but not for sale, the said Robert Kampia not then or there being registered under this act, or a practitioner not registered or licensed by the appropriate State board, in violation of the Controlled Substance, Drug, Device and Cosmetic Act, all of which is against the Act of Assembly and the peace and dignity of the Commonwealth of Pennsylvania

Count 2. ROBERT KAMPIA, on or about April 20, 1989, at the aforesaid location, did possess with intent to deliver Marijuana, a Schedule I non-narcotic controlled substance, the said Robert Kampia not then or there being registered under this act, or a practitioner not registered or licensed by the appropriate State board, in violation of the Controlled Substance, Drug, Device and Cosmetic Act, all of which is against the Act of Assembly and the peace and dignity of the Commonwealth of Pennsylvania.

Count 3. ROBERT KAMPIA, on or about April 20, 1989, at the aforesaid location, did knowingly or intentionally possess Marijuana, a Schedule I non-narcotic controlled substance, the said Robert Kampia not then or there being registered under this act, or a practitioner not registered or licensed by the appropriate State board, in violation of the Controlled Substance, Drug, Device and Cosmetic Act,

FILED FOR RECORD
MAY 26 3 43 PM '89
DANIEL LUHKEL
PROTHONOTARY
CENTRE COUNTY, PA

all of which is against the Act of Assembly and the peace and dignity of the Commonwealth of Pennsylvania.

35 PS 780-113 31, 38 & 16

Citation of Statute and Section

Attorney for Commonwealth

Kuffman

IN THE COURT OF COMMON PLEAS OF CENTRE COUNTY, PENNSYLVANIA
CRIMINAL DIVISION

COMMONWEALTH	:	No. 1989-536
VS	:	
ROBERT D. KAMPIA	:	Count 6, Criminal Conspiracy

ORDER

AND NOW, November 6, 1989, the sentence of this Court is that you, ROBERT D. KAMPIA:

1. Pay the costs of prosecution.

2. Pay for the use of the County of Centre the sum of Two Hundred Dollars ($200).

3. Pay all fines and costs in accordance with a contract in which a payment schedule will be established by the Centre County Probation Department, subject to the approval of this Court.

4. Undergo imprisonment in the Centre County Prison for a period not less than four (4) months nor more than twelve (12) months. Credit shall be given for any time previously served on this charge.

Said sentence to run concurrently with that sentence imposed to Count 2 of No. 1989-536 by the Court of Common Pleas of Centre County, Pennsylvania

In the event of a county transfer of supervision, the Probation Office of the receiving county is granted the authority to impose any special conditions deemed appropriate.

BY THE COURT:

Judge

ALL ENTRIES ON THIS FORM MUST BE TYPEWRITTEN

DOCKET TRANSCRIPT COMMONWEALTH OF PENNSYLVANIA

120329-89 | 89-536 | OTN C 328065-3

Cliff York | Robert T. May | 49 3 02

KAMPIA, ROBERT DAVID
454 Moyers Road
Henleyville, PA 19438

4 21 89 | 120329-89

Inv. Wagner, State College Police

4 49 M W | PA 0140300 | 68905231 | 628

4 21 89 | 4 21 89 | 4 21 89 | 4 21 89 11:50AM

5 5 89 Central Court, Courtroom #1, Courthouse, Bellefonte, PA

A	Possess marijuana w/intent to distribute	4 20 89	CS 13a31	M.D/CT	A	26 89	7
B	Possess w/intent/deliver marijuana	4 20 89	CS 13a30	M.D/CT	B	3 89	
C	Possession of marijuana	4 20 89	CS 13a16	MLD/CT			
D	Possess drug paraphernalia	4 20 89	CS 13a32	MLD/CT			
E							
F							

Craig Anderson | B-328064-2

C Roger Bird Bellefonte, Pa.
~~C Inv. Schreffler~~
C Inv. Wagner
C Cliff York

ATTORNEY'S NAME AND ADDRESS FOR

Commonwealth: Eileen Tucker Esquire | 41321

Defendant: Rose Kauffman Esquire | 50692

5 $10,000.00 4 21 89 | CASH NO 108 | 4 21 89

4 21 89 C Centre County Prison, Bellefonte, PA

Certified this 3 day of May, 1989

5 3 89

I, THE ABOVE NAMED ISSUING AUTHORITY CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND CORRECT TRANSCRIPT OF THE DOCKET

CLERK OF COURTS

ALL ENTRIES ON THIS FORM MUST BE TYPEWRITTEN

DOCKET - TRANSCRIPT COMMONWEALTH OF PENNSYLVANIA

387626-89

OTN C328339-4 (2-2)

Cliff Yorks — District No. 49 2 01

Clifford R. Yorks — District No. 49 2 01

5 3 89 — 387626-89

Kampis, Robert David

Inv. Wagner, SCPD
118 S. Fraser St, State College, PA

1 4 69 — M — W — PA0140300 — 489-03231 — 628

4 4 89 — 4 26 89 — 4 26 89 — 5 4 89 — 5 4 89 — 8:00AM

5 4 89 Central Court Centre County Courthouse Bellefonte, Pa.

		Description of Charges						
1	C	Criminal Conspiracy (Poss. w/ Int. to Del.)	C	F1	4 19 89	C513430	HLD/CT	4 26 89 J
2								5 4 89
3								
4								
5								
6								

Defendant(s) Name	OTN	Co-Defendant(s) Name	OTN
Anderson, Craig	C328338-3		
Costanzo, Joseph	C328337-7		

	Witnesses Names and Addresses and Names and Addresses of Persons (not more than 4) Defendant wishes to be notified for trial.	Sworn	Testified	Witness Wishing to be Notified
C	Inv. Wagner	X	X	

Attorney's Name and Address for:

Commonwealth	Eileen Tucker Esquire	43321
Complainant		
Defendant	Rose Kauffman Esquire	50692

Date of Decision — Amount — Judgment of Sentence

Name and Address of Corporate Surety and Agent or Individual Surety - Preliminary Arraignment

Bail at Preliminary Arraignment: $10,000 — 4 21 89 — Cash — 4 21 89

Name and Address of Corporate Surety and Agent or Individual Surety - Preliminary Hearing

Bail at Preliminary Hearing

Certified this 4 day of May, 19 89

5 4 89

I, the above-named issuing authority, certify that this transcript is a true and correct transcript of the docket.

ALL ENTRIES ON THIS FORM MUST BE TYPEWRITTEN

DOCKET TRANSCRIPT COMMONWEALTH OF PENNSYLVANIA

388053-89 | 89-536 | OTN C 328372-2

Cliff Yorke 49 2 01 | Clifford R. Yorke 49 2 01

3 3 89 | 388053-89

Kempis, Robert
454 Moyers Rd.
Marlayeville, PA 19438

Inv. Wagner, SCPD
118 S. Fraser St., State College, PA

1 2 69 | M | W | PA0140300 | 689-05231 | 628

3 8 89 | 5 2 89 | 5 4 89 | 5 4 89 | 8:00AM

5 8 89 | Central Court Centre County Courthouse Bellefonte, Pa.

A	Possession of Controlled Substance	M2	4 20 89	CS13a16	HLD/CT	4 26 89	J	
B						5 4 89		
C								
D								
E								
F								

Inv. Wagner

Eileen Tucker Esquire 43373

Rose Kauffman Esquire 50692

5 10,000 | 7 21 89 | Cash | 4 27 89

Certified this 4 day of May, 19 89

5 4 89

I, THE ABOVE NAMED SEALED AUTHORITY CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND CORRECT TRANSCRIPT OF THE DOCKET

CLERK OF COURTS

Mr. SOUDER. I appreciate that you are at least consistently wrong.

Dr. DuPont.

Dr. DUPONT. Mr. Chairman, it's a privilege and a pleasure to be here. I am delighted to be able to submit my written testimony and an article I've written on this topic for a more detailed analysis. I'm going to summarize just a couple of points here.

My background in this field goes back a long way. I was the first Director of the National Institute on Drug Abuse [NIDA] and was the Director from 1973, when the agency was started, until 1978. I was also the White House drug czar, head of Special Action Office for Drug Abuse Prevention [SAODAP], under Presidents Nixon and Ford. I served as head of NIDA also under President Carter. I had a period of time when I was appointed by Mr. Nixon where he said the one thing I couldn't come out and talk about was decriminalization of marijuana, since I was experiencing heroin in those days, so that was not a problem.

I had a flirtation with the decriminalization idea from 1975 to 1978, and found myself in an interesting situation under President Carter when I changed my mind and no longer supported decriminalization. President Carter did support it. So with two Presidents I was restricted in the expression of my views about marijuana.

I bring this up to make the point that I have been around this issue, including many points of view on it. I also want to point out that I enjoy a friendly relationship personally with many of the people on the opposite side of this argument. That's very important to me, because I think it's important to respect the ideas that are presented and the people who are presenting them, to discuss issues with civility and respect and to contend vigorously in the marketplace of ideas. I'm delighted to have this opportunity here.

The medical use of marijuana essentially died in the 19th century. As modern pharmacology developed, it was left for dead. It was resurrected only in the 1970's, as a stocking horse for the decriminalization and legalization of marijuana. It had a brief flurry of activity then that led to the publication of the book in 1976 called *The Therapeutic Potential of Marijuana,* edited by two of my friends, Sidney Cohen and Richard Stillman.

I want to read one quote from this book. I was the head of NIDA that commissioned this book. This was in 1976 that this was written, and here is one of the quotes from the book. "Cannabis itself will never be adopted for medical indication. It contains dozens of constituents, some of which have undesirable effects. Delta–9-tetrahydrocannabinol is a possible candidate, but it is more likely that a synthetic analog, tailored to intensify the desired action and to avoid the undesired ones, will be preferred."

We haven't gone a long way since then in terms of our understanding of this issue. And I point out that this was published, the meeting on medical marijuana was 1975, but it was published in 1976. Now, marijuana has changed dramatically over that period of time. It is much more potent now, and is used much more intensely by much younger people than it was. In those days, it was primarily used by people in their 20's and late teens. That is not the case now. It is used very early by very young people and often quiet intensely.

Marijuana and the constituents in it are better understood from a biological point of view than any other chemical in the world. It has had more research done on it. You heard Dr. Volkow, I'm very proud that she is the fifth head of NIDA and she is doing a wonderful job. I support everything that she said today. Marijuana has been very well studied. It may be that some of these chemicals will produce medicinal benefits, and I think she was eloquent in speaking about that.

It is not conceivable that we're going to have smoking as a drug delivery system, or use many chemicals like this in an uncontrolled situation. That is not medicine. It has not been medicine for more than 100 years. It's not going to be medicine in the future. Smoking is a toxic delivery system by definition. It is not scientific.

I was delighted to hear the FDA representative, Dr. Meyer, talk about the FDA approval procedure and the fact that there is a procedure even for a botanical. A marijuana chemical would have to meet the standards of safety and efficacy to be approved. Smoked marijuana has not met those, and in my opinion, it is not likely to meet those standards in the future.

The idea of medical marijuana is not a harmless idea. It is a dangerous idea in terms of the public attention, because it legitimizes the use of marijuana. During the period when this idea had ascendancy, there was an increase in marijuana use in this country that I think is directly traceable to this issue, in fact. I think that now, in the last 2 years, we have had a downturn, and I'm delighted to think about that. I think part of it has to do with confronting this issue in a much more direct fashion than has happened before, and I am delighted to see these developments and proud to be here today.

Thank you very much.

[The prepared statement of Dr. DuPont follows:]

Draft March 29, 2004

Statement of Robert L. DuPont, M.D., President
Institute for Behavior and Health, Inc.
Rockville, Maryland

To the Government Reform Committee's Subcommittee on Criminal Justice, Drug Policy, and Human Resources
Related to Hearing on April 1, 2004
"Marijuana and Medicine: The Need for a Science-Based Approach"

Thank you for this opportunity to address the Committee on the important issue of "marijuana as medicine."

I am a psychiatrist, a physician and a public servant who has worked to reduce substance abuse for over thirty years. I received an M.D. from the Harvard Medical School in Boston, Massachusetts, and completed my psychiatric training at Harvard and the National Institutes of Health in Bethesda, Maryland.

My first testimony before a Congressional Committee took place thirty five years ago, in 1969, as part of the creation of the District of Columbia's Narcotics Treatment Administration under Mayor Walter E. Washington. Four years later, in 1973, President Richard M. Nixon appointed me to lead the nation's anti-drug efforts as America's second "White House Drug Czar." In that post, I served under Presidents Nixon and Ford. During this time, I also became the first director of the National Institute on Drug Abuse (NIDA) serving under Presidents Nixon and Ford as well as President Carter.

Following my government work, I founded the Institute for Behavior and Health, Inc., (IBH). In addition to my duties as President of this non-profit research and public policy organization, I maintain an active practice of psychiatry specializing in addiction and the anxiety disorders, and have been Clinical Professor of Psychiatry at the Georgetown University School of Medicine since 1980.

I am vice president of Bensinger, DuPont and Associates (BDA), a national consulting firm dealing with workplace substance abuse and with prescription drug abuse. BDA was founded in 1982 under the leadership of Peter Bensinger, who headed the Drug Enforcement Administration (DEA) at the same time that I headed NIDA.

My efforts to promote public understanding of drug abuse have included more than two hundred and fifty professional articles and eighteen books and monographs on a variety of health-related subjects. My books include *Getting Tough on Gateway Drugs: A Guide for the Family* [1], *A Bridge to Recovery: An*

Introduction to Twelve-Step Programs (written with John F. McGovern, M.D.)[3] and *The Selfish Brain: Learning from Addiction, with a Forward by Betty Ford*[3].

I am here today, speaking as President of IBH, to warn you about the danger of accepting smoked marijuana as medicine. The concept of "medical marijuana" is ironic because smoked marijuana is the cause of many serious health problems, and it is the solution to none.

I will not review here the adverse health effects of smoked marijuana since they have been carefully and comprehensively catalogued in a variety of publications from the National Institute on Drug Abuse and other sources over many years.

In summary, marijuana is the nation's most widely used illegal drug. Reducing the use of marijuana has been a central feature of the nation's drug abuse prevention efforts for more than half a century, a goal that has been endorsed by virtually all of the health experts serving in official roles over that time and supported by the leaders in both major political parties and by the large majority of elected officials over that extended period of time.

During the past half century, what public policy debate there has been over marijuana use—and this debate has sometimes been heated and highly visible—has centered on the best strategies to achieve the goal of reducing marijuana use. There has been no debate about the central public health goal of reducing the use of marijuana in the country. There is no serious support for tolerating the current high levels of marijuana use in the United States let alone support for encouraging wider use of this dangerous illegal drug.

Americans Deserve Safe Medicines

Why, given the abundance of evidence of smoked marijuana's harmful effects, is the misconception of "medical marijuana" so hard to overcome?

Some of the answers lie in the perception of marijuana as a folk medicine, one of the few offerings that were available to pre-scientific health practitioners. While it did have applications in Asian medicine at one time [4,5], by the 19th century marijuana was virtually forgotten for health-related purposes.

The idea that smoked marijuana could have medicinal benefit has in recent years been given new life by marijuana advocates despite clear and compelling evidence to the contrary. There are important differences between modern scientific medicine and folk remedies (see Table 1).

It is reasonable for modern scientific medicine to take advantage of the experience with folk medicines to provide useful clues to prompt further systematic investigations. During the past 100 years folk medicines have often been a useful starting point for scientific study. In every case this process has

led to more specific, and almost always synthetic, substances which were administered as single chemicals by the oral route of administration.

If any chemical in marijuana smoke were shown to be safe and effective as a treatment for any specific illness, it could be approved through the same procedures as any other medicine. If that happened I would be happy to support that use of the chemical, whether or not it was found in marijuana smoke, based on clear evidence that it was safe and effective in the treatment of one or more specific illnesses.

In 1975, under my leadership, NIDA sponsored a meeting of distinguished medical researchers to report on the therapeutic potential of marijuana. The proceedings were published in a 1976 book, *The Therapeutic Potential of Marihuana* [6], edited by Sidney S. Cohen and Richard C. Stillman, two scientists who could not be described as anti-marijuana. Their wise perspective is reflected in this passage from their Foreword:

> "It should not be expected, nor is it anticipated that some cannabinoid will be available commercially in the near future. The nature of the approval process is such that years elapse between initial testing, however promising, and final approval for marketing. This is particularly true for a completely new chemical entity, and even more so for one with a checkered reputation. Cannabis, itself, will never be adopted for medical indications. It contains dozens of constituents, some of which have undesirable effects. Delta-9-tetrahydrocannabinol is a possible candidate, but it is more likely that a synthetic analog, tailored to intensify the desired action and to avoid the undesired ones, will be preferred." [6]

Cohen and Stillman were remarkably accurate in their prediction that medical science would be able to synthesize any chemicals in marijuana which showed medical promise. Synthetic THC, by the name of Marinol, is now available by prescription. On the market since 1985, it has not been widely used because patients and physicians generally eschew it in favor of alternative medicines with more reliability and efficacy and with fewer side effects.

These earlier findings about the therapeutic potentials of marijuana were comprehensively endorsed by the 1999 study of the Institute of Medicine, *Marijuana and Medicine – Assessing the Science Base* [7].

With respect to the central question of the health effects of smoked marijuana as a potential medicine here is what that IOM report said,

> "In summary, there are many reasons to worry that for people who might choose to use marijuana as medicine—and especially those who smoke it—the drug could actually

> add to their health problems. Proof that habitual marijuana smoking does or does not lead to respiratory cancer awaits the results of extensive, carefully designed epidemiological studies. In the meantime it appears that, for people with chronic medical disorders or those with compromised respiratory or immune systems, smoking marijuana is likely to do more harm than good. Likewise, for people at risk of cardiovascular disease, pregnant women, and couples trying to conceive, the potential risks of either THC or smoked marijuana appear to exceed the potential medical benefits." [8]

While I have no quarrel with the first 5 of the recommendations of the IOM report about medical marijuana I note with deep concern that the IOM committee did not address the question of whether the many recommended studies of the potential therapeutic benefits of the individual chemicals in marijuana smoke was the best use of the scare public funds available for medical research. I doubt that privately-funded commercial research will have much interest in these chemicals compared to the thousands of more attractive alternative chemicals that they might invest in, but that is a matter for the market to arbitrate. With respect to the allocation of public funds, however, there is an important question about the assessment of the best interest of the public health when it comes to the allocation of research resources. The question of the best allocation of research dollars is best answered, after thorough consideration of the most promising ways to help the sick and the suffering, by the National Institutes of Health (NIH) and not in a political forum.

The medical marijuana advocates complain that drug abuse prevention professionals, like me, are inhibiting research on medical marijuana. The exact opposite is the case: it is virtually only the political smoke they blow up that leads to any funding in this area since the scientific interest, outside this political pro-marijuana controversy, is close to zero.

There is, however, a substantial difference between my views and those of the IOM committee with respect to their sixth and final recommendation:

> "Short-term use of smoked marijuana (less than six months) for patients with debilitating symptoms (such as intractable pain or vomiting) must meet the following conditions:
>
> - Failure of all approved medications to provide relief has been documented,
> - The symptoms can reasonably be expected to be relieved by rapid-onset cannabinoid drugs,
> - Such treatment is administered under medical supervision in a manner that allows for assessment of treatment effectiveness, and

- Involves an oversight strategy comparable to an institutional review board process that could provide guidance within 24 hours of a submission by a physician to provide marijuana to a patient for a specified use." [8]

I do not believe that even this limited use of smoked marijuana until further research is conducted is in the public interest. There are more effective, safer and better-tolerated medicines now available for all of the illnesses for which the marijuana advocates propose using smoked marijuana.

However, I would not object to the temporary, limited approval proposed by the IOM committee since it would be used by few people, especially if known drug abusers were screened out as they generally are from the outpatient use of controlled substances to treat other illnesses. What the IOM's committee proposed in their sixth recommendation was a compromise within the committee. It is a political compromise that may diffuse the political controversy now raging over "medical marijuana."

It is interesting to me that the "medical marijuana" advocates are loudly and consistently opposed to using purified chemicals instead of smoked marijuana. They are also loudly and consistently opposed to any delivery system except smoking, despite the known toxicity of smoking. They pose as concerned about patient welfare. They want to be seen a compassionate. How can it be explained that the only form of this "medicine" they support is smoked marijuana even though everyone who has studied this issue has concluded, as the IOM committee did, that smoking is inherently an unreliable and toxic route of administration for any medicine?

I can think of only one explanation: they are not interested in medicine at all. They are using the "medical marijuana" issue as a Trojan Horse to legitimize the use of marijuana in this country, and throughout the world. Since the widely-shared public health goal is to reduce marijuana (and other drug) use it should not be surprising that many people, including myself, object to labeling smoked marijuana as a medicine.

Burning leaves is not a modern drug delivery system, period. "Medical marijuana" is an oxymoron.

Conclusion

For more than three decades Americans have been subjected to a well-funded and persistent, but ill-founded effort to convince them that smoking marijuana is harmless to health and that smoking marijuana should be socially accepted. According smoked marijuana the status that comes with medical treatment increases its legitimacy and "normalizes" smoking marijuana.

More people need to see "medical marijuana" for what it is: a cynical fraud and a cruel hoax. The conflict we are discussing at this hearing today, in my view, is not about medicine; it is about the political exploitation of the public's compassion for suffering sick people. Legitimizing smoked marijuana as a "medicine" is a serious threat to the health and safety of all Americans.

#

Table One – Comparison of Folk Remedies and Modern Medicines

Folk Remedies	Modern Medicines
Use plant products composed of many chemicals	Use highly purified, usually synthetic chemicals
Treat poorly defined illnesses	Treat specific illnesses
Are based on little understanding of the pathophysiology of the disorders being treated	Elucidate the nature of the illnesses
Are based on little understanding of the role of the "medicine" in the therapy	Use medicines that have a recognized effect on pathological processes
Are used in inconsistent and hard-to-quantitate amounts	Are administered in controlled doses
Sometimes use smoking as a delivery system resulting in varying levels of chemical in patient body and the toxicity of smoke	Are taken orally which leads to steady blood levels

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Mr. SOUDER. I thank each of you for your testimony, and I wanted to start with Dr. Scott and Ms. Jerzak. I'm curious, because both of you are agents of your State government. I wonder how you factor in FDA guidelines in general, first, and how you enforce State health law, and then specifically how you factor in FDA guidelines on medical marijuana.

Ms. JERZAK. Physicians have to practice the standard of care. In California, we want good medicine. That's kind of what our aim is, to protect health care consumers and ensure good medicine.

When we have a case where a concern comes up, we investigate that. Complaints come from a variety of types and sources. We don't typically have a case where somebody's asking us to investigate FDA guidelines being violated, because FDA would do those.

So although we're upholding State laws and Federal laws as a law enforcement agency, we have to look at, typically those complaints that come to us. Is this good medicine? And then we have to look at it within the standard of care, and we would go to medical experts in the community to say whether that is good medicine.

Mr. SOUDER. So you wouldn't take the FDA's position? They said today there is no medicinal benefit to marijuana. There are components inside it, they have been participating in the research, but they said flat out, there is no medicinal benefit to marijuana. And you don't follow that FDA guideline? Do you follow it on other issues? Or do you just take the State standard of care, talk to local people and forget what FDA said?

Ms. JERZAK. We would be looking at an individual case, and not be proactively setting policy about whether FDA rules are being followed. The kinds of complaints we have have not been characterized as your question would imply, and certainly we have to look at the kind of question that would come to us.

But the cases that we've looked at, the complaints that we've looked at, involve nine licensees. Some had more than one complaint. And they were in the context of whether this was good medicine.

Mr. SOUDER. How do you handle other non-FDA approved drugs? Years ago, because I'm older, Laetrile was an argument. Do you have kind of random decisions? If the FDA says there's no benefit to this drug, but the State doesn't have a ban and nobody complains about it, and then if somebody does, do you look at it in the State context? In other words, the FDA standard is that this is not an approved drug. The Federal standard that this is an illegal drug, doesn't overwrite State law.

Ms. JERZAK. My best answer would be that Laetrile is not legal in California, so we don't have that issue come up to us. The patients will go to Mexico for that.

Marijuana is the only drug that we have this apparent disparity in following the Federal law and their policies and State law. In California, we were urging the physicians to be mindful of the Federal laws, and that we said the State law was not an immunity or a defense to the Federal law. But the voters put this in, and I guess the answer being that the voters did not want to wait for the science.

In other areas of medicine, various alternative medicine modalities that the Board has been confronted with, various kinds of

treatments, NIH has moved forward to develop more information about that, and that's been very helpful to consumers and patients as well as physicians.

Mr. SOUDER. But there's a difference between a developing thing where there's not a stand, and an illegal drug. Nullification was decided a long time ago. I'd like to hear Dr. Scott on this, too. But quite frankly, this sounds so much like the civil rights debates where the Federal Voting Rights Act passed. The States didn't want to give minorities the right to vote. The local attorneys general and law enforcement people said, well, our State law says Blacks can't vote, so we're going to follow State law, not Federal law, and we'll deprive them of the vote.

But there's a Federal law here. Furthermore, the health is clear. We just heard from the national researchers. There is not a debate that they are looking for ways to provide this. My question is, does FDA and NIDA, which are the top experts, when they say, this does not work, and it's an illegal drug, do you believe State law preempts the Federal law?

Dr. SCOTT. I do not. And our Board in Oregon is charged with enforcing both Federal as well as State law. Oregon wrote its law in a very specific way. It is not a prescriptive drug, marijuana. Physicians do not prescribe marijuana. You can't go to the pharmacy and get marijuana. You cannot buy it and you cannot sell it.

The law was written that it allows the physician to discuss with the patient the use of marijuana that may be beneficial for their debilitating condition. Then the law went on to define what those specific debilitating conditions are. And the law in Oregon says that the physician will sign a document that says, "this patient has this debilitating medical condition and it qualifies under the law for medical marijuana." But the physician does not prescribe it, they don't get a prescription for it. His note indicates that this patient has pain, for example, or has nausea, and then allows State law to do what it does.

I understand your argument about State and Federal law. And I at the Board level don't get involved in that conflict, except that I feel that we do follow the Federal law as well as the State law in this case, the way the law is written in Oregon.

Mr. SOUDER. If a patient wants to get marijuana, does it have to be authorized by a doctor?

Dr. SCOTT. That is correct.

Mr. SOUDER. So doctors do in fact have to authorize it?

Dr. SCOTT. It's written specifically this way. The physician signs the statement indicating that this patient has one of these debilitating medical conditions. It's not a prescription. He says that this patient has pain. That's it. That this patient may benefit from medical marijuana. But specifically it says, this patient has nausea, signs it. He doesn't prescribe marijuana.

Ms. JERZAK. I would echo what Dr. Scott has said in terms of California. We did not look at it as the word prescribing, which would make it a violation of Federal law. We also used the word recommend, which was distinctively chosen to separate it out from the Federal law. In California, we said it would be needed to be used for seriously ill Californians, and we left that definition of se-

riously ill to our licensed physicians to be the gatekeepers of describing that category of patients.

Mr. SOUDER. So Dr. Jensen, who showed tremendous sympathy for her patients, believes that ADD was a criteria in two cases to prescribe. Is that one of the guidelines?

Ms. JERZAK. Is that one of the what?

Mr. SOUDER. Is that an approved use?

Ms. JERZAK. In terms of the seriously ill Californians, I would not be making that determination about the explanation of that. We would be relying, if we had that complaint, about whether that was the appropriate care for those patients. What else had been tried? What did she explain as the risks and benefit ratio? What was the informed consent of those involved? What other treatment modalities? How often they met in the context of medicine?

Ms. Sanchez.

Ms. SANCHEZ. I thank the Chair. Before I ask questions, I just want to state that the reason I'm here today is because the issue of medical marijuana use is a very important issue to the people in my State. The voters in California passed a medical marijuana law in 1996, and since that time, my understanding is that thousands of patients have benefited from that law.

In fact, a recent field poll demonstrated that 74 percent of Californians now favor legal protections for patients who use marijuana to cope with illnesses, compared with 56 percent who approved the medical marijuana ballot initiative in 1996.

I'm particularly concerned that State approved medical marijuana patients and providers are being targeted by the DEA. In times like this, when we have such limited Federal resources, rating State approved medical marijuana patients when neighborhoods are dealing with an epidemic in the production, for example, of methamphetamine, does not, to me, seem to be sound policy.

I'm thankful that this hearing has been called to explore science based approaches to medical marijuana, not so much the State-Federal conflict of laws. And with that in mind, I'm going to go ahead and jump into my questioning.

Dr. Jensen, I just wanted to be very clear. Is your testimony today that under physician guidance, the use of marijuana can have beneficial health effects? And if so, I'm interested in knowing what the cost differential would be, for example, for a child with ADD if they were to utilize marijuana versus a prescriptive drug form in some other drug?

Dr. JENSEN. As I said earlier, I only have a basis of two patients to discuss this issue in children. I have talked to some adults with ADD, but in regards to this particular child who had the anger management issues, his mother and father at that time, his father was disabled and they had no health insurance, which is also another problem. It was costing the mother $120 a month to pay for his Dexadrine, which is a very sophisticated form of amphetamine, and very dangerous. I don't approve of Dexadrine in general. He had Ritalin, he had Adderal, he tried Concerta, which is even more expensive. I had one of my office staff call all of our local pharmacies and get a run-down on the average cost for an average prescription, and it exceeds $100 a month in Ventura County, as of this month.

This one particular boy, who by the way is 5 feet 11, 246 pounds, so even though he's a child, physically and metabolically he functions as an adult. His father grows his medicine for him and his mother picks leaves out of the back yard and makes tea for him in the morning before school. So the cost differential is astronomically different.

Now they have health insurance. Now she can afford to buy the other medications for him, but they don't have any desire to do it because of the side effects that he was suffering from the other medications. Now he's fully functional and back in school and getting good grades, whereas before he was getting Fs and Ds. So the cost differential is just ridiculously different.

Ms. SANCHEZ. Thank you.

Dr. DuPont, I have a question for you. I'm interested in knowing what your thoughts are concerning the potential use of inhalants as British firms have proposed, versus the dangers that are specifically associated with smoking marijuana, and whether or not you think that inhalant form could be potentially beneficial?

Dr. DUPONT. I think this product shows promise. And I think it's a very attractive idea. Because it doesn't involve smoking. So I think it's good. My understanding is that it's going to be subjected to this FDA approval process. Should sativex go through that process, and I think it may very well successfully go through that, if it does, I would have no difficulty supporting it, as I have supported the use of controlled substances approved by the FDA for all kinds of indications. This would not trouble me in the least.

Ms. SANCHEZ. OK, thank you. And then Mr. Scott, I understand that your Board has investigated and suspended Dr. Phillip Leveque based on some of his recommendations that he made to patients. And I'm interested in knowing specifically what the recommendations were that led to his suspension, and how did his recommendations adversely affect his patients?

Dr. SCOTT. Part of what I can talk about with Dr. Leveque is public information. Part of it is not, and there is still some investigational information.

The public information that is available is that Dr. Leveque was originally disciplined by the Oregon Board of Medical Examiners approximately 2 years ago. The reason for that discipline was not regarding the Medical Marijuana Act, it was regarding the Medical Practice Act of Oregon and his practice as a physician.

At that time, he was signing these physician authorizations for medical marijuana usage without doing what a physician does. And a physician sees a patient, does a history, does a physical, comes to a diagnosis, proposes a treatment plan, prescribes the treatment plan, which may include medication, and then follows the patient to see the response to that treatment plan.

Dr. Leveque was not doing that. He was investigated and he ended up signing a stipulated order where our Board allowed him to continue to practice, but under a probationary period. Dr. Leveque was more recently investigated again and his license was suspended approximately a month ago because we at the Board level found he was in violation of his original stipulated order 2 years ago.

Ms. SANCHEZ. Did either of the violations adversely affect the patients?

Dr. SCOTT. That's a matter that I can't answer. His practice, quite honestly, was not as a primary care provider, but mainly to sign these medical marijuana cards. So he did not have an ongoing relationship with the patient. He was not monitoring the patients. So he was merely signing this documentation that's required to receive medical marijuana.

I would speculate that his patients, depending upon your opinion and their availability of medical marijuana is how it would affect their health. And I can't answer that question for you.

Ms. SANCHEZ. Thank you for your testimony.

Mr. Kampia, what credible research has been done to demonstrate marijuana's therapeutic use?

Mr. KAMPIA. Well, in the late 1970's and early 1980's, there were seven States, including California and New York, that did statewide research projects involving marijuana that came from the Federal Government. It involved hundreds of patients in each State. One of the States actually was Tennessee. Al Gore's sister was using marijuana for cancer back in, I think, 1981 or 1982.

And each of these States concluded their studies in 1984 or 1985, something like that. They all issued reports, and the reports showed that some patients benefited from the Marinol pill, some patients benefited from the marijuana but not the pill and some patients benefited from neither, which kind of is what we see when we talk to patients. Some respond to one, some respond to the other, some don't respond to either. So those studies were done and since then, there's a whole host of studies being done in the University of California; 10 or 11 studies going right now, I think, which was mentioned earlier today.

And there have been dozens of other studies done by private researchers here and there in the 1970's and early 1980's. Those studies were all summarized by the Institute of Medicine which released this comprehensive book in 1999. It was paid for by the White House drug czar's office. I think they were looking for some conclusions in this book that they didn't get. But we hold the book up now, because we like it, because it shows that marijuana actually does have medical value.

Furthermore, I should point out, another glitch here in how we don't follow science around here is the IOM. In the very beginning of their book, they recommended that until a non-smoked, rapid onset cannabinoid drug delivery system becomes available, we acknowledge that there is no clear alternative for people suffering from chronic conditions that might be relieved by smoking marijuana, such as pain or AIDS wasting. And they recommended on the same page that patients be able to get a 24-hour turnaround if their physician and the patient decided that they need marijuana. The Federal Government should give them the opportunity to use marijuana within 24 hours.

I have never heard any Member of Congress nor the drug czar decide if they were going to jump on that IOM recommendation and make that happen.

Ms. SANCHEZ. Thank you for your testimony. I have no more questions.

Mr. SOUDER. Dr. DuPont, do you have any comment on what he just said?

Dr. DUPONT. Well, about the Institute of Medicine report, I think there are some slippery words going on here. We talk about marijuana, and you, Mr. Chairman, pointed this out, much of the talk when we talk about medical marijuana is dealing with individual chemicals in it and not with the smoked marijuana. The IOM report specifically said with respect to smoked marijuana that smoking was a bad idea. Let me say this, in summary, there are many reasons to worry that people who might choose to use marijuana as medicine, especially those who smoke it, the drug could actually add to their health problems.

So I think that there is very little enthusiasm for smoked marijuana. And I would try to use that term, rather than just marijuana. Because marijuana is often talked about as if it's the constituent chemicals, like THC or others, that are in there.

Mr. SOUDER. Thank you for clarifying that. It's something that we had some debates about in the last administration, who failed to note in some of their reports the correct distinctions. In Canada, as they move forward, and as I've talked to the legislators, who I don't agree with, on the general policy, but agree that they are trying to move ahead without smoked marijuana and in lower intensity, even in the different pills that separate the components. In the Netherlands, the government is in the process of trying to back up, which is now a mess in Amsterdam. They are attempting to isolate chemicals. Don't get this confused with marijuana. There are substances in all kinds of things that have negative impacts on society. And I appreciate your clarifying that.

Dr. DUPONT. Mr. Chairman, I would just point out one thing about what you said that is very important. And that is that smoked marijuana is the only way it is interesting to the advocates in this field. They show no interest in the development of individual chemicals whatsoever.

That shows that their purpose is not medical, it is to influence the country's policies toward marijuana. Medical marijuana is a stocking horse for legalization of marijuana, the legitimization of smoking marijuana. You can see that very clearly with how little interest they have in individual chemicals or any alternate delivery system other than marijuana smoking. They're only interested in defending smoking.

Mr. SOUDER. Mr. Kampia, you attempted to defend smoked marijuana again today, which is far more carcinogenic than tobacco.

Mr. KAMPIA. That's wrong.

Mr. SOUDER. You said it in your testimony. But my question is, and then you can make your comments, because I want to give you your day in court here, so to speak. Why isn't your push to separate out and have your primary effort where we can actually find more agreement, and that is separating these 400 chemicals in tablet form to try and help people? Why are you mostly focused on smoked marijuana?

Mr. KAMPIA. Right. Well, Dr. DuPont was wrong on two points, and this is answering your question. One is, the IOM specifically recommended smoking marijuana. The word smoking marijuana is right amongst the words that I just read. So it's not just me and

MPP. It's the IOM that recommended that. Not as a long term solution, but as a short term solution, while we're studying marijuana in a way that could eventually be developed into additional pills or a vaporizer or what have you.

Dr. DUPONT. For a few patients, yes.

Dr. JENSEN. Congressman Souder——

Mr. KAMPIA. That's the second part to my answer, which is that not all of our work actually has to deal with smoked marijuana. The work that I referenced about the University of Massachusetts trying to get DEA permission to start growing a legal supply of marijuana so that they can do some research to get it approved by the FDA, that need not be smoked marijuana. In fact, my organization gave a grant recently to some researchers to look into whether a vaporizer could be used instead of smoking marijuana. As far as we're concerned, we want the best possible medicine out there for the patients, whether it's a vaporizer, whether it's smoked marijuana or whether it's a new pill or what have you.

The bottom line I think what differentiates the Marijuana Policy Project from, say, you, Mr. Chairman, is that in the meantime we all have the same vision for the end goal. In the meantime, what do you do with the patients who are currently smoking or eating marijuana? Your position seems to be, put them in prison. Our position is, let them do it while the research goes on and do not arrest them.

Dr. JENSEN. Congressman Souder, first of all, I wanted to leave this with you, if I might. This is a book from Dr. Mitch Earleywine. He is a clinical professor at University of Southern California. He offered it to you. It's got some of the latest science on cannabinoids. As a physician, I actually think that I can address this issue. There are so many different routes of administration and it's been very difficult for me to figure out how to advise patients. They all come to me smoking. I recommend to all of them how to quit smoking.

And as a matter of fact, I have a very effective tobacco cessation program. Because I will not give them a note if they don't make a contract with me to quit smoking cigarettes. And I give them a period of time and I give them help on how to do that.

Basically when you inhale marijuana, preferably through a vaporizer, but traditionally what most people do is they inhale it either through a cigarette, which includes papers, or through a water pipe, which changes the constituents of it. Now, I'm not an expert on this. What I've learned I've learned from patients, unfortunately, because I have not been able to go to a learned body of my peers to educate me. I have learned this from my experience with my patients. But when smoking the joint itself with the paper on it appears to help the asthmatics more than if they use it from a water pipe, it is interesting. When they inhale it from a water pipe, the asthmatics seem to actually get worse, which makes no sense. But functionally, that's what happens.

Now, they do have vaporizers available, but there are such a wide variety of vaporizers, the cheapest you can get is $100. I bought one as a demonstration tool to show patients how to use them. It broke the first week. It had never been used, but it was just mechanically so defective it broke. The best vaporizer on the market runs around $600 or $700.

Mr. SOUDER. Can I ask you a question? I hear your concern for the individual patients. But what's really hard for me to sort out in listening to this in your testimony is that you referred in your testimony that marijuana had been used as folk medicine for many years, and you're relying a lot on whether people saying a rolled joint or a water pipe is most effective.

You're a doctor.

Dr. JENSEN. I want the science.

Mr. SOUDER. But the FDA was clear. You just don't agree with it.

Dr. JENSEN. No, the FDA unfortunately failed to attend to the fact that marijuana does have medicinal use.

Mr. SOUDER. No, they didn't. That's not what——

Dr. JENSEN. He said so himself, that in chronic pain, glaucoma, there is proven evidence that it affects those conditions. By definition, it has medicinal value. It should not be Schedule I.

Mr. SOUDER. By definition, there are 400 components.

Dr. JENSEN. Right, but the point is, why do you want to take and analyze out and define each component into a little pill that could be sold from some pharmaceutical company when somebody can grow it themself? I think they need guidance. I as a physician need guidance. But it doesn't make any sense to me to try and market it. It grows right up out of the Earth.

Mr. SOUDER. You're a physician. You're supposed to follow good health practices, and you're also supposed to follow the law.

Dr. JENSEN. Congressman Souder, I am desperate for guidance from my peers. They are unwilling to give it to us. In the absence of——

Mr. SOUDER. They have given it to you.

Dr. JENSEN. In the absence of reading it in an FDA report, I have to rely on people who are doing work in the field. And I've conducted my own studies.

Mr. SOUDER. What you mean is, you disagree with the experts who have done it, and you would rather rely on people whose judgment you like better, is that it?

Dr. JENSEN. My patients, Congressman Souder, I am a patient advocate. And even if one patient benefits from this drug, then it should never, ever be Schedule I. Because Schedule I means no medicinal uses. And even if one patient is helped, we should help them.

Mr. SOUDER. Your heart is in the right place, but you are incredibly ill-advised as a doctor to depend on your patients' wisdom rather than science.

Dr. Scott, I wanted to ask a question. In Oregon, one of the things that has occurred, and I'm not sure whether you have any knowledge of this, but it's a complicating variable, and I'm just asking if you have any knowledge. Apparently a drug testing law, as it relates to the transportation department, has ruled and overturned for people who are practicing medicinal marijuana and they can't test them. Do you know anything about that?

Dr. SCOTT. I'm not aware of that, sir. I can't testify to that. I don't have any knowledge.

Mr. SOUDER. OK, I didn't know whether that's come up.

Dr. DuPont, I wanted to ask you a final question here. In the transportation bill today, a number of us have worked to see that the Federal law starts to reflect what we've done in alcohol, and that is that we have a testing process for people who are high and that abuse marijuana and are driving and endangering other drivers. It's more complicated, because while excess alcohol has an immediate devastating impact on impairing a driver, it also doesn't stay in the system as long, which is why it doesn't have the same cumulative negative effect.

My question, and I don't know the answer to this, because I haven't asked this question before, do you sense that we're going to be able to devise a test that is able to measure how impaired a person is from the marijuana? What I don't understand is, if the marijuana stays in your system for a long period of time, I presume that the level of impairment drops, but if you smoke another joint a couple days in, you're getting the most recent overlapping with the previous in impairment. The second part of that is, will we have a reasonable, reliable test to see how impaired the person is, unlike alcohol, where we can give them a breathalyzer or whatever? Because they're not going to do a hair follicle test.

Dr. DUPONT. Mr. Chairman, I mentioned that I am the president of the Institute for Behavior and Health. Drugged driving is one of our two top priorities to bring to bear testing and law enforcement in the drug driving field, as we have in the last two decades with drunk driving. It is a major problem. In highway safety the adverse effects of illegal drug use are equal to or on the same scale as, and in some cases higher, than those associated with alcohol consumption. So drugged driving is a national problem that has not been addressed. The modern drug testing technology does let us do that.

But there is a step that needs to be taken, and that is to move away from the question of impairment to the question of whether the presence of the drug is identified in the driver. This is the standard that was taken by the U.S. Department of Transportation in 1988 for commercial drivers. It is essentially a per se standard. That per se standard should be used for all drivers in the United States. The technology is there to do that now.

I am thrilled, delighted with your interest in this. It is extremely timely, and it is going to make a huge difference in highway safety and also drug abuse prevention. So I am a very enthusiastic supporter, but we're going to have to move to a per se standard, which is what has happened in the work place. That's what goes on now with people who do drug testing. Millions of American workers are drug tested using this standard. It's a per se standard. It is what is done in transportation for commercial drivers. It is the right standard to apply across the board. If you are driving a vehicle, you don't have drugs present in your body.

Mr. SOUDER. Thank you. I think that's the way we have it in Indiana. I know there is some form of this in the bill we're voting on in a little bit here. But I don't know what the final form was and how it was amended.

Are you familiar at all with the case, when I was a staffer for Senator Coates, I think Senator Danforth initiated the drug testing for transportation.

Dr. DUPONT. Yes.

Mr. SOUDER. This case in Oregon questioned whether it could be enforced if the person had a medical marijuana prescription.

Dr. DUPONT. My understanding, and there may be something that happened recently that I'm not familiar with, but my understanding is that the Federal law is preemptive. So called medical marijuana is a violation of this standard. So even if you have a medical certificate, it's a violation and you lose your license and right to drive. That's my understanding of the law.

Mr. SOUDER. I think it was a local court that challenged it.

Dr. DUPONT. But that has been the Department of Transportation standard. The previous administration took that position, and this administration takes that position. There may be something that's happened that I don't know about just recently. But that has been the position of the Department of Transportation under both the Clinton administration and the Bush administration.

Mr. SOUDER. I'm not sure how this is going to move up the court system, because it wasn't a legislative decision. It was a court decision I'm very concerned about. Because if you can have this medical waiver and be driving a truck, we have a huge loophole here unless we very tightly limit it, which I know is what the State boards are trying to do, to address the abusive excesses of this. At the same time, unless we radically control this, and somehow get over this idea of State's rights nullifying Federal law, we're in deep trouble in laws like that.

I thank each of you for coming today. If you have any additional comments, you can put them into the record. I appreciate our having a continuing debate, and I'm sure it won't have ended today.

With that, the subcommittee stands adjourned.

[Whereupon, at 4:40 p.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]

[Additional information submitted for the hearing record follows:]

STATE OF CALIFORNIA -- STATE AND CONSUMER SERVICES AGENCY ARNOLD SCHWARZENEGGER, Governor

Consumer Affairs

MEDICAL BOARD OF CALIFORNIA
EXECUTIVE OFFICE
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June 1, 2004

The Honorable Mark E. Souder
U.S. House of Representatives
Chairman
Subcommittee on Criminal Justice, Drug Policy and Human Resources
Committee on Government Reform
2157 Rayburn House Office Building
Washington, DC 20515-6143

Dear Representative Souder:

In response to your correspondence of May 19, 2004, the following response is provided, (with your questions preceding in italics).

1. *Your testimony suggests that the primary role of the Medical Board of California (the "Board") is to verify that a doctor has complied with certain procedural requirements - e.g., having a current license, conducting an examination and filling out the appropriate forms.*

   The Medical Board of California exists to regulate the professional conduct and competence of California physicians. Our Legislature has decreed that protection of the public is the highest priority for the Board, and where public protection is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. In keeping with this mandate, it is the duty of the Medical Board to investigate all complaints received regarding the professional activities of California physicians. If our investigation shows that a physician has engaged in unprofessional conduct, as defined by the governing statutes, disciplinary action will be pursued.

   a. *Does this mean that a doctor could prescribe the scientifically wrong medication and still be in compliance with your regulations? For example, if a doctor carried out all the proper "procedures" but then prescribed Viagra to a patient with high blood pressure, would the Board take any action?*

      Disciplinary action will be imposed in those instances where it has been established by clear and convincing evidence that a physician's conduct departed from the prevailing standard of practice. It must be emphasized that the Medical Board does not define the standard of practice. The standard of practice is derived

from several sources: applicable statutory and case law, regulations and most importantly, by expert peer testimony. The Board does not establish "procedures" which physicians must follow, nor does it take a position with regard to specific medications. The role of the Medical Board is to determine the applicable community standard through its objective physician experts, and to apply it to the facts of a given case.

The Board can take action if a physician falls below the standard of care, established by the medical community and opined upon by medical experts. No action can be taken based on what may be "scientifically wrong," unless it has been established that the medical procedure or treatment fell below the standard for a given patient in a given situation. If a medical treatment or procedure is contra-indicated for a particular patient, the medical expert would be expected to describe the community standard and how the contra-indicated procedure departed from that standard.

b. *Are there any medications other than marijuana for which the board takes no position as to whether they are safe and effective? If a doctor tried to prescribe thalidomide for morning sickness, for example, despite what we now know about its side effects, would the Board take action?*

As a regulatory agency the Board takes no position on any medical treatment or modality, and would rely on medical experts to state whether a specific treatment or modality, given to a particular patient, at a particular point in time, was within the standard.

c *Does the board have any responsibility for regulating the content of medical treatment, rather than merely the procedures?*

If medical treatment falls below the standard of care, as described by a Board-retained medial expert, the board would take action against the identified physician's license.

2. *The voters in your state have attempted to legalize the use of marijuana for "medical" purposes, so it is understandable that the board - as a state government agency - feels obligated to implement that policy. Nevertheless, as doctors themselves and as regulators of the medical profession, it would seem that the members of the Board are supposed to protect the public based on scientific and medical evidence - not on politics. We have some questions about whether permitting doctors and patients to use a drug in this way can ever be considered appropriate in the practice of medicine.*

The Compassionate Use Act of 1996, (commonly known as Proposition 215) was passed by California voters through the initiative process and became law in November 1996. This act added section 11362.5 to the California Health and Safety Code. The main thrust of the Act was to allow seriously ill Californians to obtain and use marijuana for medicinal purposes where such use is deemed appropriate and has been recommended by a physician.

a. *Are there any drugs other than marijuana that the Board believes can be safely smoked? If a doctor recommended that a patient smoke morphine, for example, would the Board take any action?*

The Medical Board of California exists to regulate the professional conduct and competence of California physicians. Our Legislature has decreed that protection of the public is the highest priority for the Board, and where public protection is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. In keeping with this mandate, it is the duty of the Medical Board to investigate all complaints received regarding the professional activities of a California physician. If our investigation shows that a physician has engaged in unprofessional conduct, as defined by the governing statutes, disciplinary action will be pursued.

Regarding smoking as a delivery method: As a regulatory agency the Board takes no position on any medical treatment or modality, and would rely on medical experts to state whether a specific treatment or modality, given to a particular patient, at a particular point in time, was within the standard.

b. *Does the Board have any concerns about the lack of health or safety controls on the supply of marijuana to patients - since patients are essentially allowed to grow or procure their own "medicine"? Are there any other medications that you believe can be responsibly manufactured and self-administered by patients?*

The Board has no jurisdiction over access to marijuana.

Alternative medicine, which includes a wide range of modalities and treatments, has been incorporated into the practices of many licensed physicians. The Board has no position over any particular remedy, but would rely on the medical expert opinion, in a particular case, for a particular ailment, at a particular point in time, to determine if a remedy was within or outside the standard of care.

c. *How much evidence, and what kind of evidence, does the Board believe is necessary before a drug should be used to treat a condition? Is anecdotal evidence sufficient? Should a doctor prescribe or "recommend" a drug that has not yet been properly tested?*

While the FDA has the role of ensuring drugs are safe and effective, physicians are legally allowed off-label use. This off-label use makes the physician responsible for the medical care and treatment provided to each patient under their care. The Board does not evaluate drugs or if they should be used to treat any condition but would rely on the medical expert to determine if the standard of care was met.

Much alternative medicine, which is emerging, relies on anecdotal evidence as a starting point which may be augmented by scientific studies. The Board has taken action against alternative medicine practitioners when their claims or promises to patients fall outside the standard of practice.

Physicians are responsible for the care and treatment of their patients and providing them medicine within the community standard. A physician who provides any medical treatment may be subject to peer review any may be subject to action by the Board if their treatment falls below the standard.

d. *Since the federal government has already tested and approved Marinol, a marijuana derivative, why should doctors recommend any other form of marijuana?*

Inasmuch as California Health and Safety Code section 11362.5 establishes that marijuana can be used medically in California, the question before the Medical Board is limited to whether a physician who has recommended or approved marijuana has done so in a manner consistent with the standard of practice.

The Board has no opinion about Marinol versus marijuana and would rely on a medical expert to describe the community standard in a particular situation.

e. *Should marijuana be used to treat psychiatric or psychological conditions like attention deficit disorder (ADD), depression or anxiety?* Why or why not?

It is the community practice, not Board edict, which establishes the governing standard of practice with respect to physicians who recommend or approve marijuana to patients. The Board has consistently stated that physicians who do recommend marijuana must do so in accordance with accepted standards of medical responsibility. It is important to note the process a physician is expected to follow when recommending marijuana to a patient is the same as any physician would be expected to follow when prescribing any drug or treatment. This standard includes a history and good faith examination of the patient, development of a treatment plan with objectives, provision of informed consent, periodic review of the efficacy of treatment, any necessary consultation, and proper documentation to support the physician's decision to recommend the use of marijuana. This process is not merely a "procedure" to be followed by a physician, but is the overall assessment, evaluation and medical treatment provided by the physician. Similarly, it is not for the Board to determine which medical conditions may be appropriately treated with marijuana.

California Health and Safety Code section 11362.5(b)(1)(A) states 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...or any other illness for which marijuana provides relief."

f. *Should marijuana be used to treat moderate or low-level pain? Why or why not?*

California Health and Safety Code section 11362.5(b)(1)(A) states 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...*chronic pain*...or any other illness for which marijuana provides relief."

g. *Should marijuana be used to treat epilepsy? Why or why not?*

California Health and Safety Code section 11362.5(b)(1)(A) states 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...or any other illness for which marijuana provides relief."

h. *Should marijuana be used to treat children or teenagers, including for psychiatric or psychological conditions? Why or why not?*

California Health and Safety Code section 11362.5(b)(1)(A) states 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...or any other illness for which marijuana provides relief."

3. *If a complaint is filed against a physician, alleging the improper recommendation of marijuana use in medical treatment, how does the Board determine if that use of marijuana was appropriate?*

It is the community practice, not Board edict, which establishes the governing standard of practice with respect to physicians who recommend or approve marijuana to patients. The Board has consistently stated that physicians who do recommend marijuana must do so in accordance with accepted standards of medical responsibility. It is important to note the process a physician is expected to follow when recommending marijuana to a patient is the same as any physician would be expected to follow when prescribing any drug or treatment. This standard includes a history and good faith examination of the patient, development of a treatment plan with

objectives, provision of informed consent, periodic review of the efficacy of treatment, any necessary consultation, and proper documentation to support the physician's decision to recommend the use of marijuana. This process is not merely a "procedure" to be followed by a physician, but is the overall assessment, evaluation and medical treatment provided by the physician. Similarly, it is not for the Board to determine which medical conditions may be appropriately treated with marijuana.

a. *What standards are applied?*

Licensed physicians in a particular specialty provide expert opinion to establish the standard of practice within the medical "community," within the state of California.

b. *Who determines what those standards are? If they are determined by medical experts, who are those experts, and what is the basis for their selection?*

The Board relies upon impartial, third party expert physicians to determine whether a physician has comported with the standard of practice in any given speciality or sub-specialty. These experts are board certified physicians whose licenses are in good standing who are familiar with the standard of practice for a particular ailment. The Board utilizes expert reviewers who engage in a practice that is similar to that of the physician who is under investigation. Because the ultimate question before the Medical Board is whether a physician adhered to the standard of practice for a physician in California, it is appropriate and necessary for the Board to utilize expert witnesses who practice in our state, and who are familiar with the applicable standard of practice. The experts review not only the mechanical "procedure" followed, but the quality and extent of the physician's treatment of the patient as well.

c. *Is there such a thing as a "medical expert" on the use of marijuana?*

Medical experts are divided into practice specialties, and not by a particular modality or treatment. A medical expert who provides testimony re: marijuana, could therefore, be one of many different specialty fields, e.g., ob/gyn, internal medicine, pain management.

If the expert determines that a physician fell below the standard, i.e., marijuana was contraindicated in a particular case, the Board would expect the expert to so state, and to state the reasons for that conclusion. Similarly, the expert may conclude that the evaluation conducted by the subject physician was superficial or inadequate. Our experts must review the physician's medical records, and determine whether appropriate medical records have been created. In any case, the expert may conclude that marijuana was or was not an appropriate treatment for the condition presented. In other words, the expert reviewer will consider and assess the entire clinical presentation.

d. *Why would the Board not consult with federal government experts, like those at FDA or NIDA?*

Complaints to the Board typically do not pivot on whether a particular modality was good or bad, but rather there is focus on the question if the medical care provided met the standard of practice. The standard of practice, which is generally limited to the borders of our state, is established by a physician practicing medicine in the same specialty area as the physician under investigation. Occasionally, the Board has utilized federal government experts in cases where the issues did not involve the quality of medical care provided, but involved devices which were manufactured outside of the law or did not have FDA approval. Generally speaking, federal government experts are not able to provide expert opinions regarding the California standard of practice in quality of care cases.

To further illustrate how the Board has responded to a complaint over improper recommendations of medical marijuana, please find attached a copy of an Accusation and Decision in a recent case, that resulted in physician discipline.

Sincerely,

Joan M. Jerzak
Chief of Enfocement

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Attorneys for Complainant

BEFORE THE
DIVISION OF MEDICAL QUALITY
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: TOD H. MIKURIYA, M.D. 1168 Sterling Avenue Berkeley, CA 94708 Physician's and Surgeon's Certificate No. G-9124 Respondent.	Case No. 12-1999-98783 **SECOND AMENDED ACCUSATION**

Complainant alleges:

PARTIES

1. Ron Joseph (Complainant) brings this First Amended Accusation ("Accusation") solely in his official capacity as the Executive Director of the Medical Board of California, Department of Consumer Affairs.

2. On or about October 16, 1963, the Medical Board of California issued Physician's and Surgeon's Certificate Number G-9124 to Tod H. Mikuriya, M.D. (Respondent). The Physician's and Surgeon's Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2003, unless renewed.

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JURISDICTION

3. This Accusation is brought before the Division of Medical Quality, Medical Board of California (Division), under the authority of the following sections of the Business and Professions Code (Code).

4. Section 2003 of the Code states: "The board shall consist of the following two divisions: a Division of Medical Quality, and a Division of Licensing."

5. Section 2004 of the Code states:

"The Division of Medical Quality shall have the responsibility for the following:

"(a) The enforcement of the disciplinary and criminal provisions of the Medical Practice Act.

"(b) The administration and hearing of disciplinary actions.

"(c) Carrying out disciplinary actions appropriate to findings made by a medical quality review committee, the division, or an administrative law judge.

"(d) Suspending, revoking, or otherwise limiting certificates after the conclusion of disciplinary actions.

"(e) Reviewing the quality of medical practice carried out by physician and surgeon certificate holders under the jurisdiction of the board."

6. Section 2227 of the Code provides that a licensee who is found guilty under the Medical Practice Act may have his or her license revoked, suspended for a period not to exceed one year, placed on probation and required to pay the costs of probation monitoring, or such other action taken in relation to discipline as the Division deems proper.

7. Section 2234 of the Code provides, in pertinent part, that the Division of Medical Quality shall take action against any licensee who is charged with unprofessional conduct. Unprofessional conduct includes, but is not limited to, the following:

(a) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this chapter [Chapter 5, the Medical Practice Act].

(b) Gross negligence.

(c) Repeated negligent acts . . .

(d) Incompetence.

(e) The commission of any act involving dishonesty or corruption which is substantially related to the qualifications, functions, or duties of a physician and surgeon.

(f) Any action or conduct which would have warranted the denial of a certificate.

8. Section 2242 of the Code states, in pertinent part:

"(a) Prescribing, dispensing, or furnishing dangerous drugs as defined in Section 4022 without a good faith prior examination and medical indication therefor, constitutes unprofessional conduct."

9. Section 2266 of the Code provides:

"The failure of a physician and surgeon to maintain adequate and accurate records relating to the provision of services to their patients constitutes unprofessional conduct."

10. Section 125.3 of the Code provides, in part, that the Board may request the administrative law judge to direct any licentiate found to have committed a violation or violations of the licensing act, to pay the Board a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

11. Welfare and Institutions Code section 14123.12 states, in pertinent part, as follows:

"(a) Upon receipt of written notice form the Medical Board of California, that a licensee's license has been placed on probation as a result of a disciplinary action, the department mayn to reimburse any Medi-Cal claim for the type of surgical service or invasive procedure that gave rise to the probation, that was performed by the license on or after the effective date of the probation and until the termination of all probationary terms and conditions or until the probationary period has ended, whichever occurs first. This section shall apply except in any case in which the relevant licensing board determines that compelling circumstances warrant the continued reimbursement during the probationary period of any Medi-Cal claim...In such a case, the department shall continue to reimburse the licensee for all procedures, except for those invasive or surgical procedures for which the licensee was placed on probation."

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FIRST CAUSE FOR DISCIPLINARY ACTION

(Patient R.A.)

(Unprofessional Conduct/Gross Negligence/Negligence/Incompetence)

12. Respondent is subject to disciplinary action under sections 2234, and/or 2234(b), and/or 2234(c), and/or 2234(d) of the Code in that respondent committed unprofessional conduct, and/or was grossly and/or simply negligent, and/or incompetent in the care and treatment of Patient R.A.[1] The circumstances are as follows:

A. On or about March 5, 1997, Patient R.A., a 34 year old male, self-referred to respondent for medical advice regarding treatment of R.A.'s condition with marijuana, a Schedule I controlled substance. Respondent's records do not reflect the nature of the patient's health problems at that time, nor do the records reflect what advice was given to the patient by respondent. No psychiatric history, medical history, physical examination or mental status examination is recorded. A note by respondent indicates that two pages of the original record were given away by respondent. Respondent was interviewed and stated that he did conduct an examination, which he described as "observing the patient closely" and "talking with him."

B. On or about November 6, 1998, Patient R.A. responded to a "Follow Up Visit Questionnaire", wherein he reported that marijuana had been used by him for treatment of "Gastritis/Anxiety Disorder." No psychiatric history, medical history, physical examination or mental status examination is recorded by respondent. The only remarks recorded by respondent are "irritation from low potency" and "recounts stressors of arrest + case + involvement + insomnia. Disc effects on life." Inquiry as to the status of the patient's two complaints was made in the form of a check-the-appropriate-box response ("stable", "improved" or

1. Patients' names are abbreviated to protect privacy. Full information will be provided to the respondent upon timely request for discovery.

"worse") by the patient re "illness status." A "physician's statement, dated November 18, 1998, states that Patient R.A. is under respondent's care and supervision for the treatment of gastritis and anxiety disorder, for which respondent recommends and approves the use of marijuana. The physician's statement indicates that it is an update from one dated March 5, 1997.

C. According to respondent's records, dated August 5, 1999, Patient R.A. provided a further follow-up questionnaire in which he reported treating complaints of anxiety disorder, gastritis and irritable bowel syndrome with marijuana, 15-38 grams per week. Respondent's only comments are noted as "vaporize" and "oral", presumably referring to a recommended method of marijuana utilization.

D. Respondent's records, dated April 28, 2000, indicate that R.A. complained of increased anxiety and insomnia. There is no documented medical response by Dr. Mikuriya to the patient's increased symptoms.

E. On January 4, 2001, Patient R.A. submitted a follow up questionnaire which indicated that he continued to suffer from anxiety and gastritis. No psychiatric history, medical history, physical examination or mental status examination is recorded by respondent. The patient's reported marijuana use was stated to be 60 grams or more per week -- about double what he had previously described -- and the patient stated that only price and availability prevented him from consuming four times that amount. Respondent issued a "physician's statement" which indicated that Patient R.A. was under respondent's medical care and supervision for treatment of a serious medical condition, which is noted as Anxiety Disorder, for which respondent recommended and approved the use of marijuana.

F. On March 12, 2001, Patient R.A. consulted respondent by telephone. He reported a 20 lb. weight loss and an increase in his anxiety, bowel complaints and insomnia. He also reported lumbosacral back pain. There is neither documented

medical response nor recommendation that the patient seek medical evaluation of his increased symptoms.

13. Respondent's conduct, as described above, constitutes unprofessional conduct and represents extreme and/or simple departures from the standard of care, and/or acts of incompetence in that respondent committed errors and omissions in the care and treatment of Patient R.A., including but not limited to the followings:

A. Respondent failed to evaluate R.A.'s complaints of anxiety and insomnia by means of a standard psychiatric history, medical history, physical examination and mental status examination;

B. Respondent failed to evaluate R.A.'s gastrointestinal complaints and failed to rule out serious and perhaps life threatening illness while recommending palliative treatment;

C. Respondent failed to follow up on R.A.'s complaints and used an inadequate check box questionnaire which lumped R.A.'s multiple complaints together as a single illness;

D. Respondent falsely and unethically represented that R.A. was under his care and supervision for treatment of serious medical conditions, when in fact respondent provided neither care nor treatment, but only approved the patient's use of marijuana as a palliative.

SECOND CAUSE FOR DISCIPLINARY ACTION

(Patient S.A.)

(Unprofessional Conduct/Gross Negligence/Negligence/Incompetence)

14. Respondent is subject to disciplinary action under sections 2234, and/or 2234(b) and/or 2234(c), and/or 2234(d) of the Code in that respondent committed unprofessional conduct, and/or was grossly and/or simply negligent and/or incompetent in the care and treatment of Patient S.A. The circumstances are as follows:

A. On or about May 20, 1996, Patient S.A., a 20 year old male, presented to respondent for a recommendation/approval for marijuana. The patient gave a

1 history of nausea, vomiting, motion sickness and anorexia. Medical records
2 indicate that the patient had previously been worked up by physicians for a
3 suspected ulcer. The patient also had a history significant for an arrest for
4 possession and cultivation of marijuana 18 months earlier. In respondent's
5 records there is no documentation that respondent elicited a history of other
6 medical conditions, took vital signs or performed a physical/mental status
7 examination. Respondent prescribed Marinol, a pharmaceutical containing the
8 active ingredient in marijuana, for the patients symptoms. Respondent did not
9 otherwise formulate a treatment plan or propose follow up for the patient's
10 continuing gastrointestinal problems.
11 B. On November 10, 1997, respondent charted a note indicating that the
12 patient reported that Marinol provided less relief than crude marijuana. Based
13 upon the patient's statement that the patient was "doing well with symptom
14 control", respondent issued a "physician's statement" stating that Patient S.A. was
15 under respondent's medical care and supervision for the serious medical
16 condition of gastritis and that respondent recommended marijuana for his
17 condition.
18 C. On May 12, 1998, Patient S.A. requested a renewal of his Marinol
19 prescription. The communication is stated to be a "televisit" and the patient's
20 gastritis is described by a box checked "stable." A note at the bottom of the form
21 states that a certificate, presumably for continued marijuana use, was mailed to
22 the patient.
23 D. On October 16, 1999, the patient again requested a "renewal of cannabis
24 recommendation." As with the prior 1998 communication, the communication
25 was not face-to-face, but was conducted via fax transmittal of a "Cannabis Patient
26 Follow Up Visit Questionnaire." The form contains the patient's assessment that
27 his gastritis was "stable" and his nausea was "better." The patient checked the
28 box indicating that he found the treatment "very effective" and answered "no" to

the question whether he had experienced "adverse effects."

15. Respondent's conduct, as described above, constitutes unprofessional conduct and represents extreme and/or simple departures from the standard of care, and/or acts of incompetence in that respondent committed errors and omissions in the care and treatment of Patient S.A., including but not limited to the following:

A. Respondent failed to evaluate the patient's gastrointestinal complaints by appropriate physical examination and prescribed Marinol, a Schedule III controlled substance, without ruling out progression of the previously suspected duodenal ulcer;

B. Respondent failed to re-evaluate the patient's gastrointestinal complaints on subsequent visits or to refer the patient to a physician for re-evaluation;

C. Respondent renewed the patient's medications in 1998 and 1999 without an interval history of the patient's condition and with the last examination not having been performed since on or before November 10, 1997;

D. Respondent charged the patient for medication renewal without conducting an examination.

THIRD CAUSE FOR DISCIPLINARY ACTION

(Patient J.B.)

(Unprofessional Conduct/Gross Negligence/Negligence/Incompetence)

16. Respondent is subject to disciplinary action under sections 2234, and/or 2234(b) and/or 2234(c), and/or 2234(d) of the Code in that respondent committed unprofessional conduct, and/or was grossly and/or simply negligent and/or incompetent in the care and treatment of Patient J.B.. The circumstances are as follows:

A. On August 9, 1997, Patient J.B., a 40 year old female, presented with a ten year history of chronic depression, anxiety, and acute stress secondary to a recent arrest for possession and cultivation of marijuana. Respondent's records include a one page document entitled "Mental Status" on which he recorded a diagnostic impression included of Dysthymic Disorder on Axis I and Acute Post Traumatic

Stress Disorder on Axis III.

B. Respondent was interviewed regarding J.B. and, although it is not charted, indicated that Patient J.B. had a history of alcoholism, was paranoid and abusive and was "categorically opposed to any chemicals." Respondent also recalled that the patient had additional, unrecorded, symptoms, including nausea, vomiting and diarrhea.

C. On August 9, 1997, respondent issued a "physician's statement" in which he stated that Patient J.B. was under his medical care and supervision for the treatment of medical conditions designated as Post Traumatic Stress Disorder and Dysthymic Disorder.

17. Respondent's conduct, as described above, constitutes unprofessional conduct and represents extreme and/or simple departures from the standard of care, and/or acts of incompetence in that respondent committed errors and omissions in the care and treatment of Patient J.B., including but not limited to the following::

A. Respondent conducted an inadequate evaluation of Patient J.B.'s symptoms of depression, anxiety and panic attacks;

B. Respondent arrived at diagnoses of post traumatic stress disorder and dysthymic disorder without conducting a documented clinical evaluation;

C. Respondent failed to offer Patient J.B. standard psychiatric treatment for her condition;

D. Respondent failed to provide follow up care for Patient J.B.'s complaints.

FOURTH CAUSE FOR DISCIPLINARY ACTION

(Patient J.M.B.)

(Unprofessional Conduct/Gross Negligence/Negligence/Incompetence)

18. Respondent is subject to disciplinary action under sections 2234, and/or 2234(b) and/or 2234(c), and/or 2234(d) of the Code in that respondent committed unprofessional conduct, and/or was grossly and/or simply negligent and/or incompetent in the care and treatment of Patient J.M.B.. The circumstances are as follows:

1 ///

2 A. On or about December 30, 1998, Patient J.M.B., a 26 year old male,
3 presented with a history of multiple cervical and thoracic spinal fractures alleged
4 to have been sustained in prior accidents. The patient reported that he was taking
5 multiple, prescribed, controlled substances for his back condition. He also
6 reported that he had been arrested and was facing prosecution for possession and
7 cultivation of marijuana. Patient J.M.B. requested a recommendation for the use
8 of marijuana. Respondent's records contain no vital signs, physical examination
9 or other medical evaluation of the patient's spinal complaints. On the same day,
10 respondent issued a "physician's certificate" which states that Patient J.M.B. is
11 under respondent's medical care and supervision for the treatment of
12 intervertebral disk disease.

13 B. On June 22, 1999, respondent issued a "physician's statement" to Patient
14 J.M.B., reiterating that J.M.B. was under respondent's medical care and
15 supervision for the treatment of intervertebral disk disease. There is no record
16 that respondent re-evaluated J.M.B. on this date, nor is there any evidence that
17 respondent obtained an interval history from the patient. Respondent's records
18 indicate that J.M.B. was incarcerated in September, 1999, and that it was reported
19 to respondent that J.M.B. was "bragging to other prisoners get letter from"
20 respondent. At his interview, respondent recalled that J.M.B. desired a marijuana
21 recommendation that would allow its use while incarcerated.

22 19. Respondent's conduct, as described above, constitutes unprofessional
23 conduct and represents extreme and/or simple departures from the standard of care, and/or acts
24 of incompetence in that respondent committed errors and omissions in the care and treatment of
25 Patient J.M.B., including but not limited to the following:

26 A. Respondent failed to evaluate J.M.B. for intervertebral disk disease and
27 arrived at a diagnosis without performing appropriate medical work up;

28 B. Respondent renewed the patient's recommendation without interval

history or re-evaluation;

C. Respondent's statement that J.M.B. was under his medical care and supervision for intervertebral disk disease was false and unethical.

FIFTH CAUSE FOR DISCIPLINARY ACTION

(Patient R.B.)

(Unprofessional Conduct/Gross Negligence/Negligence/Incompetence)

20. Respondent is subject to disciplinary action under sections 2234, and/or 2234(b) and/or 2234(c), and/or 2234(d) of the Code in that respondent committed unprofessional conduct, and/or was grossly and/or simply negligent and/or incompetent in the care and treatment of Patient R.B.. The circumstances are as follows:

A. On May 21, 1999, Patient R.B., a 27 year old male, presented to respondent with complaints of nausea and dizziness. Respondent made diagnoses of nausea and alcohol-related gastritis. There is no record of a history, physical examination or other appropriate methods by which to arrive at a medical diagnosis. No vital signs are recorded and no laboratory tests are ordered to investigate the patient's potentially serious symptoms. The patient was not seen again by respondent. On January 27, 2000, Patient R.B. advised that he had been arrested and charged with possession and cultivation and requested that respondent "furnish a letter confirming my use of Marijuana to control my sympton [sic] of Psychogenic Nausea and Gastritis Dyspepsia."

21. Respondent's conduct, as described above, constitutes unprofessional conduct and represents extreme and/or simple departures from the standard of care, and/or acts of incompetence in that respondent committed errors and omissions in the care and treatment of Patient R.B., including but not limited to the following:

A. Respondent diagnosed the patient with nausea and gastritis without taking a history, performing a physical evaluation, recording vital signs or ordering laboratory tests.

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SIXTH CAUSE FOR DISCIPLINARY ACTION

(Patient D.B.)

(Unprofessional Conduct/Gross Negligence/Negligence/Incompetence)

22. Respondent is subject to disciplinary action under sections 2234, and/or 2234(b) and/or 2234(c), and/or 2234(d) of the Code in that respondent committed unprofessional conduct, and/or was grossly and/or simply negligent and/or incompetent in the care and treatment of Patient D.B. The circumstances are as follows:

A. On June 26, 1998, Patient D.B., a 20 year old male, presented with a history of cerebral palsy since birth and post-traumatic arthritis "after a car wreck." No physical examination is recorded, no vital signs are noted. A release signed by the patient for the records of an Oregon physician was provided, but the records were not obtained. On June 27, 1998, respondent provided D.B. with a "physician's statement" which states that D.B. is under respondent's medical care and supervision for the treatment of cerebral palsy and post-traumatic arthritis.

B. On October 9, 1998, D.B. advised by telephone that he had been arrested for trespassing and that officers had confiscated 4-5 grams of marijuana. D.B. requested that respondent verify his status as a medical marijuana user and respondent did so for a charge of $100.00. D.B. was not re-examined at that time, but respondent relayed to law enforcement that D.B. suffered increased insomnia after his arrest.

C. On January 21, 2000, Patient D.B. submitted a follow up questionnaire. The reason for the contact was stated to be that the patient had "funds to contact" respondent. No physical examination is recorded. Respondent's comments on the questionnaire state only that the efficacy of treatment is "good" and that the patient is "now on probation but growing." The patient sent respondent a money order for $120.00 on January 29, 2000, and on February 14, 2000, respondent provided a "physician's statement" that states that Patient D.B. "is under my medical care and

supervision for treatment of the serious medical conditions: Cerebral Palsy, Traumatic Arthritis."

23. Respondent's conduct, as described above, constitutes unprofessional conduct and represents extreme and/or simple departures from the standard of care, and/or acts of incompetence in that respondent committed errors and omissions in the care and treatment of Patient D.B., including but not limited to the following:

A. Respondent recommended treatment to the patient without conducting a physical examination;

B. Respondent obtained a release from the patient for his medical records, but failed to obtain and/or document review of the records;

C. Respondent failed to provide follow up or referral for the patient's complaints;

D. Respondent charged for renewal of the patient's recommendation albeit no examination was performed;

E. Respondent's statement that D.B. was under his medical care and supervision for cerebral palsy and traumatic arthritis was false and unethical.

SEVENTH CAUSE FOR DISCIPLINARY ACTION

(Patient K.J.B.)

(Unprofessional Conduct/Gross Negligence/Negligence/Incompetence)

24. Respondent is subject to disciplinary action under sections 2234, and/or 2234(b) and/or 2234(c), and/or 2234(d) of the Code in that respondent committed unprofessional conduct, and/or was grossly and/or simply negligent and/or incompetent in the care and treatment of Patient K.J.B. The circumstances are as follows:

A. On August 24, 1998, Patient K.J.B., a 42 year old male, presented with complaints of muscle spasm which he attributed to a 1992 motor vehicle accident and resulting lumbosacral sprain. The patient reported that he was being prescribed Valium and Ultram, but was not taking the Ultram. There is no record of a physical examination of the patient by respondent, nor is there a proposed

treatment plan or plan for follow up noted on the 4 page "registration form." Respondent issued a "physician's statement", dated August 24, 1998, in which respondent stated that K.J.B. "is under my medical care and supervision for the treatment of medical condition(s): Lumbosacral Disease."

B. On September 20, 1999, Patient K.J.B. completed a "follow up visit questionnaire" to which he appended a one page document entitled "Beck's Inventory for Depression." That 21 page inventory is used by medical practitioners to assess the severity of a patient's depression. Patient K.J.B.'s inventory contained endorsements of multiple statements indicating a significant level of depression. The patient also submitted a January 21, 1999 form on which another physician certified that drug/alcohol treatment was medically necessary for K.J.B. and a form that K.J.B. had completed on which he indicated that he had suffered from depression, insomnia, weigh loss, cannabis addiction and back pain. There is no recorded assessment by respondent of the patient's multiple complaints. No plan for treatment or follow up for the patient's depression and back pain is set forth, except for a check mark in the box indicating follow up in "6-12 months."

C. On or about June 17, 2001, Patient K.J.B. submitted a follow up questionnaire in which he stated that he continued to suffer from recurrent depression and lumbosacral pain. Patient K.J.B. indicated that his marijuana use was 28-56 grams per week and, although this represented a marked increase in usage since the initial report of 3.5 grams per week in 1998, there is no inquiry noted in respondent's records. Respondent recommended regular massage and noted the efficacy of treatment as "very good."

25. Respondent's conduct, as described above, constitutes unprofessional conduct and represents extreme and/or simple departures from the standard of care, and/or acts of incompetence in that respondent committed errors and omissions in the care and treatment of Patient K.J.B., including but not limited to the following:

A. Respondent failed to conduct a physical examination of Patient K.J.B. before recommending treatment;

B. Respondent failed to conduct an evaluation of the patient's depression;

C. Respondent failed to re-evaluate the patient in light of the patient's continuing depression or to consider alternative treatments for the patient's recurrent depression;

D. Respondent's statement that K.J.B. was under respondent's medical care and treatment for lumbosacral disease was false and unethical.

EIGHTH CAUSE FOR DISCIPLINARY ACTION

(Patient J.C.)

(Unprofessional Conduct/Gross Negligence/Negligence/Incompetence)

26 Respondent is subject to disciplinary action under sections 2234, and/or 2234(b) and/or 2234(c), and/or 2234(d) of the Code in that respondent committed unprofessional conduct, and/or was grossly and/or simply negligent and/or incompetent in the care and treatment of Patient J.C.. The circumstances are as follows:

A. On December 11, 1998, Patient J.C., an 18 year old female, presented with complaints of anorexia. J.C. stated that she was in court-ordered drug diversion, was six months pregnant (Expected Due Date: 3/31/99) and used marijuana to keep food down. Donnatal and over-the-counter medications were reported by her to be ineffective.

B. Respondent failed to note the patient's height, weight or vital signs. No history relevant to the patient's anorexia is set forth. No history or mental status examination relevant to a diagnosis of prolonged traumatic stress disorder is taken. Although the patient reported that she was pregnant, respondent failed to inquire whether she had a treating Ob/Gyn and/or to consult with that physician before recommending treatment. There is no record of discussion of the relative risks and benefits of marijuana use and, although he had prescribed Marinol to other patients, he did not consider this potentially less risky alternative to smoked marijuana for J.C.

C. Respondent issued a "physician's statement" in which he stated that the patient was under his care and treatment for anorexia and prolonged traumatic stress disorder.

D. A note dated January 1, 1999, states that the patient's symptoms of nausea are well controlled and that she is undergoing prenatal testing.

27. Respondent's conduct, as described above, constitutes unprofessional conduct and represents extreme and/or simple departures from the standard of care, and/or acts of incompetence in that respondent committed errors and omissions in the care and treatment of Patient J.C., including but not limited to the following:

A. Respondent failed to adequately evaluate Patient J.C.'s reported anorexia;

B. Respondent failed to work up Patient J.C. prior to arriving at a diagnosis of prolonged traumatic stress disorder;

C. Respondent failed to contact the patient's treating Ob/Gyn;

D. Respondent failed to consider alternatives to smoked marijuana for this pregnant patient, including Marinol;

NINTH CAUSE FOR DISCIPLINARY ACTION

(Patient S.F.)

(Unprofessional Conduct/Gross Negligence/Negligence/Incompetence)

28 Respondent is subject to disciplinary action under sections 2234, and/or 2234(b) and/or 2234(c), and/or 2234(d) of the Code in that respondent committed unprofessional conduct, and/or was grossly and/or simply negligent and/or incompetent in the care and treatment of Patient S.F. The circumstances are as follows:

A. On March 18, 1999, Patient S.F., a 16 year old female, presented with multiple complaints: Migraine headaches, status post head injury, depression, painful premenstrual cramps, status post TAB. The patient gave a history of having been hit with a stick, as a result of the battery she stated that she suffered from recurring headaches. She also reported that she had a history which included stress and "flipping out." Respondent made a note that the pain was left sided and that there

was visual blurring. There is no recorded history regarding the headaches, no physical examination, no mental status examination and no charted vital signs.

B. On March 18, 1999, respondent issued a "physician's statement" that indicated that Patient S.F. "is under my medical care and supervision for the treatment of medical condition(s): Migraine headache, premenstrual syndrome."

29. Respondent's conduct, as described above, constitutes unprofessional conduct and represents extreme and/or simple departures from the standard of care, and/or acts of incompetence in that respondent committed errors and omissions in the care and treatment of Patient S.F., including but not limited to the following:

A. Respondent failed to adequately work up the etiology and nature of S.F.'s headaches;

B. Respondent failed to address the patient's stress and depression and failed to make a counseling or psychotherapy referral;

C. Respondent failed to evaluate the patient's complaints of painful premenstrual cramps and failed to make an ob/gyn referral for S.F.;

D. Respondent failed to evaluate S.F.'s head injury;

E. Respondent's statement that S.F. was under his medical care and supervision for treatment of migraine headaches and premenstrual syndrome was false and unethical.

TENTH CAUSE FOR DISCIPLINARY ACTION

(Patient D.H.)

(Unprofessional Conduct/Gross Negligence/Negligence/Incompetence)

30. Respondent is subject to disciplinary action under sections 2234, and/or 2234(b) and/or 2234(c), and/or 2234(d) of the Code in that respondent committed unprofessional conduct, and/or was grossly and/or simply negligent and/or incompetent in the care and treatment of Patient D.H. The circumstances are as follows:

A. On April 30, 1999, Patient D.H., a 36 year old female, presented with complaints of very painful headaches, as well as neck and shoulder pain. The latter

complaint was said to increase with stress. The patient reported that she had been prescribed Anaprox and Lodine, which are anti-inflammatory medications, and Norflex, which is an analgesic, for her musculoskeletal complaints. The prescriptions had "expired" and Patient D.H.'s physician did not renew them. D.H. was also treating with a chiropractor. D.H.'s self-reported history, as set forth on the 6 page questionnaire, did not reference complaints of pruritus (itching) or anxiety.

B. Respondent's records contain no record of physical examination, vital signs, mental status examination or other work up of the patient's complaints. Respondent recommended that the patient receive massages and issued a "physician's statement" in which he represented that D.H. was under his medical care and supervision for the treatment of tension headaches, pruritus and anxiety.

31. Respondent's conduct, as described above, constitutes unprofessional conduct and represents extreme and/or simple departures from the standard of care, and/or acts of incompetence in that respondent committed errors and omissions in the care and treatment of Patient D.H.., including but not limited to the following:

A. Respondent failed to evaluate Patient D.H.'s complaints of headaches and, aside from recommending the patient's use of marijuana, failed to develop a treatment plan for her;

B. Respondent failed to document and evaluate Patient D.H.'s complaints of pruritus and, aside from recommending the patient's use of marijuana, failed to develop a treatment plan for her;

C. Respondent failed to document and evaluate Patient D.H.'s complaints of anxiety and, aside from recommending the patient's use of marijuana, failed to develop a treatment plan for her;

D. Respondent's statement that D.H. was under his medical care and supervision for treatment of headaches, pruritus and anxiety was false and unethical.

ELEVENTH CAUSE FOR DISCIPLINARY ACTION

(Patient J.K.)

(Unprofessional Conduct/Gross Negligence/Negligence/Incompetence)

32. Respondent is subject to disciplinary action under sections 2234, and/or 2234(b) and/or 2234(c), and/or 2234(d) of the Code in that respondent committed unprofessional conduct, and/or was grossly and/or simply negligent and/or incompetent in the care and treatment of Patient J.K. The circumstances are as follows:

A. On or about July 23, 1999, Patient J.K., a 37 year old male, presented with complaints of "dysthemic [sic] disorder" and "steel pin in leg." Patient J.K. reported that he had previously been prescribed Trazadone and Zyrtec for his condition. His 6 page questionnaire, which is dated June 27, 1999, states that J.K. had been disabled since 1986. The patient's questionnaire also indicates that he was on parole after conviction of a felony, i.e., possession of marijuana for sale.

B. Respondent's records contain no record of psychiatric history, physical examination, vital signs, mental status examination or other work up of the patient's complaints. Respondent noted that a decrease in sleep and appetite were related to J.K.'s depression, but there is no indication of the length or severity of these symptoms. Neither J.K.'s height nor weight are noted. Respondent recommended that the patient discontinue his alcohol consumption, the extent of which is not specified, and issued a "physician's statement" in which he represented that Patient D.H. was under his medical care and supervision for "Post Traumatic Stress Disorder and Traumatic Arthritis."

33. Respondent's conduct, as described above, constitutes unprofessional conduct and represents extreme and/or simple departures from the standard of care, and/or acts of incompetence in that respondent committed errors and omissions in the care and treatment of Patient J.K., including but not limited to the following:

A. Respondent failed to evaluate Patient J.K.'s reported depression by obtaining a psychiatric history and mental status examination;

B. Respondent diagnosed Patient J.K. with post traumatic stress disorder without specifying any of the symptoms or criteria requisite to that diagnosis;

C. Respondent failed to evaluate Patient J.K. for traumatic arthritis by appropriate history and examination;

D. Respondent's statement that J.K. was under his medical care and supervision for treatment of post traumatic stress disorder and traumatic arthritis was false and unethical.

TWELFTH CAUSE FOR DISCIPLINARY ACTION

(Patient D.K.)

(Unprofessional Conduct/Gross Negligence/Negligence/Incompetence)

34. Respondent is subject to disciplinary action under sections 2234, and/or 2234(b) and/or 2234(c), and/or 2234(d) of the Code in that respondent committed unprofessional conduct, and/or was grossly and/or simply negligent and/or incompetent in the care and treatment of Patient D.K. The circumstances are as follows:

A. On June 27, 1998, Patient D.K., a 53 year old female, presented to respondent with a reported history of a stroke secondary to birth control pills at age 21 and tobacco dependence. Patient D.K.'s family history included the fact that her mother had died of a cerebral hemorrhage in her early 60's. D.K. stated that she was abstinent from tobacco for one year prior, but a smoking history is not set forth in respondent's records. There is no record of physical examination, mental status examination or other work up for either brain trauma or nicotine dependence. Although Patient D.K. gave respondent a release for her medical records from a neurosurgeon in San Mateo County, the records were not obtained and reviewed.

B. On June 27, 1998, respondent issued a "physician's statement" in which he

represented that Patient D.K. was under his medical care and supervision for brain trauma and nicotine dependence.

C. On July 24, 1999, Patient D.K. completed a 2 page patient questionnaire. In response to a check-the-box inquiry regarding "illness status" the patient

checked the box indicating that she was "improved." It cannot be determined from the response whether one or both conditions had improved. No physical or mental status examination is recorded. Respondent's only comments on the patient's status are a checked box indicating "good" efficacy of treatment and a remark that the patient discontinued tobacco use June 1, 1999.

D. On July 28, 2000, Patient D.K. completed a 2 page questionnaire and sent it to respondent via facsimile. Respondent's only comments on the patient's status are a checked box indicating "good" efficacy of treatment and a remark that the patient discontinued nicotine use June 1, 1999 and had been abstinent one year.

E. On August 10, 2000, respondent issued a "physician's statement" in which he represented that Patient D.K. was under his medical care and supervision for brain trauma and nicotine dependence. A note on the document indicates that it was "sent 8/16/00."

35. Respondent's conduct, as described above, constitutes unprofessional conduct and represents extreme and/or simple departures from the standard of care, and/or acts of incompetence in that respondent committed errors and omissions in the care and treatment of Patient D.K., including but not limited to the following::

A. Respondent failed to evaluate Patient D.K.'s brain injury, failed to establish a diagnosis of the patient's condition and failed to develop an appropriate treatment plan;

B. Respondent failed to evaluate the patient's nicotine dependency;

C. Respondent failed to document a tobacco smoking history for Patient D.K.;

D. Respondent failed to conduct appropriate follow up evaluation for Patient D.K.'s condition;

E. Respondent charged Patient D.K. for medication renewal albeit the patient was not re-examined by him.

F. Respondent's statement that D.K. was under his medical care and supervision for brain trauma and nicotine dependence was false and unethical.

THIRTEENTH CAUSE FOR DISCIPLINARY ACTION

(Patient E.K.)

(Unprofessional Conduct/Gross Negligence/Negligence/Incompetence)

36. Respondent is subject to disciplinary action under sections 2234, and/or 2234(b) and/or 2234(c), and/or 2234(d) of the Code in that respondent committed unprofessional conduct, and/or was grossly and/or simply negligent and/or incompetent in the care and treatment of Patient E.K. The circumstances are as follows:

A. On February 17, 1997, Patient E.K., a 49 year old male, presented with complaints of insomnia and back pain. The patient reported that his back pain was secondary to scoliosis and that he had been rated 4F as unfit for the military for that reason. Patient E.K. gave a history of hypertension since 1956 (age 6) and a "bad back" since 1966 (age 18). Patient E.K. dated his marijuana usage to 1965 (age 17), when he discovered that it relieved back pain. Respondent did perform a mental status examination, after which he made an Axis I diagnosis of adjustment reaction with depressed mood and an Axis III diagnosis of scoliosis, recurrent pain and muscle spasm. No physical examination is documented and no vital signs are recorded. Patient E.K. advised that he had served two years in a federal prison on marijuana charges and was on probation. A condition of E.K.'s probation was urinalysis and marijuana was causing positive urinalysis results. Respondent prescribed Marinol, 10 g., #30.

B. On March 17, 1999, Patient E.K. filled out a 1 page follow up questionnaire in which he stated that he wished to replace Marinol – which was described as having "worked" -- with crude marijuana. The patient described the conditions for which he used marijuana as "sleep, hypertension, blood pressure, blood sugar, eating." It is noted on the form that a $120.00 fee was "received" after the date of

the follow up questionnaire. E.K. reported using 25 grams of marijuana per week, with a frequency of eight times per day. Respondent noted that the patient was sleeping better, his moods were better and he had 50 days of probation left.

C. On March 13, 2000, a 1 page follow up questionnaire was completed by Patient E.K. The patient stated that his last visit (March 17, 1999) had not been a face-to-face meeting. E.K.'s complaints were extreme anxiety, insomnia (stated to be controlled with unspecified medications), blood sugar and pressure fluctuations. E.K. indicated that he used marijuana seven times per day and that his use was now up to 42 grams per week. The patient stated that he was then facing charges of marijuana cultivation in Nevada County.

D. On March 23, 2000, respondent issued a "physician's statement" in which he represented that E.K. "is under my medical care and supervision for anxiety disorder, insomnia, essential hypertension."

E. On March 8, 2001, Patient E.K. completed a follow up questionnaire in which he lists his symptoms as anxiety and insomnia. The patient stated that his last follow up (March 2000) was conducted by telephone. E.K. reported using marijuana seven or eight times per day and that his use was now 84 grams per week. There is no charted inquiry into the trebling of the patient's marijuana use. No physical examination, mental status examination or interval history is recorded. Respondent recorded that the patient had been convicted of felony marijuana possession in Nevada County. Efficacy of treatment was stated to be "good."

F. On March 14, 2001, respondent issued a "physician's statement" in which he represented that E.K. "is under my medical care and supervision" for treatment of anxiety disorder and insomnia.

37. Respondent's conduct, as described above, constitutes unprofessional conduct and represents extreme and/or simple departures from the standard of care, and/or acts of incompetence in that respondent committed errors and omissions in the care and treatment of Patient E.K., including but not limited to the following::

A. Respondent failed to evaluate Patient E.K.'s hypertension;

B. Respondent failed to evaluate Patient E.K.'s complaints of anxiety and insomnia;

C. Respondent failed to evaluate Patient E.K.'s complaints of fluctuating blood sugar;

D. Respondent's statement that E.K. was under his medical care and supervision for treatment of anxiety disorder, insomnia and essential hypertension was false and unethical;

E. Respondent dropped his diagnosis of essential hypertension without documenting normalization of the patient's blood pressure.

F. Respondent charged for medication renewal albeit the patient was not re-examined by him.

FOURTEENTH CAUSE FOR DISCIPLINARY ACTION

(Patient F.K.)

(Unprofessional Conduct/Gross Negligence/Negligence/Incompetence)

38. Respondent is subject to disciplinary action under sections 2234, and/or 2234(b) and/or 2234(c), and/or 2234(d) of the Code in that respondent committed unprofessional conduct, and/or was grossly and/or simply negligent and/or incompetent in the care and treatment of Patient F.K. The circumstances are as follows:

A. On or about June 30, 1997 Patient F.K. first consulted respondent. Respondent's record that day includes a four page "registration form", a one page typed summary of F.K.'s demographic information and cannabis use pattern and a "physician's statement." Respondent's diagnosis for F.K. was thoracic or lumbosacral neuritis or radiculitus, unspecified and alcohol dependence syndrome, unspecified. Respondent's history of the alcohol problem stated only "3 glasses of wine/wk, work." Respondent conducted no mental status examination, no adequate medical, psychiatric or substance history, no physical examination to evaluate the lumbosacral problem and no treatment plan except "D/C ETOH[alcohol] NSAIDS

vaporize 360°F F/U 6 mo-1 yr." On June 30, 1997 respondent issued F.K. a "physician's statement" that stated in part "This certifies that F.K. ...is under my medical care and supervision for the treatment of medical conditions(s): Alcoholism, Lumbosacral Radiculitis ICD9-CM 309.0 [Brief depressive reaction] (sic) 724.4 [thoracic or lumbosacral neuritis or radiculitis, unspecified]."

B. Respondent's records contain a "Physician's Statement", which is dated March 5, 1998, but not any documented evaluation or other chart notes. The diagnoses are the same as for June 30, 1997. Respondent's chart reflects another "physician's statement" on November 24, 1998, similar to those issued previously. There are no notes documenting any evaluation substantiating the November 24, 1998 physician's statement.

C. Respondent's chart contains a May 23, 2000 one page "Cannabis Patient Follow Up Questionnaire" apparently filled out by Patient F.K. The patient indicates that his previous consultation of November 24, 1998, was not a face-to-face meeting. The only notation made by respondent for the May 23 "follow up" are the words "well controlled" in reference to the alcoholism. A subsequent note, dated September 28, 2000, indicates that respondent received $120.00 for this medication renewal. Respondent's next contact with F.K. appears to be another "Cannabis Patient Follow Up Visit Questionnaire" dated July 25, 2001, wherein the only notations by respondent include ICD-9 codes, a check mark in the box indicating follow-up in 6-12 months and "VRIPTECH.COM" under the hearing "progress notes." At the bottom of the form are the words "return form and requested fee to the address on reverse side." A "Physician's Statement" of July 25, 2001 is almost identical to those issued to F.K. previously, with the same diagnoses stated. Past medical records dated 1996 and 1997 from a chiropractor and documents from the Social Security Administration documenting F.K.'s lumbosacral problem are part of the record.

39. Respondent's conduct, as described above, constitutes unprofessional conduct and

represents extreme and/or simple departures from the standard of care, and/or acts of incompetence in that respondent committed errors and omissions in the care and treatment of Patient F.K., including but not limited to the following:

A. Respondent failed to adequately evaluate or to substantiate F.K.'s reported substance abuse problem prior to issuing a diagnosis of alcoholism.

B. Respondent failed to formulate a treatment plan for F.K.'s alcoholism.

C. Respondent failed to conduct an adequate mental status or physical examination of Patient F.K.

D. Respondent charged for medication renewal albeit he did not conduct an examination of the patient.

FIFTEENTH CAUSE FOR DISCIPLINARY ACTION

(Patient R.H.)

(Unprofessional Conduct/Gross Negligence/Negligence/Incompetence)

40. Respondent is subject to disciplinary action under sections 2234, and/or 2234(b) and/or 2234(c), and/or 2234(d) of the Code in that respondent committed unprofessional conduct, and/or was grossly and/or simply negligent and/or incompetent in the care and treatment of Patient R.H. The circumstances are as follows:

A. On March 26, 1998, Patient R.H., a 50 year old male, presented to respondent with a history of alcoholism and alcohol-related cerebellar ataxia, peripheral neuropathies and spastic dysphonia. R.H. provided respondent with documents relating to a 1990 neurologic evaluation and a work readiness assessment, which records indicated that R.H.'s alcoholism rendered him disabled as of 1988. Respondent prepared a "psychiatric report and examination" and a "mental status" examination, after which he diagnosed R.H. with alcoholism, recovering, on Axis I and cerebellar ataxia and insomnia on Axis III. There is no documentation of a physical examination at that time. Respondent determined that Patient R.H. would benefit from the use of marijuana and issued a recommendation that Patient R.H. use cannabis for the treatment of "alcoholic encephalopathy, recovering alcoholic,

insomnia, post traumatic arthritis."

B. Patient R.H. was charged with violation of the terms of his court probation and on July 22, 1998, respondent provided a letter to "reconfirm the recommendation and approval for the use of cannabis for the treatment of chronic alcoholism with encephalopathy, persisten [sic] insomnia, and posttraumatic arthritis."

C. On September 18, 1998, Patient R.H. responded to a second questionnaire, reiterating his complaints of brain damage, insomnia and arthritis. There is no documentation of a physical examination. On the same day, respondent testified in Tuolumne County Superior Court in R.H.'s criminal matter. At that time, respondent admitted that he had performed no physical examination of R.H., other than observing his gait, which he said indicated cerebellar atrophy, and listening to his voice, which he said indicated vocal cord paralysis.

D. On April 16, 2001, Patient R.H. submitted a follow up questionnaire to respondent in which he indicated that his complaints of cerebellar ataxia, post traumatic arthritis and insomnia were continuing. Patient R.H. also indicated that he consumed 8-10 cups of coffee per day. This questionnaire was presented either by fax or by mail, as indicated by R.H.'s April 17 letter to respondent: "Thanks for the understanding. There's no way I can drive 240 miles round trip and pay the $120.00." Respondent did not comment on the patient's reported caffeine use and there is no documentation of an attempt to evaluate the behavioral causes of R.H.'s chronic insomnia. As on prior occasions, there is no indication of respondent's rationale in recommending use of a psychoactive drug for Patient R.H.'s post traumatic arthritis. On May 3, 2001, respondent issued a "physician's statement" in which he stated that R.H. "Is under my medical care and supervision for treatment of the serious medical condition(s): Insomnia, Traumatic Arthritis, Brain Injury."

41. Respondent's conduct, as described above, constitutes unprofessional conduct and represents extreme and/or simple departures from the standard of care, and/or acts of incompetence in that respondent committed errors and omissions in the care and treatment of Patient

R.H. including but not limited to the following::

A. Respondent failed to evaluate Patient R.H.'s complaints of insomnia or to employ standard behavioral treatment for its underlying causes;

B. Respondent failed to evaluate Patient R.H.'s arthritis or to document a medical rationale for recommendation of treatment with a psychoactive drug;

C. Respondent's statement that R.H. was under his medical care and supervision for treatment of post traumatic arthritis and chronic insomnia were false and unethical.

SIXTEENTH CAUSE FOR DISCIPLINARY ACTION

(Patient W.H.)

(Unprofessional Conduct/Gross Negligence/Negligence/Incompetence)

42. Respondent is subject to disciplinary action under sections 2234, and/or 2234(b) and/or 2234(c), and/or 2234(d) of the Code in that respondent committed unprofessional conduct, and/or was grossly and/or simply negligent and/or incompetent in the care and treatment of Patient W.H. The circumstances are as follows:

A. At some time prior to November 1, 1998, a conservator for W.H., a 58 year old man with Multiple Sclerosis, contacted respondent and asked respondent to visit W.H. for the purpose of obtaining recommendations for the use of marijuana for medical purposes. W.H. was quadriplegic and experienced muscle spasms as a result of his M.S. W.H. was bedridden and relied upon the care of his conservator and other caretakers. W.H. was capable of speech and was mentally coherent. W.H. was taking Baclofen and Ativan, but was not under the regular care of a physician.

B. On or about November 1, 1998, respondent went to W.H.'s home where he met with W.H.'s conservator. Respondent saw W.H. for a total of approximately 5 minutes. Respondent's physical examination of W.H. was described by respondent as "I looked at him and there he was lying in bed...He looked relatively comfortable...He appeared to be clean and appeared to be well-cared for, but again, I didn't lift the covers." Similarly, respondent performed no mental status

examination of W.H. and obtained virtually no medical or psychiatric history from or about W.H. Respondent made no attempt to speak with W.H., and had no discussion with W.H. regarding the possible risks or benefits of marijuana use. Respondent's complete medical record for W.H. consists of an "eligibility questionnaire", only partially completed by respondent, and several pages of medical records from other practitioners provided to respondent by the conservator. Respondent provided the conservator with a recommendation for W.H. to use marijuana for medical purposes[2]. In that recommendation, respondent represented that W.H. was under his medical care and supervision for the treatment of Multiple Sclerosis, and that respondent had discussed the medical risks and benefits of cannabis use with W.H. Respondent made no arrangements to see W.H. in the future, nor did he provide a treatment plan. In fact, W.H. had no desire to use marijuana for any purpose, had never used marijuana, an was unaware that respondent had recommended marijuana for his use.

43. Respondent's conduct, as described above, constitutes unprofessional conduct and represents extreme and/or simple departures from the standard of care, and/or acts of incompetence in that respondent committed errors and omissions in the care and treatment of Patient W.H. including but not limited to the following::

A. Respondent failed to adequately evaluate W.H.'s mental status;

B. Respondent failed to adequately evaluate W.H.'s purported complaints of pain and/or muscle spasms.

C. Respondent failed to evaluate the efficacy of W.H.'s current medication regimen.

D. Respondent failed to discuss the risks associated with marijuana and failed to address alternate treatments available to W.H.

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2. The conservator was removed from his position after it was discovered that he was stealing money from W.H. Moreover, on the same visit, respondent also issued a recommendation for the conservator's use of marijuana.

E. Respondent failed to schedule a follow-up appointment for W.H. at an appropriate interval.

F. Respondent's statement that W.H. was under his medical care and supervision for treatment of Multiple Sclerosis, and that respondent had discussed the medical risks and benefits of cannabis use with W.H. was false and unethical.

SEVENTEENTH CAUSE FOR DISCIPLINARY ACTION

(Undercover officer)

(Unprofessional Conduct/Gross Negligence/Incompetence/Dishonest or Corrupt Acts)

46. Respondent is subject to disciplinary action under sections 2234, and/or 2234(b) and/or 2234(c), and/or section 2234(d), and/or 2234(e) of the Code in that respondent committed unprofessional conduct, and/or was grossly negligent, and/or simply negligent, and/or incompetent, and/or committed acts of dishonesty or corruption, in his interactions with and care and treatment of an undercover narcotics officer. The circumstances are as follows:

A. In or about January 2003, an undercover officer associated with the Sonoma County Narcotic Task Force received information suggesting that he could obtain a recommendation for medical marijuana from a physician by simply appearing at an office with $200 cash and a California driver's license or identification card. The officer made a telephone call to a telephone number he obtained, and scheduled an appointment to see an unknown physician on January 31, 2003.

B. On January 31, 2003, the officer went to 353 30th Street in Oakland for his scheduled appointment. Signage on the office and the recording on the telephone number identified the address as "Medical Referral Services 215." The officer observed a number of people in the outer office, and they appeared to be registering for appointments. By 10 a.m. there were approximately 30 people waiting to see the doctor. An individual who identified himself as "Ben" announced that only 15 people could see the doctor on that date, but that the

remaining people could pay a $50 deposit and would be placed on a "medical priority" list for the following week. The undercover officer paid a $50 deposit and obtained a "medical priority"appointment for February 7, 2003.

C. On February 7, 2003, the officer returned to 353 30th Street, Oakland. He was advised by a female handling the sign-in sheet that he would be seen by the doctor, that he needed to pay an additional $150 cash, and to fill out some paperwork. She then provided the officer with a questionnaire form and a blank "Physician's Statement" form bearing respondent's name and license number. The officer was instructed to complete the questionnaire, except for the section regarding his current medical condition. He was advised that "Ben" would help everyone with that section. The officer was also instructed that the doctor would complete the top portion of the "Physician's Statement" form.

D. The officer completed his questionnaire form, which was then reviewed by "Ben". The officer had indicated that the reason for his visit was that he was unable to sleep due to stress, and that his shoulder hurt. He stated that his stress was due to a pending criminal case involving 54 grams of marijuana, and that he needed a medical recommendation so that the District Attorney would dismiss the criminal charges. "Ben" stated that stress and sleep would be difficult to use as a primary reason for using marijuana, but would be good "secondary" reasons. "Ben" then asked the officer about his shoulder problem, and the officer responded that his shoulder hurt sometimes. He stated that he could move the shoulder, and pointed generally to an area he said hurt. "Ben" then stated that he knew exactly what the officer was talking about, that the officer had dislocated his shoulder at one time and it still hurt. He told the officer to write down that the dislocated shoulder caused anxiety and inability to sleep, and that a friend had suggested marijuana. "Ben" told the officer that he would get "all legal today."

E. The officer proceeded to an inner room, where respondent introduced himself. Respondent reviewed the questionnaire, and asked several questions

about his family health history. In response to respondent's question about his current medical condition, the officer stated that he was stressed about his pending criminal case. The officer told respondent he had injured his shoulder 4-5 years ago, that he had not seen any doctor about the shoulder, that he did not have a regular doctor, and that he had not worked in several years. Respondent suggested that the officer should consider physical therapy. The officer spent approximately 10 minutes in respondent's office. Respondent conducted absolutely no physical examination of the officer, and made no arrangements or suggestion regarding follow-up visits or a treatment plan. He did not discuss the benefits and risks of marijuana with the officer. Respondent simply took a photograph of the officer, checked his driver's license and signed a physician's statement recommending the use of marijuana.

F. When the officer returned to the waiting room, "Ben" told him he was "all legal". He advised everyone in the waiting room to go to the Oakland Cannabis Buyers' Cooperative to get a card, and that they could grow marijuana for sale to the various marijuana "Clubs". "Ben" also announced that there was a "special treat" for everyone, after which the officer was sent to another room where he was given a small plastic container containing approximately 1.2 grams of marijuana by an unidentified female who stated that she was a representative of the Oakland Community Health & Wellness Collective, and that he could purchase his marijuana from that organization.

47. Respondent's conduct, as described above, constitutes unprofessional conduct and represents extreme and/or simple departures from the standard of care, and/or acts of incompetence, and/or dishonest or corrupt acts, in that respondent committed errors or omissions in the care and treatment and interaction with the undercover officer, including but not limited to the following:

A. Respondent recommended treatment to the officer without conducting a physical examination;

B. Respondent failed to make any effort to determine whether the officer was in fact suffering from any physical ailment or condition.

C. Respondent failed to provide follow-up or referral for the officer's complaints;

D. Respondent's statement that the officer was under his medical care and supervision for treatment of a serious medical condition diagnosed after review of available records and in person medical examination was false and unethical.

E. Respondent's conduct in permitting his office staff to fabricate medical information, to "coach" patients regarding their current medical condition, and to dispense marijuana, was unethical, and constitutes acts of dishonesty or corruption.

EIGHTEENTH CAUSE FOR DISCIPLINARY ACTION

(Inadequate/Inaccurate Medical Records)

48. The allegations of the First through Seventeenth Causes for Disciplinary Action are incorporated herein by reference.

49. Respondent is subject to disciplinary action under section 2263 of the Code in that respondent's medical records for each and every patient alleged above routinely lacked adequate documentation of physical examination, clinical findings, vital signs, mental status examination, laboratory tests, follow-up and treatment plans, and other matters relevant and necessary to an evaluation and diagnosis of the patient's condition, or to support the recommendation or prescription of any medication.

NINETEENTH CAUSE FOR DISCIPLINARY ACTION

(Prescribing Without Prior Good Faith Examination)

50. The allegations of the First through Seventeenth Causes for Disciplinary Action are incorporated herein by reference.

49. Respondent is subject to disciplinary action under section 2242 of the Code in that in each case, respondent prescribed, dispensed or furnished marijuana, a controlled substance, without conducting a prior good faith examination and/or without medical indication.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Division of Medical Quality issue a decision:

1. Revoking or suspending Physician's and Surgeon's Certificate Number G-9124, issued to Tod H. Mikuriya, M.D.;

2. Revoking, suspending or denying approval of Tod H. Mikuriya, M.D.'s authority to supervise physician's assistants;

3. Ordering Tod H. Mikuriya, M.D. to pay the Division of Medical Quality the reasonable costs of the investigation and enforcement of this case, and, if placed on probation, the costs of probation monitoring;

4. Taking such other and further action as deemed necessary and proper.

DATED: _____

_____
RON JOSEPH
Executive Director
Medical Board of California
Department of Consumer Affairs
State of California
Complainant

BEFORE THE
DIVISION OF MEDICAL QUALITY
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation filed Against:	)	
TOD H. MIKURIYA, M.D. Certificate No. G-9124	)	No: 12-1999-98783
Respondent	)	

DECISION

The attached Proposed Decision is hereby adopted by the Division of Medical Quality as its Decision in the above-entitled matter.

This Decision shall become effective at 5:00 p.m. on April 19, 2004.

IT IS SO ORDERED March 18, 2004

By: _____
RONALD WENDER, M.D.
Chair - Panel B
Division of Medical Quality

BEFORE THE
DIVISION OF MEDICAL QUALITY
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: TOD H. MIKURIYA, M.D. 1168 Sterling Avenue Berkeley, California 94708 Physician's and Surgeon's Certificate No. G-9124 Respondent.	Case No. 12-1999-98783 OAH No. N2002110020

PROPOSED DECISION

This matter was heard before Administrative Law Judge Jonathan Lew, State of California, Office of Administrative Hearings on September 3, 4, 5, 8, 9 and 24, 2003, in Oakland, California.

Complainant Ron Joseph was represented by Deputy Attorneys General Lawrence A. Mercer and Jane Zack Simon.

Respondent Tod H. Mikuriya, M.D. was present and represented by John L. Fleer, Esq., Susan J. Lea, Esq. and William M Simpich, Esq.

Submission of the matter was deferred pending receipt of closing argument. Complainant's Closing Argument and Reply Brief were received on November 7 and 20, 2003, and marked respectively as Exhibits 26 and 27 for identification. Respondent's Closing Brief and Reply Brief were received on November 7 and 21, 2003, and marked respectively as Exhibits AA and BB for identification. The case was submitted for decision on November 21, 2003.[1]

[1] On December 26, 2003, respondent also submitted an Amicus Curiae Brief filed by the California Medical Association in a matter before the California Court of Appeal that respondent believes directly concerns the facts in this case. Respondent requests that judicial notice be taken of that brief. Complainant filed an Objection to Request for Judicial Notice on December 26, 2003, and such objection is sustained.

FACTUAL FINDINGS

1. Ron Joseph (complainant) is the Executive Director of the Medical Board of California (Board), Department of Consumer Affairs. He brought the Accusation, First and Second Amended Accusations solely in his official capacity.

2. On October 16, 1963, the Board issued Physician's and Surgeon's Certificate Number G-9124 to Tod Hiro Mikuriya, M.D. (respondent). The Physician's and Surgeon's Certificate was in full force and effect at all times pertinent to this case.

3. On July 25, 2003, a Second Amended Accusation was filed against respondent alleging unprofessional conduct, gross negligence, negligence and incompetence arising out of his care and treatment of sixteen patients. In each case he recommended marijuana for medical purposes. Complainant alleges that respondent's medical records for these patients were inadequate in that they routinely lacked adequate documentation of physical examination, clinical findings, vital signs, mental status examination, laboratory tests, follow-up and treatment plans. Complainant contends such matters are relevant and necessary to an evaluation and diagnosis of each patient's condition, or to support the recommendation or prescription of any medication. Complainant further alleges that respondent prescribed, dispensed or furnished marijuana, a controlled substance, without conducting a prior good-faith examination and/or without medical indication. Finally, complainant contends that respondent committed unprofessional conduct and/or was grossly negligent, negligent, incompetent or committed acts of dishonesty or corruption in his interactions with and care and treatment of an undercover narcotics officer.

Respondent's Background

4. Respondent has been a licensed California physician for 40 years. He is recognized as an expert on the use of marijuana for medical purposes and he has conducted research and has numerous publications on the topic of medical marijuana. He founded California Cannabis Research Medical Group to facilitate shared cannabis research. Respondent has been actively involved in the efforts to legalize marijuana for medical purposes.

Respondent attended Temple University School of Medicine before completing psychiatric residencies at Oregon State Hospital in Salem, Oregon, and Mendocino State Hospital in Talmage, California. He has served as Director, Drug Addiction Treatment Center, New Jersey NeuroPsychiatric Institute, Princeton, New Jersey (1966-67); Consulting Research Psychiatrist, National Institute of Mental Health Center for Narcotics and Drug Abuse Studies (1967); Consulting Psychiatrist, Alameda County Alcoholism Clinic, Oakland (1968-69); Consulting Psychiatrist, Alameda County Health Department Drug Abuse Project (1969); Attending Staff Psychiatrist, Gladman Hospital, Oakland (1969-92); Consultant, National Commission on Marihuana and Drug Abuse (1972); Chair, Department of Psychiatry, Eden Hospital, Castro Valley (1993-94); and Psychiatric Consultant, Fairmont Hospital, San Leandro (1991-95).

He is currently an attending psychiatrist at Eden Medical Center, Castro Valley; Vencor Hospital, San Leandro; San Leandro Hospital, San Leandro; and St. Anthony's, Park View Convalescent, Clinton Village. He describes his private practice in Berkeley as all about medicinal cannabis consultations and this includes activities in his role as Medical Coordinator of California Cannabis Centers (Oakland Cannabis Buyers Cooperative, Hayward Hempery, CHAMP, San Francisco and the Humboldt Cannabis Center, Arcata).

Respondent is a member of professional organizations including the California Medical Association, Alameda-Contra Costa Medical Association (Chemical Addictions Committee), American Psychiatric Association, Northern California Psychiatric Society, East Bay Psychiatric Association, American Society of Addiction Medicine and the California Society of Addiction Medicine (CSAM). He has been on CSAM's Medical Marijuana Task Force since April 1997.

The Compassionate Use Act

5. On November 5, 1996, the voters of California passed Proposition 215, the Compassionate Use Act of 1996, also known as the Medical Marijuana Initiative. (Health & Saf. Code, § 11362.5.) The Compassionate Use Act provides 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. The Act makes specific provision for the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief. One of the Act's purposes is to ensure that seriously ill Californians have the right to obtain and use marijuana for "medical purposes" and "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." (*Ibid.*)

The Act also expressly affirms public policy against conduct that endangers others or the diversion of marijuana for non-medical purposes. It is left for the physician, as gatekeeper, to ensure that marijuana is used for "medical purposes" to benefit the seriously ill. [2] Under these circumstances it is presumed that physicians who recommend marijuana under the Act will follow accepted medical practice standards and make good faith recommendations based on honest medical judgments. (*Conant* v. *McCaffrey* (2000 WL 1281174.) The parties agree that good faith recommendations based on honest medical judgments must be made in every case. Where they differ, and rather markedly so, is on what constitute accepted medical practice standards to be followed in making such a recommendation.

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[2] In *Conant* v. *Walters* (2002) 309 F.3d 629, Justice Kozinski described the key role of physicians anticipated under the Act: "The state law in question does not legalize use of marijuana by anyone who believes he has a medical need for it. Rather, state law is closely calibrated to exempt from regulation only patients who have consulted a physician. And the physician may only recommend marijuana when he has made an individualized and bona fide determination that the patient is within the small group that may benefit from its use."

Standard of Practice Issues

6. Complainant sees no need to articulate a new standard of practice to assist physicians in recommending marijuana, believing that the standard of practice in the area of medical marijuana is not new at all, but the same as pertains to recommending any treatment or prescribing any other medication – namely history, physical examination and appropriate treatment plan. Where marijuana is being recommended for a psychiatric condition, complainant believes the examination would entail a mental status examination to establish a psychiatric diagnosis, and might either not include a physical examination or might only include a limited physical examination appropriate to the clinical situation. Complainant relies heavily upon a policy statement issued by the Board to all California physicians in its January 1997 Action Report. This statement came on the heels of Proposition 215 and recognized that there was at that time "a great deal of confusion concerning the role of physicians under this law." The policy statement specifies:

> While the status of marijuana as a Schedule I drug means that no objective standard exists for evaluating the medical rationale for its use, there are certain standards that always apply to a physician's practice that may be applied. In this area, the Board would expect that any physician who recommends the use of marijuana by a patient should have arrived at that decision in accordance with accepted standards of medical responsibility; i.e., history and physical examination of the patient; development of a treatment plan with objectives; provision of informed consent, including discussion of side effects; periodic review of the treatment's efficacy and, of critical importance especially during this time of uncertainty, proper record keeping that supports the decision to recommend the use of marijuana.

In spring of 1997, CSAM issued a position statement regarding the recommendation of marijuana, in which it stated that marijuana is a mood-altering drug capable of producing dependency, urging the Board to formally adopt the standards set forth in the January 1997 Action Report, and further suggesting that the Board's statement be expanded to include a requirement for notation of a diagnosis or differential diagnosis.

7. Respondent notes that there are only a handful of physicians, less than twenty, who consult on medical cannabis issues as a primary part of their practice and among whom there is no uniform agreement and few guidelines on practice standards. Physicians consulting in this way are not "treating physicians" and patients who are seen are primarily self-referred and come with a single question in mind – "Do I qualify for a medical cannabis recommendation?" These patients typically are already using cannabis for their medical condition and claim a benefit from so doing. In seeking a physician's recommendation their main consideration is avoiding involvement with the criminal justice system. Most physicians are very reluctant to become involved in making such recommendations. They are afraid to say anything to patients about medical cannabis for fear that they will become targets of law enforcement themselves. The Compassionate Use Act does provide that no physician shall be punished, or denied any right or privilege, for having recommended

marijuana to a patient for medical purposes. (Health and Saf. Code, § 11362.5, subd. (c).) However, as even the Board recognized early on, this language offers no protection from federal prosecution, including threat of criminal prosecution of physicians, revocation of DEA registration and exclusion from participation in the Medicare and Medicaid program for having made such recommendations.[3]

Given this history and climate respondent believes this case has been motivated politically, directed both by federal government officials and California State officials opposed to Proposition 215, and conducted from the outset in bad faith. Yet, in considering this case, every effort has been made to remain squarely focused on determining what practice standards govern medical cannabis recommendations. That is the primary issue and therefore evidence proffered on the history, motivation and other matters underlying or relating to the investigation and prosecution of this case, though considered, have been largely disregarded.[4]

8. Respondent urges as the standard of practice a more focused medical cannabis consultation model consisting of a good faith examination designed to gain needed information, no more and no less. The needed information would be limited to that sought in answering the simple question whether a patient is eligible for inclusion under the Compassionate Use Act. Respondent believes a physician would primarily be concerned with determining if there is medical evidence supporting eligibility. There would also be a future obligation to monitor patients using medical marijuana. Respondent proposes as minimum practice standards that physicians conduct an initial face to face interview, obtain identifying information, make a diagnosis and arrange for follow-up examinations that allow for incorporation of fax, e-mail or telephone exchanges of patient information. Respondent notes that while there have been uniform guidelines recommended and submitted to the California Medical Association (CMA), practice guidelines have yet to be adopted by the CMA or by the Board. Respondent views the protocols followed in making a Proposition 215 recommendation as quite different from those followed by a physician in making a prescription. He also believes that any treatment plan should address only the medical use of cannabis and not the patient's entire medical profile/condition. Respondent believes that the relevant practice standard should not require him to fully evaluate or treat every symptom present or suspected at the time the patient is evaluated.

This generally summarizes what the parties believe to be the correct practice models in making medical cannabis recommendations. In determining which governs, the appropriateness of the two models is best evaluated by considering the medical expert opinions offered in this case. The opinions relate directly to respondent's management of the sixteen patients referenced in the Second Amended Accusation and, accordingly, patient summaries and respondent's actions with respect to each patient are briefly outlined below.

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[3] January 17, 1997 Memorandum to Board Members from Ron Joseph regarding Proposition 215, Use of Marijuana for Medicinal Purposes.

[4] Respondent submitted an Offer of Proof on remaining Exhibits P – W. These exhibits have been received into evidence as marked. Objections to relevancy go largely to the weight attached, and in most cases this was very marginal.

A discussion of appropriate practice standards and whether or not respondent complied with them is incorporated within these discussions of each patient.

Patient R.A.

9. Patient R.A. was seen by respondent on March 5, 1997. Medical records include a Registration Form completed by Patient R.A., but two of the five pages from that form are missing. No other documentation reflects respondent's initial evaluation of this patient. There are no records reflecting the patient's medical complaints/health problems, medical/psychiatric history, physical/mental status examination or what advice was given by respondent. A Physician's Statement dated March 5, 1997, was issued indicating that Patient R.A. was under respondent's "medical care and supervision for the treatment of medical condition(s): Anxiety Disorder Gastritis." It also indicated that respondent had discussed the medical risks and benefits of cannabis use as a treatment and that he condoned the use of cannabis.

Patient R.A. completed a "Cannabis Patient Follow Up Visit Questionnaire" dated November 6, 1998. It indicated that marijuana had been used by him for treatment of gastritis/anxiety disorder. No psychiatric history, medical history, physical/mental status examination is recorded. Respondent noted "irritation from low potency" and "recounts stressors of arrest & case & involvement & insomnia" and that he discussed the effects on the patient's life. A Physician's Statement dated November 18, 1998, confirmed that Patient R.A. was under respondent's "medical care and supervision" for "Gastritis Anxiety Disorder." Respondent also noted that Patient R.A. "Must return by 12-2-98 for follow up."

Patient R.A. completed a follow up questionnaire dated August 5, 1999, which reported treating complaints of anxiety disorder, gastritis and irritable bowel syndrome with marijuana, 15 to 38 grams/week. An "Illness status" category on the questionnaire was checked as "Stable". There were follow up visits on April 28, 2000, and on January 4, 2001. A progress note for April 28, 2000, noted increased anxiety and insomnia. The January 4, 2001 follow up questionnaire listed gastritis and anxiety as symptoms/conditions treated with cannabis and Patient R.A.'s illness status was marked as "Stable". Respondent noted that Patient R.A. planned on relocating to Holland secondary to his fear of continuing prosecution. R.A. did leave the country and respondent maintained contact with him. On March 12, 2001, respondent consulted with Patient R.A. by telephone. He reported increased anxiety, bowel symptoms/constipation, lumbosacral back pain and a 20 pound weight loss.

10. Complainant contends that respondent committed errors and omissions in the care and treatment of Patient R.A. by: 1) failing to evaluate his anxiety and insomnia complaints by means of a standard psychiatric history, medical history, physical examination and mental status examination; 2) failing to evaluate gastrointestinal complaints to rule out serious and perhaps life threatening illness while recommending palliative treatment; 3) failing to follow up on complaints and using a questionnaire that inappropriately lumped multiple complaints into a single illness category; 4) falsely and unethically representing that Patient R.A. was under his care and supervision for treatment of serious medical conditions;

5) maintaining medical records that lacked adequate documentation of physical/mental status examination, clinical findings, vital signs, laboratory tests, follow-up and treatment plans necessary to an evaluation and diagnosis of the patient's condition, or to support the recommendation/prescription of any medication; and 6) furnishing marijuana without conducting a prior good faith examination and/or without medical indication.

11. Laura Duskin, M.D. testified as an expert witness on behalf of complainant. She is a psychiatrist with Kaiser Permanente, Adult Psychiatry Department, and a senior physician specialist, psychiatry with the San Francisco Department of Public Health, Community Clinics. Dr. Duskin is an Assistant Clinical Professor, UCSF School of Medicine. Her responsibilities there include teaching interviewing skills and diagnosis/treatment of psychiatric conditions to interns and residents at the medical school. Dr. Duskin is a Diplomate, American Board of Psychiatry and Neurology in Psychiatry (unlimited) and Geriatric Psychiatry. She has practiced psychiatry since 1983.

Dr. Duskin is familiar with the standard of practice for psychiatrists in both treating and consulting capacities. In terms of the initial patient evaluation she opines that the standard of practice is essentially the same, regardless of whether the physician is acting as a treating physician or as a consultant. She believes the standard of practice for recommending marijuana is identical to that governing any medication – mainly that the physician does an evaluation of the patient's complaints, formulates a differential diagnosis, discusses treatment options with the patient including the risks and benefits of medications, and develops a treatment plan with provision for future monitoring. There is always an initial evaluation, some more comprehensive than others depending upon the status of the patient. When marijuana is being recommended for a psychiatric condition, the examination would include a mental status examination. This is basically an assessment of the patient's behavior, speech, reported mood, coherency, short term memory, impaired insight or judgment, thoughts of suicide or harming others, obsessive thoughts, etc. In some cases formal testing is required.

Where a psychiatrist is called upon to treat a condition that is non-psychiatric in nature the standard of practice is the same as that followed by any other physician, namely history, physical examination, differential diagnosis, appropriate treatment plan and plans for follow-up and responsibility for management of the problem unless it can be referred to the patient's primary care physician. Dr. Duskin emphasizes that this is really very basic, something all physicians learn as part of their medical school education. She makes specific reference to the Board's 1997 Action Report and to CSAM's policy statement (Finding 6) noting that they both merely confirm existing and accepted medical standards for treatment or prescribing of any medication.

Dr. Duskin notes that the standard of practice when treating patients in follow-up is to reevaluate the problem(s), the efficacy or problems with treatment, and to appropriately address any new concerns. If more than one condition is the focus of treatment, each condition is evaluated independently even if the same drug is being used to treat all of the conditions. Where referral for further evaluation and follow-up is warranted, a psychiatrist is

responsible for making this referral and documenting this in the medical record. The standard of practice for medical records is for the psychiatrist to keep all records pertaining to the treatment of the patient, including prescriptions or certificates, and where copies of any portions of the medical records are provided to others, the psychiatrist retains the originals and sends copies only.

12. Dr. Duskin believes that respondent's treatment of Patient R.A. represented an extreme departure from the standard of practice in numerous areas of concern. The patient records contain no adequate initial evaluation note, no psychiatric or medical history, no mental status examination and no differential diagnosis. She notes that such lack of documentation for a patient for whom a psychoactive drug was being recommended was an extreme departure from the standard of care.

Dr. Duskin is critical of respondent's failure to document the history and make an appropriate follow-up plan for the patient's potentially serious gastrointestinal complaints. She is particularly concerned that "gastrointestinal cancer or other disease manifest with symptoms as described by this patient, and without appropriate medical evaluation the cannabis, if symptomatically effective, might only mask the problem until the disease progressed to a life threatening degree." There is no indication from the records that Patient R.A. was receiving ongoing treatment from another physician, important information that should be ascertained. If a physician is offering pain management or palliative treatment the physician is also responsible for making sure that the underlying problem is being addressed, or that the patient is refusing to have that problem addressed. If such occurred in this case it was not documented and there is no indication that respondent discussed Patient R.A.'s medical or psychiatric treatment with any other health care provider.

Respondent used a patient questionnaire that allowed for illness status to be described in single word categories such as "stable", "improved" or "worse" and that grouped multiple conditions into a single evaluation category. Thus, on August 5, 1999, in reference to anxiety disorder, gastritis and irritable bowel syndrome that were being treated with cannabis, the reevaluation of the conditions consisted of the single word "stable". Dr. Duskin notes that when a symptom or condition is the focus of treatment, a one word description of the clinical situation is grossly inadequate, and that no competent clinician would lump multiple conditions into an illness category and evaluate them together as one.

In follow-up evaluations it was noted that the patient had increased anxiety and insomnia on April 28, 2000, and on March 12, 2001. No evaluation of these symptoms was documented and no treatment plan other than to recommend cannabis was made. Dr. Duskin allows that cannabis may have been efficacious for these problems but given the ongoing nature of the problems "further evaluation and consideration of supplemental treatment with other medications, other treatment modalities or a complete change in treatment for these conditions was clearly in order." Dr. Duskin is also critical of the length of time between follow-up contacts and the lack of an interval history of the progress of the patient's conditions between contacts.

Dr. Duskin has additional concerns that respondent provided a certification indicating that the patient was under his "care and supervision," something she characterizes as false and misleading. She notes, for example, that the patient's gastritis was not being followed in any way in a manner that would be expected if he was under respondent's care and supervision for that condition.

13. Respondent did not view himself as R.A.'s primary care physician and avers that he only rendered a diagnosis sufficient for the purpose of determining that R.A. had a serious and chronic condition that was helped by marijuana. He contends that R.A. was under his care and treatment because he had seen him frequently and stayed in telephone contact and followed his condition even after he left the country. He believes that he conducted a bona fide examination in determining that R.A.'s condition was both serious, chronic and helped by cannabis. He attributes R.A.'s symptoms (psycho-physiologic gastrointestinal dysfunction) to R.A.'s anxiety related to law enforcement. He disagrees that he failed to evaluate R.A.'s gastrointestinal complaints to rule out more serious disease, dismissing the notion that marijuana was palliative treatment at all.

14. Philip Andrew Denney, M.D. testified as an expert witness on behalf of respondent. He attended the University of Southern California School of Medicine and has been in medical practice since 1976. Recent professional activities include positions as the Facility Medical Director of Meridian Occupational medicine Group, Sacramento (1996-97); Facility Medical Director of Healthsouth Medical Clinic, Rocklin (1997-99); Medical Director, Marshall Center for Occupational Health (1999-2000); and Occupational and Legal Medicine (2000 – present). From 1999 his medical legal practice has included medical cannabis recommendations. Dr. Denney's membership in professional societies includes the American College of Occupational and Environmental Medicine and the California Cannabis Research Medical Group. He remains informed about medical cannabis from the small universe of practitioners in this field who exchange information informally or through organized conferences. He describes one of respondent's publications as an authoritative and seminal work that introduces western physicians to appropriate citations in medical literature in this field. Although he believes thousands of doctors give cannabis recommendations, Dr. Denney notes that fewer than twenty consult on medical cannabis issues as a primary part of their practice. He falls within this category.

Dr. Denney views respondent's role as that of a consultant, and not as that of a treating physician. Because cannabis cannot be prescribed he notes that the physician is not involved in treatment at all, rather the patient is engaged in self treatment of a medical condition. The physician's role is that of recommending the cannabis for a medical condition. The physician is not saying that this is the sole treatment, it may be only one small part. Dr. Denney believes that the good faith examination required in these cases is only that which is necessary to gain the information needed. He considers the Board's 1997 Action Report to be advisory in nature and not the standard of practice.

With regard to Patient R.A., Dr. Denney opines that cannabis has salutary effects on gastritis but would not mask a more serious condition. He describes its effects as very mild

compared to other prescription drugs, opiates for example. He has no criticism of respondent's medical records or lack thereof. Dr. Denney notes that it is not uncommon to have cursory, largely unintelligible and useless information contained in medical records. In making a sincere medical judgment he believes physicians rely more on actual observations and face to face contact with patients, and not upon medical records or other written documents provided by the patient.

15. Dr. Denney acknowledges obtaining a patient's history and performing physical examinations in his own practice, including medical cannabis consultations. He explains that he does so primarily for administrative and legal reasons yet he has consistently taken this examination approach for patients over his entire career in an effort to practice "excellent medicine." During medical cannabis evaluations he investigates complaints raised by the patient and if warranted he advises patients to seek follow-up care. He documents such discussions in his medical records. Dr. Denney opines that respondent is a superb physician whose medical cannabis practices were both appropriate and within the standard of care. Yet Dr. Denney's own practices are very different from respondent's and his practices are entirely consistent with the Board's 1997 Action Report policy statement. In conducting his medical cannabis evaluation Dr. Denney obtains a medication history and reviews the reason for using cannabis. He discusses medical cannabis and any problems with its use with the patient, reviews any available records and tries to determine whether the patient is being truthful. He conducts a "head to toe" physical examination and evaluates the presenting complaint for each patient. Dr. Denney notes that if a patient raises a complaint of importance he would "certainly" advise the patient to seek follow-up care with a physician. He acknowledges that it is important to keep medical records documenting the medical evaluation, and that such records might be important to subsequent treating physicians.

Essentially, the good faith examination Dr. Denney performs to support a recommendation for medical marijuana is no different than what he follows in any other medical evaluation. [5] It is also consistent with the standards articulated by Dr. Duskin.

16. The above matters having been considered, it does appear that the standard of practice for conducting a medical cannabis evaluation is identical to that followed by physicians in recommending any other treatment or medication. The standard applies regardless of whether the physician is acting as a treating or as a consulting physician. The medical cannabis evaluation is certainly focused on the patient's complaints, but it does not disregard accepted standards of medical responsibility. These standards include history and physical examination of the patient; development of a treatment plan with objectives; provision of informed consent; periodic review of the treatment's efficacy and proper record

[5] Dr. Denney acknowledged in prior testimony that he makes a determination of whether a patient should be given a prescription or some kind of treatment as follows: "I take a medical history. I examine the patient. I do a physical examination. I base my opinion on those things, on records if they're available, on my opinion as to the patient's truthfulness, etc." When asked what is a recommendation for cannabis he answered: "A recommendation is an opinion based upon history and physical exam and experience that says that the patient has a condition which in the physician's opinion will benefit from cannabis use." (*People* v. *Urziceneau*, Sacramento Superior Court No. 00F06296.)

keeping. When a cannabis recommendation is being made for a psychiatric condition the examination would additionally entail a mental status examination to establish a psychiatric diagnosis and severity of the condition. In such cases a physical examination might not be included, or might only include a limited physical examination appropriate to the clinical situation. In sum, the standard of practice for a physician recommending marijuana to a patient is the same as pertains to recommending any other treatment or medication.

Respondent contends that consulting physicians would be unreasonably burdened with conducting a complete work up on each conceivable diagnosis or symptom presented or suspected and that he would have to maintain extensive notes on every item of communication between physician and patient. He is also concerned that he would be responsible for referring patients out for additional medical care if not provided personally and that patients would be required to return for further evaluations and extensive testing to independently verify medical diagnoses or symptoms.

A physician must obviously exercise some discretion in making clinical judgments and it would be unreasonable to require a comprehensive physical/mental examination in every case. Complainant's major criticism of respondent is that he failed to perform any work up on each patient's chief presenting complaint and that he failed to conduct even the most cursory of physical or mental status examinations. Dr. Denney's practice is instructive because, like respondent, he also performs numerous medical cannabis evaluations. Yet he incorporates traditional elements of a medical evaluation and the examination that he undertakes is the same that he performs on all his patients. The model is not as rigid or as burdensome as respondent suggests. Dr. Duskin allows for flexibility, noting for example that no physical examination or only a limited physical examination may be appropriate in cases where medical marijuana is recommended for a psychiatric condition. When warranted, it hardly seems burdensome at all to refer a patient out for additional evaluation or care if one is not the treating physician and a serious condition is suspected or confirmed. Failure to do so is an extreme departure from the standard of care.

17. It was established that respondent committed errors and omissions in his care of Patient R.A. in the following respects:

a. Respondent failed to evaluate R.A.'s gastrointestinal complaints, anxiety, and insomnia by means of a standard medical history, physical examination and mental status examination. Medical records for R.A. lacked adequate documentation of physical examination, clinical findings, vital signs, mental status examination, test results and treatment plan. Such failures constituted an extreme departure from the standard of care.

b. Respondent failed to evaluate or refer R.A. out for evaluation of gastrointestinal complaints to rule out serious and perhaps life threatening illness and such constituted an extreme departure from the standard of care.

c. Respondent failed to follow-up on R.A.'s complaints and used an inadequate check box questionnaire that lumped multiple complaints together into a single illness category. It was designed to be completed by the patient. The lumping of multiple complaints into a single illness category is a matter of poor questionnaire design, a departure from the standard of care.

d. Respondent falsely represented that R.A. was under his care and supervision for treatment of a serious medical condition. The choice of language on respondent's Physician Statement was intended to assist the patient in certifying eligibility under Proposition 215, no more. It was boilerplate and the form was designed by respondent at a time when there was little guidance on appropriate language to be used. Under these circumstances it reflected a departure from the standard of care.

Patient S.A.

18. Patient S.A., a 20 year old male, was seen by respondent on May 20, 1996. He reported a history of nausea, vomiting, motion sickness and anorexia. Medical records indicated that he had previously been worked up by physicians with an upper GI exam showing "probable small duodenal ulcer." Respondent's medical records for S.A. contain no documentation that he elicited a history of other medical conditions, that he took vital signs or that he performed a physical/mental status examination. No treatment plan was formulated and there was no plan for follow-up of the patient's continuing gastrointestinal problems. Respondent did prescribe Marinol, a pharmaceutical containing the active ingredient in marijuana, for the patient's symptoms.

On November 10, 1997, respondent noted that the Marinol provided less relief than crude marijuana and based upon the patient's statement that he was "doing well with symptom control" respondent issued a Physician Statement indicating that S.A. was under his medical care and supervision for the serious medical condition of gastritis and that respondent recommended marijuana for this condition.

On May 12, 1998, S.A. requested a renewal of his Marinol prescription. The communication was characterized as a "televisit" and the patient's gastritis was described by a box checked "stable." A note on the form indicates that the certificate was mailed to the patient.

On October 16, 1999, the patient again requested a "renewal of cannabis recommendation." The communication was not in person, but was conducted via fax transmittal of a "Cannabis Patient Follow Up Visit Questionnaire." The form contains the patient's assessment that his gastritis was "stable" and his nausea was "better." S.A. also checked the box indicating that he found the treatment to be "very effective" and answered

"no" to the question whether he experienced adverse effects. He issued the cannabis recommendation after he received the follow-up questionnaire and requested fee.

19. Dr. Duskin notes that S.A. was first seen by respondent approximately three years after he was diagnosed with a possible duodenal ulcer and that it was incumbent upon him to obtain an interim history to determine whether disease progression or some other gastrointestinal problem could account for current symptoms. Vital signs, frequency of vomiting, loss of blood and weight loss would all have been basic parts of a medical evaluation in this case. No vital signs or patient weight were recorded by respondent. On the basis of the patient's verbal reports, respondent justified a diagnosis of "gastritis, rule out peptic ulcer." Respondent prescribed Marinol without documenting informed consent and there is no indication that he referred S.A. back to his gastroenterologist or primary care provider for further evaluation. During his initial visit respondent noted that S.A.'s chemistry panel was within normal limits.

Two of the three follow-up visits were not face to face meetings. The standard of practice for follow-up visits is for the physician to reevaluate the clinical complaint(s) and any new problems. This entails an interval history of the symptoms or condition. A one word statement ("Stable") checked on a form by the patient is not sufficient information upon which to make a clinical decision to continue Marinol. A medication renewal to treat gastritis, nausea and motion sickness would necessitate a clinical evaluation of the patient or documentation that an appropriate clinical evaluation was done by another practitioner prior to renewing the medication. A doctor might renew a prescription for a brief period without seeing a patient if the patient had been seen recently, but in this case respondent issued a cannabis recommendation on October 29, 1999, more than seventeen months after his previous evaluation. It appears that respondent issued the cannabis recommendation only after he received the follow-up questionnaire and requested fee. Dr. Duskin opines that "to charge for what amounts to a medication renewal without reevaluating the patient is unethical and grossly inappropriate. Likewise, this action would constitute an extreme departure from the standard of practice from a clinical standpoint."

Respondent signed a statement indicating that S.A. was under his "medical care and supervision" for the treatment of gastritis. If this were the case respondent would have been coordinating the ongoing evaluation and treatment of this condition with the patient's gastroenterologist or other medical practitioner and this was not the case.

20. Respondent notes that he evaluated S.A. only for a medical marijuana recommendation and that for purposes of follow-up, telephone contact and questionnaire were sufficient. He did not see himself as the primary care physician, noting that S.A. was self treating with cannabis before he saw respondent. Respondent believes that he performed a bona fide examination on the initial as well as on follow-up evaluations. He acknowledges that he did nothing to rule out peptic ulcer or to work up the gastritis. His focus was on determining eligibility under the Compassionate Use Act. When asked if he would be concerned if S.A. did not have a physician he answered in the negative, noting that it was not his responsibility and that it was beyond the scope of a consultative exam.

21. It was established that respondent committed errors and omission in the care and treatment of Patient S.A. in the following respects:

a. Respondent failed to evaluate S.A.'s gastrointestinal complaints by means of a standard medical history, physical examination. Medical records for S.A. lacked adequate documentation of physical examination, clinical findings, vital signs, test results and treatment plan. He prescribed Marinol without ruling out progression of the previously suspected duodenal ulcer. Such failures constituted extreme departures from the standard of care.

b. Respondent failed to re-evaluate or refer S.A. out for evaluation of gastrointestinal complaints to rule out serious illness and such constituted an extreme departure from the standard of care.

c. Respondent renewed S.A.'s recommendation in 1998 and 1999 without an interval history of the patient's condition and with the last examination not having been performed since November 1997.

d. Respondent charged S.A. for medication renewal without conducting an examination, an extreme departure from the standard of practice.

Patient J.B.

22. Patient J.B., a 40 year old female, was seen by respondent only once, on August 9, 1997. She presented with a ten year history of chronic depression and anxiety. He diagnosed her with dysthymic disorder and Post Traumatic Stress Disorder (PTSD). Dr. Duskin opines that respondent's treatment represented an extreme departure from the standard of practice when he failed to evaluate her symptoms of anxiety, depression and panic attacks. Respondent did not obtain the requisite history of the onset and duration of the patient's complaints, nor did he determine whether the patient had ever been hospitalized or ever been suicidal. He conducted a mental status examination that Dr. Duskin believes was deficient because it provided information only about the patient's current state and nothing about her history. Further, he did not offer her standard treatment for these diagnosed conditions when many effective treatments are available for both PTSD and dysthymia. The medical records contain no documentation that he offered standard treatment for these conditions or that if he did that the patient refused. Dr. Duskin also opines that he inappropriately instructed her to follow-up with him as needed instead of establishing a follow-up plan given the severity of her psychiatric conditions. Dr. Duskin has no quarrel with the cannabis recommendation, only with respondent's failure to do more. She emphasizes that a treatment plan in this case would need a number of elements – life circumstances needed to be addressed, and consideration given to behavioral interventions and perhaps adjunctive medications. Respondent issued a statement indicating that J.B. was under his "medical care and supervision" for dysthymic disorder and PTSD and this simply was not the case.

Respondent views his role in this case as that of providing J.B. with medicinal justification and protection from law enforcement. His understanding is that a clinical evaluation is a visit where a clinical decision is made and he believes he conducted a bona fide examination in this case. He avers that he spent over an hour with this patient. He does not know if J.B. had another physician and notes that she was opposed to taking pharmaceuticals making treatment options and interventions limited. He did not refer her to therapy or to another physician. Respondent believes the scope of the consultative evaluation was to issue her a certificate even though he felt that she needed much more.

23. It was established that respondent committed errors and omissions in the care and treatment of J.B. in the following respects:

a. Respondent conducted an inadequate evaluation of her symptoms of depression, anxiety and panic attacks.

b. Respondent arrived at a diagnosis of PTSD and dysthymic disorder without conducting a documented clinical evaluation.

c. Respondent failed to offer or refer J.B. out for standard psychiatric treatment for her conditions.

d. Respondent failed to provide follow up care for J.B.'s complaints.

Respondent's overall treatment of J.B. as above described represented an extreme departure from the standard of care.

Patient J.M.B.

24. On December 30, 1998, Patient J.M.B., a 26 year old male, consulted respondent for complaints of chronic pain that he attributed to spinal injuries sustained in prior automobile accidents. Respondent's records contain no vital signs physical examination or other medical evaluation of the patient's spinal complaints. Respondent issued a physician's certificate stating that J.M.B. was under his medical care and supervision for the treatment of intervertebral disc disease. A physician evaluating a patient with chronic orthopedic complaints is required to perform a physical examination, to obtain a history of the patient's condition, to assess any decrease in range of motion and limitations in daily activities. Respondent did none of these things.

On June 22, 1999, respondent issued a physician's statement to J.M.B. reiterating that he remained under respondent's care and supervision for the treatment of intervertebral disc disease. There is no record that respondent re-evaluated J.M.B. on this date, nor is there any evidence that respondent obtained an interval history.

Respondent believes he performed a bona fide examination for purposes of recommending medical cannabis. When asked whether a physical examination might have

assisted in verifying complaint he explains that in most cases he takes what a patient says to be true and accurate.

25. It was established that respondent committed errors and omissions in the care and treatment of J.M.B. in the following respects:

a. Respondent failed to evaluate J.M.B. for intervertebral disc disease and arrived at a diagnosis of without performing appropriate medical work up. Such failure constituted an extreme departure from the standard of care.

b. Respondent renewed the patient's recommendation without interval history or re-evaluation, an extreme departure from the standard of care.

c. Respondent's statement that J.M.B. was under his medical care and supervision for intervertebral disc disease was false, a departure from the standard of care.

Patient R.B.

26. Respondent saw R.B., a 27 year old male, on May 21, 1999. R.B. presented with complaints of nausea and dizziness and respondent made diagnoses of nausea and alcohol-related gastritis. In doing so he recorded no vital signs and ordered no laboratory tests. Medical records do not document any history, physical examination or other appropriate methods by which respondent arrived at a diagnosis. Dr. Duskin opines that respondent's treatment of R.B. "represented an extreme departure from the standard of practice when he made two diagnoses without obtaining an adequate medical history e.g. review of the onset, course of illness, alleviating and exacerbating factors in enough detail to make an accurate diagnoses."

R.B. did bring medical and other records, 40 pages worth, with him to his examination with respondent along with his medications. He had a primary care physician with Kaiser and had undergone extensive medical work-up and treatment prior to being seen by respondent. R.B. indicated that he was told that Kaiser would not permit its doctors to sign Proposition 215 recommendations and that was why he sought out respondent.

Respondent notes that he reviewed the records that R.B. brought with him and that he examined him. This included a family and past medical history, present illness, treatment plan and a review of cannabis use pattern. Respondent believes vital signs and laboratory tests were irrelevant in that they have nothing to do with the specific question of whether medical cannabis is appropriate. He acknowledges that he does not take vital signs, including blood pressure, for any of his patients. He notes that he conducted a bona fide examination of R.B.

27. It was established that respondent diagnosed R.B. with nausea and gastritis without performing a physical evaluation, recording vital signs or ordering laboratory tests.

Medical records for R.B. lacked adequate documentation of physical examination, clinical findings, vital signs, test results and treatment plan. Such failures constituted extreme departures from the standard of care. It was not established that respondent failed to take an adequate history given the information that R.B. provided to him via patient records and clinical interview.

Patient D.B.

28. Respondent saw D.B. on June 26, 1998, with complaints of cerebral palsy and post-traumatic arthritis. No physical examination and no vital signs were recorded. On June 27, 1998, respondent issued a recommendation for the patient's medical cannabis use and indicating that D.B. was under his medical care and supervision for the treatment of cerebral palsy and post-traumatic arthritis. There were no treatment goals and no baseline data upon which progress could be measured. By the time of a follow-up evaluation on January 21, 2000, there were still no records of any kind, nor any type of appropriate referral for medical reevaluation of the physical condition of concern. D.B. was charged $100 for "confirming status" without any apparent examination. Dr. Duskin notes that even though cannabis was reportedly beneficial to the patient "other adjunctive treatments would need to be explored including possible medication, physical therapy, occupational therapy for assistive or corrective devices, etc." Just addressing the cannabis portion of treatment did not amount to "medical care and supervision."

It was established that respondent committed errors and omissions in the care and treatment of D.B. in the following respects:

a. Respondent recommended treatment to D.B. without conducting a physical examination. Medical records for D.B. lacked adequate documentation of physical examination, clinical findings, vital signs, test results and treatment plan.

b. Respondent failed to provide follow up or referral for the patient's complaints.

c. Respondent charged for renewal of the patient's recommendation even though no examination was performed.

d. Respondent's statement that D.B. was under his medical care and supervision for cerebral palsy and traumatic arthritis was false.

Respondent's overall treatment of D.B. as above described represented an extreme departure from the standard of care.

Patient K.J.B.

29. Respondent first saw K.J.B., a 42 year old male with complaints of muscle spasm and lumbosacral pain, on August 24, 1998. There is no record of a physical examination of the patient, nor is there a proposed treatment plan or plan for follow-up. Respondent issued a physician statement indicating that K.J.B. was under his medical care and supervision for the treatment of Lumbosacral Disease. On September 20, 1999, K.J.B. again contacted respondent and on that occasion he provided respondent with a Beck Inventory, a self-administered questionnaire that is used to measure the degree of a patient's depression. K.J.B. endorsed a number of items and multiple statements indicating a significant level of depression. K.J.B. also completed a form indicating that he suffered from depression, insomnia, weight loss, cannabis addiction and back pain. There is no recorded assessment by respondent of the patient's multiple complaints and there was no plan for treatment or follow-up for the patient's depression and back pain except for a box indicating follow-up in 6 – 12 months.

The standard of practice for treating musculoskeltal pain and muscle spasm is to taken an adequate history, do a pertinent physical examination, obtain old records when available, make or confirm the diagnosis and develop a treatment plan presenting all reasonable treatment options and making referrals as appropriate. The same standard applies to treating depression except that the examination would consist of a mental status examination and pertinent parts of the physical examination. In this case there was not an adequate evaluation of either the psychiatric or the musculoskeletal complaints.

K.J.B. believed that respondent was his treating psychiatrist and was the "best" in the field and it is therefore troubling that respondent indicates that he did not perform a formal mental status examination and that K.J.B. was mistaken if he believed that he was his psychiatrist. Dr. Duskin notes that though cannabis may have helped in the patient's depression, there are many effective treatments for depression including both antidepressants and psychotherapy, treatments that respondent failed to provide or refer out for. Respondent avers that he did not suggest therapy or standard treatment for K.J.B. because he believed K.J.B. was not the sort of person who would be accepting of therapy.

30. It was established that respondent committed errors and omissions in the care and treatment of K.J.B. in the following respects:

a. Respondent failed to conduct a physical examination of K.J.B. before recommending treatment. Medical records for K.J.B. lacked adequate documentation of physical/mental status examination, clinical findings, vital signs, test results and treatment plan.

b. Respondent failed to conduct an evaluation of the patient's depression.

c. Respondent failed to reevaluate the patient in light of the patient's continuing depression or to consider alternative treatments for the patient's recurrent depression.

d. Respondent's statement that K.J.B. was under his medical care and supervision for lumbosacral disease was false.

Respondent's overall treatment of K.J.B. as above described represented an extreme departure from the standard of care.

Patient J.C.

31. Respondent saw J.C., an 18 year old female, on December 11, 1998. She complained of anorexia and stated that she was 6 months pregnant and had used marijuana to keep food down. Donnatal and over-the-counter medications were apparently ineffective. Dr. Duskin opines that such complaints in pregnant patients are potentially serious for the patient and for the fetus. The standard of care requires that a physician evaluate, first, the type of anorexia that is being addressed and include a description of the patient, her weight, vital signs and a detailed history. Respondent failed to record the patient's height, weight or vital signs and no history relevant to the patient's anorexia is documented, nor with regard to his diagnosis of prolonged traumatic stress disorder. There is no record of discussion of the relative risks and benefits of marijuana use. Dr. Duskin believes the failures above described were simple departures from the standard of care, but given the multiple simple departures represented an extreme departure.

J.C. and her mother both testified. As soon as J.C. began using cannabis she began to gain weight and her pregnancy was a healthy one. She provided a substantial number of patient records to respondent that he reviewed at the time of his evaluation. Respondent is criticized for his failure to contact J.C.'s treating obstetrician, but he explains that J.C.'s mother told him that the obstetrician approved of her daughter receiving cannabis but was afraid to provide a written recommendation. Under the circumstances respondent believed it unnecessary to contact this physician. Respondent also recommended cannabis instead of Marinol because he believed that J.C.'s stomach would be too sensitive and that through vaporization technique J.C. would be able to inhale therapeutic resins without other contaminants.

32. It was established that respondent committed errors and omissions in the care and treatment of J.C. in the following respects:

a. The medical records for J.C. lacked adequate documentation of physical/mental status examination, clinical findings, vital signs, test results and treatment plan.

b. He failed to work up J.C. prior to arriving at a diagnosis of prolonged traumatic stress disorder.

Respondent's overall treatment of J.C. as above described represented an extreme departure from the standard of care. However, it was not established that he failed to adequately evaluate J.C.'s reported anorexia given the amount of information about her condition that was made available to him. Similarly, it was not established that he failed to consider alternatives to smoked marijuana for J.C. His decision not to prescribe Marinol was based on his reasonable clinical judgment that her stomach would not be able to tolerate this medication. Respondent also provides a reasonable explanation for his decision not to contact J.C.'s treating physician.

Patient S.F.

33. Patient S.F. was 16 when she saw respondent on March 18, 1999, complaining of migraine headaches, depression and painful menstrual cramps that had worsened following a therapeutic abortion. She had no treating physician and had received no medical work up for any of these conditions. Her reported history included stress and "flipping out" during periods of extreme anger. Respondent recorded no history regarding the headaches. No physical or mental status examination and no vital signs are documented in the records. Respondent issued a physician's statement indicating that S.F. was under his medical care and supervision for the treatment of migraine headache and premenstrual syndrome.

Dr. Duskin agrees that marijuana might be helpful for these complaints but notes that respondent took only a partial history from S.F. regarding her headaches and did not adequately assess their triggering factors, duration and progression. Regarding the complaints of persistent and severe menstrual cramping, the standard of care would require an evaluating physician to obtain a history, including cycle, where in the cycle the symptoms are occurring, whether the menses are heavy or light, as well as what has helped or aggravated the condition. Infertility issues should be considered for a patient this young with a history of therapeutic abortion and referral for gynecological examination was indicated.

S.F. reported past medical history of depression, stress and head injuries and there is no indication that respondent undertook an evaluation of these conditions. The standard of practice upon hearing that a patient has had a head injury is to do a full history and neurological examination, or arrange for same.

34. Respondent relied upon information provided to him by S.F. and her father. He believes that he did an adequate work up regarding the etiology of the headaches and he determined that the head injury had occurred some time in the distant past and that she had recovered with diminishing sequela. He made a specific recommendation for psychological evaluation to S.F. and to her father. There were significant behavior problems at issue in their home.

35. It was established that respondent committed errors and omissions in the care and treatment of S.F. in the following respects:

a. Respondent failed to adequately work up the etiology and nature of S.F.'s headaches. The medical records for S.F. lacked adequate documentation of physical/mental status examination, clinical findings, vital signs, test results and treatment plan.

b. Respondent failed to evaluate the patient's complaints of painful menstrual cramps and failed refer her to an obstetrician/gynecologist for further evaluation.

c. Respondent's statement that S.F was under his medical care and supervision for treatment of migraine headaches and premenstrual syndrome was false.

Respondent's overall treatment of S.F. as above described represented an extreme departure from the standard of care. However, it was not established that respondent failed to address her stress and depression or that he failed to make a counseling or psychotherapy referral. He did so. He also made a clinical determination that her head injury was not recent and that she had recovered with no ill effects.

Patient D.H.

36. Respondent saw D.H., a 36 year old female, on April 30, 1999. She complained of very painful headaches as well as neck and shoulder pain associated with stress. Respondent issued a recommendation for the patient to use marijuana for tension headaches, pruritus and anxiety disorder. Medical records for D.H. contain no record of physical examination, vital signs, mental status examination or other work up of her complaints. The records consist largely of a questionnaire completed by the patient. There is no written evaluation by respondent.

Dr. Duskin opines that respondent failed to conduct an adequate history and physical examination to make or confirm the diagnoses presented by D.H. This was particularly important for headache complaints given the different causes and the need for a physician to develop a treatment plan specific to the cause of headache symptoms. [6] D.H. brought with her to her appointment medical reports and evidence of her condition. She told him that she had benefited from the use of cannabis in that her headaches were less intense and the itching was not as bad. She had a primary physician and had also been to a chiropractor and respondent advised her to also follow what her other doctors had recommended.

37. It was established that respondent committed errors and omissions in the care and treatment of D.H. in the following respects:

[6] Causes may include benign conditions as tension headache, uncorrected vision problems, teeth clenching and migraine, to much more serious conditions such as carbon monoxide poisoning, subdural hematoma or even brain tumor.

a. Respondent failed to adequately work up the etiology and nature of D.H.'s headache complaints and, aside from recommending marijuana, did not develop a treatment plan for her. The medical records for D.H. lacked adequate documentation of physical examination, clinical findings, vital signs, test results and treatment plan.

b. Respondent failed to document and evaluate D.H.'s complaints of pruritus and, aside from recommending marijuana, did not develop a treatment plan for her.

c. Respondent failed to document and evaluate D.H.'s complaints of anxiety and, aside from recommending marijuana, did not develop a treatment plan for her.

d. Respondent's statement that D.H. was under his medical care and supervision for treatment of headaches, pruritus and anxiety was false.

Respondent's overall treatment of D.H. as above described represented an extreme departure from the standard of care.

Patient J.K.

38. Respondent issued a physician's statement dated July 23, 1999, indicating that J.K., a 37 year old year old male, was under his care and supervision for posttraumatic stress disorder and traumatic arthritis. J.K. completed a questionnaire dated June 27, 1999, describing his present illness as dysthymic disorder and steel pin in right leg. Respondent's records contain no record of psychiatric history, physical examination, vital signs, mental status examination or other work up of the patient's complaints. The standard of practice for a psychiatrist evaluating a patient with a history of dysthymia is to complete a psychiatric history and to perform a mental status examination to determine the degree of depression. In diagnosing PTSD the standard of practice is to determine whether the diagnosis is justified in light of symptoms and history. Dr. Duskin opines that respondent's treatment represented an extreme departure from the standard of practice when he diagnosed PTSD without specifying any of the symptoms/criteria necessary for this diagnosis.

Respondent avers that he learned sufficient medical history from this patient to indicate that he suffered from these conditions but acknowledges that documentation supporting PTSD was not present. With regard to traumatic arthritis, he believes that the fact of an indwelling pin indicates serious trauma with consequent arthritis.

39. It was established that respondent committed errors and omissions in the care and treatment of J.K. in the following respects:

a. Respondent failed to evaluate J.K.'s reported depression by obtaining a psychiatric history and mental status examination. The medical records for

J.K. lacked adequate documentation of physical examination, clinical findings, vital signs, test results and treatment plan.

b. Respondent diagnosed J.K. with PTSD without specifying the symptoms or criteria requisite to that diagnosis.

c. Respondent failed to evaluate J.K. for traumatic arthritis by appropriate history and examination.

d. Respondent's statement that J.K. was under his medical care and supervision for treatment of PTSD and traumatic arthritis was false.

Respondent's overall treatment of J.K. as above described represented an extreme departure from the standard of care.

Patient D.K.

40. D.K., a 54 year old female, was seen by respondent on June 27, 1998, with a history of stroke and tobacco dependence. Respondent issued a physician's statement representing that D.K. was under his medical care and supervision for brain trauma and nicotine dependence. Other than that which was apparent through observation, respondent did not conduct an evaluation of her brain trauma nor did he evaluate her tobacco smoking addiction. Dr. Duskin opines that the standard of practice when treating symptoms associated with prior brain injury is to specifically identify the symptoms, onset, intensity, exacerbating and relieving factors, and effectiveness of past treatments. Though cannabis might be very effective for symptoms of brain trauma, other psychotropic medications may be equally or more effective and the patient needs to be made aware of therapeutic options. Dr. Duskin recognizes the value of cannabis being of assistance in a harm reduction treatment of nicotine dependence but notes that the standard of practice requires obtaining a smoking history (pack years, recent history including attempts to quit, etc.) and discussing treatment options.

Respondent notes that D.K. was specifically seeking recommendation for use of medical cannabis that she had found useful for symptoms of organic brain damage she suffered at age 21. He observed her peculiar speech patterns, that she was emotionally labile, depressed and had difficulty controlling her reactions. Cannabis helped her become less agitated and less disorganized. He felt that he was able to adequately evaluate her brain injury and determine that it was a serious chronic condition that would be helped by cannabis. His response to criticism of his practice regarding evaluation, diagnosis and treatment plans is that these were matters beyond his role as a medical cannabis consultant and that he had all the information that he needed to determine whether D.K. had a condition that would benefit from the use of marijuana. Respondent believed that she would also benefit from neuropsychological testing and possible eligibility for public rehabilitation programs. He issued a written recommendation for such testing.

D.K. returned to see respondent on July 24, 1999, and July 28, 2000, and records consist largely of a questionnaire completed by the patient indicating status by checked categories on the form that lumped multiple serious conditions together.

41. It was established that respondent committed errors and omissions in the care and treatment of D.K. in the following respects:

a. Respondent failed to evaluate D.K.'s brain injury, failed to establish a diagnosis of the patient's condition and failed to develop a treatment plan. The medical records for D.K. lacked adequate documentation of physical/mental status examination, clinical findings, vital signs, test results and treatment plan.

b. Respondent failed to evaluate D.K.'s nicotine dependency and to document her tobacco smoking history.

c. Respondent failed to conduct an appropriate follow-up evaluation for D.K.'s condition and charged for renewal without reexamining her.

d. Respondent's statement that D.K. was under his medical care and supervision for treatment of brain trauma and nicotine dependence was false.

Respondent's overall treatment of D.K. as above described represented an extreme departure from the standard of care.

Patient E.K.

42. Respondent saw E.K., a 49 year old male with complaints of insomnia and back pain, on February 17, 1997. He reported that he had a back pain since age 18 secondary to scoliosis and that he had been using marijuana to relieve pain symptoms. He also reported a history of hypertension. No physical examination is documented and no vital signs were recorded. Respondent prescribed Marinol.

On March 17, 1999, E.K. completed a follow-up questionnaire indicating a desire to replace Marinol with crude marijuana. He sought marijuana for conditions of "sleep, hypertension, blood pressure, blood sugar, eating." Respondent charged E.K. $120 and sent him a recommendation for the use of marijuana for anxiety disorder and persistent insomnia. E.K. contacted respondent in March 2000 and March 2001, and received recommendation renewals, all without examination. The recommendations indicated that E.K. was under his care and supervision for anxiety disorder, insomnia and essential hypertension, except that the 2001 statement omitted the reference to hypertension. No explanation is documented for this change.

Dr. Duskin notes that the standard of practice for a psychiatrist evaluating a patient with these conditions is to evaluate each condition and develop a treatment plan specific to each. She opines that his treatment of E.K. constituted an extreme departure from the standard of practice because he failed to evaluate the patient insomnia and anxiety in even a basic way – type, severity, duration, accompanying symptoms, exacerbating and alleviating factors. He also failed to evaluate the blood sugar and blood pressure complaints, not even taking a blood pressure reading or ordering or referring him for appropriate laboratory tests that are routine in the evaluation of a hypertensive patient.

Respondent explains that E.K. sought no more than a cannabis recommendation from him, that he conducted a sufficient examination, that he determined that the conditions were both serious and chronic and by E.K.'s account relieved by cannabis. He notes that E.K. is a Christian Scientist and his personal/religious beliefs precluded him from consultation with most physicians. Respondent did not believe he was being consulted for hypertension or high blood sugar and notes that they were conditions that were mentioned in passing. Yet, respondent listed hypertension as a condition for which E.K. was under his care and supervision and that cannabis was recommended for same.

43. It was established that respondent committed errors and omissions in the care and treatment of E.K. in the following respects:

a. Respondent failed to evaluate E.K.'s hypertension, fluctuating blood sugar and complaints of anxiety and insomnia. The medical records for E.K. lacked adequate documentation of physical examination, clinical findings, vital signs, test results and treatment plan.

b. Respondent's statement that E.K. was under his medical care and supervision for treatment of anxiety disorder, insomnia and essential hypertension was false.

c. Respondent dropped his diagnosis of essential hypertension without documenting normalization of the patient's blood pressure.

d. Respondent charged for renewal of recommendation without re-examining the patient.

Respondent's overall treatment of E.K. as above described represented an extreme departure from the standard of care.

Patient F.K.

44. Respondent saw F.K., on June 30, 1997, for complaints of alcohol dependency and lumbosacral radiculitis. His diagnosis for F.K. was thoracic or lumbosacral neuritis or radiculitis, unspecified and alcohol dependence syndrome, unspecified. He documented no mental status examination, no adequate medical, psychiatric or substance history, no physical

examination to evaluate the lumbosacral problem and no treatment plan other than to discontinue alcohol. Respondent issued a physician's statement indicating that F.K. was under his care and treatment for lumbosacral thoracic radiculitis and alcoholism. Dr. Duskin opines that the standard of practice when diagnosing substance abuse or dependence is to document the substance abuse history, psychiatric history, perform a mental status examination and perform relevant physical examination and laboratory tests. A treatment plan addressing the problem should be stated in the medical record. She notes that respondent's evaluation seemed to consist only of references to three glasses of wine per week and this was inadequate. A mental status exam is needed to assess whether there is a primary or secondary psychiatric problem associated with the substance abuse. Simply informing a patient that he should "stop drinking" is not sufficient treatment.

Patient F.K. brought with him Veterans Administration (V.A.) medical records to his initial interview and they were reviewed by respondent. He had begun self-medicating with marijuana well before this meeting. It eased his back pain. V.A. physicians told him they could not recommend medical marijuana but also told him that respondent was an expert. F.K. prefers not to use opiates. In the past he drank a six pack and a couple of glasses of wine daily after work. He drinks a single glass per day with dinner if he is using marijuana. Respondent believes he adequately evaluated F.K.'s drinking problem and that he engaged in thorough telephonic interviews for all follow-up evaluations. Telephone contacts were on March 5, 1998, November 24, 1998, and July 25, 2001. They typically lasted up to fifteen minutes after which a medical cannabis recommendation would be issued. Respondent charged F.K. $120 for this service.

45. It was established that respondent committed errors and omissions in the care and treatment of F.K. in the following respects:

a. Respondent failed to substantiate F.K.'s reported substance abuse problem prior to issuing a diagnosis of alcoholism and failed to formulate a treatment plan. The medical records for F.K. lacked adequate documentation of physical examination, mental status examination, clinical findings, vital signs, test results and treatment plan.

b. Respondent charged for recommendation renewal without conducting an examination of the patient.

Respondent's overall treatment of F.K. as above described represented an extreme departure from the standard of care.

Patient R.H.

46. Respondent saw R.H., a 50 year old male with a history of alcoholism and alcohol-related cerebellar ataxia on March 26, 1998. He issued a recommendation for marijuana for the treatment of "Alcoholic encephalopathy & Recovering alcoholic Insomnia & Posttraumatic arthritis." A follow-up questionnaire dated April 16, 2001 indicated "No

Change" on these three diagnoses. Though the patient specified that he drinks up to ten cups of coffee daily, there was no comment in the record regarding its relevance to the insomnia complaint. The standard of practice for a psychiatrist diagnosing and evaluating insomnia is to obtain a full history including onset, type, exacerbating and ameliorating factors, medications taken, drugs, caffeine history, etc. The treatment plan should be directed at the primary cause of the insomnia, and may include both a pharmacologic and behavioral component. Respondent issued a physician's statement on May 3, 2001, indicating that R.H. was under his medical care and supervision for treatment of the serious medical conditions insomnia, traumatic arthritis and brain injury an that he recommended and approved his use of cannabis for these conditions. The medical record contains no documentation of traumatic arthritis.

47. It was established that respondent committed errors and omissions in the care and treatment of R.H. in the following respects:

a. Respondent failed to evaluate R.H.'s complaints of insomnia or to consider standard treatments for its underlying cause. He also failed to evaluate and document R.H.'s arthritis. The medical records for R.H. lacked adequate documentation of physical examination, clinical findings, vital signs, test results and treatment plan.

b. Respondent's statement that R.H. was under his medical care and supervision for post traumatic arthritis and chronic insomnia were false.

Respondent's overall treatment of R.H. as above described represented an extreme departure from the standard of care.

Patient W.H.

48. Respondent saw W.H., a 58 year old male with advanced multiple sclerosis, on November 1, 1998. W.H. was bedridden and under the care of a conservator who had requested respondent's services. Respondent met with the conservator and then saw W.H. for approximately 5 minutes. He obtained virtually no medical or psychiatric history from or about W.H. Medical records consist of an eligibility questionnaire partially completed by respondent, and several pages of medical records from other practitioners given to respondent by the conservator. He performed no physical and no mental status examination. He did not discuss the risks and benefits of cannabis with W.H. and documented no diagnosis or treatment plan. Respondent noted: "I looked at him and there he was lying in bed...He looked relatively comfortable...he appeared to be clean and appeared to be well-cared for, but again, I didn't lift the covers." Respondent issued a recommendation stating that W.H. was under his medical care and supervision for treatment of Multiple Sclerosis, and that he had discussed the medical risks and benefits of cannabis use with W.H.

Respondent avers that he briefly evaluated W.H. and observed ashtrays full of the ends of smoked joints near the bed. He opines that his condition was very serious, chronic

and that he attained some relief from cannabis for muscle spasticity and depression. He avers that he got W.H. to articulate whether he knew about medical marijuana and was able to use it. Respondent believes discussion of the risks with W.H. was irrelevant because he had been using it for years. The conservator indicated to respondent that W.H. was deriving benefit from its use.

Dr. Duskin opines that though W.H. had severe difficulties with speech, and likely fatigued easily, this did not preclude a mental status examination, an evaluation of the painful muscle groups (rigidity, range of motion, etc.) and a focused evaluation of the pain intensity, duration, alleviating and exacerbating factors, efficacy of the current medication regimen, etc. If changing the dosing of existing medications (Baclofen and Ativan) had been tried in the past and was not efficacious, respondent did not document this fact and he was not in a position to recommend discontinuation or taper of either drug on a trial basis if either one or both were not helpful.

The standard of practice when a psychiatrist provides a focused consultation is to determine if follow-up is necessary, and if so to see the patient in follow-up at an appropriate interval, depending upon the diagnosis and severity of the problem. Respondent failed to schedule a follow-up appointment at an appropriate interval. For pain management of a bedridden patient, planned follow-up in 6 – 12 months is inappropriate.

49. It was established that respondent committed errors and omissions in the care and treatment of W.H. in the following respects:

a. Respondent failed to adequately evaluate W.H.'s mental status.

b. Respondent failed to adequately evaluate W.H.'s complaints of pain and or muscle spasm. The medical records for W.H. lacked adequate documentation of physical examination, clinical findings, vital signs, test results and treatment plan.

c. Respondent failed to evaluate the efficacy of W.H.'s current medication regimen.

d. Respondent failed to discuss the risks associated with marijuana and alternative treatments available to W.H.

e. Respondent failed to schedule a follow-up appointment for W.H. at an appropriate interval.

f. Respondent's statement that W.H. was under his medical care and supervision for treatment of Multiple Sclerosis, and that respondent had discussed the medical risks and benefits of cannabis use with W.H. was false.

Respondent's overall treatment of W.H. as above described represented an extreme departure from the standard of care.

Undercover Officer

50. In early 2003, Detective Steve Gossett, lead investigator for the Sonoma County Narcotics Task Force, was involved in a marijuana investigation of a couple implicated in illegal cultivation. He was provided the telephone number of an Oakland clinic where they had intended to obtain a medical marijuana recommendation. Detective Gossett made a telephone call to the clinic and made an appointment for himself using the undercover name Scott Burris. He went to the clinic, but because there were so many people waiting to be seen he paid $50 for a medical priority appointment for the following week. He returned to the clinic on February 7, 2003, signed in for an appointment, paid an additional $150 and was given a blank questionnaire to complete. He was asked by the receptionist to fill out all questions except for his current condition, and was told that "Ben" would be helping everyone with this particular section.

Detective Gossett disregarded instructions and filled in "sleep, stress, shoulder" for his current medical condition. A Ben Morgan came to assist him with the form and told him that stress was not the best medical condition. When Detective Gossett told him that his shoulder hurt, Ben asked him to move his shoulder up and down and then suggested that Detective Gossett state on the form that he had a dislocated shoulder.

Detective Gossett was escorted into a separate room where respondent was sitting behind a desk. Respondent reviewed the paperwork and asked him questions about his parents' health, his current medical problems and his stress over a pending criminal case. Detective Gossett made up a story about being arrested for possession of 54 grams of marijuana. He also told respondent that he did not have a regular doctor and that he was an unemployed construction worker. Respondent did not conduct any type of physical examination. He did not ask which shoulder had been injured.

Respondent observed that Detective Gossett's complexion was coarse and somewhat puffy, suggesting to him that he had a drinking problem, although he stopped short of diagnosing alcoholism. Respondent did advise him not to drink so much alcohol and suggested physical therapy. He issued a medical cannabis recommendation that indicated that Scott Burris (Detective Gossett) was under his medical care and supervision for treatment of serious medical conditions. The entire session lasted 10 to 15 minutes. Following the visit with respondent, Detective Gossett returned to the waiting area and was told to go to the Oakland Cannabis Club to obtain an identification card and that he and others were now "all legal" and could grow marijuana for sale to the different clubs. Ben Morgan advised the group to stick around for a "special treat" and Detective Gossett was given a bag of marijuana by an unknown female.

51. Respondent contends that Detective Gossett's law enforcement bias from past participation on a DEA task force, his prior statements that respondent was a "quack", his

failure to wear a wire and his inconsistent statements all combine to make him a highly biased witness whose testimony should be discredited. Respondent notes that his overwhelming observation of Detective Gossett was that of a person with a serious drinking problem whose chronic shoulder pain had benefited from his alleged cannabis use and that respondent acted sincerely after performing a good faith medical examination. He acknowledges that he did not perform a physical examination. Respondent felt that marijuana would help ease his anxiety and his abuse of alcohol could be avoided. Respondent's challenge of Detective Gossett's credibility is somewhat moot because he does not dispute what occurred during the course of the medical interview itself. Their accounts differ only in terms of the length of the evaluation, respondent recalling that it was 20 minutes.

Respondent avers that he had no role in setting up the protocols and procedures followed at the Oakland Clinic. He was not the medical director and he had no authority to hire or supervise staff. He did not own or lease the property. He characterizes his position as that of an independent contractor there for the specific purpose of performing clinical evaluations. He was paid cash, $150 per patient seen. The medical records were his and they went home with him. Respondent had no role or knowledge of Ben Morgan's role in helping patients prepare questionnaires and he was unaware that cannabis samples were being given away on the premises. Ben Morgan had asked respondent to participate in a number of different clinics. Respondent does not know if Ben Morgan had any health or medical license and he does not know if any other physicians worked out of the clinic. Respondent made no inquiries into whether the owners of the clinic were non-physicians and he is apparently unaware of laws governing physician practice under non-physicians. He avers that he did not view the clinic as carrying out full medical functions because it was a consultative venue as opposed to a medical clinic per se.

52. It was established that respondent committed errors or omissions in the care and treatment and interaction with an undercover officer in the following respects:

a. Respondent recommended treatment to the officer without conducting a physical examination. He undertook minimal effort to determine whether the officer was in fact suffering from any physical ailment or condition. The medical records for Detective Gossett lacked adequate documentation of physical examination, clinical findings, vital signs, test results and treatment plan.

b. Respondent failed to provide follow-up or referral for the stated complaints.

c. Respondent's statement that the patient was under his medical care and supervision for treatment of a serious condition diagnosed after review of available records and in person medical examination was false.

Respondent's overall treatment of Detective Gossett as above described represented an extreme departure from the standard of care.

By virtue of his position as the physician practicing at the clinic, respondent assumed shared responsibility for the actions of the clinic facilitator/receptionist (Ben Morgan) in exaggerating information regarding patient medical conditions and for dispensation of marijuana on the premises. However, it was not established that respondent was aware of any of these practices. Whether respondent's license should be subject to disciplinary action for the acts of Ben Morgan is reserved for discussion in the Legal Conclusions section.

Cost Recovery

53. The Board has incurred the following costs in connection with the investigation and prosecution of this case:

Medical Board of California Investigative Services

Year	Hours[7]	Hourly Rate	Charges
1999	4	103.07	$ 412.28
2000	234	109.93	25,723.62
2001	52	110.84	5,763.68
2002	78	110.84	8,645.52

An additional 61 hours @ $100 were spent by medical experts for reviewing and evaluating case-related materials, report writing, hearing preparation and examinations. Board investigative costs total $46,645.16.

Attorney General Costs

The costs of prosecution by the Department of Justice for Deputy Attorneys General Jane Zack Simon and Lawrence A. Mercer total $23,608, and $30,884, respectively. The declarations of both have been reviewed and the time and charges are found to be in reasonable performance of tasks necessary for the prosecution of this case.[8] Investigative and prosecution costs total $101,137.

[7] Approximately 27 hours were spent conducting interviews, 53 hours for record review, 53 hours for travel, 173 hours on report writing and 62 hours on telephone, subpoena service, court, meetings with the Attorney General and Medical Consultant.

[8] Though a breakout of hours for each task was not provided cost certifications detailed tasks including 1) conducting an initial case evaluation, 2) obtaining, reading and reviewing the investigative material and requesting further investigation, as needed; 3) drafting pleadings, subpoenas, correspondence, memoranda, and other case-related documents; 4) researching relevant points of law and fact; 5) locating and interviewing witnesses and potential witnesses; 6) consulting and/or meeting with colleague deputies, supervisory staff, experts, client staff, and investigators; 7) communicating and corresponding with respondent's counsel; 8) providing and requesting discovery; 9) preparing for and attending trial setting, status, prehearing and settlement conferences, as required, and 10) preparing for hearing.

LEGAL CONCLUSIONS

Immunity

1. Respondent contends that the Compassionate Use Act of 1996 confers absolute immunity upon a licensed physician who recommends medical marijuana. He relies upon Health and Safety Code section 11362.5, subdivision (c), which provides:

> 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.

Respondent believes that his medical marijuana recommendations should be protected by the "absolute immunity" afforded under section 11362.5. He asserts that California law enforcement officials from various jurisdictions began bringing complaints against him to the Board based almost entirely on their own failed prosecutions of various medical marijuana patients and that no patient has initiated or joined a complaint against respondent. He suggests that this action is politically motivated by law enforcement officials who are now working in tandem with the Board to circumvent Proposition 215, along with other protections afforded him and his patients under the First Amendment and patient confidentiality laws.

Complainant characterizes this case as having "virtually nothing to do with medical marijuana" and notes that Board medical expert Dr. Duskin was not even critical of the recommendation, or use, of marijuana medicinally. Rather, complainant's criticism is leveled at respondent's alleged failure in virtually every case to examine the patient, to obtain a history, to perform an appropriate work up of the patient's symptoms and findings, or to follow up with or monitor the patients.

2. Respondent contends that by its use of the term "notwithstanding any other provision of law," a legal term of art, the Compassionate Use Act confers absolute immunity of doctors for their actions related to recommending or approving medical marijuana. He notes that conduct necessary to perform the immunized act falls within the scope of the grant of immunity and is thus not subject to Board discipline. Specifically, he argues that a doctor must always take some action attendant upon approving or recommending medical marijuana and that recognizing immunity for the approval or recommendation, but not the *approving* or *recommending*, is logically impossible, and legally unsupportable. Complainant would instead draw a clear distinction between the physician's recommendation, and the process by which that recommendation was reached.

Generally, decisions about when, where or how to carry out the immunized act is conduct that comes within the privilege because the methods of doing the immunized act are typically matters so intimately linked to the immunized act itself "that they are within the scope of the privilege." (*Katsaris* v. *Cook* (1986) 180 Cal.App.3d 256, 266-267; *Scozzafava* v. *Lieb* (1987) 190 Cal.App.3d 1575.) Both *Katsaris* and *Scozzafava* considered a statute

that immunized the killing of dogs trespassing on the property of livestock owners. In *Scozzafava*, a chicken farmer's employee wounded a dog that was attacking the farmers' chickens. The dog returned to its owner, who then brought the dog to a veterinarian. The dog later bit a veterinary assistant as she was attempting to pick it up. The veterinary assistant brought a negligence action against the chicken farmer, who raised the immunity statute as a defense. In construing the immunity rather broadly to bar the claim the Court of Appeal held:

> The context of *Katsaris* makes it clear that the test of acts or conduct "necessary to the killing" is not rigidly limited to such obvious incidents as loading and aiming, but is instead generously construed so as to reach categories of specific decisions pertaining to more general areas such as employment practices, business policies, and most manner of matters concerning firearms. These are precisely the issues for which plaintiff seeks to impose liability on defendant. Just as we did in *Katsaris*, we hold that these acts and omissions constitute decisions necessary to the exercise of the privilege to kill.

(*Scozzafava* v. *Lieb*, *supra*, 190 Cal.App.3d at 1581.)

Respondent contends that every single fact relied upon by the Board refers to the methods by which he went about recommending or approving the use of marijuana, and nothing more. He believes that the Board has no jurisdiction or authority to discipline, or even investigate him for the methods by which he recommended medical marijuana because such matters are shielded by absolute immunity.

3. Immunity statutes, like privileges, are either absolute or conditional. Absolutely privileged conduct does not permit any remedy by way of a civil action, regardless of whether or not the privileged conduct was undertaken in bad faith or with malice. (*Saroyan v. Burkett* (1962) 57 Cal.2d 706, 708) A qualified or conditional privilege protects the actor only if he or she acts for the purpose of advancing or protecting the interest which the privilege seeks to protect. "Thus, under a qualified privilege an actor may be liable for conduct which he undertakes with an improper motive. Likewise a qualified privilege may be lost if the actor engages in conduct outside the scope of the privilege, thus 'abusing' it." (*Katsaris* v. *Cook*, *supra*, 180 Cal.App.3d at 265.) To determine the scope of privilege the analytical model adopted by courts in defamation cases has been applied to immunity statutes, incorporating a two step analysis. (*Id.* at p. 266.) First, what is the policy rationale which underlies the privilege? Second, does that policy justify applying the privilege to this particular conduct? (*Ibid.*; *Bradley* v. *Hartford Acc. & Indem. Co.* (1973) 30 Cal.App.3d 818, 824.)

In this case the immunity afforded physicians under Health and Safety Code section 11362.5 does appear to be conditional. The language of the Compassionate Use Act is instructive in this regard. Subdivision (b)(2) provides that "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 nonmedical purposes." One

of the Act's purposes is to ensure that seriously ill Californians have the right to obtain and use marijuana for "medical purposes" and "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." Yet, the Act also expressly affirms public policy against conduct that endangers others or the diversion of marijuana for nonmedical purposes. It is left for the physician, as gatekeeper, to ensure that marijuana is used for "medical purposes" to benefit the seriously ill. Under these circumstances it is presumed that physicians who recommend marijuana under the Act will follow accepted medical practice standards and make good faith recommendations based on honest medical judgments. (*Conant* v. *McCaffrey* (2000 WL 1281174) Complainant correctly notes that to hold otherwise and to extend absolute immunity to physicians would allow them to simply issue marijuana recommendations without the exercise of sound medical judgment and with no oversight.

4. The primary function of the Board is protection of the public. (Bus. & Prof. Code, § 2229, subd. (a).) The various provisions of the Medical Practice Act dealing with physician misconduct are designed to promote public safety by ensuring that the standards of practice for physicians are maintained and enforced. The language of the Compassionate Use Act does not conflict with these goals. Thus, the immunity afforded physicians who recommend marijuana to patients for medical purposes provides that they may not be punished, or denied any right or privilege, for having made that recommendation. However, it does not exempt them from standards or regulations generally applicable to physicians, including those that govern the manner or process by which the physician's recommendation was reached. [9] Judge Kozinski reached the same conclusion in contemplating the role of the physician in determining legal and illegal marijuana use under the Compassionate Use Act:

> [D]octors are performing their normal function as doctors and, in so doing, are determining who is exempt from punishment under state law. If a doctor abuses this privilege by recommending marijuana without examining the patient, without conducting tests, without considering the patient's medical history or without otherwise following standard medical procedures, he will run afoul of state as well as federal law. But doctors who recommend medical marijuana to patients after complying with accepted medical procedures are not acting as drug dealers; they are acting in their professional role in conformity with the standards of the state where they are licensed to practice medicine.

(*Conant* v. *Walters* (2002) 309 F.3d 629, 647.)

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[9] That respondent also has a First Amendment right to recommend medical marijuana to his patients is undisputed. (*Conant* v. *Walters* (2002) 309 F.3d 629.) The Board has not imposed any content-based restrictions on his speech and he is able to communicate freely, candidly and meaningfully with his patients and to offer sincere medical judgments about the pros and cons of medical marijuana. For these reasons respondent's First Amendment challenge to the Board's action is overruled.

Application of Business and Professions Code Section 2242

5. Respondent contends that he did not "prescribe" marijuana and for that reason he cannot be held accountable for his failure to conduct a prior good faith examination nor for his failure to determine that a medical indication existed for treatment recommended by him. Business and Professions Code section 2242 provides that it is unprofessional conduct for a physician to prescribe, dispense or furnish drugs without a good faith prior examination and medical indication therefore. Respondent did not "prescribe" marijuana because one cannot prescribe a Schedule I controlled substance. (Health & Saf. Code, § 11054, subd. (d)(13).) Yet, the standard for prescribing cannot be distinguished from the standard of practice which proscribes recommending any other treatment without examination or medical work-up and the standard of practice is no different for "recommending" or "approving" marijuana than it is for prescribing any other medication. Section 2242 is intended to prevent persons from obtaining drugs that are "unsafe for self-use" unless and until a physician has conducted a medical examination and has verified that a valid medical indication for administration of the drug exists. (See also Bus. & Prof. Code, § 4022.) Moreover, the term "furnish" has been given a broad reading, in keeping with the purpose of the statutes in which it is used, to include any means by which an unauthorized person comes into possession of a dangerous drug. [10] This would surely include coming into possession of medical cannabis following a physician's recommendation.

The physician is the gatekeeper whose professional responsibility it is to insure that patients are not inappropriately self-medicating with dangerous drugs. That was the intent in enacting Health and Safety Code section 11362.5:

> 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** ...

[emphasis added.]

Therefore, a physician's professional responsibility under Business and Professions Code section 2242 requires the doctor to first conduct a good faith medical examination and determine that a medical indication exists before recommending medical cannabis. The standard for "prescribing" is not different than that for "recommending" or "approving" the use of marijuana.

[10] Thus, the provisions of the Controlled Substances Act (Health & Saf. Code, §11000 *et seq.*) are parallel to section 2242 and treat the "furnishing" of a drug the same as the "prescribing" of a drug. For example, section 11153 provides that a "prescription" for a controlled substance may issue only for a legitimate purpose and similarly section 11153.5 prohibits "furnishing" except for a legitimate medical purpose.

Standard of Practice

6. The standard of practice for conducting a medical cannabis evaluation is as set forth in Finding 16. It is identical to that followed by physicians in recommending any other treatment or medication and it applies regardless of whether the physician is acting as a treating or as a consulting physician. Although focused on the patient's complaints, the evaluation does not disregard accepted standards of medical responsibility. These standards include history and physical examination of the patient; development of a treatment plan with objectives; provision of informed consent; and periodic review of the treatment's efficacy. When a cannabis recommendation is being made for a psychiatric condition the examination would additionally entail a mental status examination. In such cases a physical examination might not be included, or might only include a limited physical examination appropriate to the clinical situation. In sum, the standard of practice for a physician recommending marijuana to a patient is the same as that for recommending any other treatment or medication.

The standard of practice requires that the evaluation be supported by adequate documentation. That documentation must reflect the physician's initial history and physical/mental status exam, evaluation of each condition in question and a diagnosis and/or differential diagnosis. A physician must document pertinent physical and/or psychiatric findings, referrals, a treatment plan and follow-up. Business and Professions Code section 2266 provides that "[t]he failure of a physician and surgeon to maintain adequate and accurate records relating to the provision of services to their patients constitutes unprofessional conduct."

Disciplinary Grounds

7. Under Business and Professions Code section 2234 the Division of Medical Quality shall take action against any licensee who is charged with unprofessional conduct. Unprofessional conduct includes gross negligence, repeated acts of negligence, incompetence and the commission of any act involving dishonesty or corruption which is substantially related to the qualifications, functions or duties of a physician and surgeon. (Bus. & Prof. Code, § 2234, subds. (b) – (e).)

8. Cause for disciplinary action exists under Business and Professions Code section 2234, subdivision (b), by reason of the matters set forth in Findings 17, 21, 23, 25, 27, 28, 30, 32, 35, 37, 39, 41, 43, 45, 47, 49 and 52. Respondent's errors and omissions in connection with his care and treatment of sixteen patients and the undercover officer constituted gross negligence.

9. Cause for disciplinary action exists under Business and Professions Code section 2234, subdivision (c), by reason of the matters set forth in Findings 17, 21, 23, 25, 27, 28, 30, 32, 35, 37, 39, 41, 43, 45, 47, 49 and 52. Respondent's errors and omissions in connection with his care and treatment of sixteen patients and the undercover officer constituted repeated negligent acts.

10. No cause for disciplinary action exists under Business and Professions Code section 2234, subdivision (d), by reason of the matters set forth in Finding 4. The above described errors and omissions do not reflect respondent's incompetence, but rather choices consistent with his belief that a different standard was applicable to the evaluation of patients for purposes of medical cannabis recommendations. Incompetence generally is defined as a lack of knowledge or ability in the discharging of professional obligations and it often results from a correctable fault or defect. (*James* v. *Board of Dental Examiners* (1985) 172 Cal.App.3d 1096, 1109.) There are no apparent deficits in his education, knowledge, training, or skills as a physician. He is clearly capable of observing standard medical evaluation protocols for history, physical and mental status examination, development of a treatment plan, informed consent and follow up or referral. He has also demonstrated that he can maintain proper records when he chooses to do so.

11. No cause for disciplinary action exists under Business and Professions Code section 2234, subdivision (e), by reason of the matters set forth in Finding 52. It was not established that respondent had any awareness of the activities of Ben Morgan, an element necessary to a finding that he committed an act involving "dishonesty or corruption" under this particular subdivision. Generally, a licensee is responsible for the acts of agents, whether independent contractors or employees, acting in the course of the licensee's business. This is true even when the licensee does not have actual knowledge of the agent's activities. Thus, a licensee was charged with submitting false statements in MediCal billings that were done through an office manager without his review, and a pharmacist may be disciplined by the pharmacy board for the unlawful acts of his employee for illegally filling prescriptions. (*Heisenberg* v. *Myers* (1983) 148 Cal.App.3d 814, 824; *Arenstein* v. *State Board of Pharmacy* (1968) 265 Cal.App.2d 179, 192.) But even where respondent is ultimately responsible for the actions of agents, it does not also follow that he engaged in unprofessional conduct. Unprofessional conduct under section 2234, subdivision (e) contemplates more than vicarious liability for the actions of an agent and a licensee should not be found to have engaged in unprofessional conduct unless directly implicated for committing acts involving "dishonesty or corruption." A violation of this subdivision (e) should be based upon findings of respondent's own acts of dishonesty or corruption, or on such acts by those working for him of which he had personal knowledge and which he actually ratified.[11] That is not the case here.

12. Cause for disciplinary action exists under Business and Professions Code section 2242, by reason of the matters set forth in Findings 17, 21, 23, 25, 27, 28, 30, 32, 35, 37, 39, 41, 43, 45, 47, 49 and 52. Respondent recommended and approved the use of marijuana, a controlled substance, without conducting a prior good faith examination. Section 2242 is determined to be controlling, notwithstanding its reference to "prescribing, dispensing, or furnishing dangerous drugs." (See Legal Conclusion 5.)

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[11] See also *James* v. *Board of Dental Examiners*, *supra*, 172 Cal.App.3d at 1110, where the Court of Appeal noted: "An important factor in our review is that any attack to revoke the personal license to practice dentistry of Dr. James of course must be based upon findings of his own acts of misfeasance, or on such acts by those working with him of which he had personal knowledge and which he actually ratified."

13. Cause for disciplinary action exists under Business and Professions Code section 2266, by reason of the matters set forth in Findings 17, 21, 23, 25, 27, 28, 30, 32, 35, 37, 39, 41, 43, 45, 47, 49 and 52. Respondent failed to maintain adequate and accurate records relating to the provision of services to his patients.

14. Cost Recovery. Under Business and Professions Code section 125.3 the Board may request the administrative law judge to direct any licentiate found to have committed a violation or violations of the licensing act to pay the Board a sum not to exceed the reasonable costs of the investigation and enforcement of the case. Requested costs total $101,137. (See Finding 53.)

The Board must not assess the full costs of investigation and prosecution when to do so will unfairly penalize a licensee who has committed some misconduct, but who has used the hearing process to obtain dismissal of other charges or a reduction in the severity of the discipline imposed. The Board must consider the licensee's "subjective good faith belief in the merits of his or her position" and whether the licensee has raised a "colorable challenge" to the proposed discipline. (*Zuckerman* v. *Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, 45.) Such factors have been considered in this matter.

This is a case of first impression. The scope of physician immunity under Health and Safety Code section 11362.5 and other legal issues had not been considered previously and required greater time and preparation on the part of complainant. Respondent should not bear the full burden of such costs. The Board acknowledged in its own policy statement on Proposition 215 that there was "a great deal of confusion concerning the role of physicians under this law" and following passage of the Compassionate Use Act there was uncertainty over what protocols physicians should follow in making medical cannabis recommendations. Some uncertainty persisted, notwithstanding the Board's January 1997 policy statement. There was credible testimony that among the handful of physicians who consult regularly on medical cannabis issues there was no uniform agreement on practice standards. Respondent had a good faith belief in the merits of his position and he raised a colorable challenge, factually and legally, to accusation allegations. He successfully defended allegations against him based upon incompetence, dishonesty or corruption. An adjustment of approximately 25 percent would fairly and equitably accounts for these several factors. Accordingly, reasonable investigation and prosecution costs are adjusted to $75,000.

15. Other Considerations. The protection of the public is the Board's highest priority. Yet, in determining appropriate disciplinary action and in exercising disciplinary authority the Board shall, whenever possible, "take action that is calculated to aid in the rehabilitation of the licensee." (Bus. & Prof. Code, § 2229.) This includes ordering restrictions as are indicated by the evidence. Respondent's competence was really not at issue in this case. He understands what the traditional medical examination model entails. He has applied it when patients have been evaluated for reasons outside his focused medical cannabis consultation model and indeed, when Dr. Duskin was asked to review nine of respondent's inpatient case files, she found all to be within the standard of care. In a few cases she determined his care to be excellent. He is clearly capable of observing standard

medical evaluation protocols for history, physical and mental status examination, development of a treatment plan, informed consent and follow up or referral. He has also demonstrated that he can maintain proper records in such cases. Dishonesty or corruption allegations against respondent were not sustained.

Respondent strongly believed that Proposition 215 contemplated something very different than the traditional medical examination model. Such beliefs were based upon his active involvement in efforts to legalize marijuana for medical purposes and his own good faith interpretation of Proposition 215. This, combined with his practice experience as a medical cannabis consultant, resulted in rather rigid yet consistent adherence to the more focused medical cannabis consultation model. He did so even after he was on notice of the accusation allegations. The question now is whether he is willing and able to set aside these very strong views regarding the type of examination he feels is necessary to support a medical cannabis recommendation and comply with traditional medical examination standards. Complainant characterizes respondent as "obviously intransigent" and is concerned that this will impede not only his ability to successfully complete probation, but the Board's ability to adequately supervise and monitor his activities. Respondent should only be placed on probation if there is a reasonable likelihood that he will conform his practice to acceptable standards, and if he can reasonably be expected to abide by necessary practice restrictions and oversight. Respondent has certainly been a forceful advocate for his approach throughout the investigation, prosecution and hearing of this case. He has raised colorable factual and legal defenses to accusation allegations and several first impression issues were considered in this case. Importantly, he has indicated that he would be willing to conform his practices if required and it is not unreasonable to expect that he will do so. [12] He should be given that opportunity.

It would therefore not be contrary to the public interest to place respondent on probation at this time. One of the conditions should include appointment of a practice monitor and the development of a monitoring plan. Respondent has suggested that if his practice were monitored or supervised by a physician who was not a medical cannabis consultant he would "reject" it. [13] This is a case where compliance can best be ensured through a physician monitor/supervisor approved by the Board. This physician monitor may be a medical cannabis consultant, but this is certainly not a necessary requirement. The Board normally allows licensees, in lieu of having a practice monitor, to participate in a professional enhancement program equivalent to the one offered by the Physician Assessment and Clinical Education (PACE) Program

[12] Respondent's failure to conform his behaviors after he was on notice that the Board took issue with his evaluation process and his lack of medical documentation is troubling, but it is countered somewhat by his sincere belief that he was breaking new ground in setting standards under Proposition 215 for recommending and approving medical cannabis. He has also persisted in his belief that this case has been driven from the start by federal and state government officials opposed to Proposition 215.

[13] Respondent's own expert, also a medical cannabis consultant, documents all medical cannabis evaluations and conducts a good faith examination that is identical to any other medical evaluation he performs. He does so consistent with his philosophy of practicing excellent medicine in all cases. If a medical cannabis consultant such as Dr. Denney performs the same medical evaluation for all patients, then it should really make no difference whether a physician assigned to monitor respondent's practice is also a medical cannabis consultant.

at the University of California, San Diego School of Medicine, that includes, at minimum, quarterly chart review, semi-annual practice assessment, and semi-annual review of professional growth and education. While respondent may opt to participate in program such as PACE, it remains critical that an approved practice monitor be in place to monitor his practice. Participation in PACE should not be done in lieu of having a practice monitor.

ORDER

Physician's and Surgeon's Certificate No. G-9124 issued to respondent Tod H. Mikuriya, M.D. is revoked pursuant to Legal Conclusions 8, 9, 12 and 13, separately and for all of them. However, revocation is stayed and respondent is placed on probation for five (5) years upon the following terms and conditions:

1. Monitoring of Practice. Within 30 calendar days of the effective date of this Decision, respondent shall submit to the Division or its designee for prior approval as a practice monitor, the name and qualifications of one or more licensed physicians and surgeons whose licenses are valid and in good standing, and who are preferably American Board of Medical Specialties (ABMS) certified. A monitor shall have no prior or current business or personal relationship with respondent, or other relationship that could reasonably be expected to compromise the ability of the monitor to render fair and unbiased reports to the Division, including but not limited to any form of bartering, shall be in respondent's field of practice, and must agree to serve as respondent's monitor. Respondent shall pay all monitoring costs.

The Division or its designee shall provide the approved monitor with copies of the Decision and Accusation, and a proposed monitoring plan. Within 15 calendar days of receipt of the Decision, Accusation, and proposed monitoring plan, the monitor shall submit a signed statement that the monitor has read the Decision and Accusation, fully understands the role of a monitor, and agrees or disagrees with the proposed monitoring plan. If the monitor disagrees with the proposed monitoring plan, the monitor shall submit a revised monitoring plan with the signed statement.

Within 60 calendar days of the effective date of this Decision, and continuing throughout probation, respondent's practice shall be monitored by the approved monitor. Respondent shall make all records available for immediate inspection and copying on the premises by the monitor at all times during business hours and shall retain the records for the entire term of probation.

The monitor shall submit a quarterly written report to the Division or its designee which includes an evaluation of respondent's performance, indicating whether respondent's practices are within the standards of practice of medicine

or billing, or both, and whether respondent is practicing medicine safely, billing appropriately or both.

It shall be the sole responsibility of respondent to ensure that the monitor submits the quarterly written reports to the Division or its designee within 10 calendar days after the end of the preceding quarter.

If the monitor resigns or is no longer available, respondent shall, within 5 calendar days of such resignation or unavailability, submit to the Division or its designee, for prior approval, the name and qualifications of a replacement monitor who will be assuming that responsibility within 15 calendar days. If respondent fails to obtain approval of a replacement monitor within 60 days of the resignation or unavailability of the monitor, respondent shall be suspended from the practice of medicine until a replacement monitor is approved and prepared to assume immediate monitoring responsibility. Respondent shall cease the practice of medicine within 3 calendar days after being so notified by the Division or designee.

Failure to maintain all records, or to make all appropriate records available for immediate inspection and copying on the premises, or to comply with this condition as outlined above is a violation of probation.

2. Notification. Prior to engaging in the practice of medicine respondent shall provide a true copy of the Decision and Accusation to the Chief of Staff or the Chief Executive Officer at every hospital where privileges or membership are extended to respondent, at any other facility where respondent engages in the practice of medicine, including all physician and locum tenens registries or other similar agencies, and to the Chief Executive Officer at every insurance carrier which extends malpractice insurance coverage to respondent. Respondent shall submit proof of compliance to the Division or its designee within 15 calendar days. This condition shall apply to any change in hospitals, other facilities or insurance carrier.

3. Supervision of Physician Assistants. During probation, respondent is prohibited from supervising physician assistants.

4. Obey All Laws. Respondent shall obey all federal, state and local laws, all rules governing the practice of medicine in California and remain in full compliance with any court ordered criminal probation, payments, and other orders.

5. Quarterly Declarations. Respondent shall submit quarterly declarations under penalty of perjury on forms provided by the Division, stating whether there has been compliance with all the conditions of probation. Respondent

shall submit quarterly declarations not later than 10 calendar days after the end of the preceding quarter.

6. Probation Unit Compliance. Respondent shall comply with the Division's probation unit. Respondent shall, at all times, keep the Division informed of respondent's business and residence addresses. Changes of such addresses shall be immediately communicated in writing to the Division or its designee. Under no circumstances shall a post office box serve as an address of record, except as allowed by Business and Professions Code section 2021(b). Respondent shall not engage in the practice of medicine in respondent's place of residence. Respondent shall maintain a current and renewed California physician's and surgeon's license.

Respondent shall immediately inform the Division or its designee, in writing, of travel to any areas outside the jurisdiction of California which lasts, or is contemplated to last, more than thirty (30) calendar days.

7. Interview with the Division or Its Designee. Respondent shall be available in person for interviews either at respondent's place of business or at the probation unit office, with the Division or its designee upon request at various intervals and either with or without prior notice throughout the term of probation.

8. Residing or Practicing Out-of-State. In the event respondent should leave the State of California to reside or to practice respondent shall notify the Division or its designee in writing 30 calendar days prior to the dates of departure and return. Non-practice is defined as any period of time exceeding thirty calendar days in which respondent is not engaging in any activities defined in sections 2051 and 2052 of the Business and Professions Code.

All time spent in an intensive training program outside the State of California which has been approved by the Division or its designee shall be considered as time spent in the practice of medicine within the State. A Board-ordered suspension of practice shall not be considered as a period of non-practice. Periods of temporary or permanent residence or practice outside California will not apply to the reduction of the probationary term. Periods of temporary or permanent residence or practice outside California will relieve respondent of the responsibility to comply with the probationary terms and conditions with the exception of this condition and the following terms and conditions of probation: Obey All Laws; Probation Unit Compliance; and Cost Recovery.

Respondent's license shall be automatically cancelled if respondent's periods of temporary or permanent residence or practice outside California totals two years. However, respondent's license shall not be cancelled as long as respondent is residing and practicing medicine in another state of the United

States and is on active probation with the medical licensing authority of that state, in which case the two year period shall begin on the date probation is completed or terminated in that state.

9. Failure to Practice Medicine - California Resident. In the event respondent resides in the State of California and for any reason respondent stops practicing medicine in California, respondent shall notify the Division or its designee in writing within 30 calendar days prior to the dates of non-practice and return to practice. Any period of non-practice within California, as defined in this condition, will not apply to the reduction of the probationary term and does not relieve respondent of the responsibility to comply with the terms and conditions of probation. Non-practice is defined as any period of time exceeding thirty calendar days in which respondent is not engaging in any activities defined in sections 2051 and 2052 of the Business and Professions Code.

All time spent in an intensive training program which has been approved by the Division or its designee shall be considered time spent in the practice of medicine. For purposes of this condition, non-practice due to a Board-ordered suspension or in compliance with any other condition of probation, shall not be considered a period of non-practice.

Respondent's license shall be automatically cancelled if respondent resides in California and for a total of two years, fails to engage in California in any of the activities described in Business and Professions Code sections 2051 and 2052.

10. Violation of Probation. Failure to fully comply with any term or condition of probation is a violation of probation. If respondent violates probation in any respect, the Division, after giving respondent notice and the opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If an Accusation, or Petition to Revoke Probation, or an Interim Suspension Order is filed against respondent during probation, the Division shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

11. Cost Recovery. Within 90 calendar days from the effective date of the Decision or other period agreed to by the Division or its designee, respondent shall reimburse the Division the amount of $75,000 for its investigative and prosecution costs. The filing of bankruptcy or period of non-practice by respondent shall not relieve the respondent his obligation to reimburse the Division for its costs.

12. License Surrender. Following the effective date of this Decision, if respondent ceases practicing due to retirement, health reasons or is otherwise

unable to satisfy the terms and conditions of probation, respondent may request the voluntary surrender of respondent's license. The Division reserves the right to evaluate respondent's request and to exercise its discretion whether or not to grant the request, or to take any other action deemed appropriate and reasonable under the circumstances. Upon formal acceptance of the surrender, respondent shall within 15 calendar days deliver respondent's wallet and wall certificate to the Division or its designee and respondent shall no longer practice medicine. Respondent will no longer be subject to the terms and conditions of probation and the surrender of respondent's license shall be deemed disciplinary action.

If respondent re-applies for a medical license, the application shall be treated as a petition for reinstatement of a revoked certificate.

13. Probation Monitoring Costs. Respondent shall pay the costs associated with probation monitoring each and every year of probation, as designated by the Division, which may be adjusted on an annual basis. Such costs shall be payable to the Medical Board of California and delivered to the Division or its designee no later than January 31 of each calendar year. Failure to pay costs within 30 calendar days of the due date is a violation of probation.

14. Completion of Probation. Respondent shall comply with all financial obligations (e.g., cost recovery, restitution, probation costs) not later than 120 calendar days prior to the completion of probation. Upon completion successful of probation, respondent's certificate shall be fully restored.

DATED: January 30, 2004

JONATHAN LEW
Administrative Law Judge
Office of Administrative Hearings

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Mark E. Souder
Chairman
Subcommittee on Criminal Justice,
Drug Policy, and Human Resources
Committee on Government Reform
House of Representatives
Washington, D.C. 20515-6143

JUL 1 2004

Dear Mr. Chairman:

Thank you for the letter of April 12, 2004, containing follow-up questions from the April 1, 2004, hearing entitled, "Marijuana and Medicine: The Need for A Science-Based Approach." We have restated your questions below with our response for the record.

1. Legislation has been introduced in Congress to allow states to bypass the FDA process and allow marijuana to be promoted and sold as a medical therapy – without being proven to be safe and effective as required by federal law. Do you believe patients are well served by such political efforts or is the health of patients and the public best served when science is used by the FDA to demonstrate the safety and effectiveness of all drugs including marijuana?

The Food and Drug Administration (FDA or the Agency) believes that all drugs considered for medical use, including marijuana, should be proven safe and effective for their intended indication(s). The Federal Food, Drug, and Cosmetic (FD&C) Act requires that new drugs be shown to be safe and effective for their intended use before being marketed in this country. This statutory provision affords patients the most effective protection against untested and unproven products. FDA's drug approval process requires well-controlled clinical trials that provide the necessary scientific data upon which FDA makes its approval decisions. The disciplined, systematic, scientific conduct of such trials is the best means of obtaining the data documenting the safe and effective use of a drug so that it will have the most beneficial effect.

2. If pharmaceutical companies wished to bring new or even existing medical product to market and chose to bypass the FDA approval process by using ballot initiatives or state legislative approval, would the FDA take any action? If so, what would the Agency do? For example, if a company tried to pass a state referendum allowing oxycodones or hydrocodones to be "recommended" by a doctor for any condition whatsoever, would the FDA take action? If so, what action would the agency take?

The type of state laws you discuss would not change either the Federal prohibition on the sale of an unapproved new drug under the FD&C Act or the restrictions placed on a controlled substance under the Controlled Substances Act (CSA). FDA is the sole governmental agency that approves drug products as safe and effective for particular indications, and efforts that seek to bypass the FDA drug approval process would not serve the interests of public health. Physician recommendations of approved prescription drug products for indications other than those indications approved by FDA (off-label use) are generally considered to be within the scope of the practice of medicine by FDA and are not regulated by the Agency.

Currently, there are FDA approved oxycodone and hydrocodone products available by prescription for specific indications. If a company promotes their drug for an off-label use, FDA will review the materials related to the promotion and can take action under certain conditions. Merely sponsoring or supporting a referendum, however, is not likely to lead to a violation of the FD&C Act.

3. As a result of the public campaigns of pro-marijuana activists, many Americans erroneously believe that smoking marijuana is a legitimate medical treatment. The FDA was established – and is funded by Congress – to ensure that such confusion does not exist. Will the FDA now consider issuing warning letters to all states and localities that have attempted to approve "medicinal" marijuana use, and to all sellers of "medical" marijuana, explaining that botanical marijuana has not been approved by the FDA for medical use and cannot be advertised as such? Will it consider imposing penalties, as appropriate, on those that continue to illegally promote this dangerous drug as medicine?

The Department of Health and Human Services (HHS) does not support the availability of marijuana for medical use as it has not been proven safe and effective as required by Federal law. In 2001, HHS completed an extensive analysis in response to a request to reschedule marijuana to a less restrictive schedule. After looking at all the relevant data on marijuana, HHS concluded that the weight of the scientific evidence supported the findings that marijuana should continue to be scheduled as Schedule I because it has a high potential for abuse, no currently accepted medical use in the United States, and a lack of accepted evidence about the safety of using marijuana under medical supervision.

As a Department, HHS has been actively involved in the Administration's effort to educate Americans about the status and dangers of marijuana. FDA is committed to working in cooperation with the Office of National Drug Control Policy (ONDCP), the Drug Enforcement Administration (DEA), the National Institute on Drug Abuse (NIDA), and the Substance Abuse and Mental Health Services Administration (SAMHSA) to inform the public about the dangers of marijuana and that it is not approved for any medical use.

One very successful education campaign that warns against marijuana use is provided by HHS' NIDA. NIDA has a very comprehensive website (at: *www.marijuana-info.org*) that includes specific information about the effects of marijuana on health. The information details the physical and neurological effects of marijuana on the brain, lungs, heart and immune responses. There is also information about the effects of marijuana use on pregnancy, learning, social behavior, genetic makeup and the potential for addiction. NIDA is also actively involved in

research on marijuana and in March 2004 published the Marijuana Research and Dissemination Update detailing the research efforts of the institute. FDA works with NIDA and actively reviews all investigational new drug (IND) applications for marijuana. FDA's role is to ensure that the research is conducted in accordance with regulatory requirements of the FD&C Act. HHS' SAMHSA works to bring effective substance abuse prevention to every community nationwide. SAMHSA's Center for Substance Abuse Prevention supports the National Clearing House for Alcohol and Drug Information, the largest Federal source of information about substance abuse research, treatment, and prevention available to the public. SAMHSA is also actively engaged in substance abuse treatment through the promotion of high-quality and available community-based substance abuse treatment services for individuals and families who need them. SAMHSA is on the frontlines in helping programs to treat individuals with addictions to alcohol and drugs, including marijuana.

For the reasons explained below, FDA believes that DEA is the more appropriate agency to continue to lead in taking action against entities that appear to be violating the law by illegally using or distributing marijuana. Under some circumstances, the sale of marijuana would violate both the FD&C Act and the CSA. However, there are considerably more elements to prove to bring an enforcement action under the FD&C Act than under the CSA. To bring a case under the FD&C Act, FDA would need to gather evidence that the marijuana was a drug within the meaning of the FD&C Act. To do so, FDA would have to prove that under the specific facts of the case, it was intended to cure, mitigate, or treat a disease or to affect the structure or function of the body of man. In addition, FDA would need evidence that the marijuana was received or distributed in interstate commerce. FDA would also need either labeling associated with the marijuana sufficient to prove that the marijuana is a new drug or proof that the marijuana is adulterated or misbranded under the FD&C Act.

In addition, the penalties are more significant under the CSA. Assuming FDA was able to prove the elements mentioned above and brought a criminal action against a seller of marijuana who believed that marijuana is effective for medical use, the offense would be a misdemeanor unless there was evidence that the seller either took steps to evade detection by FDA or another government agency or somehow defrauded his or her customers. By contrast, a violation of the CSA related to the sale of marijuana requires fewer elements of proof and would be a felony subject to much higher penalties than those available under the FD&C Act.

We also note that warning letters are a specific regulatory tool sent by FDA when we have evidence that a violation of the FD&C Act has occurred. These letters require corrective action on the part of the recipient and if attempts at corrective action fail to remedy the FD&C Act violation, further enforcement action is pursued.

DEA is the lead Federal agency responsible for enforcing restrictions placed on the sale, distribution and possession of controlled substances under the CSA. DEA has the authority, expertise, and resources to interdict the illegal use of controlled substances and the CSA provides greater penalties and requires proof of far fewer elements to establish a violation. However, FDA still works cooperatively with DEA when necessary on any investigative or enforcement matters that may be appropriate under the CSA and the FD&C Act. For example, FDA's Office of Criminal Investigations (OCI) is responsible for managing and conducting the Agency's criminal

investigations. As a part of its duties, OCI works closely with DEA on criminal investigations involving the illegal sale, use, and diversion of controlled substances including controlled substances sold over the Internet. OCI and DEA have worked together to utilize the full range of regulatory and administrative tools available to them to pursue cases involving controlled substances.

The primary responsibility for implementing the CSA, however, resides with DEA, and FDA generally defers to DEA on criminal enforcement efforts related to violations of the CSA involving Schedule I controlled substances. FDA has not taken independent criminal enforcement action related to the sale, promotion, or marketing of botanical marijuana as medicine. FDA has worked closely with the Department of Justice and DEA on certain legal actions involving marijuana. These cases include Kuromiya v. United States, 37 F. Supp. 2d 717 and 78 F. Supp. 2d 367 (E.D. PA 1999) in which the plaintiffs sought access to marijuana for medical use and the government explained the importance of the drug approval process and the fact that marijuana has not been proven safe and effective for medical use and United States v. Oakland Cannabis Buyers' Cooperative, 532 U.S. 483 (2001), in which the Supreme Court ruled that there was no medical necessity defense to the CSA prohibitions on manufacture and distribution of marijuana. The government briefs in the case clearly spelled out the importance of FDA's drug approval process in making safe and effective medications available to the public.

It is a more efficient use of government resources to allow the agency that has more expertise and stronger penalties for violations of law involving controlled substances to take the lead in such cases. FDA believes that DEA is the more appropriate agency to handle enforcement matters involving Schedule I controlled substances and NIDA and SAMHSA, working through its state partners, are the appropriate HHS component to continue its work educating and informing the public of the health implications of marijuana use. FDA will continue its primary responsibility to review and monitor clinical trials investigating marijuana for medical uses under the IND provisions of the FD&C Act, and will continue to work with DEA, ONDCP, and NIDA to continue to inform the public that marijuana has not been proven effective for any indication.

4. According to a September 25, 2003, letter to this Subcommittee, the FDA stated, "Evaluation indicates that sound scientific studies supporting the claims of marijuana's usefulness are lacking." The FDA letter further states that, "there is some concern that the use of smoked marijuana may be harmful to individuals suffering from the conditions for which it is touted as a safe and effective treatment." The letter also noted, "botanical marijuana has not been approved by the Food and Drug Administration as a safe and effective drug. Will the FDA consider issuing a clear statement to the public clearly stating that smoked marijuana has not been proven to be useful as medicine and may actually be harmful? Will the FDA undertake a public educational and awareness campaign on this subject, similar to those it has undertaken for obesity and herbal supplements?

FDA's April 1, 2004, Statement to this Committee, which can be found on FDA's website, *http://www.fda.gov/ola/2004/marijuana0401.html*, clearly states that FDA has not approved marijuana for medical use in the U.S. From the perspective of Federal law, there currently is no medical marijuana. Above, we highlighted several other forums where HHS agencies have publicly posted information on marijuana's abuse potential, health effects, and status as an

unapproved drug. As noted previously, marijuana is a Schedule I drug and Schedule I substances are defined as having a very high potential for abuse, no accepted medical use in the U.S., and lacking accepted safety data for use under medical supervision. Nevertheless, Schedule I substances can still be the subject of an IND under the FD&C Act, although the conditions for their use are more restrictive. As noted in our statement, there has been considerable interest in the use of marijuana for the treatment of a number of conditions, including glaucoma, AIDS wasting, neuropathic pain, treatment of spasticity associated with multiple sclerosis, and chemotherapy-induced nausea.

HHS and FDA support the medical research community, which intends to and is currently studying marijuana in scientifically valid and well-controlled clinical trials as part of FDA's drug approval process. These clinical trials are the foundation of an objective, science-based approach to evaluating the merits of marijuana for medicinal purposes. Also, as detailed in the response to Question 3, NIDA and SAMHSA, two other components of HHS, are actively involved in a public and educational awareness campaign on the health effects of marijuana use. While there are no proven benefits from marijuana use, there are many short and long-term risks associated with marijuana use. FDA has not approved any drugs for which the preferred form of administration is smoking.

FDA has been involved in both the obesity and herbal supplement campaigns based on FDA's jurisdictional responsibilities. While HHS is the primary sponsor of the obesity educational campaign, FDA has been active in this area based on its statutory responsibility for nutritional labeling. In March 2004, FDA issued a report outlining its action plan on obesity, as part of HHS' comprehensive strategy for combating the epidemic of obesity in the U.S. The report by FDA's Obesity Working Group is focused on providing consumers with accurate, helpful information that allows them to make wise food choices at home, at supermarkets and in restaurants; such nutrition information is within FDA's statutory authority and scientific and regulatory expertise. For example, the report includes recommendations to strengthen food labeling, to educate consumers about using nutritional information to maintain a healthy diet and weight, and to encourage restaurants to provide calorie and nutrition information. It recommends increasing enforcement to ensure food labels accurately portray serving size. The report also recommended revising and reissuing an FDA draft Guidance for the Clinical Evaluation of Weight-Control Drugs and strengthening the coordination of research into obesity and the development of foods that are healthier and lower in calories with other HHS agencies, the U.S. Department of Agriculture, and other public and private sector partners.

FDA's work regarding dietary supplements likewise stems from its primary jurisdiction over the regulation of these products under the Dietary Supplement Health and Education Act of 1994 (DSHEA). Under responsibilities imposed by DSHEA, FDA has conducted a number of public education campaigns on dietary supplements.

FDA regulates smoked marijuana, a botanical product, when it is being investigated for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals, as a drug, under the FD&C Act. Under the FD&C Act, FDA's primary role is to review and monitor objective data collected in adequate and well-controlled clinical trials regarding the potential merits of marijuana for medical uses.

We do cooperate in many arenas with DEA and with ONDCP on matters that are connected to FDA's jurisdiction. As you may know, on March 1, 2004, the Administration announced a coordinated drug strategy to confront the illegal diversion and abuse of prescription drugs. Director of the White House Office for National Drug Control Policy, John Walters, then-FDA Commissioner Dr. Mark McClellan, DEA Administrator Karen Tandy, Surgeon General Dr. Richard Carmona, and Chairman Tom Davis, Committee on Government Reform, joined together to release the President's National Drug Control Strategy, which outlines the extent of prescription drug abuse in the U.S. and new Federal programs designed to address the problem. FDA will participate in this coordinated program. In addition, FDA directs readers to the NIDA website for information on teens and marijuana: *http://www.fda.gov/oc/opacom/kids/html/7teens.htm.*

5. The L.A. Times recently reported that researchers are studying the potential uses of nicotine or its derivatives as medicine. If a cigarette manufacturer began claiming in its advertising that cigarettes could be used as treatment for certain medical conditions – such as obesity or attention deficit disorder (ADD) – would the FDA take action? If so, what action would it take?

If a manufacturer were to market a tobacco product for treatment of the conditions you cite -- obesity or attention deficit disorder -- those product claims would render the tobacco product a drug within the meaning of section 201(g) of the FD&C Act. Whether FDA would take action to regulate such a product as an unapproved new drug depends on a variety of factors, and FDA generally makes enforcement decisions on a case-by-case basis.

In general, FDA employs a risk-based enforcement approach with respect to marketed unapproved drugs. This approach includes efforts to identify illegally marketed drugs, prioritization of those drugs according to potential public health concerns or other impacts on the public health, and subsequent regulatory follow-up. Some of the specific actions the Agency has taken have been precipitated by evidence of safety or effectiveness problems that has either come to our attention during inspections or was brought to our attention by outside sources. FDA has issued a draft Compliance Policy Guide (*htt:///www.fda.gov/cder/guidance/5704dft.pdf*) for comment that provides the Agency's current thinking on its enforcement policies for unapproved drugs. Scarce resources prevent the Agency from taking many legally supportable actions against products that meet the legal definition of unapproved drugs. The particular example above differs from physician recommendation of marijuana in several important respects. First, the drug product identified is not a controlled substance, much less one designated as Schedule I, which Congress has defined as the top enforcement priority for DEA under the CSA. Second, the example involves a direct connection between the sale and promotional activities, which is generally a necessary prerequisite to trigger drug approval requirements. Third, the example implies a large-scale manufacturing and promotional enterprise that would not usually raise jurisdictional questions involving interstate commerce.

6. In a letter to this Subcommittee dated March 31, 2004, the FDA says it has not taken a strong role in discouraging the promotion of marijuana as medicine because it is the agency's practice to refer "matters involving controlled substances" to the DEA. Just last week, the FDA issued new regulations on generic versions of oxycodones, which is a

controlled substance. Please explain why FDA has chosen to regulate one controlled substance – oxycodone – while failing to regulate another, namely marijuana?

FDA's primary mission as defined in the FD&C Act is to help ensure that only safe and effective medical products, including drugs, are marketed in the U.S. The Agency carries out this mission by administering the regulatory system under which drugs are evaluated, and determining when drugs have been shown to be safe and effective for their intended use. FDA's regulatory authority is usually triggered when a manufacturer submits an application either to study or to market a drug, including a drug scheduled as a controlled substance under the CSA. Thus, FDA regulates the controlled substance oxycodone because manufacturers submitted applications to FDA for approval of this drug for marketing for a medical use under the FD&C Act. FDA's recent action on oxycodone was a result of the submission of a number of applications to market generic versions of the drug. The FD&C Act requires the Agency to approve generic applications once all statutory requirements are met. FDA is also regulating marijuana because sponsors have submitted IND applications to study marijuana for a variety of medical uses. FDA would take appropriate regulatory actions with respect to approval of marijuana if FDA received an application to review for the approval of that drug.

As noted previously, FDA regulates controlled substances when applications are submitted to the Agency seeking approval for their study or marketing. In addition, the CSA gives HHS a role in determining the proper scheduling of a substance. When questions arise regarding the sale, distribution, or possession of marijuana as a Schedule I controlled substance, then the provisions of the CSA are triggered and DEA has primary authority to take action under that statute. As discussed above, enforcement actions are deferred to DEA because that Federal agency is best suited to enforce the CSA particularly when the substance at issue is a Schedule I controlled substance.

7. The Washington Post reported this morning that the FDA has begun to regulate health claims for walnuts. Similar health claims for other nuts are being reviewed by the FDA. Yesterday, another report appeared indicating that FDA will begin "scrutinizing" ultrasound imaging of unborn children, despite any real record of negative health effects. Why does FDA have the time and resources to review health claims of nuts and to scrutinize ultrasound but not to review the health claims of marijuana?

Under the FD&C Act, FDA is the primary Federal agency tasked with regulating radiological health and food, other than certain meat, poultry, and egg products. FDA is the primary agency tasked with the review of pending INDs evaluating botanical marijuana for the treatment of various conditions. As long as marijuana is a Schedule I controlled substance, FDA will defer to DEA on enforcement actions related to the illegal distribution or manufacture of marijuana. FDA is committed to working with the ONDCP, DEA, and NIDA to convey to the public the Administration's position on the use of marijuana.

8. In your testimony, you state that FDA defers to DEA to take the lead in regulating controlled substances like marijuana. This feeds a perception in the pro-marijuana movement and in the public at large, however, that the federal government is only interested in the law enforcement problems of marijuana – not the medical or health problems created

by marijuana. Wouldn't you agree that it's about time for the FDA to provide some assistance to DEA to avoid creating that misconception?

As discussed in the above responses, FDA has provided assistance to DEA in certain legal actions as well as investigations. More importantly, two other HHS component, NIDA and SAMHSA, have primary responsibility for educational and public awareness efforts related to the health effects of marijuana use. These efforts complement the efforts of ONDCP and DEA with respect to marijuana use. FDA has also made a number of public statements, including through congressional testimony, that marijuana has not been approved by the Agency as safe and effective for any medical use and that its use may be harmful to health. These statements are posted on FDA's website, *www.fda.gov*. Further, FDA will actively cooperate with the ONDCP, DEA, and NIDA in alerting the public about the current status of marijuana.

9. We are very puzzled about how silent FDA has been in the face of state laws that bypass FDA regulations and permit marijuana to be used for "medical" purposes. If the FDA continues to do so little, this will encourage other special interest groups to seek similar state laws for other popular drugs. It appears to us that this will not just undermine FDA's authority – it will destroy it. Is FDA at all concerned about this trend? What, if anything, will FDA do to counteract it?

FDA has not been silent in these matters. FDA has worked closely with DEA and has provided active assistance, when it has been requested, in certain legal cases and investigations involving the illegal use of marijuana. FDA's authority has not been affected or pre-empted by these state actions. Approval of marijuana as a drug for specific medical indications still remains within the purview of FDA. Several states have passed referenda making marijuana available for a variety of medical conditions, but these laws are in conflict with the CSA and often with the FD&C Act. Our position continues to be that these ballot measures send the wrong message to the public– too many of whom do not recognize the dangers of marijuana – and that these measures are inconsistent with our efforts to ensure that approved medications have undergone rigorous scientific scrutiny and FDA's approval process.

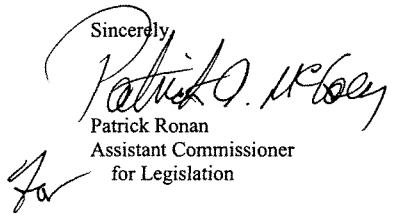
FDA will continue to state, as it did in its Congressional testimony, that marijuana is not an approved drug and that only the disciplined, systematic, scientific conduct of clinical trials can establish whether there is any medicinal value to marijuana, smoked or otherwise. As with other efforts attempting to pre-empt FDA's authority, FDA will evaluate and address the effort in accordance with its priorities and in the most efficient use of limited government resources. In this circumstance, in which the primary jurisdiction of a Schedule I controlled substance, a substance with no approved medical use, rests with DEA, and for which there are significant criminal penalties and easier elements of proof under DEA's jurisdiction, FDA will continue to defer to DEA for appropriate enforcement action.

FDA will work with the ONDCP, DEA, and NIDA to convey to the public the Administration's position on the use of marijuana. 1) FDA has not approved marijuana for any indication, 2) DHHS' current evaluation indicates that sound scientific studies sufficient to support claims of marijuana's usefulness as a medication are lacking, despite anecdotal claims to the contrary, and

3) there is a lack of accepted safety for use of smoked marijuana, the known risks of which are not outweighed by any potential benefits.

Thank you again for contacting us concerning this matter. FDA appreciates the opportunity to testify before the Subcommittee. Please let us know if there are further questions.

Sincerely,



Patrick Ronan
Assistant Commissioner
for Legislation

cc. DEA
NIDA
SAMHSA

U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

October 13, 2004

The Honorable Mark Souder
Chairman
Subcommittee on Criminal Justice, Drug Policy
and Human Resources
Committee on Government Reform
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclose please find responses to questions posed to Ms. Patricia Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, following Ms. Good's appearance before the Subcommittee on April 1, 2004. The subject of the Subcommittee's hearing was "Marijuana and Medicine: The Need for a Science-Based Approach."

We hope this information is helpful to you. Please do not hesitate to call upon us if we may be of additional assistance in connection with this or any other matter.

Sincerely,

William E. Moschella

William E. Moschella
Assistant Attorney General

Enclosure

cc: The Honorable Elijah Cummings
Ranking Minority Member

COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES

UNITED STATES HOUSE OF REPRESENTATIVES

"MARIJUANA AND MEDICINE: THE NEED FOR A SCIENCE-BASED APPROACH"

APRIL 1, 2004

FOLLOW-UP QUESTIONS FOR THE RECORD FOR MS. PATRICIA GOOD, CHIEF, LIAISON AND POLICY SECTION, OFFICE OF DIVERSION CONSTROL, DRUG ENFORCEMENT ADMINISTRATION

QUESTION SUBMITTED BY CHAIRMAN MARK SOUDER

1. **Question: One common argument made by the pro-marijuana movement is that decisions about whether to use marijuana should be made by each doctor and patient. To better help Congress and the public evaluate this argument, please provide whatever historical data or statistics the DEA has on the following:**

a. **The number of doctors who have been investigated, indicted and/or convicted of narcotics-related offenses.**

First and foremost, it is necessary to clarify the statistics that are being provided in response to questions "a" through "c." DEA's Office of Diversion Control maintains statistical information pursuant to all criminal and complaint investigations of doctors who have been investigated for violations of Title 21 of the United States Code. The statistics, however, are not maintained by category as outlined in your questions "a" and "b," (*i.e.*, "narcotics- related" offenses as compared to over prescribing drugs, insufficiently supervising patients and/or other practices involving controlled substances). In addition, there are a variety of means by which those investigations can be resolved that reach beyond the "indictments and convictions" information you requested. In an effort to provide a more comprehensive overview, statistics reflecting the other dispositions are also included in this response.

Action Taken	FY2001	FY2002	FY2003
*Doctor Criminal/ Complaint Investigations Initiated	861	622	736
Arrests	78	68	51
Indictments	38	38	28
Civil Fines	14	10	8
Administrative Hearings & MOU	40	34	35
Letters of Admonition	63	30	33

*Doctors include the following degrees: MD (Medical Doctor), DO (Osteopath), DDS/DMD (Dentist), DPM (Podiatrist), DVM/VMD (Veterinarian), ND (Naturopath)

b. The number of doctors who have otherwise been investigated for over prescribing drugs, insufficiently supervising patients for whom they wrote drug prescriptions, and/or other practices involving controlled substances.

See response to "a," above.

c. The number of doctors who have had their licenses to prescribe controlled substances suspended or revoked for over prescribing drugs, insufficiently supervising patients for whom they wrote drug prescriptions, or other practices involving controlled substances.

As stated in "a," the statistical information maintained by DEA's Office of Diversion Control is comprehensive for all violations of Title 21 of the United States Code; the response provided here is not specific to any one violation.

Registration Action	FY2001	FY2002	FY2003
Surrendered for Cause (Code 1)	502	415	425
Revoked (Code 2)	1	11	34
Suspended (Code 9)	1	8	12

d. The number of medical patients who have been investigated, indicted and/or convicted of narcotics-related offenses involving controlled substances for which they were given prescriptions by medical professionals.

DEA does not maintain a database from which this information can be obtained.

QUESTIONS SUBMITTED BY CONGRESSMAN WILLIAM L. CLAY, JR

1. Question: In your testimony – both oral and written – you said that international treaty obligations required the United States to limit the number of manufacturers of controlled substances to the smallest number possible to produce an adequate supply. You said further that this principle was incorporated in 21 U.S.C. 823(a)(1). Yet, 21 U.S.C. 823(a)(1) provides that the Attorney General, in registering applicants to manufacture controlled substances in schedule I or II, shall consider limiting the manufacture of such controlled substances "to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions." Similarly, the Code of Federal Regulations (21C.F.R. 1301.33(b) provide the following guidance to the DEA Administrator: "*In order to provide adequate competition, the Administrator shall not be required to limit the number of manufacturers* in a basic class to a number less than that consistent with maintenance of effective controls against diversion solely because a smaller number is capable of producing an adequate and uninterrupted supply." (Emphasis added.)

Could you please explain how your reading of 21 USC 823(a)(1) and 21 CFR 1301.33(b) – including their references to adequate competition – leads you to the conclusion that "the cultivation of marijuana should be limited to the minimum number of producers who can provide an adequate supply to meet the country's legitimate medical, scientific, and research needs"? And if 21 USC 823(a)(1) incorporated the "basic principle as you describe it?"

Along these lines, could you please explain how you interpret the phrase "under adequately competitive conditions" and the phrase "shall not be required to limit the number of manufacturers."

Finally, would you or your agency consider "adequate competition" to exist where there is only one manufacturer of a controlled substance?

Your question seeks an explanation of a provision of the CSA and a related provision of the DEA regulations governing the issuance of a registration to manufacture a schedule I controlled substance. These provisions, 21 USC Section 823(a) and 21 CFR Section 1301.33, work in unison as follows.

Under section 823(a), in order for DEA to grant an applicant a registration to manufacture a schedule I controlled substance, DEA must determine that the registration is consistent with the public interest and with United States obligations under international drug control treaties. Section 823(a) enumerates the six factors that DEA must consider in determining whether such an application is consistent with the public interest. In 21 CFR 1301.34(b), the DEA regulations repeat the criteria that Congress mandated in section 823(a).

The first of the six public interest factors, subsection 823(a)(1), requires DEA to determine whether, if the proposed registration were granted, there would be maintenance of effective controls against diversion "by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes." This principle is also addressed in the regulatory provision about which you inquired, 21 CFR 1301.33. Specifically, as you note, section 1301.33(b) states: "In order to provide adequate competition, the Administrator shall not be required to limit the number of manufacturers in any basic class to a number less than that consistent with maintenance of effective controls against diversion solely because a smaller number is capable of producing an adequate and uninterrupted supply." The meaning of this provision can be restated as follows: *If DEA determines there is inadequate economic competition among the existing manufacturers of the particular controlled substance that the applicant seeks to produce* (*e.g.*, substantial overcharging by the existing manufacturers due to an insufficient number of competing manufacturers of that controlled substance), and provided further that granting the applicant's registration (and thereby increasing the total number of manufacturers) is consistent with maintenance of effective controls against diversion, DEA is not required to deny the application solely because the number of manufacturers currently registered can adequately supply the market for that controlled substance in terms of quantity and quality of product. Thus, 21 USC 823(a)(1) and 21 CFR 1301.33(b) and 1301.34 are consistent with one another.

The foregoing provisions are consistent with United States obligations under international treaties. Among the international drug control treaties to which the United States is a party is the Single Convention on Narcotic Drugs, 1961 ("Single Convention"). The Single Convention requires parties that allow the cultivation of the cannabis plant (marijuana) for legitimate research purposes to have all such production come under the oversight of a federal agency which shall, among other things, monopolize distribution of all cannabis produced by the country for legitimate purposes and designate the areas in which, and the plots of land on which, cultivation shall be permitted. To carry out these duties properly, the Official Commentary to the Single Convention explains that the federal agency should first estimate the size of the cannabis crop needed to supply the legitimate needs of the country and then determine the extent of land required to obtain this crop. The Commentary further explains that to facilitate more effective control, such plots of land should be definitive administrative units that are, to the greatest extent possible, located in the same part of the country and contiguous.

Moreover, the Single Convention requires parties to provide the International Narcotics Control Board (the organ of the United Nations which oversees compliance with the treaty) with annual estimates of their drug requirements and, commensurate therewith, to establish production quotas for each authorized manufacturer to prevent production and accumulation of drugs in excess of that required to meet the country's legitimate needs. The CSA likewise requires DEA to establish individual and aggregate production quotas for each basic class of controlled substances in schedules I and II.

Thus, the CSA provision that requires DEA to limit the number of manufacturers of schedule I controlled substances to that which can produce an adequate and uninterrupted supply under adequately competitive conditions is consistent with the controls on cannabis mandated by the Single Convention. The consistency between the CSA and the Single Convention is not a mere coincidence. Rather, when Congress crafted the various provisions of the CSA in 1970, one of its aims was to ensure that the United States meets its obligations under the Single Convention. This is expressly indicated in various parts of the CSA, such as 21 USC 823(a), which provides that DEA may only grant a schedule I or II manufacturing registration if the agency determines that such registration is consistent with United States obligations under international treaties.

Also in question 1, you ask whether DEA "consider[s] 'adequate competition' to exist where there is only one manufacturer of a controlled substance." This question cannot be definitively answered in the abstract as the determination of adequate competition within the meaning of 21 USC 823(a) (as discussed above) is a fact-intensive inquiry that must be determined on a case-by-case basis. It is possible that there can be adequate competition within the meaning of Section 823(a) with just a single manufacturer of a particular scheduled I controlled substance, provided that manufacturer can produce the substance in sufficient quantity and quality to meet legitimate United States research needs and without charging unreasonable prices. It bears repeated emphasis that the facts of every application will vary and the ultimate determination of whether DEA should grant any particular application will depend on the

agency's evaluation of each of the criteria in section 823(a) in view of the specific facts presented to the agency in connection with that application.

2. **Question: You also noted in your testimony that there are six factors to be evaluated when considering an application to manufacture a controlled substance in Schedule I or II. The one factor that seems to be vague is the sixth: "such other factors as may be relevant to and consistent with the public health and safety." The only "Notes of Decisions" entry related to this provision (21 U.S.C. 823(a)(6)) in the U.S. Code describes a situation where the domestic production of a controlled substance might have resulted in "a substantial increase in the availability of illicit drugs." Could you explain some other ways - aside from possible diversion - the manufacture of a particular controlled substance for research purposes could be detrimental to public health and safety?**

Your second question pertains to 21 USC 823(a)(6), which contains the sixth factor that DEA must consider in determining whether a proposed registration to manufacture a schedule I controlled substance is consistent with the public interest. As stated in this provision, DEA shall consider "such other factors as may be relevant to and consistent with the public health and safety." With respect to this provision, you ask: "Could you explain some other ways - aside from possible diversion - the manufacture of a particular controlled substance for research purposes could be detrimental to public health and safety?"

By its express terms, Subsection 823(a)(6), is a catchall provision that is as broad in scope as is the concept itself of public health and safety within the meaning the CSA. Thus, we cannot provide an exhaustive list of every conceivable scenario that might be relevant under subsection 823(a)(6). Nonetheless, for your assistance, we offer the following hypothetical examples of conduct that could be considered under this subsection.

Example 1: An applicant seeking to become registered to manufacture a schedule I controlled substance has engaged in the distribution and possession of an illicit controlled substance while abroad. Assuming such conduct does not subject the applicant to criminal or other legal liability under United States Federal, State, or local law, it would not fit within any of the first five public interest factors enumerated in section 823(a). Yet, if DEA were aware that someone seeking to become registered to manufacture a schedule I controlled substance had engaged in such illicit drug conduct, it would be plainly relevant for DEA to consider such conduct pursuant to subsection 823(a)(6) in deciding whether the proposed registration is consistent with the public interest.

Example 2: An applicant seeking to become registered to manufacture a schedule I controlled substance will be acting at the direction of a convicted drug dealer in making decisions such as to whom the marijuana will be supplied. Since the manufacture and distribution of schedule I controlled substances (and marijuana in particular) warrant safeguards against diversion of the highest order and can only be entrusted to those whose likelihood of

compliance with the CSA is beyond reproach, such information could properly be considered pursuant to subsection 823(a)(6).

3. Question: In your testimony, you said, "Upon receipt of a completed application (to bulk manufacture marijuana), the DEA publishes a notice of application in the Federal Register . . . the DEA concurrently conducts an investigation of the applicant in order to obtain the information necessary to make determination" on the application. The University of Massachusetts Amherst ("UMass") submitted a completed application to bulk manufacture marijuana in 2002. (The original application was actually submitted in June 2001, but DEA said that it "lost" this application. Strangely, the June 2001 application was later returned unprocessed to the University.) On December 16, 2002, DEA Agents met with UMass officials to discuss this application. Yet notice of the application did not appear in the Federal Register until more than seven months after this December 2002 meeting - July 24, 2003. I understand that you do not wish to discuss pending applications, but since this question does not address the merits of the application, but merely the basic process, I am hoping you can explain why such a drastic disregard of procedure occurred in this instance.

Along the same lines, I am concerned that it has now been more than six months since the close of the comment period on the University of Massachusetts' application to bulk manufacture marijuana. This despite the fact that you said in your testimony that "the DEA concurrently conducts an investigation of the applicant during the 60 days in which other bulk manufacturers may file written comments. Surely you understand that there is a controversy in this country over the use of medical marijuana. This is a major state-federal conflict, especially in states like California where state agents have raided homes and arrested medical marijuana providers. When discussing this issue, many people say that they think the issue should be settled based on research. Despite this, your agency has taken years on this one application, which many believe could facilitate better research. Quite simply, without discussing this application specifically, how long do you think it is appropriate to delay an important decision like this?

Your third question concerns the application submitted by the University of Massachusetts to become registered to manufacture marijuana to supply researchers. As you note, it would be inappropriate for DEA to comment on the merits of this or any other pending application. However, as a general matter, you are correct in pointing out that all applications for registration should be handled in a timely manner consistent with appropriate regulations. The DEA has taken steps to ensure such applications will be so handled in the future.

No decision has yet been made by DEA on the application of the University of Massachusetts to manufacture marijuana. Any such decision will be made in accordance with the criteria mandated by Congress under the CSA.

TOM DAVIS, VIRGINIA
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INDEPENDENT

April 12, 2004

Dr. James D. Scott, M.D.
Member
Oregon Board of Medical Examiners
1500 SW 1st Avenue, Suite 620
Portland, OR 97201-5826

Re: "Marijuana and Medicine: The Need For A Science-Based Approach"

Dear Dr. Scott:

Thank you very much for your testimony on April 1, 2004 before the Subcommittee on Criminal Justice, Drug Policy and Human Resources. We found your testimony both insightful and helpful. Due to the limited amount of time available for the hearing, however, we were unable to address all of the issues involved. To better help the Subcommittee understand these significant issues, we are submitting to you the attached list of questions for the record.

In order to help the Subcommittee move forward with its work on this subject, we request that you respond to these questions in writing no later than the close of business on Wednesday, May 12, 2004. Your answers will be included in the written record.

Thank you very much for your time and assistance. If you have any questions, you may contact Nick Coleman, a member of the Subcommittee staff, at 202-225-2577.

Sincerely,

Mark E. Souder
Chairman
Subcommittee on Criminal Justice,
Drug Policy and Human Resources

TOM DAVIS, VIRGINIA
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INDEPENDENT

August 18, 2004

Dr. James D. Scott, M.D.
Member
Oregon Board of Medical Examiners
1500 SW 1st Avenue, Suite 620
Portland, OR 97201-5826

Re: "Marijuana and Medicine: The Need For A Science-Based Approach"

Dear Dr. Scott:

On April 12, 2004, we sent you a list of questions for the record as a follow-up to your testimony at our Subcommittee's April 1 hearing. To date, we have not received your responses. Your answers are important, as they help both Congress and the public to understand these issues and consider potential solutions. As it has been over four months, we would appreciate receiving your answers promptly. Accordingly, please send your responses by September 1, 2004.

Thank you again for your time and assistance. If you have any questions, you may contact Nick Coleman, a member of the Subcommittee staff, at 202-225-2577.

Sincerely,

Mark E. Souder
Chairman
Subcommittee on Criminal Justice,
Drug Policy and Human Resources

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INDEPENDENT

September 30, 2004

Dr. James D. Scott, M.D.
Board Member
Oregon Board of Medical Examiners
1500 SW 1st Avenue, Suite 620
Portland, OR 97201-5826

Dear Dr. Scott,

The Subcommittee held a hearing on April 1, 2004 entitled, "Marijuana and Medicine: The Need For a Science-Based Approach." Thank you for your testimony at that hearing. As of today, we have not yet received your response to the additional questions provided to you. If we do not receive a reply from you by October 25, 2004, your response will not be included in the official hearing record.

Attached you will find another copy of the additional questions directed to you by the Subcommittee, for publication in the hearing record.

Thank you.

Sincerely,

Mark E. Souder
Chairman,
Subcommittee on Criminal Justice,
Drug Policy and Human Resources

Enclosures

COMMITTEE ON GOVERNMENT REFORM
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES

"MARIJUANA AND MEDICINE: THE NEED FOR A SCIENCE-BASED APPROACH"

APRIL 1, 2004

FOLLOW-UP QUESTIONS FOR THE RECORD FOR DR. JAMES D. SCOTT, MEMBER, OREGON BOARD OF MEDICAL EXAMINERS

1. You testified that the Oregon Board of Medical Examiners (the "Board") cannot take any position on whether marijuana is a safe or effective drug. Instead, your testimony suggests that the Board's role is simply to verify that doctors have complied with certain procedural requirements – e.g., having a current license, conducting an examination and filling out the appropriate forms.

   a. Does this mean that a doctor could prescribe the scientifically wrong medication and still be in compliance with your regulations? For example, if a doctor carried out all the proper "procedures" but then prescribed Viagra to a patient with high blood pressure, would the Board take any action?

   b. Are there any medications other than marijuana for which the Board takes no position as to whether they are safe or effective? If a doctor tried to prescribe thalidomide for morning sickness, for example, despite what we now know about its side effects, would tbe Board take action?

   c. Does the Board have any responsibility for regulating the content of medical treatment, rather than merely the procedures?

2. The voters in your state have attempted to legalize the use of marijuana for "medical" purposes, so it is understandable that the Board – as a state government agency – feels obligated to implement that policy. Nevertheless, as doctors themselves and as regulators of the medical profession, it would seem that the members of the Board are supposed to protect the public based on scientific and medical evidence – not on politics. We have some questions about whether permitting doctors and patients to use a drug in this way can ever be considered appropriate in the practice of medicine.

   a. Are there any drugs other than marijuana that the Board believes can be safely smoked? If a doctor recommended that a patient smoke morphine, for example, would the Board take any action?

b. Does the Board have any concerns about the lack of health or safety controls on the supply of marijuana to patients – since patients are essentially allowed to grow or procure their own "medicine"? Are there any other medications that you believe can be responsibly manufactured and self-administered by patients?

c. How much evidence, and what kind of evidence, does the Board believe is necessary before a drug should be used to treat a condition? Is anecdotal evidence sufficient? Should a doctor prescribe or "recommend" a drug that has not yet been properly tested?

d. Since the federal government has already tested and approved Marinol, a marijuana derivative, why should doctors recommend any other form of marijuana?

e. Should marijuana be used to treat psychiatric or psychological conditions like attention deficit disorder (ADD), depression or anxiety? Why or why not?

f. Should marijuana be used to treat moderate or low-level pain? Why or why not?

g. Should marijuana be used to treat epilepsy? Why or why not?

h. Should marijuana be used to treat children or teenagers, including for psychiatric or psychological conditions? Why or why not?

3. How often has the Board taken disciplinary action against doctors for improper use of marijuana in treatment? What were the circumstances?

FDA Statement Re: Marijuana Legislation

The Food and Drug Administration (FDA) has concerns about any legislation that would prevent the Department of Justice or the Drug Enforcement Administration (DEA) from enforcing the Controlled Substances Act (CSA) with respect to marijuana either generally or in specified States. Marijuana is a Schedule I drug under the CSA. Schedule I substances are defined as having a high potential for abuse and no accepted medical use in the U.S. In 2001, the Department of Health and Human Services (HHS) completed an extensive analysis in response to a request to reschedule marijuana to a less restrictive schedule. After looking at all the relevant data on marijuana, HHS concluded that marijuana should continue to be controlled under Schedule I. DEA is the Federal agency with primary jurisdiction regarding enforcement actions relating to the sale or distribution of marijuana. FDA will continue to cooperate with DEA in these actions.

Several states have passed referenda making marijuana available for a variety of medical conditions, but these laws are in conflict with the CSA and often with the Federal Food, Drug, and Cosmetic (FD&C) Act. FDA's position continues to be that these ballot measures send the wrong message to the public– too many of whom do not recognize the dangers of marijuana – and that these measures are inconsistent with our efforts to ensure that approved medications have undergone rigorous scientific scrutiny and FDA's approval process.

FDA is the sole Federal agency that approves drug products as safe and effective for particular indications, and efforts that seek to bypass the FDA drug approval process would not serve the interests of public health. FDA has not approved marijuana for any indication. Only the disciplined, systematic, scientific conduct of clinical trials can establish whether there is any medicinal value to marijuana, smoked or otherwise.

We reiterate that any legislation that would prevent the Department of Justice or the DEA from enforcing the CSA with respect to marijuana either generally or in specified States would not serve the interests of public health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 25 2003

The Honorable Mark E. Souder
Chairman
Subcommittee on Criminal Justice,
Drug Policy, and Human Resources
Committee on Government Reform
House of Representatives
Washington, D.C. 20515-6143

Dear Mr. Chairman:

Thank you for the letter of June 26, 2002, regarding the promotion of marijuana for medical use. As you know, marijuana has not been approved for medical use in the United States. Despite its status as an unapproved new drug under the Federal Food, Drug, and Cosmetic (FD&C) Act, there has been considerable interest in its use for the treatment of a number of conditions.

The Department of Health and Human Services (HHS) has been actively involved in evaluating the current state of knowledge regarding the therapeutic use of marijuana. This evaluation indicates that sound scientific studies supporting the claims of marijuana's usefulness as medication are lacking, despite anecdotal claims to the contrary. A review of the existing pre-clinical and human data does not support the safety or efficacy of marijuana for any indication. In fact, as noted in your letter, there is some concern that the use of smoked marijuana may be harmful to individuals suffering from the conditions for which it is touted as a safe and effective treatment.

Accordingly, HHS does not support facilitating the availability of marijuana for medical use until it has been proven safe and effective as required by Federal law. However, as indicated by the enclosed 1999 "Guidance on Procedures for the Provision of Marijuana for Medical Research," controlled multi-patient clinical trials that comply with all applicable Federal statutes and regulations are permitted to study the safety and efficacy of marijuana.

We appreciate your concerns and have restated your questions and provided answers below.

1. **Has smoked marijuana been reviewed and approved by the FDA as a safe and effective medicine?**

Botanical marijuana has not been approved by the Food and Drug Administration (FDA) as a safe and effective drug.

2. **What, if anything, is the FDA doing to stop the illegal promotion and use of marijuana?**

As you are aware, marijuana is controlled under Schedule I of the Controlled Substances Act (CSA). Schedule I substances have a high potential for abuse, no accepted medical use in the U.S., and are not safe for use under medical supervision. HHS recently performed a scientific and medical evaluation of marijuana and provided its recommendation to the Drug Enforcement Agency (DEA) that marijuana remain in Schedule I pursuant to section 201(b) of the CSA. HHS's scientific and medical evaluation and scheduling recommendation can be found at Volume 66, *Federal Register,* page 20038 (April 18, 2001). After receiving HHS's evaluation and recommendation, DEA is responsible for scheduling substances and has primary responsibility for the regulation and distribution of Schedule I substances. FDA generally defers to DEA on criminal enforcement efforts related to Schedule I controlled substances. The criminal penalties for distribution of a Schedule I controlled substance are far greater under the CSA than those available under the FD&C Act for the distribution of an unapproved new drug.

3. **Is marijuana an exceptional case or are there other drugs that the FDA has allowed to be made available on a state-by-state basis without first undergoing FDA clinical trials and receiving approval as being safe and effective for patient use?**

At this time, botanical marijuana is not an FDA approved drug. As you know, the FD&C Act prohibits the sale of unapproved drugs. Clinical trials (trials in humans) are required to demonstrate that a drug is safe and effective and provide the basis for FDA approval of a drug.

State laws known as "medical marijuana" laws are generally amendments to the state's criminal statute that modify state criminal penalties for those that possess marijuana for medical use. These state laws do not change the Federal prohibition on the sale of an unapproved drug or the unauthorized distribution of a Schedule I substance. In fact, in 2001, the U.S. Supreme Court held that there was no medical necessity exception to the CSA prohibitions on the manufacture and distribution of marijuana (*United States* v. *Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483).

4. **Since marijuana is not available from any manufacturers who have received FDA approval to produce the drug, how can the FDA ensure that marijuana being used under the guise as medicine is not contaminated with other harmful ingredients or that the facilities of those currently providing marijuana meet FDA manufacturing safety standards?**

HHS ensures that the marijuana that is being used in legitimate medical research is safe for that research. Currently, the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health, is the sole source for legal marijuana in the U.S., and this supply is only available for authorized research. NIDA oversees the cultivation of research-grade marijuana on behalf of the U.S. government, assuring that the marijuana used for legitimate approved research has a consistent and predictable potency, is free of contamination and is available in sufficient amounts to support the needs of the research. Clinical research with marijuana must be conducted under an investigational new drug application granted by FDA, requires Institutional

Review Board approval, and requires approval and a special Schedule I license issued by DEA. FDA has limited, if any, jurisdiction over the illegal and/or individual cultivation of marijuana for personal use (see HHS Guidance on Procedures for the Provision of Marijuana for Medical Research, dated May 21, 1999).

5. **What precedent does the availability of a drug that has not undergone trials or been approved by the FDA set? Will the manufacturers of other illegal drugs or even legitimate health products be permitted to promote and distribute their products without FDA review or approval?**

Under the FD&C Act, an application must be submitted to FDA before clinical research (research in humans) is conducted on a new drug, and a new drug must be approved by FDA prior to its marketing and distribution in the U.S. There have been instances whereby new drugs have been illegally distributed and marketed without FDA knowledge. However, once notified, FDA's Office of Compliance and Office of Criminal Investigation have taken appropriate enforcement action, which may include seizures and injunctions as provided by the FD&C Act, and/or obtaining assistance from other government sources, including DEA if the substance at issue is a controlled substance.

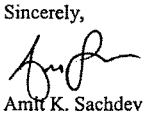
Botanical marijuana is not an FDA approved drug. As noted in your letter, two drugs, which contain one of the active ingredients that is present in botanical marijuana (marinol and nabilone), are approved for therapeutic use in the U.S. The FD&C Act and the *Code of Federal Regulations* (CFR) delineate the requirements for studying investigational drugs, the drug review process, and the marketing of new drugs (see section 505 of the FD&C Act and Title 21, CFR, Parts 312 and 314).

6. **What penalties, if any, is the FDA levying on those who are prescribing and selling marijuana for "medical" use?**

As stated above, FDA generally defers to DEA and the states for matters related to the illegal distribution of controlled substances.

Thank you again for contacting us concerning this matter. If you have further questions, please let us know.

Sincerely,



Amit K. Sachdev
Associate Commissioner
for Legislation

Enclosure

cc: The Honorable Elijah E. Cummings
Ranking Member
Subcommittee on Criminal Justice,
Drug Policy, and Human Resources
Committee on Government Reform
House of Representatives
Washington, D.C. 20515-2007

ANNOUNCEMENT OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES' GUIDANCE ON PROCEDURES FOR THE PROVISION OF MARIJUANA FOR MEDICAL RESEARCH

Release Date: May 21, 1999

National Institutes of Health

I. Introduction

The intent of this document is to provide guidance to the biomedical research community who intend to study marijuana in scientifically valid investigations and well-controlled clinical trials on the procedures of the Department of Health and Human Services (HHS) for providing research-grade marijuana to sponsors.(i)

The production and distribution of marijuana for clinical research, is carefully restricted under a number of federal laws and international commitments. The manufacture, acquisition, and distribution of marijuana is subject to control under Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801 et seq.), the most restrictive of the five federally regulated classes of controlled substances. Persons who wish to conduct research using Schedule I substances such as marijuana must obtain a special registration under the CSA from the Drug Enforcement Administration (21 U.S.C. 823(f)). To receive such a registration, a researcher must first be determined by HHS to be qualified and competent, and the proposed research must be determined by HHS to have merit (id.). Moreover, persons who intend to study marijuana for use in the cure, mitigation, treatment, or prevention of disease are subject to the "drug" and "new drug" provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

The United States is also a party to the Single Convention on Narcotic Drugs, an international narcotics control treaty. Parties to the Single Convention have agreed to limit production, distribution, and possession of cannabis and cannabis resins to authorized medical and scientific purposes (Art. 4). In addition to these and other controls, Articles 23 and 28 of the Single Convention provide that if a country allows cultivation of the cannabis plant for research purposes, the country must establish a national agency to control the cultivation and distribution of the crop. Currently, the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), oversees the cultivation of research-grade marijuana on behalf of the United States government.

An appropriate scientific study of a drug substance requires, among other things, that the substance used in the research must have a consistent and predictable potency, must be free of contamination, and must be available in sufficient amounts to support the needs of the study. NIDA allocates resources to cultivate a grade of marijuana that is suitable for research purposes. Recently, there has been considerable interest in determining, through scientifically valid investigations, whether cannabinoids can provide positive medical benefits. In February 1997, an NIH-sponsored workshop analyzed available scientific information and concluded that "in order to evaluate various hypotheses concerning the potential utility of marijuana in various therapeutic areas, more and better studies would be needed."(ii) Most recently, the Institute of Medicine issued a detailed report that supports the absolute need for evidence-based research into the effects of using marijuana and, in particular, the cannabinoid components of marijuana, for patients with specific disease conditions.(iii) Moreover, recent State-level public initiatives, including referenda in support of the medical use of marijuana, have generated additional interest in the medical community for high quality clinical investigation and comprehensive safety and

effectiveness data.

Against this backdrop are the real concerns regarding the toxicity of smoked marijuana. Indeed, the IOM report emphasized that smoked marijuana is a crude drug delivery system that exposes patients to a significant number of harmful substances and that "if there is any future for marijuana as a medicine, it lies in its isolated components, the cannabinoids and their synthetic derivatives". As such, the IOM recommended that clinical trials should be conducted with the goal of developing safe delivery systems.

HHS recognizes the need for objective evaluations of the potential merits of cannabinoids for medical uses. If a positive benefit is found, HHS also recognizes the need to stimulate development of alternative, safer dosage forms. Through this document, HHS is announcing procedures that are intended to facilitate the research needed to evaluate these pending public health questions by making research-grade marijuana available for well-designed studies on a cost-reimbursable basis.

II. Availability of Marijuana for Research Purposes

To facilitate research on the potential medical uses of cannabinoids, HHS has determined that it will make research-grade marijuana available on a cost-reimbursable basis, subject to the priorities and conditions described in section III, below.

HHS will also consider the extent to which a proposed study incorporates the trial design elements outlined by the participants in the 1997 NIH Workshop. Such studies are the most likely to yield high quality, scientifically valid data on the safety and effectiveness of cannabinoids. The goal of this program must be to determine whether cannabinoid components of marijuana administered through an alternative delivery system can meet the standards enumerated under the Federal Food, Drug, and Cosmetic Act for commercial marketing of a medical product (see e.g., 21 U.S.C. 355). As the IOM report stated, "Therefore, the purpose of clinical trials of smoked marijuana would not be to develop marijuana as a licensed drug, but such trials could be a first step towards the development of rapid-onset, nonsmoked cannabinoid delivery systems."

III. Elements for Considering Proposed Studies

The focus of HHS's program is the support of quality research for the development of clinically meaningful data. HHS intends to make available a sufficient amount of research-grade marijuana to support those studies that are the most likely to yield usable, essential data. However, it should be noted that NIDA's supply of marijuana is subject to a number of constraints associated with the cultivation of a research-grade crop and that the supply at times may be variable.

For protocols submitted by non-NIH funded sources, institutional peer-review is strongly recommended prior to submission to HHS. After submission, the scientific merits of each protocol will be evaluated through a Public Health Service interdisciplinary review process. This process will take into consideration a number of factors, including the scientific quality of the proposed study, the quality of the organization's peer-review process, and the objectives of the proposed research. For example:

The extent to which the protocol incorporates the elements of good clinical and laboratory research;

The extent to which the protocol describes an adequate and well-controlled

clinical study to evaluate the safety and effectiveness of marijuana and its constituent cannabinoids in the treatment of a serious or life threatening condition;

The extent to which the protocol describes an adequate and well-controlled clinical study to evaluate the safety and effectiveness of marijuana and its constituent cannabinoids for a use for which there are no alternative therapies;

The extent to which the protocol describes a biopharmaceutical study designed to support the development of a dosage form alternative to smoking;

The extent to which the protocol describes high-quality research designed to address basic, unanswered scientific questions about the effects of marijuana and its constituent cannabinoids or about the safety or toxicity of smoked marijuana.

In the event that supplies become limited, marijuana will be made available in the order of priority described below.

1. Protocols that have been reviewed and funded by NIH.

2. Protocols sponsored or conducted by other governmental organizations.

3. Protocols sponsored or conducted by other sources.

The sponsor of a proposed protocol must be able to demonstrate the ability to fully reimburse NIDA's contractor for the cost of research-grade marijuana supplied through the completion of the study. In addition, researchers who propose to conduct investigations in humans must be able to fulfill the Food and Drug Administration's investigational new drug (IND) requirements and must obtain a valid registration from the Drug Enforcement Administration (DEA) for research with Schedule I drugs.

IV. Marijuana Trial Design Elements

A clinical study involving marijuana should include certain core elements, many of which reflect recommendations made by the 1997 NIH Workshop. A study that incorporates the NIH Workshop recommendations will be expected to yield useful data and therefore, will be more likely to be eligible to receive marijuana under the HHS program. The full report can be accessed on the Internet at http://www.nih.gov/news/medmarijuana/MedicalMarijuana.htm. HHS will consider if additional guidelines are needed on the essential elements of clinical trial design for medical marijuana studies.

HHS also notes that within each of the categories described in section III, preference will be given to those protocols that are designed around specific safety or efficacy endpoints. Protocols for open-ended or "ongoing" trials that do not include ending dates are not likely to be eligible to receive marijuana. In addition, proposed protocols must be determined to be acceptable under FDA's standards for authorizing the clinical study of investigational new drugs, which state in part:

FDA's primary objectives in reviewing an IND are, in all phases of the investigation, to assure the safety and rights of subjects, and, in Phase 2 and 3, to help assure that the quality of the scientific evaluation of drugs is adequate to permit an evaluation of the drug's effectiveness and safety. Therefore, although FDA's review of Phase 1 submissions will focus on assessing the safety of Phase 1 investigations, FDA's review of Phases 2 and 3 submissions will also include an assessment of the scientific quality of

the clinical investigations and the likelihood that the investigations will yield data capable of meeting statutory standards for marketing approval.

21 CFR 312.22(a).

Finally, HHS intends to direct its program toward multi-patient clinical studies. As previously determined by the Public Health Service, single-patient requests for marijuana raised a number of concerns including the fact that the single-patient IND process would not produce useful scientific information and we do not foresee that they would be supported under this program.

V. Procedures for Obtaining Research-Grade Marijuana

Researchers who intend to conduct clinical studies of marijuana should first make an inquiry to NIDA to determine the availability and costs of marijuana. Such an inquiry must address the considerations outlined in sections III and IV of this document for establishing research priority.

Because research-grade marijuana will be provided to researchers on a cost-reimbursable basis only, researchers also will be expected to include a plan for ensuring timely reimbursement for all costs associated with the cultivation and delivery of the marijuana.

In addition, specific information (including full justification) should be provided as to the number and potency of marijuana cigarettes or bulk marijuana needed, and the timing of the intended use of the marijuana. This information must be updated annually with NIDA in order that adequate supplies can be maintained and future needs estimated. Continued provision of marijuana is subject to availability and to continued compliance with these policies and procedures and with all applicable statutes and regulations.

This information and requests to NIDA concerning availability and costs should be sent to:

Program Administrator
Drug Supply and Analytical Services
National Institute on Drug Abuse
6001 Executive Blvd
Bethesda, MD 20892

If NIDA determines that marijuana is available to support the study, NIDA will provide the researcher with authorization to reference NIDA's marijuana Drug Master File (DMF).

If the researcher is proposing a study in humans, after obtaining the right of reference to the DMF, the researcher must proceed through the FDA process for filing an IND application under 21 CFR part 312. Information on the requirements for obtaining an IND can be found on the FDA web site at http://www.fda.gov.

In addition, all researchers must obtain from DEA registration to conduct research using a Schedule I controlled substance. Information on the requirements for obtaining a DEA registration for research with marijuana can be obtained following the process outlined in 21 CFR part 1301.

VI. Implementation

This procedure will apply to the provision, through NIDA, of marijuana

cigarettes (of varying THC content, including placebo), as well as bulk marijuana. HHS will apply this procedure beginning on December 1, 1999. HHS will re-evaluate these procedures periodically and determine within five years whether or not the procedures should be continued. Requests for marijuana may be submitted prior to that time. However, shipments should not be expected before then and definitive information regarding costs may not be available until that time.

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i Once implemented, this document will represent HHS's current approach with respect to biomedical research involving marijuana. It does not create or confer any rights for or on any person and does not operate to bind HHS or the public. An alternative approach may be used if such an approach would satisfy all applicable legal requirements.

ii Workshop on the Medical Utility of Marijuana: Report to the Director, National Institutes of Health. National Institutes of Health, February 19-21, 1997.

iii "Marijuana and Medicine: Assessing the Science Base", Institute of Medicine, March 17, 1999.

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Department of and Human Services

National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892

What Americans Need To Know About MARIJUANA

Important facts about our nation's most misunderstood illegal drug

OFFICE OF NATIONAL DRUG CONTROL POLICY

What Americans Need to Know About

MARIJUANA

Important facts about our nation's most misunderstood illegal drug

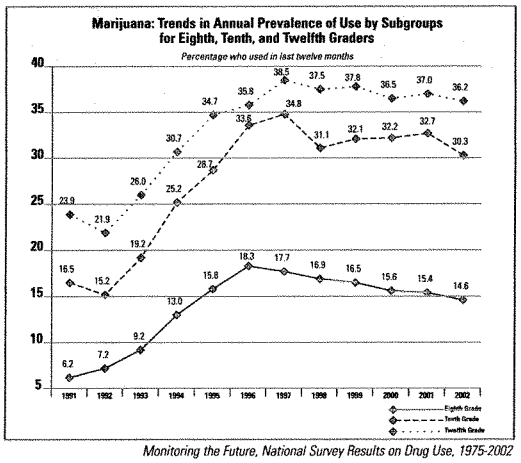
OFFICE OF NATIONAL DRUG CONTROL POLICY

I. There is a serious drug problem in this country, and marijuana is a much bigger part of the problem than most people realize.

- Marijuana is the most widely used illicit drug in America. Of the nearly 20 million current illicit drug users, 14.6 million (about 75 percent) are using marijuana.[1]
- Of the 7.1 million Americans suffering from illegal drug dependence or abuse, 60 percent abuse or are dependent on marijuana.[2]
- Of all youth age 12-17 in drug treatment in 2000, nearly 62 percent had a primary marijuana diagnosis.[4] Approximately half were referred to treatment through the criminal justice system and half through other sources, including self-referral.[5]

> More young people are now in treatment for marijuana dependency than for alcohol or for all other illegal drugs combined.[3]

- The average age of initiation for marijuana use generally has been getting younger.[6]
- Along with the bad news, however, come signs of improvement (see graph, below):
  - ➤ Among 10th graders, past-year and past-month use of marijuana or hashish decreased from 2001 to 2002, as did daily use in the past month.[7]
  - ➤ There has been slow but steady progress toward reduced marijuana use rates among 8th graders. Their past-year marijuana-use rate of 14.6 percent in 2002 is the lowest since 1994, and well below their recent peak of 18.3 percent in 1996.[8]
  - ➤ At 30.3 percent for past-year marijuana use, 10th graders are at their lowest level since 1995 and somewhat below their recent peak of 34.8 percent in 1997. The past-year use rate for 12th graders is down, albeit only modestly, from 38.5 percent in their recent peak year (1997) to 36.2 percent in 2002.[9]



Monitoring the Future, National Survey Results on Drug Use, 1975-2002

II. Myths and Misperceptions

Many of the things Americans "know" about marijuana are myths or misperceptions. People need to know the truth about this harmful drug.

MYTH 1
Marijuana is harmless.

Marijuana is far from harmless; in fact, recent scientific findings about the drug are startling. Most of the drug treatment for young people in the United States is for marijuana alone. Marijuana emergency-room mentions have skyrocketed over the past decade, and the drug is associated with an increased risk of developing schizophrenia, even when personality traits and pre-existing conditions are taken into account.

FACTS:

Health Consequences

- Marijuana smoke contains 50 percent to 70 percent more carcinogenic hydrocarbons than does tobacco smoke.[10] Using marijuana may promote cancer of the respiratory tract and disrupt the immune system.[11]
- Marijuana smokers have a heightened risk of lung infection.[12]
- Long-term use of marijuana may increase the risk of chronic cough, bronchitis, and emphysema, as well as cancer of the head, neck, and lungs.[13]
- Mentions of marijuana use in emergency room visits have risen 176 percent since 1994, surpassing those of heroin.[14]
- In 2001, marijuana was a contributing factor in more than 110,000 emergency department visits in the United States.[15]
- Marijuana can cause the heart rate, normally 70 to 80 beats per minute, to increase by 20 to 50 beats per minute or, in some cases, even to double.[17]
- In a 2003 study, researchers in England found that smoking marijuana for even less than six years causes a marked deterioriation in lung function. The study suggests that marijuana use may rob the body of antioxidants that protect cells against damage that can lead to heart disease and cancer.[18]
- Marijuana affects alertness, concentration, perception, coordination, and reaction time—skills that are necessary for safe driving. A roadside study of reckless drivers in Tennessee found that 33 percent of all subjects who were not under the influence of alcohol and who were tested for drugs at the scene of their arrest tested positive for marijuana.[20] In a 2003 Canadian study, one in five students admitted to driving within an hour of using marijuana.[21]

> Smoking marijuana leads to changes in the brain similar to those caused by the use of cocaine and heroin.[16]

- Marijuana users have more suicidal thoughts and are four times more likely to report symptoms of depression than people who never used the drug.[22]
- The *British Medical Journal* recently reported: "Cannabis use is associated with an increased risk of developing schizophrenia, consistent with a causal relation. This association is not explained by use of other psychoactive drugs or personality traits relating to social integration."[23]

> The British Lung Foundation reports that smoking three or four marijuana joints is as bad for your lungs as smoking 20 tobacco cigarettes.[19]

Social Consequences

- Heavy marijuana use impairs the ability of young people to concentrate and retain information during their peak learning years. Tetrahydrocannabinol (THC), the main active chemical in marijuana, changes the way sensory information gets into and is processed by the part of the brain that is crucial for learning and memory.[24]
- Animal studies indicate that marijuana use may interfere with brain function and create problems with the perception of time, possibly making the user less adept at tasks that require sustained attention.[25]
- Marijuana use has been associated with poor performance in school. One report showed that youths with an average grade of D or below were more than four times as likely to have used marijuana in the past year as youths with an average grade of A.[26]
- Marijuana users in their later teen years are more likely to have an increased risk of delinquency and more friends who exhibit deviant behavior. They also tend to have more sexual partners and are more likely to engage in unsafe sex.[27]

Economic Consequences

- Use of marijuana and other illicit drugs comes at significant expense to society in terms of lost employee productivity, public health care costs, and accidents.[28]
- Americans spent $10.6 billion on marijuana purchases in 1999.[29]

MYTH 2
Marijuana is not addictive.

Marijuana has been proven to be a psychologically addictive drug. Scientists at the National Institute on Drug Abuse have demonstrated that laboratory animals will self-administer THC in doses equivalent to those used by humans who smoke marijuana.[30]

FACTS:

- Marijuana is much more powerful today than it was 30 years ago, and so are its mind-altering effects. Average THC levels rose from less than 1 percent in the mid-1970s to more than 6 percent in 2002. Sinsemilla potency increased in the past two decades from 6 percent to more than 13 percent, with some samples containing THC levels of up to 33 percent.[31]
- Subjects in an experiment on marijuana withdrawal experienced symptoms such as restlessness, loss of appetite, trouble with sleeping, weight loss, and shaky hands.[32]
- According to one study, marijuana use by teenagers with prior serious antisocial problems can quickly lead to dependence on the drug. The study also found that, for troubled teenagers using tobacco, alcohol, and marijuana, progression from their first use of marijuana to regular use was about as rapid as their progression to regular tobacco use, and more rapid than the progression to regular use of alcohol.[33]

> Some heavy users of marijuana show signs of dependence, developing withdrawal symptoms when they have not used the drug for a period of time.

MYTH 3

Youth experimentation with marijuana is inevitable.

Drug use can be prevented. The majority of young people do not use drugs, and there are proven ways to keep kids from starting. Contrary to popular belief, marijuana use is not a rite of passage. It is a risky behavior with serious consequences. Every American has a role to play in the effort to reduce marijuana use—at home and on the job, in schools, places of worship, and civic or social organizations. Working together, we can reaffirm healthy attitudes about marijuana use.

FACTS:

- Surveys show that parents are the biggest influence in their children's decisions about drug use.[34] Parents must actively engage in educating their children and help them make healthy decisions.
- We know that when we push back against the drug problem, it recedes. Marijuana use has been dramatically lower in the past—even in the last decade—and it can be reduced again.[35]

Contrary to popular belief, marijuana use is not a rite of passage. It is a risky behavior with serious consequences.

MYTH 4

Marijuana is not associated with violence, as are drugs like cocaine and heroin. The criminalization of marijuana is what leads to crime, not the drug itself.

It's not simply the trafficking of drugs that causes crime at home and abroad. Crime also results from the behavior of people who have drug dependencies.

FACTS:

- Research shows a link between frequent marijuana use and increased violent behavior.[36]
- Young people who use marijuana weekly are nearly four times more likely than nonusers to engage in violence.[37]
- More than 41 percent of male arrestees in sampled U.S. cities tested positive for marijuana.[38]

MYTH 5

Prisons are filled with non-violent, casual marijuana users.

Most law enforcement officials would attest that simple marijuana users rarely get sent to jail. In fact, a substantial number of states and localities rate simple possession of marijuana as a misdemeanor, subject only to a small fine. Our prisons are not filled with people whose only crime was smoking marijuana. The vast majority of those behind bars for marijuana offenses are mid- and large-scale traffickers and distributors.

FACTS:

- Less than one percent of all state prison inmates in 1997 were serving time just for marijuana possession (0.7 percent), and only 0.3 percent of marijuana-possession offenders were in prison on a first offense.[39]
- On the federal level, nearly 98 percent of the 7,991 offenders sentenced for marijuana crimes in 2001 were guilty of trafficking. Only 2.3 percent—186 people—were sentenced for simple possession of marijuana.[40]
- The median amount of marijuana involved in the conviction in federal court of marijuana-only possession offenders in 1997 was 115 pounds. In other words, half of all federal prisoners convicted just for marijuana possession were arrested with quantities exceeding 115 pounds.[41]

> The vast majority of those behind bars for marijuana offenses are mid- and large-scale traffickers and distributors.

III. The Mission

Responsible public policy seeks to reduce access to and availability of marijuana. Once people know the facts about the drug, it is important that they work to develop a comprehensive approach for preventing and reducing its use. Moreover, law enforcement agencies at all levels should make it a top priority to intensify detection and removal of marijuana-growing operations.

- Curbing access to marijuana is a major challenge. A 2001 survey found that 55 percent of kids age 12-17 agreed that marijuana would be "fairly easy" or "very easy" to obtain and was available from a wide variety of sources.[42]

Our responsibility as employers, colleagues, neighbors, family members, and friends is to get the marijuana user beyond denial and into effective treatment and lifelong recovery.

- Reduce the denial gap
  - ➤ Of the 5.6 million people who met the criteria for drug dependence and abuse specified in the 4th edition of the *Diagnostic and Statistical Manual of Mental Disorders* in 2001, 4.6 million (92 percent) did not acknowledge they had a problem.[43]
- Treatment works
  - ➤ Federal spending for substance-abuse treatment has risen sharply in recent years, increasing from about $2.2 billion in 1993 to nearly $3.3 billion in 2003.[44]
  - ➤ The federal government sponsored the Cannabis Youth Treatment Study (CYT),[45] which developed innovative and effective treatment methodologies.
    - ❖ Using these treatment approaches, the percentage of young people reporting abstinence from marijuana use went from 4 percent upon entering the study to 13 percent within 3 months, and to 34 percent after 6 months. The percentage of those having no past-month symptoms of marijuana abuse or dependence went from an initial 19 percent to 39 percent within 3 months, and to 61 percent after 6 months.
    - ❖ The CYT study found that brief interventions, or structured efforts to interrupt and stop an individual's drug use, could be very successful, especially with low-severity clients (such as those who are not yet dependent).
    - ❖ The advantage of brief interventions is that they can be carried out in non-medical environments by non-medical staff. The screening and brief intervention approach is currently being used in a variety of settings (such as emergency rooms and social service agencies), and it has been found to be both clinically and cost effective.

> Treatment for marijuana is widely available in a variety of forms. There is no "wrong pathway" to treatment.

- ➤ Drug courts, or supervised programs that offer alternatives to incarceration, are a common means of providing treatment for drug users. Established to handle the growing caseload of low-level drug offenses, drug courts separate non-violent users from people charged with trafficking and other serious drug crimes.
  - ❖ Recidivism rates among all drug court participants have ranged from 5 percent to 28 percent; for graduates of drug courts, the recidivism rate is less than 4 percent.[46]
  - ❖ Drug courts are expanding rapidly, and the federal government is helping to fuel this growth. The President's proposed FY 2004 budget includes an increase in drug-court funding from the currently enacted $45 million to $68 million.[47] More than 1,000 drug courts are in operation around the country, and approximately 400 are in development. To date, some 300,000 adults and juveniles have enrolled in drug court programs.[48]
- ➤ Communities can take action now. We urge treatment programs and providers to employ these proven methods. For materials and more information, visit www.health.org.

Related Issues

1. Marijuana v. tobacco and alcohol: the case against legalization

- Alcohol and tobacco pose significant risks, especially to young people.
- Alcohol and tobacco cost society a great deal every year in terms of crime, lost productivity, tragedies, and deaths. Why legalize marijuana and add a third drug to the current list of licit threats?
- As a result of legal settlements and vigorous public education efforts, many Americans are aware of the dangers of dependence and addiction associated with alcohol and tobacco use. Even so, alcohol and tobacco remain a significant part of the American health problem.

> Why legalize marijuana and add a third drug to the current list of licit threats?

2. Gateway theory

- A direct cause-and-effect relationship between marijuana use and subsequent use of other drugs is hard to prove. Studies show, however, that of the people who have ever used marijuana, those who started early are more likely to have other problems later on. For example, adults who were early marijuana users were found to be:
  - ➤ 8 times more likely to have used cocaine;[49]
  - ➤ 15 times more likely to have used heroin;[50]
  - ➤ 5 times more likely to develop a need for treatment of abuse or dependence on *any* drug.[51]
- The *Journal of the American Medical* Association reported a study of more than 300 sets of same-sex twins. The study found that marijuana-using twins were four times more likely than their siblings to use cocaine and crack cocaine, and five times more likely to use hallucinogens such as LSD.[52]

3. Medical marijuana

- Our medical system relies on proven scientific research, not polling results.
- About 100 years ago, leaders in this country created the U.S. Food and Drug Administration (FDA) to make sure that medicine falls under the "safe and effective" standard before it is sold on the open market.
- Research has not demonstrated that smoked marijuana is helpful as medicine.[53]
- A component in marijuana—THC—has been approved in pill form by the FDA. It's called Marinol, and though it is not frequently prescribed, the U.S. supports the right of doctors to prescribe this drug if they feel it would best serve their patients' needs. The U.S. Drug Enforcement Administration (DEA) even lowered the scheduling on Marinol to make it easier for doctors to prescribe the drug.
- Marijuana smoke contains more than 400 chemicals and increases the risk of cancer, lung damage, and poor pregnancy outcomes.[54]
- The U.S. continues to support research into the medical efficacy of certain isolated properties of marijuana.
- Even if smoking marijuana makes people "feel better," that is not enough to call it a medicine. If that were the case, tobacco cigarettes could be called medicine because they are often said to make people feel better. For that matter, heroin certainly makes people "feel better" (at least initially), but no one would suggest using heroin to treat a sick person.
- Marijuana use causes precancerous changes in the body similar to those caused by tobacco use. Smoking pot delivers 3 to 5 times the amount of tars and carbon monoxide into the body. It also damages pulmonary immunity and impairs oxygen diffusion.[55] How could changes such as these be good for someone dying of cancer or AIDS?

4. State initiatives

- Voters at the state and local levels want to make decisions that are appropriate for their communities, but to so so they must have accurate information.
- Well-financed and organized campaigns have contributed to the misperception that marijuana is harmless or may even have health benefits.
- These campaigns are led not by medical professionals or patients-rights groups, but by pro-drug donors and organizations in a cynical attempt to exploit the suffering of sick people.

> Marijuana is being used as a wedge issue by a small minority to push a political agenda calling for drug legalization.

5. The European experience

- The "nirvana" offered by the Dutch example is extremely dubious; in fact, the Dutch government is now reconsidering its laws and policies regarding drugs.
- Increased availability of marijuana leads to increased use of this and other drugs, and it creates additional problems as well:
  - ➤ After coffee shops started selling marijuana and use of the drug became normalized, marijuana use between 1984 and 1996 nearly tripled—from 15 percent to 44 percent—among 18- to 20-year-old Dutch youth.[56]
  - ➤ While our nation's consumption of cocaine has decreased by 70 percent over the past 15 years, cocaine consumption in Europe (primarily Western Europe) has increased.[57]

6. Drug testing in schools

- Marijuana use affects the growth and development of young minds; it can inhibit students' ability to concentrate and retain information during the critical learning years.
- Student drug testing can be an important tool in preventing and treating youth drug use.
- It is important for parents, school officials, and community leaders to examine the nature and extent of their youth drug problem to determine if testing is appropriate for their schools.
- The goal of school-based drug testing is not to trap and punish students who do drugs. Rather, it is to prevent drug dependence and to help drug-using students stop and find treatment before the problem gets worse.[58]
- According to the *Journal of Adolescent Health*, a school in Oregon that drug-tested student-athletes had a rate of drug use that was one-fourth that of a comparable school with no drug-testing policy.[59]
- After two years of a drug-testing program, Hunterdon Central Regional High School in New Jersey saw significant reductions in 20 of 28 drug-use categories. Cocaine use by seniors, for example, dropped from 13 percent to only 4 percent.[60]
- Testing provides a way for teens to resist peer pressure.[61]
- Testing helps prevent drug use at a critical time in young people's lives. Research shows a strong link between drug dependence and the age of initiation. If people can be prevented from using drugs as teenagers, their chances of experiencing drug problems as adults are greatly diminished.[62]

Student drug testing helps prevent drug use at a critical time in young people's lives.

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A Peek into Pandora's Box: The Medical Excuse Marijuana Controversy

Eric A. Voth, MD, FACP

ABSTRACT. The smoking of marijuana for medicinal applications is a volatile and difficult issue for the medical and regulatory communities which has reached the forefront of discussions of public policy.

Any consideration of this issue must take into account the substantial toxicity, impurity, and morbidity associated with marijuana use. Several states have passed ballot initiatives or legislation that allow a medical excuse for possession of marijuana. These initiatives bypass the Food and Drug Administration process of proving safety and efficacy, and they have created serious regulatory dilemmas for state regulatory boards. Several examinations of the issue have consistently drawn question to the validity of smoking an impure substance while voicing concern for the well being of patients in need. The historical, social, medical, and legal issues are examined. *[Article copies available for a fee from The Haworth Document Delivery Service: 1-800-HAWORTH. E-mail address: <docdelivery@haworthpress.com> Website: <http://www.HaworthPress.com> © 2003 by The Haworth Press, Inc. All rights reserved.]*

KEYWORDS. Marijuana, cannabis, medicinal marijuana

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HISTORY

In 1972, the Department of Justice Drug Enforcement Administration (DEA) was petitioned to reschedule marijuana from a Schedule I drug (unable to be prescribed, high potential for abuse, not currently accepted for medicinal use, and lack of safety of the drug) to a Schedule II drug (high potential for abuse, currently accepted for medical use, but able to be prescribed).[1]

This rescheduling petition was initiated by the National Organization for the Reform of Marijuana Laws (NORML), Alliance for Cannabis Therapeutics (ACT), and the Cannabis Corporation of America. It is significant that these organizations lobby for the legalization of marijuana and have neither a medical base, nor do they represent any accredited or respected medical entity.

Because of continued controversy surrounding the rescheduling of marijuana, Administrative Law Judge Francis Young was retained by the DEA in 1988 to rule on the merits of rescheduling marijuana to Schedule II. Judge Young ruled that marijuana should be rescheduled to Schedule II for nausea associated with cancer chemotherapy and spasticity.[2] He concluded, however, that insufficient evidence existed to warrant use of crude marijuana for glaucoma or other applications.

The administrator of the DEA ultimately denied the petition to reschedule. In the face of extensive expert testimony provided to the DEA which opposed the rescheduling of marijuana, the marijuana lobby only produced evidence consisting of anecdotes and testimony of a handful of physicians with limited or no clinical experience with the medical areas in question. During the rescheduling hearings it became clear that crude, especially smoked, marijuana had not been accepted as a medicine by any reputable medical entity.

The denial of the rescheduling petition by the DEA resulted in an appeal by marijuana advocates to the United States Court of Appeals for the District of Columbia. In a decision handed down in February 1994[3] the Court set forth the guidelines that only rigorous scientific proof can satisfy the requirement of "currently accepted medical use" (Table 1). Crude marijuana does not meet these guidelines.

TABLE 1. Criteria for Designation for a Drug to Be Considered a Medicine[91]

1. The drug's chemistry must be known and reproducible.
2. There must be adequate safety studies.
3. There must be adequate and well-controlled studies proving efficacy.
4. The drug must be accepted by *qualified* experts.
5. The scientific evidence must be widely available.

Several voter initiatives have been undertaken by marijuana advocates to circumvent the FDA process and the DEA scheduling rules. While not actually legalizing marijuana for medical use, the initiatives create a "defense to possession" for those possessing a medical recommendation to use marijuana. The ballot initiatives were heavily financed by individuals and organizations who seek the legalization of marijuana and other drugs (Table 2, and Appendix 1). The funding bought media consultants, airtime, and legal expertise. While the initiatives were promoted as being "compassionate" for suffering patients, they also created legal protection to those claiming medical ailments as justification for possession and personal use.

The danger of such ballot initiatives is that they create an atmosphere of "medicine by popular vote" rather than the rigorous processes required by federal law that all medicines must undergo. There also exists great concern that the movement to accept marijuana for medicinal applications is having the secondary effect of softening public attitudes on marijuana use. In the 2002 election cycle, initiatives in Florida, Michigan, and Ohio ostensibly sought to

TABLE 2. Examples of Funding for State Marijuana Ballot Initiatives

Proposition 215 California	
(California Secretary of State)	
George Soros	$550,000
Peter Lewis	$500,000
John Sperling	$200,000
George Zimmer	$100,000
Life AIDS Lobby	$344,750
TEAMSTERS	$195,000
(ILLEGAL CONTRIBUTION)	
TOTAL	$1,889,750
Proposition 36 California	
George Soros	$983,080
Peter Lewis	$1,026,337
John Sperling	$1,066,337
Proposition 200 Arizona	
(Arizona Secretary of State)	
George Soros	$430,000
Drug Policy Foundation	$200,000
Peter Lewis	$330,000
John Sperling	$430,000
Social Policy Reform	$100,000
TOTAL	$1,490,000
Arizona-2000, HB 2518	
(Arizona Secretary of State)	
As of 11/4/99	
George Soros	$105,000
Peter Lewis	$105,000
John Sperling	$105,000
Massachusetts-Initiative P H4976	
(Mass. Secretary of State)	
As of December 31, 1999	
Peter Lewis	$122,500
George Soros	$122,500
John Sperling	$122,500
Arizona 2002 Proposition 203	
Soros	$406,467
Sperling	$590,383
Ohio Drug Treatment Initiative 2002	
Bogus treatment intiative	
Soros	$271,276
Sperling	$271,276
Lewis	$271,276
Nevada 2002	
$1.6 million raised, $184,000 of this from small donors.	

require treatment for drug-related arrests. Underlying what would be perceived as a positive change, however, were no controls on what drugs nor what criminal acts would be eligible for treatment. Furthermore, the definitions of "treatment" were generally quite loose. Even literacy or vocational training could have qualified for hard core felons with long-standing drug problems. The Florida and Michigan propositions did not require drug abstinence even during treatment. All three created a situation where criminal addicts would have statutory preference for treatment over none-criminals and were deemed unconstitutional.

This year, proposals in San Francisco and San Diego would require the cities to provide marijuana to individuals with medical excuses. This type of action puts the cities in the difficult situation of assessing the validity of excuses, the purity of the marijuana, and the potency of the marijuana. It also raises the question as to what legal risks the cities would be exposed to if complications such as accidents, infections, or other problems which might arise from the marijuana provided.

Recently, the Justice department filed an injunction in United States District Court against the Oakland Cannabis Buyers Cooperative in an attempt to close down the apparent open dealing of marijuana. This injunction was overturned upon appeal. A subsequent appeal to the United States Supreme Court has set the legal tone for the medicinal marijuana issue. The Supreme Court[4] ruled on May 14, 2001 that the Controlled Substances Act may not be violated by the sale of marijuana for medicinal purposes, and that there is no medical necessity exception to the Controlled Substances Act's prohibitions on manufacturing and distributing marijuana. The Supreme Court decision will likely have a chilling effect on future legislation and litigation regarding the use of marijuana for medicinal purposes.

Serious regulatory questions have also been raised regarding the standard of care that have not been adequately dealt with by ballot initiatives (Table 3). These questions may serve as a template for regulatory boards who are faced with the medical excuse marijuana issue. Unfortunately, regulatory agencies have also been handed a difficult situation to assess.

MEDICINAL APPLICATIONS OF THC OR MARIJUANA

Several medical surveys have examined physician attitudes regarding the use of marijuana for medicinal purposes. Kleiman and Doblin reported[5] that 48% of the respondents would prescribe marijuana if rescheduled for legal prescription. Upon closer review, the survey had a low response rate of approximately 40%. Respondents only accounted for 9% of practicing oncologists. Sixteen percent of those surveyed felt that marijuana was effective in 50% or

TABLE 3. Standards to Consider Before Recommending Marijuana (adapted from reference 92)

* Is there documentation that the patient has had failure of all other conventional medications to treat his or her ailment? Have you counseled the patient (documented by the patient's signed informed consent) regarding the medical risks of the use of marijuana–at a minimum to include infection, pulmonary complications, suppression of immunity, impairment of driving skills, and habituation?

* Has the patient misused marijuana or other psychoactive and addictive drugs?

* Do you periodically provide drug testing of the patient who has been prescribed marijuana, and have patients been excluded from being prescribed marijuana who are found to be using other illicit drugs? Who does the drug testing and by what means?

* Is the use of smoked marijuana part of a study and/or will the monitoring of that use be under the supervision of an investigational review board?

* Have you carefully reviewed exactly which patients should be allowed to use this drug medicinally and for how long?

* Do you carefully examine and consistently follow up patients who use smoked marijuana as a medical treatment, including pulmonary function testing, evaluation of immune status, and the presence of any super infection?

* Have you exercised due care in assuring the standardization of the tetrahydrocannabinol potency content of the marijuana to be considered for medicinal use and whether it is free of microbial contaminants?

* Because marijuana is a federally controlled substance, has a system been established in the state to track all patients and their source of marijuana, as with other controlled substances? Are you complying with such requirements?

* Will you be required to be licensed by the state or federal government?

* Have you shown knowledge, training, or certification in addiction medicine? Do you have demonstrable knowledge of the physiologic effects of marijuana, its side effects, and its interaction with other drugs before prescribing it?

more of patients. Unfortunately, inaccurate interpretations of this survey were widely released, widely publicized by the media, and incorrectly gave the impression that *about half* of oncologists generally want smoked marijuana available as medicine.

The author of this survey, Rick Doblin, was a student at Harvard at that time. He is also the President of the Multidisciplinary Association for Psychedelic Studies (MAPS). MAPS specializes in trying to gain legal access and status for psychedelic substances and marijuana. Doblin has openly admitted that this study was initiated so that the results could be used in the marijuana rescheduling suit against the DEA.

Concurrent with Doblin and Kleiman, Schwartz surveyed oncologists in the Washington D.C. area[6] and determined that pure THC in pill form ranked ninth in preference for the treatment of mild nausea and sixth for the treatment of severe nausea. It is important to recognize that this form of THC is not smoked marijuana.

Only 12% had recommended THC (by prescription or illegally) for more than 50 patients. It was felt that nausea was relieved in only 50% of patients and that 25% had adverse side effects.

Because of the exclusion of newer antiemetics from the two earlier surveys, Schwartz and Voth[7] surveyed 1500 clinical adult oncologists in 1994 with a 75% response rate. Over 88% of respondents had never recommended crude marijuana to patients. Twelve percent had ever recommended a marijuana cigarette, and 1% of the respondents estimated that they had recommended crude marijuana more often than 5 times per year. Only 9% said that they would prescribe crude marijuana more than ten times per year. In contrast, the median annual use of the antiemetics ondansetron (Zofran) and granisetron (Kytril) was 250 prescriptions. Furthermore, the support of making crude marijuana available to patients was strongest among physicians who also supported the concept of general legalization of marijuana for recreational use.

In 1993, Grinspoon published a compilation of anecdotes[8] which now serves as the bible of the "medical excuse marijuana" movement. He suggests that marijuana should be used for nausea associated with cancer chemotherapy, glaucoma, wasting in AIDS, depression, menstrual cramps, pain, and miscellaneous ailments. His anecdotes contained no controls, no standardization of dose, no quality control, and no independent medical evaluation for efficacy or toxicity

The discussion of historical uses of marijuana cited in Grinspoon's book include such cultures as India, Asia, the Middle East, South Africa, and South America and are considered by the medical excuse marijuana movement as evidence of appropriate medical uses of the drug. The Chinese allegedly used marijuana to "quicken the mind, induce sleep, cure dysentery, stimulate appetite, relieve headaches, and cure venereal disease." One of Grinspoon's references from 1860 states marijuana provided beneficial medical effects "without interfering with the actions of the internal organs." Such folk medicine applications of marijuana from the 1700s and 1800s are referenced by the authors as evidence justifying the modern medical applications.

The field of medicine in those earlier years was fraught with potions and herbal remedies. Many of those were absolutely useless, or conversely were harmful to unsuspecting subjects. This situation gave rise to the development and evolution of our current Food and Drug Administration and drug scheduling processes.

Advocates of marijuana contend that the smoking of marijuana has the advantage of providing a rapidly absorbed, titratable dose of THC. While rapid absorption could be an advantage in some arenas, neither anecdotal nor controlled studies have delineated whether anti-emetic qualities appear before, after, or concurrent to the intoxicating effects. Indeed, the therapeutic end point for successful administration of smoked marijuana has not been established.

Research on the utility of THC has demonstrated some effectiveness of the purified form of the drug in treating nausea associated with cancer chemotherapy or appetite stimulation, but even researchers are cautious about using smoked substances. Tramer[9] evaluated the state of the research on cannabinoids and concluded that in selected patients they may be useful as mood enhancing agents, but serious adverse side effects will likely limit their usefulness. They also stated,

> These results should make us think hard about the ethics of clinical trials of cannabinoids when safe and effective alternatives are known to exist and when efficacy of cannabinoids is known to be marginal. (p. 6)

An example of the therapeutic benefits of cannabinoids for nausea was work by Sallan et al.[10] who dealt with pure THC in the treatment of chemotherapy-associated nausea, not smoked marijuana. Chang[11] tested THC and then followed treatment failures with marijuana, thus conclusions regarding effectiveness cannot be readily attributed to either THC or crude marijuana. Levitt et al.[12] actually determined that purified THC was more effective than smoked marijuana.

Vinciguerra et al.[13] found that smoked marijuana had some beneficial effect for nausea in patients who had failed other conventional forms of antiemetic therapy. Responders tended to have had prior marijuana experience. This study was uncontrolled and patients' self-evaluated results. Smokers were required to inhale deeply, hold the smoke for ten seconds, and then smoke four cigarettes completely each day of chemotherapy. Twenty-five percent refused to smoke the marijuana. Over 20% of the subjects dropped out of the smoking group prior to the end of the study and 22% of the remaining subjects reported no benefit from smoking marijuana. Dosing was also variable because of the fact that the dose was rounded to the nearest one-fourth marijuana cigarette and no THC levels were checked for consistency of dose response.

Mattes et al.[14] evaluated oral and rectal suppository preparations of THC in comparison to smoked marijuana for appetite stimulation. All of the study subjects were experienced marijuana users thus accounting for a relatively high drug acceptance. Smoked marijuana was no more effective than suppository THC in stimulating appetite as measured by caloric energy intake. Rectal suppositories and oral THC were dosed at 2.5 mg twice daily. Smoking marijuana

required the subjects to inhale over 3 seconds, hold the smoke deeply in their lungs for 12 seconds, and then continue the process until the cigarette was smoked to a stub. The plasma THC levels peaked more quickly with the inhaled THC, but also fell more quickly, whereas the suppository THC maintained a more sustained level.

Several comprehensive reviews have been undertaken to assess the potential medical uses of marijuana. Voth and Schwartz extensively reviewed available therapies for chemotherapy associated nausea, glaucoma, multiple sclerosis, and appetite stimulation[15] and concluded that no compelling need exists to make crude marijuana available as a medicine for physicians to prescribe. They recommended that the most appropriate direction for cannabinoid research is to research specific cannabinoids or synthetic analogs rather than pursuing the smoking of marijuana as a way to deliver THC.

Former Assistant Secretary of Health Lee[16] at the request of Congress solicited opinions from investigators at the National Institute on Allergy and Infectious Diseases, who commented on the AIDS wasting syndrome; the National Cancer Institute which commented on the use of marijuana as an antiemetic in cancer chemotherapy; the National Eye Institute which commented on marijuana's use in glaucoma; and the National Institute for Neurological Disorders and Stroke which commented on marijuana's role as an antispasticity drug in multiple sclerosis.

The summary opinion stated:

> This evaluation indicates that sound scientific studies supporting these claims are lacking despite anecdotal claims that smoked marijuana is beneficial. Scientists at the National Institutes of Health indicate that after carefully examining the existing preclinical and human data, there is no evidence to suggest that smoked marijuana might be superior to currently available therapies for glaucoma, weight loss associated with AIDS, nausea and vomiting associated with cancer chemotherapy, muscle spasticity associated with multiple sclerosis, or intractable pain.

The National Institutes of Health reconsidered this issue in 1997[17] and has called for further research into alternate delivery systems for pure THC as well as research into the comparative efficacy of marijuana with newer available medicines which have added heightened efficacy to medication regimes. The summary also expressed concern over pulmonary, neuro, and immunotoxicity of cannabis.

In 1997 the White House Office of National Drug Control Policy commissioned the National Academy of Science, Institute of Medicine (IOM) to evaluate the utility of marijuana for medicinal applications.[18] The study concluded (Table 4) that the challenge for future research will be to find cannabinoids

TABLE 4. Institute of Medicine (IOM) Recommendations[93]

Recommendation 1: Research should continue into the physiological effects of synthetic and plant-derived cannabinoids and the natural function of cannabinoids found in the body. Because different cannabinoids appear to have different effects, cannabinoid research should include, but not be restricted to, effects attributable to THC alone. Scientific data indicate the potential therapeutic value of cannabinoid drugs for pain relief, control of nausea and vomiting, and appetite stimulation. This value would be enhanced by a rapid onset of drug effect.

Recommendation 2: Clinical trials of cannabinoid drugs for symptom management should be conducted with the goal of developing rapid-onset, reliable, and safe delivery systems.
The psychological effects of cannabinoids are probably important determinants of their potential therapeutic value. They can influence symptoms indirectly which could create false impressions of the drug effect or be beneficial as a form of adjunctive therapy.

Recommendation 3: Psychological effects of cannabinoids such as anxiety reduction and sedation, which can influence perceived medical benefits, should be evaluated in clinical trials.
Numerous studies suggest that marijuana smoke is an important risk factor in the development of respiratory diseases, but the data that could conclusively establish or refute this suspected link have not been collected.

Recommendation 4: Studies to define the individual health risks of smoking marijuana should be conducted, particularly among populations in which marijuana use is prevalent.
Because marijuana is a crude THC delivery system that also delivers harmful substances, smoked marijuana should generally not be recommended for medical use. Nonetheless, marijuana is widely used by certain patient groups, which raises both safety and efficacy issues.

Recommendation 5: Clinical trials of marijuana use for medical purposes should be conducted under the following limited circumstances: trials should involve only short-term marijuana use (less than six months); be conducted in patients with conditions for which there is reasonable expectation of efficacy; be approved by institutional review boards; and collect data about efficacy.
If there is any future for marijuana as a medicine, it lies in its isolated components, the cannabinoids and their synthetic derivatives. Isolated cannabinoids will provide more reliable effects than crude plant mixtures. Therefore, the purpose of clinical trials of smoked marijuana would not be to develop marijuana as a licensed drug, but such trials could be a first step towards the development of rapid-onset, non-smoked cannabinoid delivery systems.

Recommendation 6: Short-term use of smoked marijuana (less than six months) for patients with debilitating symptoms (such as intractable pain or vomiting) must meet the following conditions:

* failure of all approved medications to provide relief has been documented;
* the symptoms can reasonably be expected to be relieved by rapid-onset cannabinoid drugs;
* such treatment is administered under medical supervision in a manner that allows for assessment of treatment effectiveness;
* and involves an oversight strategy comparable to an institutional review board process that could provide guidance within 24 hours of a submission by a physician to provide marijuana to a patient for a specified use.

which enhance therapeutic benefits while minimizing side effects such as intoxication and dysphoria. Useful delivery systems for isolated or synthetic cannabinoids could include nasal sprays, metered dose inhalers, transdermal patches, and suppositories. The future for medicinal applications of cannabinoids and whether cannabinoids are equal or superior to existing medicines remains to be determined, but the IOM evaluation is particularly clear on the smoking of marijuana:

> If there is any future for marijuana as a medicine, it lies in its isolated components, the cannabinoids and their synthetic derivatives. Isolated cannabinoids will provide more reliable effects than crude plant mixtures. Therefore, the purpose of clinical trials of smoked marijuana would not be to develop marijuana as a licensed drug, but such trials could be a first step towards the development of rapid-onset, non-smoked cannabinoid delivery system.

The advocates for marijuana would have the public and policy makers incorrectly believe that crude marijuana is the only treatment alternative for large populations of patients who are inadequately treated for the nausea associated with chemotherapy, glaucoma, multiple sclerosis, and other ailments. Numerous effective medications are however currently available for conditions such as nausea. To date, no compelling data substantiates the existence of significant numbers of marginally treated or untreated patients for the maladies which marijuana is advanced.

MEDICAL COMPLICATIONS OF MARIJUANA USE

Marijuana continues to be widely used in our society. While its use declined in the late 1980s and early 1990s, a trend toward increasing use has recently be seen in high school students[19] (Table 5). Marijuana remains the most frequently used illegal drug. The chronic use of marijuana has now been demonstrated to be associated with higher utilization of the health care system and associated cost,[20] a long suspected phenomenon.

The negative side effect profile of marijuana far exceeds most of the other effective agents available. In the studies performed to examine THC for chemotherapy-associated nausea, elderly patients could not tolerate the drug well. Chronic, daily doses of the drug would be necessary to treat many of the proposed medical conditions. This would unnecessarily expose the patients to the toxic effects.

Mental, affective, and behavioral effects are the most easily recognized consequences of acute and chronic marijuana use. Concentration, motor coordination, and memory[21-25] are all adversely impacted.

TABLE 5. Drug Use Rates–Marijuana[94]

PERCENT OF HIGH SCHOOL SENIORS USE OF MARIJUANA

	1978	1986	1987	1988	1991	1992	1993	1994	1995	2000
LAST 12 Mo.	50.2	39	36	33.1	23.9	21.9	26	30.7	35	36.5
LAST 30 DAYS	37.1	23.4	21	18	13.8	11.9	15.5	19	21.2	21.6
DAILY	10.7	4.0	3.3	2.7	2.0	1.9	2.4	3.6	4.6	6.0

The ability to perform complex tasks, such as flying[26-27] is impaired even 24 hours after the acute intoxication phase. The association of marijuana use with trauma and intoxicated motor vehicle operation is also well established.[28-33] Evaluations[34] of the effect of marijuana on driving have determined that the combination of blood alcohol concentrations (BAC) of 0.07 and marijuana at 100 μg/kg gave effects similar to BAC alone of 0.09. Blood alcohol concentrations of 0.07 and marijuana levels of 200 μg/kg demonstrated effects similar to a BAC alone of 0.14 when measuring reaction time, on-road performance, and vehicle following. The study concluded, "Under marijuana's influence, drivers have reduced capacity to avoid collisions if confronted with the sudden need for evasive action." A second related study found that BAC of .05 combined with moderate marijuana had significant drop in the visual search frequency. This is of central importance in an ambulatory environment where patients may smoke marijuana and then drive automobiles.

Several biochemical models have demonstrated abnormal changes in brain cells, brain blood flow, and evidence of brain wave changes.[35-36] Pathologic behavior such as psychosis is also associated with marijuana use.[37-39] Solowij et al. reported that the ability to focus attention and filter out irrelevant information was progressively impaired with the number of years of use, but was not related to the frequency of use.[40] Solowij also determined in a separate report that even among ex-cannabis smokers, the inability to reject complex irrelevant information persisted despite a mean abstinence of two years from marijuana use.[41]

In an examination of college students,[42] daily use of marijuana was associated with impairment of "executive functions" such as learning of lists, perseverations, and attention. In that study, heavy use was defined as use only 29 out of the last 30 days which could have actually been as little as one time daily.

Positron scanning[43] of subjects whose mean use of marijuana was 17 times per week for last 2 years found lower blood flow in a large region of the posterior cerebellum. Not only does this have implications on motor coordination

and function, but also cognition, timing, processing sensory information, and attention.

Despite arguments from marijuana advocates to the contrary, marijuana is a dependence-producing drug. Strangely, in the course of the DEA rescheduling hearings, the marijuana petitioners admitted that "marijuana has a high potential for abuse and that abuse of the marijuana plant may lead to severe psychological or physical dependence" (2). This dependence and associated "addictive" behaviors have been well described in the marijuana literature.[44-49] Marijuana dependence consists of both a physical dependence (tolerance and subsequent withdrawal) and a psychological dependence. Withdrawal from marijuana has been demonstrated in both animals[50] and humans.[51]

The gateway effect of marijuana along with tobacco and alcohol is also well established in research.[52,53] The use of cocaine and heroin is virtually always preceded by marijuana. Kandel and co-workers have pioneered research in this area and continue to find clear evidence of a gateway phenomenon.[54,55] Golub and Johnson contends that the importance of marijuana as a gateway drug has actually increased in recent years.[56]

While the dependence producing properties of marijuana are probably a minimal issue for chemotherapy associated nausea when treatment is required short term or sporadically, it is a major issue for the chronic daily use necessary for glaucoma, AIDS wasting syndrome, and other alleged chronic applications.

The respiratory difficulties associated with marijuana use preclude the inhaled route of administration as a medicine. Smoking marijuana is associated with higher concentrations of tar, carbon monoxide, and carcinogens than are found in cigarette smoking.[57] Marijuana adversely impairs some aspects of lung function and causes abnormalities in the respiratory cell lines from large airways to the alveoli.[58-66] Marijuana smoke causes inflammatory changes in the airways of young people that are similar to the effects of tobacco.[67] In addition to these cellular abnormalities and consequences, contaminants of marijuana smoke are known to include various pathogenic bacteria and fungi.[68-70] Those with impaired immunity are at particular risk for the development of disease and infection when these substances are inhaled.

The effects of marijuana on the unborn were long suspected after original studies in Rhesus monkeys demonstrating spontaneous abortion. While these are insignificant issues for terminal cancer patients, they are serious issues for young women potentially using marijuana for migraines or dysmenorrhea.

Exposure to marijuana during pregnancy,[71-76] is associated with changes in size, weight, and neurologic abnormalities in the newborn. A very alarming association also exists between maternal marijuana use and the development of non-lymphocytic leukemia in offspring.[77-78] Additionally, hormonal function in both males and females is disrupted.[79-83] The potential for hormonal abnor-

malities in the unborn is undetermined, but real. Day et al. identified a negative effect on intelligence parameters among three year olds when mothers used marijuana during the first and second trimesters of pregnancy.[84] Dahl et al. have discovered sleep disruption among three year olds when exposed during pregnancy.[85] Consistent with the reports of delayed performance, Fried[86] reported that children exposed in utero demonstrate increased behavioral problems, language comprehension, sustained attention, and memory at age 4.

One of the earliest findings in marijuana research was the effect on various immune functions, which is now evidenced by an inability to fight herpes infections and the discovery of a blunted response to therapy for genital warts during cannabis consumption.[87,88] Abnormal immune function is, of course, the cornerstone of problems associated with HIV. The use of chronic THC in smoked form for AIDS wasting not only exposes the patient to unnecessary pathogens, but also risks further immunosuppression. Evaluation of the effect of THC on NK-kB has suggested a possible effect on the HIV genome.[89] In chronic use or use in populations at high risk for infection and immune suppression, the risks are unacceptable.

LOOKING TOWARD THE FUTURE

Bypassing the usual safety and efficacy process of the FDA is a dangerous and unnecessary precedent which widely enhances the availability and acceptance of marijuana. Smoking an impure and toxic substance is of questionable value in the modern medical armamentarium. It is no more reasonable to consider crude marijuana a medical treatment than it is to consider tobacco as medicine.

If marijuana is to be examined for medicinal applications, rigorous research protocols should be focused on pure THC or other cannabinoids rather than crude forms of marijuana. Examples could include the formulation of rectal suppository or aerosol forms, nasal inhalers, or transdermal delivery systems of dronabinol. An exciting new arena of THC analogs and synthetic cannabinoids may yet produce cannabinoid-like substances which enhance efficacy while having minimal or no toxicity.[90] Naturally occurring substances with medicinal value are well known to medicine. Substances such as Digitalis are found in foxglove plant, but modern medicine either purifies or synthesizes such substances to create pure and reliable medicine. The same can be done for the therapeutically beneficial cannabinoids found in marijuana.

While recognizing that there may exist a small group of inadequately treated patients for whom isolated or synthetic cannabinoids may be beneficial, the general use of crude or leaf marijuana for medicinal purposes cannot be supported except in highly circumscribed, controlled, research settings.

Regulatory agencies have a critically important role in the examination of the use of marijuana. They have, unfortunately, been handed a difficult problem to monitor, which has emerged from an atmosphere of "medicine by popular vote." The use of marijuana in states who allow it needs to be tempered by careful patient selection and monitoring. Unless marijuana were approved as a safe and effective treatment by the FDA, allowing it to be used as a medicine is a step backward to the times of potions and herbal remedies.

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APPENDIX 1. States Adopting Medical Excuse Marijuana

Arizona*	Nevada***
Alaska	Oregon
California**	Washington
Colorado	Hawaii****
Maine	Maryland*****

* Arizona Proposition 203 (a follow up to prop 200) in 2002 was voted down. It decriminalized up to 2 ounces of marijuana possession. If an individual could produce a recommendation from any type of health-related provider, the department of public safety (i.e., state police) would have been required to produce marijuana out of seized stores.

** Proposition 215 allows marijuana to be used with a recommendation from a physician. The subsequent initiative, Proposition 36, prohibits incarceration of first and second offenders. The California initiative will only allow 30 days in jail maximum for offenders beyond the first and second offense. Prop. 36 specifically prohibits any funding for drug testing, choosing instead to trust drug addicts to hold themselves accountable; prohibits payment for any treatment over 12 months; does not provide funding for treatment programs to help addicts in California prisons. Since the initiation of Prop 36, courts have been flooded with addicts electing "treatment." Forty percent of the defendants who opted for rehabilitation failed to appear or dropped out of treatment programs in the first 6 months of the initiative.

***Nevada 2002 voters rejected an initiative to legalize marijuana possession.

****Hawaii legislature passed defense to possession legislation.

***** May 22, 2003. The new law was passed by the legislature and does not legalize marijuana, but reduces the penalty to a maximum $100 fine with no jail time if defendants convince a judge they need marijuana for medical reasons.

ORIGINAL CONTRIBUTION

Prevalence of Marijuana Use Disorders in the United States

1991-1992 and 2001-2002

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Context Among illicit substance use disorders, marijuana use disorders are the most prevalent in the population. Yet, information about the prevalence of current *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)* marijuana use disorders and how prevalence has changed is lacking.

Objective To examine changes in the prevalence of marijuana use, abuse, and dependence in the United States between 1991-1992 and 2001-2002.

Design, Setting, and Participants Face-to-face interviews were conducted in 2 large national surveys conducted 10 years apart: the 1991-1992 National Longitudinal Alcohol Epidemiologic Survey ([NLAES] n=42 862) and the 2001-2002 National Epidemiologic Survey on Alcohol and Related Conditions ([NESARC] n=43 093).

Main Outcome Measures Rates of past year marijuana use, abuse, and dependence.

Results Among the adult US population, the prevalence of marijuana use remained stable at about 4.0% over the past decade. In contrast, the prevalence of *DSM-IV* marijuana abuse or dependence significantly ($P=.01$) increased between 1991-1992 (1.2%) and 2001-2002 (1.5%), with the greatest increases observed among young black men and women ($P<.001$) and young Hispanic men ($P=.006$). Further, marijuana use disorders among marijuana users significantly increased ($P=.002$) in the absence of increased frequency and quantity of marijuana use, suggesting that the concomitant increase in potency of delta-9-tetrahydrocannabinol (Δ^9-THC) may have contributed to the rising rates.

Conclusions Despite the stability in the overall prevalence of marijuana use, more adults in the United States had a marijuana use disorder in 2001-2002 than in 1991-1992. Increases in the prevalence of marijuana use disorders were most notable among young black men and women and young Hispanic men. Although rates of marijuana abuse and dependence did not increase among young white men and women, their rates have remained high. The results of this study underscore the need to develop and implement new prevention and intervention programs targeted at youth, particularly minority youth.

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Marijuana has been the most common illicit substance used in the United States for several decades.[1,2] Understanding changes in the use of marijuana over time is important for a number of reasons. Marijuana use is associated with impaired educational attainment,[3] reduced workplace productivity,[4] and increased risk of use of other substances.[5] Marijuana use plays a major role in motor vehicle crashes[6] and has adverse effects on the respiratory and cardiovascular systems.[7-10]

Marijuana use also is a necessary, although not a sufficient, condition for developing marijuana abuse and dependence as defined in the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)*, which are clear indicators of problems in and of themselves.[11] *Marijuana abuse* is defined in the *DSM-IV* as repeated instances of use under hazardous conditions; repeated, clinically meaningful impairment in social/occupational/educational functioning, or legal problems related to marijuana use. *Marijuana dependence* is defined in the *DSM-IV* as increased tolerance, compulsive use, impaired control, and continued use despite physical and psychological problems caused or exacerbated by use. Beyond the seriousness of these disorders in their own right, marijuana abuse and dependence increase the risk of other serious consequences, most significantly, major mood, anxiety, and personality psychopathology.[12-14]

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Despite the seriousness of *DSM-IV* marijuana abuse and dependence, no long-term trend information is available about whether the prevalence of these disorders is increasing, decreasing, or remaining stable in the United States. Such information was recently added to the National Household Survey on Drug Abuse, but this has only been since 2000.[1] For public health efforts, accurate information on changes in potentially vulnerable groups may highlight the need for focused planning on both a national and local level and form the basis of rational, scientifically based prevention and intervention programs. The current study was designed, in part, to address this gap.

To assess changes in marijuana use, abuse, and dependence in the US population, we compared data from the 1991-1992 National Longitudinal Alcohol Epidemiologic Survey ([NLAES] n=42862) and the 2001-2002 National Epidemiologic Survey on Alcohol and Related Conditions ([NESARC] n=43093).[15,16] Both surveys were conducted by the National Institute on Alcohol Abuse and Alcoholism (NIAAA). Because changes in the prevalence of marijuana use may not reflect changes in the prevalence of marijuana use disorders, rates are presented separately for marijuana use and abuse or dependence in the total population. To assess the risk of marijuana abuse or dependence independent of these baseline rates, conditional rates of past-year marijuana abuse or dependence among users also are presented.

METHODS

Samples

Both the 1991-1992 NLAES and the 2001-2002 NESARC are nationally representative samples of the adult population of the United States and have been described in detail elsewhere.[15,16] The target population for each survey was the civilian noninstitutionalized population, 18 years and older, residing in the United States. The fieldwork for both studies was conducted by the US Census Bureau, under the direction of NIAAA staff. For the NESARC, the overall survey response rate was 81% and for the NLAES, 90%.

The NESARC's sample consisted of 655 primary sampling units (PSUs); however, in the final NESARC datafile, only 435 PSUs are shown because smaller PSUs were collapsed to minimize disclosure risks. The NLAES sample consisted of 198 PSUs. Oversampling of blacks and Hispanics in the NESARC and of blacks in the NLAES, completed at the design phase, increased the proportion of each of these groups in the total samples. In the final selection phase, 1 individual was randomly selected from a list of persons living in the household. At this stage of the survey, young adults (ages 18-24 years in the NESARC and ages 18-29 years in the NLAES) were oversampled at a rate of 2.25:1.00.

The complex sampling design necessitated weighting the data from both surveys to reflect the probability of the following: selection of a PSU within stratum, selection of housing units within the sample PSU, oversampling of young adults, and nonresponse at the household and person levels. The NESARC data were also adjusted to reduce the variance arising from selecting 2 PSUs to represent an entire stratum. The weighted data for both groups were then adjusted to be representative of the US population for a variety of socioeconomic variables including region, age, sex, and race/ethnicity using the Decennial Census of Population and Housing (1990 for the NLAES and 2000 for the NESARC). All potential NESARC respondents were informed in writing about the nature of the survey, the statistical uses of the survey data, the voluntary aspect of their participation, and the federal laws that rigorously provided for the strict confidentiality of the identifiable survey information. Those respondents consenting to participate after receiving this information were interviewed. The research protocol, including informed consent procedures, received full ethical review and approval from the US Census Bureau and US Office of Management and Budget.

Interviewers and Training

All interviews for both the NLAES and NESARC were conducted by professional interviewers from the US Census Bureau. On average, the 1000 NLAES and 1800 NESARC interviewers had 5 years of survey administration experience. All completed a 5-day self-study course followed by a 5-day in-person training session at one of the US Census Bureau's 12 regional offices.

Quality of interviewing was ensured by regional supervisors who recontacted a random 10% of all respondents by telephone and reasked a set of 30 questions from different parts of the interview to verify answers.

Diagnostic Assessment

All diagnoses in the NLAES and NESARC were made according to the criteria of the *DSM-IV* using the NIAAA *Alcohol Use Disorder and Associated Disabilities Interview Schedule-DSM-IV Version (AUDADIS-IV)*, a fully structured diagnostic interview designed for use by professional interviewers who are not clinicians.[17] Although the *DSM-IV* classification was not published until 1994, proposed diagnostic criteria for *DSM-IV* marijuana abuse and dependence were published by the American Psychiatric Association prior to the fieldwork for the NLAES and were incorporated into the *AUDADIS-IV* in their entirety.[18] What was not known at the time was which diagnostic criteria would be assigned to the abuse or dependence categories. However, since all proposed *DSM-IV* diagnostic criteria had been incorporated into the *AUDADIS-IV*, computer algorithms were able to produce diagnoses of abuse and dependence that accurately represented the placement of the criteria within abuse and dependence categories of the final *DSM-IV* revision.

The NLAES and NESARC included the same core questions to assess marijuana abuse and dependence. One minor difference is that, in the NLAES, duration associated with a particular criterion was assessed separately from the criterion itself. For example, if a respondent endorsed a particular crite-

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rion symptom for marijuana, the next question asked whether that criterion had happened more than once with marijuana. In the NESARC, duration associated with marijuana abuse and dependence criteria was embedded directly into the symptom questions. Another difference is that, in the NLAES, the *AUDADIS-IV* was administered using a paper-and-pencil instrument, while in the NESARC, the *AUDADIS-IV* was computerized and responses were entered directly into laptop computers. However, in both studies, all questions were asked by highly trained interviewers. Thus, the computerization did not change the way respondents were exposed to the questions.

In the *AUDADIS-IV*, symptom questions associated with *DSM-IV* abuse and dependence were asked separately for marijuana and each other substance. Consistent with *DSM-IV*, past-year diagnoses of marijuana abuse required a respondent to report at least 1 of the 4 criteria of marijuana abuse within the 12 months prior to the interview.[11] These included recurrent marijuana use resulting in failure to fulfill major role obligations, recurrent marijuana use in physically hazardous situations, recurrent marijuana-related legal problems, and continued marijuana use despite having persistent or recurrent social or interpersonal problems caused by or exacerbated by use. The diagnosis of marijuana dependence required that at least 3 criteria from a list of 6 during the preceding 12 months be met: (1) need for increased amounts of marijuana to achieve the desired effect or markedly diminished effect with continued use of the same amount of marijuana; (2) using marijuana in larger amounts or over a longer period than intended; (3) persistent desire or unsuccessful efforts to cut down or reduce marijuana use; (4) a great deal of time spent obtaining, using, or recovering from the effects of marijuana; (5) giving up important social, occupational, or recreational activities in favor of using marijuana; and (6) continued marijuana use despite persistent or recurrent physical or psychological problems caused or exacerbated by use.

Consistent with the *DSM-IV*, diagnoses of marijuana abuse and dependence were mutually exclusive. A marijuana dependence diagnosis preempts a diagnosis of marijuana abuse. Thus, respondents classified with marijuana abuse had marijuana abuse only, and respondents classified as dependent included those who were dependent with and without abuse. Because the *DSM-IV* does not include specific criteria for marijuana withdrawal, no criterion for marijuana withdrawal is included in the diagnosis and the typical list of 7 *DSM-IV* dependence criteria is reduced to 6 criteria for marijuana. While a number of studies have indicated that a withdrawal syndrome can be defined and assessed for marijuana,[19,20] this point has not yet been fully resolved. Our method of diagnosing marijuana dependence is therefore consistent with the *DSM-IV* in its current standard form.

The reliability and validity of the *AUDADIS-IV* are well documented in numerous national and international psychometric studies conducted in clinical, and particularly in general, population studies, the population for which it was designed.[21-32] The psychometric properties of the *AUDADIS-IV* alcohol and drug modules also were shown to be good in numerous countries in the World Health Organization/National Institutes of Health Joint Project on Reliability and Validity.[22,23,28-32]

Data Analysis

To account for the complex sample designs of both the NLAES and NESARC, SUDAAN software was used to estimate standard errors of all prevalence estimates in both studies across sex, age, and race-ethnic subgroups of the population.[33] Prevalence estimates and standrad errors, derived separately for the NLAES and NESARC, were compared using *t* tests designed for independent samples. To take into account the sampling design, all standard errors of the prevalence estimates were calculated using SUDAAN, a software program that uses Taylor series linearization to make adjustments for weighted data. In all cases, results are not displayed when standard errors are greater than or equal to 50% of the weighted prevalence because these are too imprecise to be reliable.

RESULTS

Past-Year Marijuana Use

Past-year marijuana use was reported by 4.0% of the respondents in the 1991-1992 NLAES and 4.1% of the respondents in the 2001-2002 NESARC (TABLE 1). Marijuana use did not significantly increase in the full sample or among males or females, or among whites, blacks, or Hispanics overall. However, some subgroups did show significant increases and no subgroups showed significant decreases. Increased rates of marijuana use were observed among 18- to 29-year-old black and Hispanic women. The prevalence of marijuana use also increased significantly over the last decade among 45- to 64-year-old men and women overall and white men and black women in this age group.

Past-Year Marijuana Abuse and Dependence

In both the NLAES and NESARC, past-year marijuana abuse was more common than dependence. For the total population in 1991-1992 (the NLAES), past-year prevalence of marijuana abuse was 0.9% and dependence was 0.3%. Similarly, in 2001-2002 (the NESARC), past-year marijuana abuse was reported by 1.1% and dependence by 0.4%. This pattern of abuse, representing approximately 75% to 80% of the total marijuana use disorder cases, was consistent across age, sex, and race-ethnic subgroups, and all further results are described for combined abuse and dependence rates (TABLE 2). For instance, in the total population, past-year prevalence of marijuana abuse or dependence increased from 1.2% in 1991-1992 to 1.5% in 2001-2002 ($P = .01$). This can be translated into an increase from 2.2 million to 3.0 million, respectively, in terms of population estimates.

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While most subgroups showed increases over the decade, these reached statistical significance for females, blacks, Hispanics, and those ages 18 to 29 years and 45 to 64 years overall, for 18- to 29-year-old women, for 45- to 64-year-old men, for black men and women overall, for 18- to-29-year-old black men and women, and for Hispanic men and Hispanics ages 18 to 29 years overall as well as 18- to-29-year-old Hispanic men.

Past-Year Marijuana Abuse and Dependence Among Past-Year Marijuana Users

Among past-year marijuana users, overall rates of past-year abuse or dependence increased from 30.2% in 1991-1992 to 35.6% in 2001-2002 ($P<.01$) (TABLE 3). Almost without exception, the conditional rates of abuse or dependence were larger in the more recent survey, although not all increases were significant. However, significant increases in the prevalence of marijuana abuse or dependence among users were found for both males (33.9% to 38.9%) and females (22.7% to 29.2%), and most notably among 18- to 29-year-old black men (21.8% to 43.0%), 18- to 29-year-old black women (19.1% to 47.2%), and 18- to 29-year-old Hispanic men (29.8% to 53.7%).

COMMENT

The results of this study show that marijuana use in the total adult population has remained substantially unchanged over the decade from 1991-1992 to 2001-2002. However, significant increases in use among some subgroups are important to note, for instance, young black and Hispanic women. In contrast to the results for use among the overall population, rates of abuse or dependence increased from 1991-1992 to 2001-2002. What is perhaps even more significant is that marijuana abuse or dependence increased among marijuana users by 18% from 30.2% in 1991-1992 to 35.6% in 2001-2002.

These results, taken together, suggest that factors affecting addiction potential are operating to produce the increase in prevalence in marijuana abuse or dependence. A number of factors could have led to increases in addiction potential, operating either independently or conjointly. The first is increased marijuana potency. The potency of delta-9-tetrahydrocannabinol

Table 1. Past-Year Prevalence of Marijuana Use, NLAES 1991-1992 and NESARC 2001-2002*

Sociodemographic Characteristic	Men		Women		Total	
	NLAES, % (SE)	NESARC, % (SE)	NLAES, % (SE)	NESARC, % (SE)	NLAES, % (SE)	NESARC, % (SE)
Total	5.5 (0.22)	5.6 (0.24)	2.5 (0.12)	2.6 (0.14)	4.0 (0.13)	4.1 (0.15)
Age group, y						
18-29	12.1 (0.68)	13.3 (0.72)	6.4 (0.37)	7.8 (0.50)†	9.3 (0.41)	10.5 (0.47)†
30-44	6.1 (0.35)	5.8 (0.42)	2.8 (0.20)	2.6 (0.22)	4.4 (0.20)	4.1 (0.24)
45-64	0.8 (0.15)	2.5 (0.26)‡	0.3 (0.07)	0.7 (0.10)‡	0.6 (0.08)	1.6 (0.14)‡
≥65	. . .	0.1 (0.04)	0.0 (0.00)	0.0 (0.00)	. . .	0.0 (0.00)
White						
Total	5.7 (0.25)	5.7 (0.29)	2.7 (0.14)	2.6 (0.17)	4.2 (0.15)	4.1 (0.17)
Age group, y						
18-29	13.9 (0.81)	15.1 (0.98)	7.7 (0.50)	8.6 (0.66)	10.8 (0.51)	11.8 (0.61)
30-44	6.5 (0.39)	6.2 (0.53)	3.1 (0.24)	2.9 (0.30)	4.8 (0.23)	4.5 (0.31)
45-64	0.8 (0.17)	2.5 (0.31)‡	0.3 (0.09)	0.6 (0.12)	0.5 (0.09)	1.6 (0.17)‡
≥65	. . .	. . .	0.0 (0.00)	0.0 (0.00)	. . .	. . .
Black						
Total	6.1 (0.66)	6.9 (0.73)	2.1 (0.26)	3.0 (0.32)†	3.9 (0.34)	4.7 (0.35)
Age group, y						
18-29	10.4 (1.50)	14.2 (1.94)	3.4 (0.59)	6.8 (0.97)‡	6.6 (0.79)	10.1 (1.03)‡
30-44	6.8 (1.20)	6.4 (1.01)	3.0 (0.51)	3.0 (0.52)	4.7 (0.62)	4.5 (0.51)
45-64	1.8 (0.66)	3.0 (0.76)	0.3 (0.14)	1.1 (0.32)†	1.0 (0.31)	1.9 (0.37)†
≥65	0.0 (0.00)	. . .	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.2 (0.11)
Hispanic						
Total	3.9 (0.61)	4.6 (0.51)	1.3 (0.25)	2.1 (0.34)	2.6 (0.34)	3.3 (0.31)
Age group, y						
18-29	6.3 (1.22)	8.7 (1.03)	2.7 (0.63)	5.1 (0.90)†	4.5 (0.70)	7.1 (0.71)†
30-44	4.3 (1.13)	3.3 (0.63)	0.8 (0.30)	0.9 (0.30)	2.6 (0.63)	2.1 (0.35)
45-64	. . .	1.0 (0.32)	. . .	. . .	. . .	0.7 (0.19)
≥65	0.0 (0.0)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
Total§	n = 982	n = 996	n = 640	n = 607	n = 1622	n = 1603

Abbreviations: NESARC, National Epidemiologic Survey on Alcohol and Related Conditions; NLAES, National Longitudinal Alcohol Epidemiologic Survey.
*Ellipses indicate that the estimate does not meet precision standard.
†$P<.05$, 1991-1992 compared with 2001-2002.
‡$P<.01$, 1991-1992 compared with 2001-2002.
§Unweighted number of past-year marijuana users in each group.

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(Δ^9-THC) in confiscated marijuana from police seizures increased by 66% from 3.08% in 1992 to 5.11% in 2002.[34,35] Average potency of Δ^9-THC in these studies was consistently calculated as the simple arithmetic mean (ie, the sum of the Δ^9-THC concentrations divided by the number of seizures), which is more useful in discerning changes over time relative to normalized averages. This increase could have led to greater addiction potential for marijuana use disorders over the last decade. Moreover, there was no systematic change in the frequency of marijuana use between 1991-1992 and 2001-2002: use every day or nearly every day (18.7% and 21.7%); use 1 to 4 times per week (23.8% and 19.7%); use 1 to 3 times per month (22.6% and 20.2%); and 1 to 11 times per year (34.9% and 38.4%). Similarly, very little change in the usual quantity (ie, number of joints or joint equivalents) of marijuana used on smoking days was observed for each time period: 1 joint (65.6% and 63.7%), 2 to 3 joints (26.9% and 22.0%), 4 to 6 joints (4.0% and 8.1%), and 7 or more joints (3.5% and 6.2%). Increasing rates of marijuana use disorders among marijuana users in the absence of increased quantity and frequency of use strengthens the argument that the increasing rates may be attributable, in part, to increased potency of marijuana.

The increased prevalence of marijuana use disorders among marijuana users also may be due, in part, to increases in marijuana use among the youngest individuals observed in this and other studies (such as the Monitoring the Future and the National Survey of Drug Use and Health studies) during the past decade.[1,2] The early onset of drug use has been consistently associated with greater risk of the development of abuse and dependence.[5,36,37] Thus, the marked increase in marijuana use among the youngest age group may be linked to the increases in abuse and dependence. These factors, combined with factors increasing rates of marijuana use in certain subgroups, are all possible explanations of the increased prevalence in rates of marijuana abuse and dependence among marijuana users.

One of the most striking findings of this study was that the rates of marijuana use disorders did not increase among white young adults (ages 18-29 years), but did increase among young

Table 2. *Past-Year Prevalence of DSM-IV Marijuana Abuse or Dependence, NLAES 1991-1992 and NESARC 2001-2002**

Sociodemographic Characteristic	Men		Women		Total	
	NLAES, % (SE)	NESARC, % (SE)	NLAES, % (SE)	NESARC, % (SE)	NLAES, % (SE)	NESARC, % (SE)
Total	1.9 (0.14)	2.2 (0.14)	0.6 (0.05)	0.8 (0.07)†	1.2 (0.07)	1.5 (0.08)†
Age group, y						
18-29	5.1 (0.46)	6.4 (0.51)	1.6 (0.18)	2.5 (0.27)‡	3.3 (0.26)	4.4 (0.30)‡
30-44	1.5 (0.16)	1.7 (0.19)	0.6 (0.09)	0.7 (0.11)	1.0 (0.09)	1.2 (0.12)
45-64	0.2 (0.08)	0.7 (0.15)‡	...	0.2 (0.06)	0.1 (0.04)	0.4 (0.08)‡
≥65	0.0 (0.00)	...	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	...
White						
Total	2.1 (0.17)	2.1 (0.17)	0.6 (0.06)	0.7 (0.08)	1.3 (0.09)	1.4 (0.10)
Age group, y						
18-29	6.3 (0.60)	7.2 (0.69)	2.0 (0.25)	2.7 (0.37)	4.2 (0.35)	4.9 (0.39)
30-44	1.6 (0.19)	1.7 (0.25)	0.6 (0.60)	0.7 (0.15)	1.1 (0.11)	1.2 (0.15)
45-64	...	0.7 (0.16)	...	...	...	0.4 (0.08)
≥65	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
Black						
Total	1.3 (0.28)	2.6 (0.40)‡	0.4 (0.10)	1.2 (0.22)‡	0.8 (0.14)	1.8 (0.22)‡
Age group, y						
18-29	2.3 (0.71)	6.1 (1.19)‡	0.7 (0.21)	3.2 (0.66)‡	1.4 (0.34)	4.5 (0.67)‡
30-44	1.4 (0.48)	2.3 (0.56)	0.6 (0.23)	1.0 (0.34)	1.0 (0.26)	1.6 (0.30)
45-64	...	...	...	...	...	0.4 (0.17)
≥65	0.0 (0.00)	...	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	...
Hispanic						
Total	0.9 (0.26)	2.0 (0.30)‡	0.3 (0.10)	0.4 (0.10)	0.6 (0.14)	1.2 (0.17)‡
Age group, y						
18-29	1.9 (0.65)	4.7 (0.79)‡	0.6 (0.25)	0.9 (0.27)	1.2 (0.35)	2.9 (0.46)‡
30-44	...	0.9 (0.41)	...	...	0.4 (0.17)	0.5 (0.21)
45-64	...	...	0.0 (0.00)	...	...	...
≥65	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)

Abbreviations: *DSM-IV, Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*; NESARC, National Epidemiologic Survey on Alcohol and Related Conditions; NLAES, National Longitudinal Alcohol Epidemiologic Survey.
*Ellipses indicate that estimate does not meet precision standard.
†$P<.05$, 1991-1992 compared with 2001-2002.
‡$P<.01$, 1991-1992 compared with 2001-2002.

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adult black men and women and among young adult Hispanic men. It should also be noted that the prevalences of marijuana use disorders among white young adults have remained high, even though these rates have not significantly increased over the last decade.

The reasons for the rise in marijuana use disorders among these minority youth are not entirely known. Recently, researchers have highlighted the deleterious effects of acculturation on marijuana and other drug use disorders among the growing number of Hispanics faced with adapting to a new culture.[38,39] Lower educational and occupational expectations among minorities have also been implicated in this research. Alternatively, the growing number of minority youth attending college over the last decade might have been exposed to the risks of marijuana use commonly noted among college students, among whom the prevalence of past year marijuana use has increased from 23.0% to 30.0% over the last decade.[40,41]

What is clear is that no single environmental factor can explain the increases in marijuana use disorders observed in this study among certain minority subgroups of the population. Numerous environmental factors, including sociodemographic (increases in single-parent households, urbanicity), socioeconomic (education, income), individual lifestyle (grades, truancy, religious commitment), and economic factors, are all likely to serve as mediators of the observed changes.[42,43] A recent study also has demonstrated that decreases in the perceived risk of harmfulness and in disapproval of marijuana use can explain the recent historic changes in marijuana use among youth.[44] With regard to putative economic factors, recent studies have examined how changes in prices, taxes, and policies affecting tobacco and alcoholic beverages may have had an impact on the prevalence of marijuana use disorders.[44] For example, one study has shown that increases occurring over the past decade in the minimum drinking age had the unintended consequence of increasing marijuana use among high school seniors.[45] Further research on how prices and policies affecting tobacco and alcoholic beverages can affect marijuana use among important subgroups of the population defined in terms of race/ethnicity and other sociodemographic and socioeconomic characteristics is sorely needed and may help

Table 3. *Past-Year Prevalence of DSM-IV Marijuana Abuse or Dependence Among Past-Year Marijuana Users, NLAES 1991-1992 and NESARC 2001-2002**

Sociodemographic Characteristic	Men		Women		Total	
	NLAES, % (SE)	NESARC, % (SE)	NLAES, % (SE)	NESARC, % (SE)	NLAES, % (SE)	NESARC,% (SE)
Total	33.9 (1.83)	38.9 (1.86)†	22.7 (1.92)	29.2 (2.03)‡	30.2 (1.35)	35.6 (1.37)‡
Age group, y						
18-29	41.6 (2.46)	47.8 (2.66)†	25.4 (2.59)	32.2 (2.78)†	36.0 (1.97)	42.1 (1.97)†
30-44	23.7 (2.22)	29.2 (3.25)	19.6 (2.94)	25.0 (3.81)	22.4 (1.79)	27.9 (2.63)†
45-64	22.1 (8.89)	27.0 (4.83)	...	21.7 (6.99)	16.9 (6.51)	25.8 (4.22)
≥65	0.0 (0.00)	...	...	...	0.0 (0.00)	...
White						
Total	36.7 (2.17)	37.6 (2.34)	22.1 (2.10)	27.9 (2.72)†	31.8 (1.63)	34.4 (1.81)
Age group, y						
18-29	45.7 (2.90)	47.4 (3.29)	25.5 (2.91)	30.8 (3.64)	38.6 (2.36)	41.3 (2.45)
30-44	25.2 (2.52)	27.8 (3.76)	18.2 (3.10)	25.3 (4.73)	22.9 (2.01)	27.0 (3.11)
45-64	19.0 (10.73)	26.1 (5.26)	...	...	...	24.0 (4.48)
≥65	0.0 (0.00)	0.0 (0.00)	...	...	0.0 (0.00)	0.0 (0.00)
Black						
Total	21.6 (4.29)	37.9 (4.76)‡	20.1 (4.27)	39.9 (5.28)‡	21.2 (3.28)	38.6 (3.64)‡
Age group, y						
18-29	21.8 (6.25)	43.0 (7.39)†	19.1 (5.87)	47.2 (6.41)‡	21.0 (4.80)	44.5 (5.16)‡
30-44	21.0 (6.36)	36.7 (6.53)†	21.0 (6.35)	33.5 (9.13)	21.0 (4.76)	35.5 (5.50)†
45-64	24.4 (15.64)	...	...	21.0 (12.88)	...	18.4 (7.74)
≥65	...	61.6 (23.77)	...	0.0 (0.00)	...	61.6 (23.77)
Hispanic						
Total	24.1 (6.22)	44.8 (4.05)‡	22.6 (7.63)	19.3 (4.56)	23.7 (5.11)	37.1 (3.45)†
Age group, y						
18-29	29.8 (8.75)	53.7 (6.77)†	20.5 (8.65)	18.3 (4.94)	27.1 (6.74)	41.8 (4.84)†
30-44	...	26.0 (11.02)	...	...	15.2 (6.41)	24.3 (9.10)
45-64	70.4 (29.45)	...	0.0 (0.00)	...	...	26.6 (11.91)
≥65	...	...	...	...	...	...

Abbreviations: *DSM-IV, Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*; NESARC, National Epidemiologic Survey on Alcohol and Related Conditions; NLAES, National Longitudinal Alcohol Epidemiologic Survey.
*Ellipses indicate that estimate does not meet precision standard.
†$P<.05$, 1991-1992 compared with 2001-2002.
‡$P<.01$, 1991-1992 compared with 2001-2002.

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explain the increases observed among minority young adults.

Historical and cultural factors that shape the life history of various racial/ethnic minorities in the United States are potentially equally important in understanding the observed changes. Within this context, future research will need to more fully address the extraordinary heterogeneity within racial/ethnic groups in the search for the explanations of why rates of marijuana use disorders increased among some minority young adults as opposed to white young adults. For example, rates of marijuana use disorders are likely to differ among Mexican Americans, Cuban Americans, and Puerto Rican Americans. It is clear that achieving an understanding of changes in the prevalence of marijuana use disorders among minority young adults will require further research and is an important public health priority.

The results of this study indicate that the vast majority of individuals who use marijuana or have marijuana use disorders are young. Despite this generalization, this study is the first to report significant increases in marijuana use among 45- to 64-year-old men and women combined as well as a modest but significant increase in marijuana abuse or dependence among 45- to 64-year-old men. This indicates that the upper age limit for marijuana use, abuse, and dependence has shifted in a meaningful way. Such a shift is consistent with increased lifetime exposure to marijuana availability in the group who were adolescents in the late 1960s or early 1970s and were ages 45 to 64 years in 2001-2002. Given this shift, the extent to which marijuana use may be a contributing cause of illness in the aging population deserves further research attention.

The major findings from this study have significant research and public health implications. With regard to research, more periodic epidemiologic observational studies are needed to rapidly detect emerging epidemics in marijuana use disorders (and other drug use disorders) as revealed in this study. The apparent epidemic of marijuana use disorders among young adult minorities has possibly been occurring for many years and the failure to detect it sooner lies in the lack of epidemiologic monitoring data. Concerning public health implications, it is important to communicate that the increased potency of marijuana over the past decade may, in part, be responsible for increases in abuse and dependence among users. This is critical information for parents, teachers, peers, physicians, and other health professionals. From a broader public health perspective, the results of this study highlight the need to strengthen existing prevention and intervention efforts and to develop and implement widely new programs with the sex, racial/ethnic, and age differentials observed in this study in mind. Specifically, programs targeting young adults, especially black and Hispanic young adults, need to be designed and tested for their effectiveness as quickly as possible.

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Study concept and design: Grant.
Acquisition of data: Grant, Stinson.
Analysis and interpretation of data: Compton, Grant, Colliver, Glantz, Stinson.
Drafting of the manuscript: Compton, Grant.
Critical revision of the manuscript for important intellectual content: Compton, Grant, Colliver, Glantz, Stinson.
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> If length of days be thy portion, make it not thy expectation. Reckon not upon a long life: think every day the last, and live always beyond thy account. He that so often surviveth his expectations lives many lives.
> —Sir Thomas Browne (1603-1682)

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PERSPECTIVES

Medicinal Applications of Delta-9-Tetrahydrocannabinol and Marijuana

Eric A. Voth, MD, and Richard H. Schwartz, MD

The use of crude marijuana for herbal medicinal applications is now being widely discussed in both the medical and lay literature. Ballot initiatives in California and Arizona have recently made crude marijuana accessible to patients under certain circumstances. As medicinal applications of pure forms of delta-9-tetrahydrocannabinol (THC) and crude marijuana are being considered, the most promising uses of any form of THC are to counteract the nausea associated with cancer chemotherapy and to stimulate appetite.

We evaluated the relevant research published between 1975 and 1996 on the medical applications, physical complications, and legal precedents for the use of pure THC or crude marijuana. Our review focused on the medical use of THC derivatives for nausea associated with cancer chemotherapy, glaucoma, stimulation of appetite, and spinal cord spasticity. Despite the toxicity of THC delivered in any form, evidence supports the selective use of pure THC preparations to treat nausea associated with cancer chemotherapy and to stimulate appetite. The evidence does not support the reclassification of crude marijuana as a prescribable medicine.

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Marijuana has been widely used for hundreds of years as an intoxicant or an herbal remedy. Pure delta-9-tetrahydrocannabinol (THC) is the major active ingredient in marijuana and is 1 of 66 cannabinoid constituents of marijuana. It is now available by prescription as dronabinol. The use of crude marijuana as a medicine would entail smoking the drug or creating herbal preparations of it. Crude marijuana, an undefined herb containing approximately 480 substances (1), has not been approved by the U.S. Food and Drug Administration for use as a medicine.

We examine the use of THC for medicinal applications in various forms, including pure THC (given orally or as suppositories) and crude marijuana. We also consider the therapeutic benefits and drawbacks of THC.

Methods

Resources discussing the medicinal applications of pure THC and marijuana were identified from our personal libraries and by searching MEDLINE for research published between 1975 and 1996. We used the following MEDLINE search terms: *cannabis*, *cannabinoids*, *marijuana*, and *marijuana smoking*; the search yielded 6059 titles. These titles were then cross-searched with the following terms: *therapeutic use*, *antiemetics*, *glaucoma*, *cachexia/appetite*, *multiple sclerosis*, *palliative care*, or *terminal care*. This search yielded 194 titles on antiemetic properties, 56 on glaucoma, 10 on multiple sclerosis, 23 on appetite, and 11 on palliative or terminal care. Editorials, opinion statements, abstracts, and studies not done in humans were eliminated. Any clinical trials that involved the use of crude marijuana were included. We identified no recent clinical trials of medicinal applications (other than antiemetic properties) done in humans. Thus, we included case reports and summary articles for glaucoma, enhancement of appetite, and multiple sclerosis.

Studies on the physical effects of THC or marijuana were selected from among those that primarily involved human participants, presented recent or new data, and provided information that would illustrate potential complications related to different modes of THC delivery. These studies were also organized to illustrate risks associated with short- or long-term exposure. Most research has focused on either THC or crude marijuana.

Therapeutic Indications for Delta-9-Tetrahydrocannabinol

Nausea Associated with Cancer Chemotherapy

By far, most research on THC has involved the use of oral THC (dronabinol), which does not naturally occur in crude marijuana (2, 3). The studies that we evaluated examined a wide and heterogeneous representation of tumors and chemotherapy regimens (**Table 1**). We found no pattern of THC efficacy for any one type of tumor or chemotherapy. None of the studies compared any form of THC

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Table 1. Studies That Used Delta-9-Tetrahydrocannabinol as an Antiemetic Agent for Patients with Cancer Receiving Chemotherapy*

Study (Reference)	Dosage and Form of THC	Patients	Design	Patient Age	Results
		n		*y*	
Sallan et al. (4)	15 mg or 10 mg/m² body surface area orally every 4 hours for 3 days	10	Randomized, double-blind, cross-over	29.5†	THC better than prochlorperazine
Sallan et al. (5)	10 mg/m² orally every 4 hours for 3 days	46	Randomized, double-blind, cross-over	32.5‡	THC better than prochlorperazine
Chang et al. (6)	10 mg/m², orally and smoked, every 3 hours for 5 days	15	Randomized, cross-over	24†	THC better than prochlorperazine
Frytak et al. (7)	15 mg orally	116	Prospective, double-blind	61†	THC equal to prochlorperazine and both drugs better than placebo
Kluin-Neleman et al. (8)	10 mg/m² orally	11	Double-blind, cross-over	34.6†	THC better than placebo
Ekert et al. (9)	10 mg/m² orally compared with metoclopramide	33	Double-blind, cross-over	5–19	THC better than prochlorperazine or oral metoclopramide
Lucas and Laszlo (10)	5–15 mg/m² orally every 4–6 hours 24 hours after chemotherapy	53	Randomized, cross-over	Adults	THC effective
Orr et al. (11)	7 mg/m² orally every 4 hours for 3 days	55	Randomized, double-blind, cross-over	46‡	THC better than prochlorperazine and both drugs better than placebo
Gralla et al. (12)	10 mg/m² orally every 3 hours for 5 days compared with intravenous metoclopramide	27	Randomized, double-blind	Adults	Metoclopramide better than THC
Ungerleider et al. (13)	7.5–12.5 mg orally	214	Randomized, double-blind, cross-over	47‡	THC equal to prochlorperazine
Levitt et al. (14)	Oral THC and smoked marijuana	20	Randomized, double-blind	54.5‡	Oral THC better than smoked THC
Vinciguerra et al. (15)	Approximately 5 mg of smoked marijuana per m²	56	Prospective, uncontrolled	40‡	Smoked THC effective; no controls used
Lane et al. (16)	10 mg oral THC plus prochlorperazine	60	Randomized, double-blind	55‡	Combination more effective than individual drugs

* THC = delta-9-tetrahydrocannabinol.
† Median age.
‡ Mean age.

with the serotonin antagonists ondansetron or granisetron. In fact, numerous safe and effective noncannabinoids are available for the control of chemotherapy-associated nausea (**Table 2**); this is an important point, given the side effects found in studies of THC.

Oral THC has generally been found to be as effective or more effective for nausea than prochlorperazine. Studies by Ungerleider (13), Sallan (4, 5), Frytak (7), and Chang (6) and their colleagues support this conclusion. Because of their uncertainty about the drug being used, 75 of 214 participants withdrew from the study by Ungerleider and colleagues. The other three studies, however, give useful information about side effects and dosage. In the studies by Sallan and colleagues (5, 6), negative side effects occurred in 81% of patients. Nine percent of these patients experienced hallucinosis, distortion of reality, and mental depression. The effectiveness of THC was usually correlated to the onset of a "high" or intoxicated feeling. Frytak and colleagues (7) determined that 32% of patients had toxicity during their study, in which peak levels of THC ranged from 2.7 to 6.3 ng/mL. However, the median age of this study group was 61 years, whereas the median age of the groups in Sallan and colleagues' study was 29.5 years. This older age may explain the increased toxicity seen by Frytak and colleagues.

According to the study by Chang and colleagues (6), plasma THC levels of at least 10 ng/mL were effective in preventing nausea. If nausea occurred after the initial treatment, patients were assigned to smoked THC or placebo. Absorption by the oral and smoked routes varied. The efficacy of the drug with either route is difficult to interpret because the two routes were mixed. However, both THC and prochlorperazine were found to be more effective than placebo.

Placebo was also found to be less effective than THC in the studies by Kluin-Neleman and colleagues (8) and Orr and colleagues (11). Kluin-Neleman and colleagues found the toxicity of THC to be so profound that most patients preferred nausea to THC. Some of the plasma THC levels were high (300 ng/mL), but they were consistent with levels that marijuana users may reach during intoxication (17) and levels that are easily obtainable through smoked or high oral doses. Orr and colleagues studied patients who were refractory to other antiemetic regimens and found that THC was superior to prochlorperazine. The latter, in turn, was superior to placebo. The selection of refractory patients, how-

ever, introduces bias against the regimens that do not include THC.

Patients refractory to other agents were also studied by Lucas and Laszlo (10). The initial dose, 15 mg of THC per m^2 of body surface area, was too toxic and thus was reduced to 5 mg/m^2. Even at the lower dose, nausea completely or partially resolved in 72% of patients.

Although Ekert and colleagues (9) found that oral THC was more effective than oral metoclopramide and prochlorperazine, Gralla and associates (12) (in the only study that used intravenous metoclopramide) found that metoclopramide provided more protection than did THC. Ekert and colleagues found that drowsiness, the major side effect in their study, was more common with THC than with either metoclopramide or prochlorperazine.

In one of the few studies that actually used smoked marijuana to treat nausea caused by cancer chemotherapy, Vinciguerra and colleagues (15) found that smoked marijuana controlled nausea in patients in whom other conventional forms of antiemetic therapy had failed. Persons who responded to smoked marijuana tended to have previously used marijuana. This study was uncontrolled, and patients themselves evaluated the results. Smokers were required to inhale deeply and hold the smoke for 10 seconds; this technique was used to completely smoke four cigarettes during each day of chemotherapy. Twenty-five percent of the patients refused to smoke the marijuana. More than 20% of the patients dropped out of the smoking group before the end of the study, and 22% of the remaining patients reported no benefit from smoking marijuana. Dosing also varied because the dose was rounded to the nearest one fourth of a marijuana cigarette, and THC levels were not checked for consistency of dose response.

In a randomized, double-blind study comparing pure THC with smoked marijuana, Levitt and colleagues (14) found that pure THC was more effective for nausea than smoked marijuana in 35% of patients. Forty-five percent of patients voiced no preference between the two.

Lane and associates (16) compared dronabinol plus prochlorperazine with single antiemetic agents. The combination regimen seemed to slightly mitigate the toxic effects of THC. However, 23% of the 60 patients withdrew from the study because of adverse effects (which were psychotropic effects in all but 1 patient who withdrew).

In summary, oral THC doses of 5 to 15 mg/m^2 have been effective in treating nausea associated with cancer chemotherapy if patients are pretreated and doses are then repeated every 3 to 6 hours for approximately 24 hours. Efficacy is often associated with a sensation of intoxication.

Table 2. Noncannabinoid Medications Used for Nausea Associated with Cancer Chemotherapy*

Phenothiazines	
Prochlorperazine (Compazine)	•
Chlorpromazine (Thorazine)	
Thiethylperazine (Torecan)	•
Perphanazine (Trilafon)	
Promethazine (Phenergan)	
Corticosteroids	
Dexamethasone (Decadron)	
Methylprednisolone (Medrol)	
Anticholinergics	
Scopolamine (Transderm Scop)	
Butyrophenones	
Droperidol (Inapsine)	
Haloperidol (Haldol)	
Domperidone (Motilium)	•
Benzodiazepines	
Lorazepam (Ativan)	
Alprazolam (Xanax)	
Substituted benzamides	•
Metoclopramide (Reglan)	
Trimethobenzamide (Tigan)	
Alizapride (Plitican)	
Cisapride (Propulsid)	
Antihistamines	
Diphenhydramine (Benedryl)	
Serotonin antagonists	
Ondansetron (Zofran)	
Granisetron (Kytril)	
Tropisetron (Navoban)	
Dolasetron	

* Adapted with permission from Grunberg SM, Hesketh PJ. Control of chemotherapy-induced emesis. N Engl J Med. 1993;329:1790-6.

Appetite Stimulation

The appetite-stimulating effect of THC may be beneficial for patients with wasting related to the acquired immunodeficiency syndrome (AIDS) and those with severe cancer-related anorexia. The literature contains few studies with objective data on the use of either pure THC or crude marijuana for appetite stimulation. This issue is complex because appetite stimulation is a surrogate measure for useful weight maintenance or gain and for effective calorie intake, which are far more important measures than appetite alone. In one trial (18), appetite improved in patients with terminal cancer who received low-dose oral THC (2.5 mg twice daily, 1 hour after meals). Twenty-two percent of patients withdrew from the trial because of typical cannabinoid toxicity. Only low doses of oral THC were necessary, a factor that helped avoid the toxicity of the typically higher doses received from smoked marijuana. This study was a prospective, unblinded, uncontrolled study; controlled studies are needed.

In a double-blind, placebo-controlled, parallel-group study (19), 2.5 mg of oral THC twice daily effectively stimulated appetite in patients with AIDS. The investigators did not evaluate muscle mass or total body fat but did find that in patients who received oral THC, weight was maintained or increased slightly.

Mattes and colleagues (20) compared the effects of oral and rectal suppository preparations of THC

on appetite stimulation and calorie intake with those of smoked marijuana in healthy persons. All participants in this double-blind, placebo-controlled study were experienced marijuana users; thus, the drug acceptance rate was relatively high. Smoked marijuana was no more effective than suppository THC in stimulating appetite, as measured by calorie intake. Rectal suppositories and oral THC were given at a dosage of 2.5 mg twice daily. Patients assigned to smoked marijuana had to inhale for 3 seconds and hold the smoke deeply in their lungs for 12 seconds; this process was continued until the cigarette was smoked to a stub. The plasma THC levels peaked more quickly with the inhaled THC but also decreased more quickly; in contrast, the levels achieved with suppository THC were more sustained.

Glaucoma

Along with other cannabinoids, THC has been shown to reduce intraocular pressure in laboratory animals and humans who have glaucoma (21–23). Cannabinol, nabilone, THC, and delta-8-tetrahydrocannabinol have been found to decrease intraocular pressure, whereas cannabidiol had no effect. Merritt and colleagues (24) concluded that such side effects as hypotension, tachycardia, palpitations, and altered mental status precluded the use of these drugs in the general population with glaucoma. Intraocular pressure is reduced only if patients stay under the effects of THC almost continuously. Although the reduction in pressure may suggest that THC is beneficial for the treatment of glaucoma, no evidence indicates that either pure THC or crude marijuana affects or arrests the underlying disease.

In summarizing the therapeutic potential of cannabis for glaucoma, Mechoulam and colleagues (25) observed that

> the cannabinoids tested so far appear to be of limited use in the treatment of glaucoma. They appear to act only against a primary symptom of the disease rather than against the underlying disease process, which remains uncertain. The side-effects of those cannabinoids particularly effective in lowering intraocular pressure restrict their clinical usefulness.

Multiple Sclerosis

Anecdotal reports (25) and a case report (26) have suggested that THC has benefits for patients with the spasticity of multiple sclerosis. Objective data on the efficacy of THC or crude marijuana are scant. However, a double-blind, randomized, placebo-controlled study of the effect of smoking marijuana in patients with multiple sclerosis (27) showed that posture and balance were negatively affected by the treatment and were actually worse than at baseline. These findings are consistent with the deterioration of mental, motor, and postural functions seen in normal volunteers by Kiplinger and colleagues (28).

Complications of Delta-9-Tetrahydrocannabinol Use

The toxic or negative effects of exposure to THC largely depend on the route of delivery, the duration of exposure, and the patient's age and immunologic status. For the treatment of nausea, exposure to THC would be brief but repetitive and dependent on the chemotherapy regimen. Short- or long-term use often affects the central nervous system. Both smoked and oral THC have been associated with distortion of reality, euphoria, dysphoria, and changes in coordination and concentration (4–8, 10, 15). Some investigators have found more serious toxic effects, including hallucinosis (7), depersonalization (8), and paranoia (11).

Concentration, motor coordination, memorization, memory retrieval, and the ability to sort unimportant information are all adversely affected by the use of crude marijuana (29–36). One study (17) showed that short-term use impairs driving performance; the performance of complex tasks, such as flying, is also negatively affected (37, 38). Marijuana seems to play a major role in vehicular trauma and impaired driving (39–44). Psychosis is more commonly associated with heavy marijuana use, but serious dysphoria and even hallucinosis have been reported with brief use (45–47).

Such cardiac effects as tachycardia and hypotension are commonly noted with short-term exposure to THC (6, 7, 16, 24). Although this effect may be of minimal consequence to younger persons, elderly patients tend to have worse tolerance of THC (7). It can be anticipated that long-term use in patients with such a disorder as glaucoma would not be well tolerated and might be dangerously toxic.

Respiratory problems are often prevalent in patients with cancer, and persons with AIDS may be harmed by smoking any substance. Smoking marijuana exposes patients to 50% higher levels of the procarcinogen benz-α-pyrene than does smoking tobacco (48). Marijuana smoking results in carboxyhemoglobin levels that are five times higher and tar levels that are three times higher than those produced by tobacco smoking (49). Numerous pathogenic bacteria (such as *Klebsiella*, *Enterobacter*, group D *Streptococcus*, and *Bacillus* species) (50) have been cultured from marijuana, and infections with salmonella (51) and fungi (52) have been associated with marijuana use. Thus, immunosuppressed patients (such as those receiving chemotherapy and those with AIDS) are at particular risk.

As access to marijuana broadens with such legis-

lative actions as proposition 200 in Arizona and proposition 215 in California, various age and demographic groups could have long-term exposure. In addition, if THC or marijuana is used for such applications as treating glaucoma or multiple sclerosis or enhancing appetite in patients with wasting related to AIDS, the patient faces long-term exposure. The possibility of central nervous system, pulmonary, cardiac, and infectious toxicities are of course greatly increased during the repetitive exposure of long-term therapy. Researchers have shown that long-term exposure to smoked marijuana is associated with many adverse effects, including impaired lung function (53–55), reduced specific conductance and increased airway resistance (56), heightened alveolar cellular response (57), and pathologic bronchial abnormality (58). In vitro studies have demonstrated DNA damage to human alveolar macrophages (59) and suppression of antiherpes activity by alveolar macrophages (60). Long-term marijuana smokers have also been found to use health care resources at an increased rate because of respiratory problems (61). Several researchers have voiced concern about the effects of marijuana or THC on systemic immune function (62–64) and other biochemical functions (65).

The long-term use of marijuana by young women for medicinal applications may affect the offspring of these women. In utero exposure to marijuana has been linked to changes in birth length, changes in birth weight, and neurologic abnormalities in newborns (66–71); prevalence of nonlymphocytic leukemia in offspring (72); negative effects on measures of intelligence among 3-year-old children (73); sleep disruption (74); and increased problems with behavior, language, sustained memory, and sustained attention in 4-year-old children (75).

Long-term and repetitive use of THC derivatives, especially by young persons, poses the problem of addiction (76–81). Although this is of minimal concern in patients with terminal cancer, it could be a major problem for persons with glaucoma and those intending to use marijuana as a household herbal remedy.

Medicinal Uses of Crude Marijuana: Past, Present, and Future

The use of marijuana as an intoxicant and its use as an herbal remedy are two separate issues that have become intertwined. The salient questions about the medicinal uses of marijuana are 1) is marijuana safe and effective as medicine and 2) what actually constitutes a medicine?

At the request of the U.S. Congress, the National Institutes of Health (Lee PR. Letter to Congressman Dan Hamburg; 13 July 1994) reviewed the preclinical and human data on the use of crude marijuana as a medicine. The summary opinion stated that

> This evaluation indicates that sound scientific studies supporting these claims are lacking despite anecdotal claims that smoked marijuana is beneficial. Scientists at the National Institutes of Health indicate that after carefully examining the existing preclinical and human data, there is no evidence to suggest that smoked marijuana might be superior to currently available therapies for glaucoma, weight loss associated with AIDS, nausea and vomiting associated with cancer chemotherapy, muscle spasticity associated with multiple sclerosis, or intractable pain.

Supporters of the use of crude marijuana as a medicine have proposed that marijuana be made available as a prescribable medication (82) for the treatment of a wide variety of illnesses, including those discussed here and such conditions as headache, dysentery, menstrual cramps, pain, and depression. The anecdotes supporting the use of crude marijuana as a medicine are not usually submitted to independent medical or scientific evaluation of efficacy or toxicity (83).

Since the early 1970s, supporters of crude marijuana as a medicine have pursued a petition to force the U.S. Drug Enforcement Administration to reschedule marijuana under the Controlled Substances Act from Schedule I (high abuse potential, not available to prescribe) to Schedule II (high abuse potential). In our MEDLINE search, we found almost no evidence of studies on the use of marijuana for medicinal applications that were done before this petition was filed.

Because of long-standing controversy about the rescheduling issue, administrative law judge Francis Young was asked by the Drug Enforcement Administration in 1988 to comment on the merits of rescheduling marijuana (84). Young suggested that marijuana be rescheduled for nausea associated with cancer chemotherapy. He also concluded that the evidence was insufficient to warrant the use of crude marijuana for glaucoma or pain. The administrator of the Drug Enforcement Administration rejected Young's opinion and stated that Young had relied mostly on anecdotal information and ignored the prevailing scientific opinion (85).

The rescheduling petition was then appealed to

Table 3. Criteria for a Drug To Be Considered a Medicine*

The chemistry of the drug must be known and reproducible
Adequate safety studies must have been done
Adequate and well-controlled studies must have proven the efficacy of the drug
The drug must be accepted by qualified experts
The scientific evidence must be widely available

* Information obtained from reference 86.

the U.S. Court of Appeals for the District of Columbia. In rejecting the petition to reschedule marijuana (86), the Court determined that only rigorous scientific proof can satisfy the requirement of "currently accepted medical use," which is necessary for a substance to be considered a medicine (**Table 3**). All potential medicines are submitted to this standard.

Several surveys have examined oncologists' choices of therapy for the nausea caused by chemotherapy. Doblin and Kleiman (87) surveyed 2430 oncologists (response rate, 43%) and found that 44% of the respondents had recommended illegal marijuana to at least one patient having chemotherapy. The results of this survey have been widely misquoted (88, 89). For example, Grinspoon and Bakalar (89) incorrectly stated in a major medical journal that "44% of oncologists," rather than 44% of oncologists responding to the survey, had recommended marijuana to their patients. The results actually corresponded to 6% of practicing oncologists.

Schwartz and Beveridge (90) surveyed oncologists practicing in the Washington, D.C., area to determine their preferences for the treatment of nausea caused by chemotherapy. Oral THC or smoked marijuana ranked ninth out of nine choices for mild nausea and sixth out of nine for severe nausea. Approximately 25% of the respondents who treated their patients with marijuana reported that the patients had adverse side effects.

We posed the same question to 1500 clinical adult oncologists in a survey conducted in 1994 (91) that had a 75% response rate. The choice of serotonin receptor antagonists was also considered in the survey. More than 88% of respondents had never recommended crude marijuana to a patient. Only 1% estimated that they had recommended crude marijuana more than five times a year.

In November 1996, ballot initiatives in California and Arizona allowed physicians to either recommend (California) or prescribe (Arizona) crude marijuana. These initiatives placed no limitations on age or on the disorders for which crude marijuana could be used. The medical significance of these initiatives is that they circumvent the U.S. Food and Drug Administration process for assuring safety and efficacy and that they may expose patients to the delivery of a crude herbal substance through smoking.

Conclusions

The literature suggests that pure THC is useful for nausea associated with cancer chemotherapy and that it may be useful in low doses for appetite stimulation in patients with the AIDS wasting syndrome. Both marijuana and pure THC may have toxic effects, and the therapeutic benefits of these substances must be carefully weighed against these effects.

Research has recently defined the presence of a cannabinoid receptor and the existence of an endogenous cannabinoid, anandamide (92). It has also shown that cannabinoids have affinity for various locations in the brain. It is conceivable that synthetic cannabinoids could be developed to minimize toxicity and maximize therapeutic benefits, and active research into these possibilities seems appropriate. New delivery systems (such as suppositories [20] or nasal inhalers) for the administration of pure THC, as well as the current availability of numerous effective antiemetic agents, precludes the perceived need to smoke crude marijuana for medicinal purposes. Pure THC is already available as a prescription medication. Crude marijuana does not qualify as a medicine and remains a Schedule I drug.

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VIA FACSIMILE
(202) 456-2461

May 7, 2004

President George W. Bush
The White House
1600 Pennsylvania Ave
Washington, D.C. 20500

Dear Mr. President:

On behalf of the 5,000 coalition members that Community Anti-Drug Coalitions of America (CADCA) represents, I am writing to strongly urge you to instruct the Food and Drug Administration (FDA) to issue warning letters to all states, local governments, medical boards, website operators and sellers of marijuana explaining that the FDA has not approved botanical marijuana for "medicinal use" and that it cannot be advertised as such. Furthermore, I respectfully request that you direct the FDA to take action against entities that continue to falsely advertise marijuana as medicine with appropriate penalties.

It has recently come to my attention that the FDA has issued a multitude of warning letters to websites over: (1) weight loss claims, (2) the relationship between walnuts and the risk of heart disease, and (3) the potential risk of ultrasound 'keep-sake' images. Many, if not most of these claims, are based on little or no conclusive, scientific evidence. Mel Stratmeyer, Ph.D., in the FDA's Office of Science and Technology was quoted in an article related to the ultrasounds as saying, "...if there's even a possibility of potential risk, why take the chance?"

If the FDA uses the standard of "possibility of potential risk," don't Americans also deserve to be protected from the demonstrably false claims being made about "medical marijuana." The public relies upon the FDA to advise them on medicine, based on sound medical evidence. To date, the FDA has not approved nor has it found *any* medicinal value in botanical marijuana, which is why it remains a Schedule I controlled substance. Despite this fact, websites, state and local governments, private vendors and doctors continue to advertise and endorse the medicinal value of smoked marijuana.

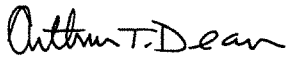
Marijuana is not a harmless drug: it is the most widely abused illicit drug in the nation. According to the Substance Abuse and Mental Health Services Administration's Treatment Episode Data Set, approximately 60% of adolescent treatment cases in 2001 were for marijuana abuse. Research shows that the decline in the use of any illegal drug is directly related to its perception of harm or risk by the user. Advertising smoked marijuana as medicine sends the wrong message to America's youth – that marijuana is not dangerous. The efforts of the drug legalization movement, to promote "medical

marijuana" to the public severely dilutes the prevention messages that community anti-drug coalitions across America are trying so hard to communicate: marijuana is dangerous and has serious consequences.

An April 2nd story in Reuters Health ("FDA Warns 16 Websites Over Weight Loss Claims) shows that the FDA is issuing warnings in these cases based on "false and misleading claims" that may have significant health consequences to the public. These same kind of claims are being made regarding "medical marijuana." Doctors and websites are giving false hope to patients by telling them that marijuana will help them, without warning these patients of the potentially serious side effects of smoking marijuana. At a hearing before the House Government Reform Subcommittee on Criminal Justice, Drug Policy and Human Resources, Dr. Nora Volkow, Director of the National Institute on Drug Abuse (NIDA), the government's lead agency on drug abuse research, testified that even if marijuana were found to have medicinal value at some point in the future, doctors could not in good faith recommend patients smoke it because it is inherently toxic as a delivery system. When considering new drug therapies, any positive effects must outweigh the negative side effects.

Mr. President, I strongly urge you to instruct the FDA to send warning letters to all states, local governments, medical boards, websites and sellers of marijuana explaining that the FDA has not approved botanical marijuana for medicinal use and that it cannot be advertised as such. Thank you for considering my views.

Sincerely,



Arthur T. Dean
Major General, U.S. Army, Retired
Chairman and CEO

cc: Lester Crawford, D.V.M., PhD, Acting Commissioner of Food and Drugs
John P. Walters, Director of the White House Office of National Drug Control Policy

http://www.examiner.com/news/default.jsp?story=n.study.0609w

San Francisco Examiner

06/09/2003

Study: Many HIV patients use pot for mental health

BY SARA ZASKE
Of The Examiner Staff

SAN MATEO -- Results coming out of the medical marijuana research project at the San Mateo Medical Center are making waves in the scientific community.

The first clinical trials, which ended in February, are still being analyzed. But psychologists were treated to some surprising data from an initial Medical Center survey of HIV patients at the American Psychiatric Association conference in May. **The study indicated that more HIV patients smoked marijuana for mental rather than physical reasons.**

"We expected to see people smoking marijuana to alleviate nausea, pain and to increase their appetite -- all the reasons that are commonly cited," said Diane Prentiss, a research epidemiologist with the Medical Center. "In this case, we were surprised that 57 percent say they smoked to relieve anxiety or depression."

To gather baseline information for use in clinical trials of medical marijuana, researchers at the San Mateo Medical Center surveyed 252 HIV patients. Of that number, 23 percent (58 patients) admitted to smoking marijuana in the last four weeks.

When asked for the main reasons they used the drug, most cited several reasons. Mental health issues topped the list. Curbing nausea and increasing appetite was the second, with 52 percent. Recreational use came in third with 33 percent. Only 28 percent said they smoked to alleviate pain.

The prevalence of the mental health issue is a significant finding that raises some interesting questions, said Dr. Dennis Israelski, chief of staff and chief research officer at the Medical Center.

"In terms of understanding the whole field, it is safe to say that there is a fair amount of self-medication that physicians are not aware of," he said. "It does speak to whether it's appropriate medication. Are physicians doing a good enough job when patients are using outside medication? Do we have better treatments for anxiety and depression? These are very important issues related to quality of life."

Mental health is especially important for HIV patients, Israelski said, pointing to studies showing that mental health impacts a patients' ability to adhere to the strict medical regimens used to combat the often-fatal disease.

Dr. Cheryl Koopman, an associate professor of psychiatry at Stanford, said that many of her colleagues were intrigued by the results of the Medical Center's study presented at the conference.

"There was a lot of interest. A number of clinicians in the room felt it was relevant to patients they are working with," she said. "Because of the illegality of marijuana there's a lack of research. We don't know if self-medication is systemic. It's another reason for large studies to be conducted in a scientifically rigorous way."

The San Mateo Medical Center's work with medical marijuana is the only publicly funded research of its kind in the country. "It is not an easy field to study," said Israelski. "People don't want to touch it for political reasons."

The Bush administration has come out strongly against any legalization of marijuana, even for medical purposes, claiming there is no research proving it has health benefits.

"It's a Catch-22," said Israelski. "If they make it tough to study, how do you get scientific evidence?"

The Medical Center has managed to complete one round of clinical trials studying medical marijuana and HIV patients, but Israelski is still negotiating for federal approval for two more studies. The AIDS researcher credits the political support at the county level -- particularly from Supervisor Mike Nevin and County Manager John Maltbie -- for the success of the project so far.

The first round of the Medical Center clinical trials focused on marijuana's affect on peripheral neuropathy, a severe debilitating leg pain associated with HIV.

For the next trials, the Medical Center research team wants to expand the study to include potential effects on nausea, gastrointestinal disorders and wasting syndromes associated with HIV. A third round of trials would study the drug's effects on cancer patients. These second and third trials are still awaiting federal approval.

Significant benefits to marijuana, marijuana-related or "cannabinoid" products may not be found, even if studies are conducted, Israelski said.

"I'm not a believer. I am approaching this as a scientist to see if there are merits, and then let the dust settle," he said. "I have no axe to grind, but we should be able to do the study."

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Los Angeles Times
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Monday, February 23, 2004

Health; Features Desk

Medicine; Unorthodox uses for medicinal **marijuana**; The drug is being recommended by some doctors for conditions such as depression and ADD.
Daniel Costello
Special to The Times

Buoyed by a recent federal court decision, a small but growing number of California doctors are treating patients with **marijuana** for a host of medical conditions, including some controversial ones, such as adult depression and attention deficit disorder in children. Experts say most of these doctors are recommending medicinal **marijuana** only for the treatment of conditions for which there is some scientific research supporting its benefit: pain management, glaucoma and as an appetite enhancer for cancer and AIDS patients. But others already are raising concerns about doctors who recommend **marijuana** for purposes for which there is little or no science demonstrating its effectiveness.

It is common for doctors to use medications to treat "off-label" conditions for which the drug is not approved. However, some experts are concerned that patients using **marijuana** for unorthodox treatments may not be receiving medications proven to be effective.

Doctors are split about the overall safety of using **marijuana**. Some consider it extremely safe, noting that an estimated one-third of U.S. adults have tried it, with few reported medical complications. Others, however, contend that smoking **marijuana** may be as harmful as tobacco, doing more harm than good.

"**Marijuana** shows encouraging results in some areas like pain management and nausea. But there is little evidence to suggest it has any benefit beyond a few defined areas," says Igor Grant, director of the University of California's Center for Medicinal Cannabis Research in San Diego.

Physicians who recommend cannabis insist its health benefits are plentiful, and they advise patients to use it only after other medications and treatment have failed.

Dr. Claudia Jensen, a Ventura family doctor, says she is treating dozens of patients with **marijuana** for a range of medical conditions, including children with ADD.

Jensen acknowledges that the science is lacking to justify some of her unorthodox uses, but says she has seen many patients for whom **marijuana** is the only treatment that seems to work. For patients younger than 18, Jensen says she first recommends Marinol, an FDA-approved synthetic oral form of the drug available by prescription. If that doesn't work -- and the children's parents agree -- she recommends growing **marijuana** at home and incorporating the drug into prepared foods, such as brownies.

Only as a last resort does Jensen recommend young patients smoke the drug. She says the amount she recommends varies.

A spokeswoman for the Medical Board of California says that few doctors recommend **marijuana** as a treatment for children and that doing so isn't necessarily improper. The board's position, however, is that it should be done in only extreme cases, such as with cancer patients and only with careful doctor supervision.

The science surrounding medical **marijuana** is as controversial as its politics. A widely cited study in 1999 by the influential Institute of Medicine found that cannabis may benefit several conditions, especially pain and loss of appetite. The report found little evidence to support its use beyond those areas.

Separate research shows that **marijuana** may have counterproductive effects on young users. Dr. Martin Stein, a San Diego pediatrician who specializes in ADD, says that recommending **marijuana** to minors is "extremely controversial" and that "there are better and safer medications and behavioral treatments we have available to us." The Bush administration's position is that cannabis has no medical value, and it has strongly opposed its use by doctors. But last October, after challenges by the federal government, the 9th U.S. Circuit Court of Appeals ruled that doctors have a constitutional right to discuss **marijuana** with patients. The federal ruling covers California and four other states with their own medical **marijuana** laws.

Partially because of the ruling, some doctors say they are more comfortable with prescribing **marijuana**. Earlier this month, two Lake Forest doctors opened a storefront clinic for patients seeking medical **marijuana**. And San Francisco is studying how to set up growing cooperatives to provide **marijuana** to chronically and terminally ill patients in the city.

Many patients say they aren't concerned with all the legal and scientific confusion surrounding **marijuana**. They just know it works for them. Matt Farrell, a 27-year-old Los Angeles cameraman, says he began smoking **marijuana** several times a day three years ago after his doctor recommended it to treat his recurrent depression and insomnia. Farrell says he tried a half dozen other

medications first, including the antidepressants Paxil and Zoloft, but they either didn't work or had too many side effects. "I have some medication before bed, or in the afternoon when I am feeling stressed. It just makes me feel better," he says.

Frank Lucido, a Berkeley family physician who treats patients with **marijuana** for conditions including depression and post traumatic stress disorder, says he plans to continue recommending cannabis. "How are we ever going to know how much this drug can do unless we try?" he asks.

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PHOTO: (F1) (no caption)

---- INDEX REFERENCES ----

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March 29, 2004

STATEMENT CONCERNING COMMITTEE ON GOVERNMENT REFORM HEARING APRIL 1, 2004

GENERAL SUBJECT: *PREVENTING MASS LIBERALIZATION OF LAWS RESTRICTING CONTROLLED SUBSTANCES USE*

The health of Americans is increasingly at risk each time that a law restricting the use of a controlled substance is weakened or eliminated by the enactment of legislation designed to make it easier for people to obtain currently illegal substances.

Among the fifty states, there has been a barrage of such legislation, most of which is poorly written, sometimes self-contradictory, and all of which has as its basic thrust to circumvent all levels of the court system.

For more than a quarter of a century, false arguments have been brought forward that the only justice for users lies in eliminating the laws under which they were convicted of possession of illegal substances.

I submit that the **National Conference of State Trial Judges** (American Bar Association) should be "given a place at the tables" of all groups involved in such actions, including the **Committee on Government Reform.** The purpose of their inclusion should be to construct a fifty state uniform measure that will eliminate the need for the hundreds of state laws currently in effect on the subject and replace them with a just solution for the nation.

If judges' decrees, including sentencing, were fair and uniform for the nation, there would be no need to "rescue" users from so-called unjust sentences. If such judgements contained provisions **for medical assistance for individuals who are drug dependent**, including **mandates for implementation** of such assistance, we could eliminate the return of drug dependent users to the street to continue their search for addictive substances. **Please, do not tell me this is not possible**!

If law enforcement and the medical community work together, the problems of the perpetually addicted user can be eliminated. These problems are not presently being solved, nor will they be until all addicted persons, in or out of prison, are able to permanently "shake the habits" they have formed.

Will this be a difficult task? **YES !**

Can this be accomplished? **YES!!**

Submitted by: Cornelia J. Munroe, Retired Director, Fresh Air Concerns Everyone

Testimony for inclusion in the hearing on marijuana
April 1, 2004 (and/or any extension of that date),
before the
Subcommittee on Criminal Justice, Drug Policy, and Human Resources,
Committee on Government Reform

From:
The national "American Consumers' Association"
Primary contact address:
1666 Garnet Ave. - Mail Stop: PMB-203
San Diego, CA 92109
858/488-8222

As presented by:
Jonathan West, Director
"American Consumers' Association"

TO ALL WHOM THIS MAY CONCERN,

Introduction

This association, and in fact, a growing number of Americans are becoming alarmed by the well financed and well organized efforts to legalize dangerous drugs here in our nation. And, as can be clearly seen, this effort is being put forward in simple increments to make it seem less dangerous and less threatening to the people of America, and in particular, to our youth.

This effort has started with attempts to legalize the drug called "marijuana." The first push is to legalize it for "medical uses." This is to be followed by a strong drive to remove all legal barriers to the drug for the population in general. And, for many who are of this persuasion, the next step is to legalize other drugs as well.

We understand that it is felt that if marijuana can be given a "medical" acceptance, the next step will be far less difficult. This "philosophy" of drug users has been substantially verified by some of the adherents through their own public statements. I would imagine that some on this committee have read one or more of these admissions in the occasional media coverage that infrequently notes such comments.

In San Diego, California, there has been a concerted effort to push this first step in the drug's legalization. There was the state of California law on the use of "medical" marijuana (standing against the Federal regulations) and, in 2003, the San Diego City Council voted to further support that law with the implementation of its own marijuana distribution system.

This, from a city council that has proven itself as a very questionable body with everything from stripper club bribe allegations that brought the F.B.I. down on City Hall, to numerous financial abuses and an enormous city debt that has put the taxpayers in serious jeopardy.

We had warned the people (through the local media wasn't too much interested in reporting it) that, "...the 'medical' legalization of marijuana in San Diego will encourage increased use of pot by our young people which also will lead to increases in even more dangerous drugs.

"Now, on this date (July 7, 2003), John Walters , who is the director of the White House office of National Drug Control Policy, announced that San Diego has had a recent increase in the use of marijuana and cocaine. It's exactly what we said would happen."

We also previously attempted to present the proven medical consequences of the use of marijuana, but we found most local officials and much of local media, are not interested in hearing that which goes contrary to position of those in favor of the drug. It is a very bad situation.

And yes, the crime rate, in general, is up in San Diego and other problems are arising. Slowly but surely we are destroying a beautiful city, known for its wonderful climate, and now also becoming known for its liberal drug use and crime.

It is hoped that you will consider such issues when you examine the uses of marijuana.

The Medical Report

The following medical report will give you good reason to be even further concerned. The evidence speaks for itself. The report is as follows:

Outline of Comprehensive Medical Research on Marijuana

The information printed here can also be found in the book, "Good-bye, America?" (as seen in the Book Review section of the New York Times, and on numerous network and individual station broadcasts). The information is as follows:

U.S. Dept. of Health & Human Services:
Marijuana distorts perception, damages short-term memory, and impairs judgement and complex motor skills.

Dr. Donald Tashkin, UCLA Research Physician:
Persons smoking 3 or 4 joints a day often suffer noticeably from bronchitis.

New England Journal of Medicine article:
There seems to be a direct correlation between heavy pot smokers and male breast enlargements.

American Council for Drug Education:
Marijuana negatively affects driving abilities to the degree that such use is found associated with an unusually high percentage of traffic accidents and fatalities.

Research at the University of Illinois in Chicago:
The "THC" in pot seems to weaken the immune system.

Columbia University researcher, Dr. Wylie C. Hembree:
He found that heavy and sustained use of marijuana negatively effects male smokers' ability to produce normal sperm.

American Lung Association Bulletin:
Marijuana smoke is more damaging to the heart and lungs than tobacco smoke.

American Medical Association handbook for physicians:
Marijuana smoke contains larger amounts of cancer-causing hydrocarbons than tobacco smoke, and lung damage can appear within 3 months.

A report from The Institute of Medicine of the National Academy of Sciences:
Marijuana negatively effects the ability to detect a flash of light, to follow a moving object with your eyes, your oral communication, your short-term memory, and the ability to learn.

Dr. Philip Landfield of Wake Forest University, North Carolina:
The active ingredient in pot (THC) causes a definite loss of brain cells in rats, similar to an effect attributed to aging.

A Science Digest report by Dr. Robert Heath, of Tulane University School of Medicine:
Regular use of marijuana may very well end up widening the gaps between nerve endings in the brain.

University of California research report:
Prolonged doses of the active ingredient in marijuana shrinks the frontal brain lobes of test monkeys.

The National Institute of Drug Abuse:
Found pot-induced damage to the region of the brain involved with memory and emotion.

University of Hawaii scientist, Barbara Siegel:
Found the distinct possibility of mercury poisoning associated with smoking marijuana.

The Centers for Disease Control:
Some marijuana can be expected, from time to time, to be found to be salmonella-contaminated.

Journal of the American Medical Assn. report by Dr. Harold Kolansky & Dr. William Moore:
Marijuana smoking on a regular basis can cause grave psychiatric ills, including psychosis.

Senate testimony by Dr. William Pollin, when Dir. Of the National Institute on Drug Abuse:
There is a strong link between original marijuana use leading to cocaine and heroin use.

Dr. Haroin Jones, Prof. Of Physiology and Medical Physics, UC, Berkeley, Calif:
Marijuana is the most dangerous of drugs because the user is least aware of its effect, which can be devastating.

ADDITIONAL NOTATIONS:

This medical research outline can also be found on the following web site –
http://SanDiegoExpose.tripod.com

Listed researchers and institutions noted in this outline will enable reader to thoroughly check on the validity and importance of this information through Internet inquiry and investigation.

END OF REPORT

We trust that this information will be given proper consideration and that your body will act in the best interest of the people of our nation, and in particular, for the safety and well-being of our children.

We thank you for the opportunity to present these important facts to you at this time.

Most sincerely,

Jonathan West, Director
"American Consumers' Association"
April 1, 2004 San Diego

http://www.ctnow.com/news/opinion/op_ed/hc-pot0430.artapr30,1,6782622.story?coll=hc-headlines-oped

Don't Fall For Pot-Smoking Con

Andrea Barthwell, M.D.

April 30 2004

At the beginning of the last century, America was mired in near medicinal anarchy. Fly-by-night swindlers traveled from town to town hawking miracle medicines that claimed cures for everything from baldness to life-threatening diseases. Although the tonics rarely cured what their proponents claimed, consumers often did report feeling better after taking them.

If these people felt better, then these tonics were no doubt good, effective medicines, right? Not exactly. In reality, people felt better because these "medicines" most often contained large amounts of alcohol, opium or other feel-good agents. This chaotic medicinal marketplace, where legitimate medicine competed with unproven and often dangerous snake oils, compelled Congress to create the Food and Drug Administration to verify and regulate the effectiveness and safety of all medicines. More than making people feel better, the FDA was established to ensure that medicines helped people get better.

Unfortunately, Connecticut is the latest stop on a traveling medicine show being conducted by the snake-oil proponents of our age: the marijuana legalization lobby. Funded by millions of dollars from a handful of billionaires who want to legalize all drugs, marijuana lobbyists have been deployed to Hartford. They are cynically abusing Americans' natural compassion for the sick by garnering support for a far different agenda. These modern-day snake-oil proponents cite testimonials - not science - that smoking marijuana helps patients suffering from AIDS, cancer and other painful diseases "feel better."

Most of us know a loved one who has suffered from chronic illness. We wouldn't want to deny them any relief. So why is it important that Connecticut legislators reject this proposal? The reasons go to the very foundation of our medical system, which relies on science, not easily manipulated public opinion, to determine what medicines are safe and effective. Endorsing marijuana smoking turns our medical system on its head, allowing pressure-group politics rather than medical judgment to determine what is safe and effective, and sends a dangerous message about marijuana to children.

The FDA's process for approving medicine has contributed to the United States having the world's finest medical system. In the century that the FDA has been regulating medicines, it has shown a willingness to approve potentially harmful and addictive substances if it can be proved that the benefits outweigh the risks. The numerous medicinal derivatives of the opium poppy and the coca plant clearly demonstrate this principle.

But smoked marijuana has never passed this test. There is no compelling scientific evidence that smoking marijuana relieves the myriad ailments that its proponents claim. Moreover, the medical community prescribes drugs that are safer and easier to administer and that have been scientifically

proved to be far more effective in treating the ailments that marijuana proponents claim are relieved by smoking marijuana.

In addition, many Americans are unaware that in 1985 the FDA approved Marinol, a pill that contains marijuana's active ingredient and that leaves marijuana legalizers in the awkward and exposed position of trying to explain why smoking a crude weed is superior to a pill or other nonsmoking delivery systems currently in development. In light of these scientifically proven medicinal alternatives, the idea of telling suffering patients that the best we can do for them is to encourage them to inhale the hot smoke of a burning weed seems medieval.

Connecticut lawmakers face an important decision. At a time when teen marijuana use is finally on the decline nationally (down 11 percent since 2001), lawmakers must ask themselves if endorsing marijuana as medicine is going to have a positive effect on Connecticut teens, including the estimated 19,000 12- to 17-year-olds in the state who decide to use marijuana for the first time each year. And is this outcome for thousands of Connecticut children acceptable in order to placate a handful of questionable marijuana proponents that claim they know some people who "feel better" when they smoke marijuana?

Let's hope the Connecticut legislature doesn't miss the simple answers in all of the marijuana lobby's pro-drug rhetorical smoke.

Andrea Barthwell, M.D., is deputy director for demand reduction at the federal Office of National Drug Control Policy in Washington.

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CESAR FAX

May 10, 2004
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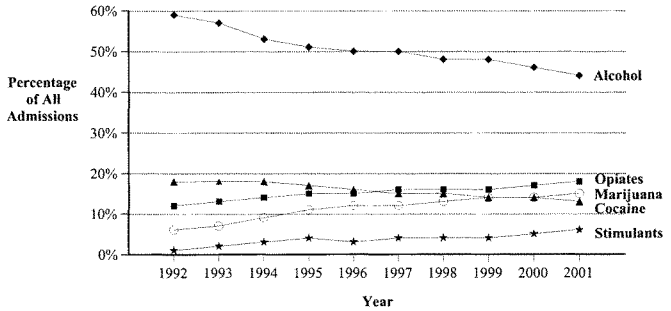
A Weekly FAX from the Center for Substance Abuse Research

University of Maryland, College Park

National Treatment Admissions for Primary Alcohol and Cocaine Abuse Decline; Opiates, Marijuana, and Stimulants Increase Since 1992

The percentage of admissions to state-funded substance abuse treatment facilities for alcohol abuse has declined since 1992, according to data from the national Treatment Episode Data Set (TEDS). While alcohol continues to be the substance most frequently cited as a primary substance of abuse, primary alcohol abuse accounted for less than one-half (44%) of all admissions in 2001, down from 59% in 1992. A decline was also seen in admissions for primary cocaine abuse (from 18% in 1992 to 13% in 2001). At the same time, there was an increase in the proportion of admissions for primary abuse of opiates (from 12% to 18%), marijuana (from 6% to 15%), and stimulants (from 1% to 6%). Other drugs, including sedatives, tranquilizers, hallucinogens, inhalants, and PCP each accounted for less than 1% of yearly admissions during the nine year period (data not shown).

Primary Substance of Abuse at Admission to U.S. State Licensed or Certified Substance Abuse Treatment Facilities, 1992-2001



NOTE: TEDS is based on admissions and not individuals. Therefore, an individual could be admitted to treatment more than once during the course of a calendar year, accounting for more than one admission.

SOURCE: Adapted by CESAR from the Office of Applied Studies, SAMHSA, "National Admissions to Substance Abuse Treatment Services," *Treatment Episode Data Set (TEDS) 1992-2001*, December 2003. Available online at http://wwwdasis.samhsa.gov/teds01/TEDS2K1Index.htm.

Advertise Your Substance Abuse-Related Job Opening or Upcoming Event on CESAR's Website

As a service to the substance abuse community, CESAR will begin posting job openings and upcoming events on the CESAR website (www.cesar.umd.edu). If you have an employment opportunity or event that you would like considered for posting, please contact Jessica Woodruff at jwoodruff@cesar.umd.edu.

•• 301-405-9770 (voice) •• 301-403-8342 (fax) •• CESAR@cesar.umd.edu •• www.cesar.umd.edu ••

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National Survey on Drug Use and Health

The NSDUH Report

January 9, 2004

Marijuana Use and Delinquent Behaviors among Youths

Research suggests that among youths, frequency of marijuana use is associated with problem behaviors,[1,2] including delinquent behaviors. The National Survey on Drug Use and Health (NSDUH), formerly the National Household Survey on Drug Abuse (NHSDA), asks youths aged 12 to 17 to report how often they engaged in the following delinquent behaviors during the past year: (a) serious fighting at school or work, (b) taking part in a fight where a group of friends fought against another group, (c) attacking someone with the intent to seriously hurt them, (d) stealing or trying to steal anything worth more than $50, (e) selling illegal drugs, or (f) carrying a handgun.[3] Youths also are asked whether they used marijuana or hashish during the past 12 months. Past year marijuana users are asked how many days they used marijuana or hashish during the past year.

In Brief

- More than 5 million youths (21 percent) engaged in serious fighting at school or work, and almost 4 million (16 percent) took part in a group-against-group fight in the past year
- In 2002, 4 million youths (16 percent of those aged 12 to 17) used marijuana in the past year
- The percentages of youths engaging in delinquent behaviors in the past year rose with increasing frequency of marijuana use

Frequency of Marijuana Use among Youths

In 2002, almost 4 million youths aged 12 to 17 (16 percent) reported using marijuana during the past year. Nearly 1.5 million (38 percent of past year users) used marijuana on 1 to 11 days in the past year, 21 percent used on 12-49 days, 9 percent used on 50-99 days, 23 percent used on 100-299 days, and 9 percent (358,000 youths) used marijuana 300 or more days in the past year.

The NSDUH Report (formerly **The NHSDA Report**) is published periodically by the Office of Applied Studies, Substance Abuse and Mental Health Services Administration (**SAMHSA**). All material appearing in this report is in the public domain and may be reproduced or copied without permission from **SAMHSA**. Additional copies of this report or other reports from the Office of Applied Studies are available on-line: http://www.DrugAbuseStatistics.samhsa.gov. Citation of the source is appreciated.

Figure 1. Percentages of Youths Aged 12 to 17 Participating in Delinquent Behaviors One or More Times in the Past Year: 2002

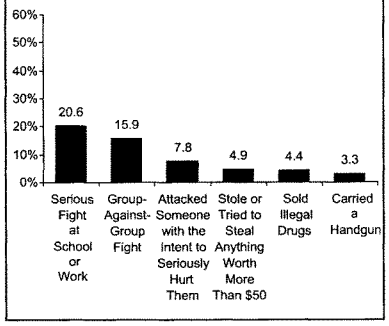
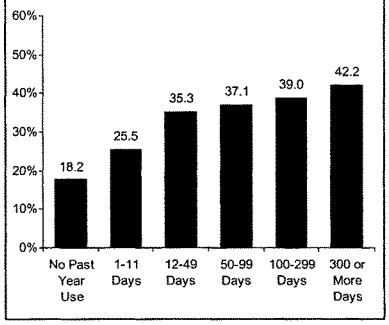


Figure 2. Percentages of Youths Aged 12 to 17 Who Took Part in Serious Fighting at School or Work in the Past Year, by Frequency of Past Year Marijuana Use: 2002



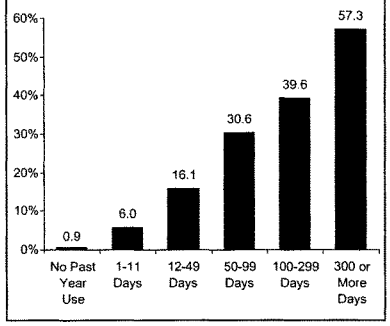
Prevalence of Delinquent Behaviors among Youths

In 2002, approximately 21 percent of youths (5 million) engaged in serious fighting at school or work, almost 16 percent (4 million) took part in a group-against-group fight, and almost 8 percent (2 million) attacked someone with the intent to seriously hurt them during the past year (Figure 1). Nearly 5 percent of youths (1.2 million) stole or tried to steal something worth more than $50, more than 4 percent (1.1 million) sold illegal drugs, and more than 3 percent (800,000) carried a handgun during the past year.

Delinquent Behaviors and Frequency of Marijuana Use

In 2002, the percentages of youths engaging in delinquent behaviors was higher among past year marijuana users than among those who had not used marijuana. For all six of the delinquent behaviors examined, the percent of youths engaging in the behavior rose with increasing frequency of past year marijuana use (Figures 2-7).

Figure 3. Percentages of Youths Aged 12 to 17 Who Sold Illegal Drugs in the Past Year, by Frequency of Past Year Marijuana Use: 2002



3. Youths were asked how many times in the past year they had participated in each delinquent behavior. The response options are: (a) 0 times, (b) 1 or 2 times, (c) 3 to 5 times, (d) 6 to 9 times, and (e) 10 or more times in the past year. For this report, youths were counted as engaging in the behavior if they reported participating one or more times.

End Notes

1. Donovan, J. E. (1996). Problem-behavior theory and the explanation of adolescent marijuana use. *Journal of Drug Issues, 26*, 379-404.

2. Greenblatt, J.C. (1998). Adolescent self-reported behaviors and their association with marijuana use. In: Substance Abuse and Mental Health Services Administration, Office of Applied Studies, *Analysis of Substance Abuse and Treatment Need Issues* (DHHS Publication No. SMA 98-3227, Analytic Series A-7). Rockville, MD.

Figure Note

Source: SAMSHA 2002 NSDUH

Figure 4. Percentages of Youths Aged 12 to 17 Who Stole or Tried to Steal Anything Worth More Than $50 in the Past Year, by Frequency of Past Year Marijuana Use: 2002

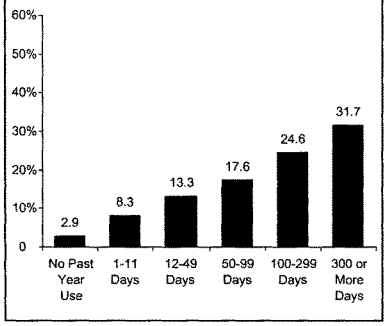


Figure 5. Percentages of Youths Aged 12 to 17 Who Attacked Someone With the Intent to Seriously Hurt Them in the Past Year, by Frequency of Past Year Marijuana Use: 2002

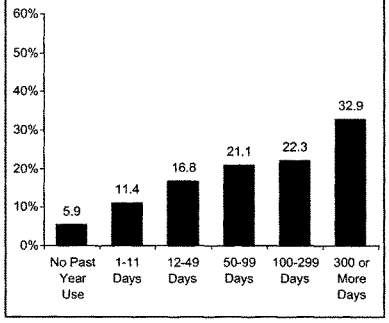


Figure 6. Percentages of Youths Aged 12 to 17 Who Took Part in a Group-Against-Group Fight in the Past Year, by Frequency of Past Year Marijuana Use: 2002

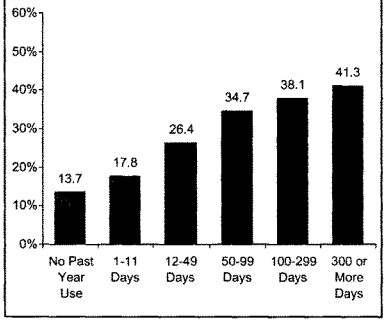
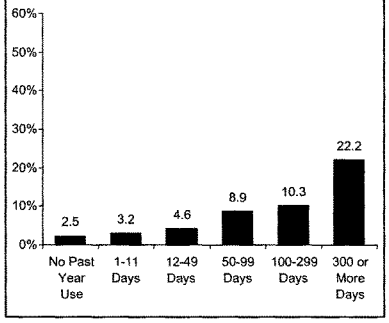


Figure 7. Percentages of Youths Aged 12 to 17 Who Carried a Handgun in the Past Year, by Frequency of Past Year Marijuana Use: 2002



The National Survey on Drug Use and Health (NSDUH) is an annual survey sponsored by the Substance Abuse and Mental Health Services Administration (SAMHSA). Prior to 2002, this survey was called the National Household Survey on Drug Abuse (NHSDA). The 2002 data are based on information obtained from 68,216 persons aged 12 or older, including 23,645 youths aged 12 to 17. The survey collects data by administering questionnaires to a representative sample of the population through face-to-face interviews at their place of residence.

The NSDUH Report is prepared by the Office of Applied Studies (OAS), SAMHSA, and by RTI in Research Triangle Park, North Carolina.

Information and data for this issue are based on the following publication and statistics:

Office of Applied Studies. (2003). *Results from the 2002 National Survey on Drug Use and Health: National findings* (DHHS Publication No. SMA 03-3836, NHSDA Series H-22). Rockville, MD: Substance Abuse and Mental Health Services Administration.

Also available on-line: http://www.DrugAbuseStatistics.samhsa.gov.

Because of improvements and modifications to the 2002 NSDUH, estimates from the 2002 survey should not be compared with estimates from the 2001 or earlier versions of the survey to examine changes over time.

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Substance Abuse & Mental Health Services Administration
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April 19th, 2004

Congressman Mark Souder
Chairman
Sub-Committee on Criminal Justice, Drug Policy and Human Resources
Committee on Government Reform

Dear Congressman Souder,

I am writing in regard to the hearing you held on the issue of medical marijuana. I am firmly opposed to the legalization of so called "medical marijuana" In 1998 I lost my only daughter Angela to a heroin overdose. She did not wake up one morning to become a heroin addict; her addiction began with inhalants and marijuana. We battled her addiction for over 4 years until her body was found thrown down a muddy embankment near a creek. She was left there by her drug dealer. He did not want to be implicated in her death. Since her death, I founded MOMStell (MOMS on a mission to advocate for drug treatment, education, and lobby for legislation). Our mission is to educate parents about the dangers of drugs and create a resource to join parents to advocate for positive change regarding drug and alcohol issues.

We at MOMStell are constantly educating ourselves to give parents the latest updates on the drug trends and their dangers. The FDA has not approved smoking marijuana as a legitimate medicine. We know the dangers of smoking and the Surgeon General's attempt to warn the people of this danger. I attended the hearings and spoke at the national press conference on the steps of the Supreme Court when they heard the case regarding medical marijuana. They ruled unanimously that there was no medical necessity defense for marijuana. According to the Pennsylvania Department of Health's CIS data, the number one drug of choice used by children ages 12-17 entering public funded treatment was marijuana. When you move up to the 18-24 years olds, the top drug choice moves to heroin, even above alcohol. My daughter moved from marijuana at about age 15 to heroin by age 18. She died before reaching her 19th birthday!

I urge you to look at the evidence and stop the legalization of this drug for any use. The safety and well being of the children of this nation is at stake. We must not let our future generations think this illegal and FDA unapproved drug is safe. The repercussions will be devastating. I unfortunately know the reality of this first-hand.

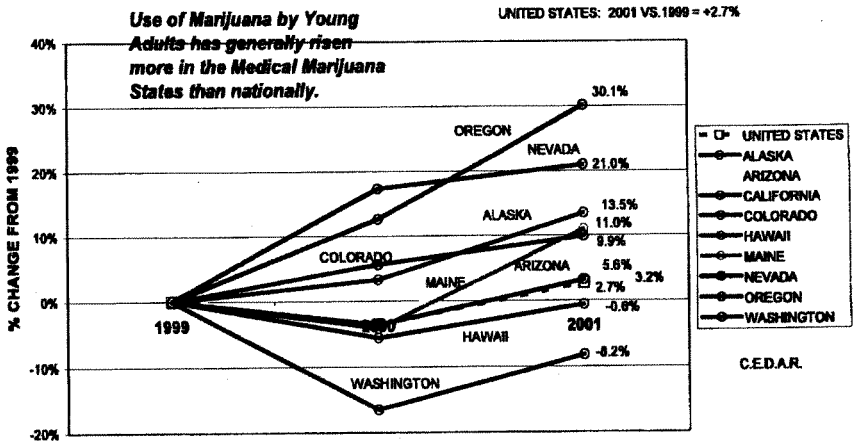
Sincerely

Sharon L. Smith,

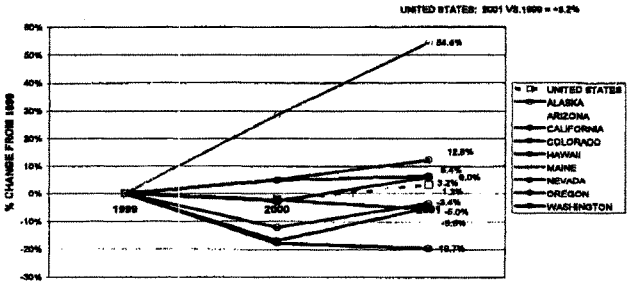
Sharon L. Smith

President/MOMStell

MARIJUANA USE TRENDS IN THE 9 MEDICAL MARIJUANA STATES VS. TREND IN NATIONAL AVERAGE USE: YOUNG ADULTS (18-25 YEAR OLDS); % WITH PAST MONTH MARIJUNA USE / EACH YEAR AS % CHANGE FROM 1999



MARIJUANA USE TRENDS IN THE 9 MEDICAL MARIJUANA STATES V/S. TREND IN NATIONAL AVERAGE USE: JUNVENILES (12-17 YEAR OLDS); % WITH PAST MONTH MARIJUANA USE / EACH YEAR AS % CHANGE FROM 1999



Testimony for inclusion in the hearing on marijuana
April 1, 2004 (and/or any extension of that date),
before the
Subcommittee on Criminal Justice, Drug Policy, and Human Resources,
Committee on Government Reform

From:
The national *"American Consumers' Association"*
Primary contact address:
1666 Garnet Ave. - Mail Stop: PMB-203
San Diego, CA 92109
858/488-8222

As presented by:
Jonathan West, Director
"American Consumers' Association"

TO ALL WHOM THIS MAY CONCERN,

Introduction

This association, and in fact, a growing number of Americans are becoming alarmed by the well financed and well organized efforts to legalize dangerous drugs here in our nation. And, as can be clearly seen, this effort is being put forward in simple increments to make it seem less dangerous and less threatening to the people of America, and in particular, to our youth.

This effort has started with attempts to legalize the drug called "marijuana." The first push is to legalize it for "medical uses." This is to be followed by a strong drive to remove all legal barriers to the drug for the population in general. And, for many who are of this persuasion, the next step is to legalize other drugs as well.

We understand that it is felt that if marijuana can be given a "medical" acceptance, the next step will be far less difficult. This "philosophy" of drug users has been substantially verified by some of the adherents through their own public statements. I would imagine that some on this committee have read one or more of these admissions in the occasional media coverage that infrequently notes such comments.

In San Diego, California, there has been a concerted effort to push this first step in the drug's legalization. There was the state of California law on the use of "medical" marijuana (standing against the Federal regulations) and, in 2003, the San Diego City Council voted to further support that law with the implementation of its own marijuana distribution system.

This, from a city council that has proven itself as a very questionable body with everything from stripper club bribe allegations that brought the F.B.I. down on City Hall, to numerous financial abuses and an enormous city debt that has put the taxpayers in serious jeopardy.

We had warned the people (through the local media wasn't too much interested in reporting it) that, *"...the 'medical' legalization of marijuana in San Diego will encourage increased use of pot by our young people which also will lead to increases in even more dangerous drugs.*

"Now, on this date (July 7, 2003), John Walters, who is the director of the White House office of National Drug Control Policy, announced that San Diego has had a recent increase in the use of marijuana and cocaine. It's exactly what we said would happen."

We also previously attempted to present the proven medical consequences of the use of marijuana, but we found most local officials and much of local media, are not interested in hearing that which goes contrary to position of those in favor of the drug. It is a very bad situation.

And yes, the crime rate, in general, is up in San Diego and other problems are arising. Slowly but surely we are destroying a beautiful city, known for its wonderful climate, and now also becoming known for its liberal drug use and crime.

It is hoped that you will consider such issues when you examine the uses of marijuana.

The Medical Report

The following medical report will give you good reason to be even further concerned. The evidence speaks for itself. The report is as follows:

Outline of Comprehensive Medical Research on Marijuana

The information printed here can also be found in the book, "*Good-bye, America?*" (as seen in the Book Review section of the New York Times, and on numerous network and individual station broadcasts). The information is as follows:

U.S. Dept. of Health & Human Services:

Marijuana distorts perception, damages short-term memory, and impairs judgement and complex motor skills.

Dr. Donald Tashkin, UCLA Research Physician:
Persons smoking 3 or 4 joints a day often suffer noticeably from bronchitis.

New England Journal of Medicine article:
There seems to be a direct correlation between heavy pot smokers and male breast enlargements.

American Council for Drug Education:
Marijuana negatively affects driving abilities to the degree that such use is found associated with an unusually high percentage of traffic accidents and fatalities.

Research at the University of Illinois in Chicago:
The "THC" in pot seems to weaken the immune system.

Columbia University researcher, Dr. Wylie C. Hembree:
He found that heavy and sustained use of marijuana negatively effects male smokers' ability to produce normal sperm.

American Lung Association Bulletin:
Marijuana smoke is more damaging to the heart and lungs than tobacco smoke.

American Medical Association handbook for physicians:
Marijuana smoke contains larger amounts of cancer-causing hydrocarbons than tobacco smoke, and lung damage can appear within 3 months.

A report from The Institute of Medicine of the National Academy of Sciences:
Marijuana negatively effects the ability to detect a flash of light, to follow a moving object with your eyes, your oral communication, your short-term memory, and the ability to learn.

Dr. Philip Landfield of Wake Forest University, North Carolina:
The active ingredient in pot (THC) causes a definite loss of brain cells in rats, similar to an effect attributed to aging.

A Science Digest report by Dr. Robert Heath, of Tulane University School of Medicine:
Regular use of marijuana may very well end up widening the gaps between nerve endings in the brain.

University of California research report:
Prolonged doses of the active ingredient in marijuana shrinks the frontal brain lobes of test monkeys.

The National Institute of Drug Abuse:
Found pot-induced damage to the region of the brain involved with memory and emotion.

University of Hawaii scientist, **Barbara Siegel**:
Found the distinct possibility of mercury poisoning associated with smoking marijuana.

The Centers for Disease Control:
Some marijuana can be expected, from time to time, to be found to be salmonella-contaminated.

Journal of the American Medical Assn. report by Dr. Harold Kolansky & Dr. William Moore:
Marijuana smoking on a regular basis can cause grave psychiatric ills, including psychosis.

Senate testimony by Dr. William Pollin, when Dir. Of the National Institute on Drug Abuse:
There is a strong link between original marijuana use leading to cocaine and heroin use.

Dr. Haroin Jones, Prof. Of Physiology and Medical Physics, UC, Berkeley, Calif:
Marijuana is the most dangerous of drugs because the user is least aware of its effect, which can be devastating.

ADDITIONAL NOTATIONS:

This medical research outline can also be found on the following web site —
http://SanDiegoExpose.tripod.com

Listed researchers and institutions noted in this outline will enable reader to thoroughly check on the validity and importance of this information through Internet inquiry and investigation.

END OF REPORT

We trust that this information will be given proper consideration and that your body will act in the best interest of the people of our nation, and in particular, for the safety and well-being of our children.

We thank you for the opportunity to present these important facts to you at this time.

Most sincerely,

Jonathan West, Director
"American Consumers' Association"

April 1, 2004 San Diego

No. 03-1454

In The
Supreme Court of the United States

JOHN D. ASHCROFT, Attorney General, et al.,

Petitioners,

v.

ANGEL McCLARY RAICH, et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF U.S. REPRESENTATIVE MARK E. SOUDER; U.S. REPRESENTATIVE CASS BALLENGER; U.S. REPRESENTATIVE DAN BURTON; U.S. REPRESENTATIVE KATHERINE HARRIS; U.S. REPRESENTATIVE ERNEST J. ISTOOK, JR.; U.S. REPRESENTATIVE JACK KINGSTON; AND U.S. REPRESENTATIVE DOUG OSE, AS AMICI CURIAE IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Whether the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, exceeds Congress's power under the Commerce Clause as applied to the intrastate cultivation and possession of marijuana for purported personal "medicinal" use or to the distribution of marijuana without charge for such use.

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INTEREST OF AMICI AND SUMMARY OF ARGUMENT[1]

Amici are Members of the U.S. House of Representatives, each of whom has taken a strong interest in drug and narcotics policy. Representative Mark E. Souder is Co-Chair of the Speaker's Task Force For a Drug-Free America ("Speaker's Task Force"), and Chairman of the Subcommittee on Criminal Justice, Drug Policy and Human Resources (Government Reform Committee), which has oversight over all aspects of federal narcotics policy. Representative Cass Ballenger is a member of the Speaker's Task Force, and Chairman of the Subcommittee on the Western Hemisphere (International Relations Committee). Representative Dan Burton is a member of the Speaker's Task Force, and Chairman of the Subcommittee on Human Rights and Wellness. Representative Katherine Harris is a member of the Speaker's Task Force, and Vice Chair of the Subcommittee on the Western Hemisphere (International Relations Committee). Representative Ernest J. Istook, Jr., is a member of the Speaker's Task Force, and Chairman of the Subcommittee on Transportation and Treasury, and Independent Agencies (Committee on Appropriations), which has responsibility for the annual budget of the federal Office of National Drug Control Policy. Representative Jack Kingston is a member of the Speaker's Task Force, and Chairman of the Subcommittee on the Legislative Branch (Committee on

[1] The parties have consented to the filing of this brief. Counsel for a party did not author this brief in whole or in part. No person or entity, other than the Amici Curiae, the Subcommittee on Criminal Justice, Drug Policy and Human Resources (Government Reform Committee), or their counsel, made a monetary contribution to the preparation and submission of this brief

Appropriations). Representative Doug Ose is a member of the Speaker's Task Force, and Chairman of the Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs (Government Reform Committee).

Drug abuse remains the nation's most important public health problem. Each year, over 20,000 people die as a direct consequence of drug abuse, while many thousands more end up in emergency rooms due to drug-related causes. *See* Centers for Disease Control, *Deaths: Preliminary Data for 2002*, National Vital Statistics Reports, at 18 (Feb. 11, 2004); Substance Abuse & Mental Health Servs. Admin., *Emergency Department Trends From the Drug Abuse Warning Network, Final Estimates 1995-2002* (July 2003). The annual economic costs of drug abuse to the nation as a whole have been estimated at $143.2 billion, including $12.9 billion in health care costs (such as emergency medical care, and drug abuse treatment) and $98.5 billion in lost productivity. Executive Office of the President, Office of National Drug Control Policy, *The Economic Costs of Drug Abuse in the United States, 1992-1998*, at 2, 4-6 (2001).

Drug abuse is facilitated by an illegal but nationwide and flourishing market for illicit drugs. Congress and the Executive Branch have responded by attacking this commercial trade in illicit drugs, through regulation of the market backed by vigorous law enforcement. *See, e.g.*, Executive Office of the President, Office of National Drug Control Policy, *National Drug Control Strategy 2004*, at 31 (2004).

This case raises a fundamental issue: Will the Congress continue to be able to take *effective* action against the national problem of drug trafficking and abuse? In the decision here on appeal, the Ninth Circuit Court of Appeals held that

the federal government may not regulate what the court believed to be essentially "local" and "medical" illegal drug production and distribution. *Raich v. Ashcroft*, 352 F.3d 1222, 1228-34 (9th Cir. 2003). This ruling is inconsistent with this Court's Commerce Clause jurisprudence, which holds that even intrastate activities may be regulated by the federal government where, among other things, those activities have "a substantial relation to interstate commerce." *United States v. Lopez*, 514 U.S. 549, 558-60 (1995).

Marijuana is a commercial product, and its cultivation and distribution are "economic" activities, even when taking place within one state. No one state is able to take complete and effective action against this illegal market; rather, Congressional action is required. That action takes the form of a sophisticated and scientifically-based federal regulatory framework for drugs (whether medical or non-medical), including the statute at issue here – the Controlled Substances Act (CSA), 21 U.S.C. 801 *et seq.* (2004). If local marijuana production, possession and distribution are excised from that regulatory framework, the nation's ability to address the narcotics epidemic will be seriously undermined.

ARGUMENT

I. MARIJUANA, WHETHER USED FOR "MEDICAL" PURPOSES OR NOT, IS PART OF THE LARGER, COMMERCIAL MARKET FOR DRUGS, AND AS SUCH MAY BE REGULATED BY CONGRESS UNDER THE COMMERCE CLAUSE.

The Ninth Circuit's ruling is inconsistent with this Court's Commerce Clause jurisprudence. Under Article I, Section 8 of the U.S. Constitution, Congress is empowered to "regulate Commerce with foreign Nations, and among

the several States." Although the Commerce Clause speaks only to interstate commerce, Article I, Section 8 also provides that Congress shall "make all Laws which are necessary and proper for carrying into Execution the foregoing Powers." Pursuant to the "Necessary and Proper" clause, this Court has held that even intrastate activities may be regulated by the federal government where, among other things, those activities have "a substantial relation to interstate commerce." *United States v. Lopez*, 514 U.S. 549, 558-60 (1995) ("Where economic activity substantially affects interstate commerce, legislation regulating that activity will be sustained.").

A. Marijuana Is a Commercial Product Subject to Congressional Regulation, Even When Used For So-Called "Medical" Purposes

In the post-New Deal era, this Court has struck down acts of Congress as exceeding the scope of the Commerce Clause only where the regulated activity lacks an "economic" character. Conversely, where federal regulations are targeted at economic activity, they have been sustained. *See Lopez*, 514 U.S. at 559; *United States v. Morrison*, 529 U.S. 598, 611 (2000). The Court of Appeals erred in holding that the cultivation, possession, and distribution of marijuana for "medical" purposes are not economic activities within the scope of the Commerce Clause. *Raich v. Ashcroft*, 352 F.3d 1222, 1228 (9th Cir. 2003). First, marijuana is an economic commodity, with a large and well-defined national market. Second, as a fungible, highly portable product, marijuana grown in one state can easily find its way to other states, necessitating a national system of regulation.

1. Marijuana Is an Inherently Commercial Product, With a Substantial National Market

Like all drugs, marijuana is an essentially commercial product. The fact that it may be used for alleged medical purposes certainly does not remove it from "commerce"; on the contrary, there are few commercial markets larger than that for "medical" products. In 2002, Americans spent over $1.3 trillion on personal healthcare and healthcare products; of that amount, $162.4 billion were spent on (legitimate) prescription drugs. Paulette C. Morgan, Congressional Research Service, *Health Care Spending: Past Trends and Projections*, Order Code RL31094, at CRS-1, -2 (2004).

As an illegal drug, marijuana is part of an equally commercial – albeit illegitimate – market. It is estimated that in 1998, Americans spent approximately $66 billion on illegal drugs, including $11 billion on marijuana alone. Executive Office of the President, Office of National Drug Control Policy, *What America's Users Spend on Illegal Drugs, 1988-1998*, at 1 (2000).[2] Marijuana is, in fact, the most widely used illegal drug in the United States; of the nearly 20 million current drug users in this country, approximately 14.6 million (75 percent) are using marijuana. Substance Abuse & Mental Health Servs. Admin., *2002 National Survey on Drug Use and Health* (2003).

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[2] The billions of dollars in drug proceeds produced here in the U.S. (including those from marijuana trafficking) have also spawned a massive money laundering industry, which uses our transportation and financial services networks to smuggle funds out of the country. *See* National Drug Intelligence Center, U.S. Dept. of Justice, *National Drug Threat Assessment 2004*, at 97-99.

The fact that some medical marijuana is ostensibly distributed free of charge or on a "non-profit" basis does not make this commodity any less "economic." The drug retains its value and its potential for sale, even when it is distributed for free and kept for ostensibly "medical" use. A bottle of the powerful opiate OxyContin, for example, does not lose its commercial potential while it sits in a patient's medicine cabinet.

Moreover, even "free" distribution can be economically motivated. Many companies provide certain goods or services free of charge to customers, often to build their reputations and market share; drug dealers have also been known to build their client base by providing "free samples" to prospective users. *See, e.g.*, Executive Office of the President, Office of National Drug Control Policy, *Pulse Check: Trends in Drug Abuse*, at 66 (2004) ("Some dealers distribute free drugs to 'testers' early in the morning, and then count on word-of-mouth to bring them more buyers throughout the day based on the quality or purity of the drug."). As the California court of appeals noted in 1998, permitting "non-profit" sales would allow businesses to use marijuana as an enticement to customers for other services. *People ex rel. Lungren v. Peron*, 59 Cal. App. 4th 1383, 1392-3, 70 Cal. Rptr. 2d 20, 27 (Cal. Ct. App. 1997).

2. Marijuana Is a Fungible, Portable Commodity That Can Easily Move From State to State

Marijuana is a highly fungible and portable product. As Judge Beam noted in his dissent in the opinion below, marijuana is a fungible, transferable, and therefore fundamentally economic product – even if a particular amount of marijuana has not actually been exchanged for

cash. *Raich*, 352 F.3d at 1242 ("While it is clear that plaintiffs did not propose to sell or share their marijuana with others similarly situated (or even not similarly situated), they *could*.") (emphasis in original).

Not only is marijuana a fungible product, it is extremely difficult to trace back to its source; there is currently no operational "marijuana signature" (source identification) program, as there is for cocaine and heroin. *See* National Drug Intelligence Center, U.S. Dept. of Justice, *National Drug Threat Assessment 2004*, at 48. This makes proof that the drug actually moved through interstate commerce extremely difficult, and overly burdensome to effective regulation – which is why Congress dispensed with this requirement when it enacted the CSA. *See United States v. Lopez*, 459 F.2d 949, 953 (5th Cir. 1972).

3. Effective Regulation of Marijuana Requires Federal Control of all Aspects of the Market, Including Initial Production and Distribution

As a valuable, fungible, portable, and untraceable product, marijuana presents significant challenges that can only be completely met by federal regulation. The individual states cannot adequately control marijuana trafficking. We live in a national, not a state or regional, market; if one state permits marijuana production to flourish within its borders, that production will quickly spill over into neighboring states. Stopping the flow would require each state to set up its own customs controls at its border, a solution that would be highly burdensome to the national economy, and likely to be ineffective. *See, e.g.*, Executive Office of the President, Office of National Drug

Control Policy, *2002 Final Report on the 1998 National Drug Control Strategy: Performance Measures of Effectiveness*, at 24-25 (2002) (reporting that, despite efforts of federal border and interdiction authorities, 94 percent of heroin, and 69 percent of cocaine targeted for the U.S. market entered the country).

The solution is provided by federal enforcement of the CSA. Unlike individual state regulators, the federal government can reach activity in every state. This Court has previously upheld, as valid enactments under the Commerce Clause, federal regulations of intrastate activities that affect more than one state. *See, e.g., Hodel v. Virginia Surface Mining and Reclamation Ass'n*, 452 U.S. 264, 282 (1981) (upholding environmental regulations). The CSA should be upheld on these grounds as well. *See Lopez*, 514 U.S. at 574 (Kennedy, J., concurring) ("Congress can regulate in the commercial sphere on the assumption that we have a single market and a unified purpose to build a stable national economy.").

B. Congress Has Created a Carefully Calibrated Regulatory Scheme for National Drug Markets (Including the Marijuana Market), Which Requires Effective Enforcement Even on the Local Scale

Congressional narcotics statutes are designed to deal with the local, national, and even international aspects of this enormous, complex drug market. As this Court has noted, a regulation of apparently local activity may be upheld as "an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated." *Lopez*, 514 U.S. at 561. Examples of such regulatory

frameworks upheld by this Court include price controls and quotas for wheat production, *Wickard v. Filburn*, 317 U.S. 111, 128-29 (1942); grain storage regulations, *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947); civil rights regulations of the public accommodations industry, *Heart of Atlanta Motel v. United States*, 379 U.S. 241, 261 (1964); prohibitions on "loan sharking," *Perez v. United States*, 402 U.S. 146, 156 (1971); national wage and salary restrictions, *Fry v. United States*, 421 U.S. 542, 547-48 (1975); and environmental restrictions on coal mining, *Hodel,* 452 U.S. at 283.

Congressional regulation of narcotic drugs falls into this category as well. To regulate the frequently intersecting legal and illegal drug markets, Congress has established a finely calibrated regulatory system over the course of nearly a century. That system provides for regulations of how drugs are tested, approved, and marketed as medicines; and enforcement against those who refuse to comply with the regulations.

1. Congressional Regulation of the Drug Testing, Approval, and Marketing Process

Congress began establishing the modern-day system of medical drug regulation in 1906, with the passage of the original Pure Food and Drug Act. Prior to that Act, America "was mired in near medicinal anarchy." *See* Andrea Barthwell, M.D., *Don't Fall For Pot-Smoking Con*, Hartford Courant, Apr. 30, 2004, *available in* http://reform.house.gov/CJDPHR/Hearings/EventSingle.aspx?EventID=975. Traveling salesmen hawked "miracle medicines" that rarely actually cured anything; instead, they made patients feel better through the use of alcohol or opiates. *Id.*

This was the age of "patent medicines" which were heavily marketed and advertised with false claims as to their contents and efficacy. *See* Philip J. Hilts, *Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation*, 25-30 (2003).

The 1906 Act created the agency that later came to be known as the U.S. Food and Drug Administration (FDA). *See* Hilts, *supra* at 74. The 1906 Act was superseded by the Food, Drug and Cosmetic Act (FDCA, 21 U.S.C. 301, *et seq.*) in 1938, which, for the first time, forced pharmaceutical companies to test their drugs for safety and efficacy, under the regulation of the FDA. *See* Hilts, *supra* at 95. The drug approval process under the FDCA requires rigorous scientific proof, careful review by the FDA's scientific staff, and the assurance that drugs will be marketed only for the specifically approved indications. *See Marijuana and Medicine: The Need for a Science-Based Approach, Hearing Before the Subcomm. on Criminal Justice, Drug Policy & Human Resources of the House Comm. on Government Reform*, 108th Cong., 2d Sess. (Apr. 1, 2004) (statement of Robert J. Meyer, M.D., Director, Office of Drug Evaluation II, Center for Drug Evaluation & Research, U.S. Food & Drug Admin.), at 2-7.

These Congressional actions are largely responsible for creating the modern market in safe, effective medicines. One historian argues that after the passage of the FDCA, a "revolution in medicine took place . . . [T]he pharmaceutical industry went from a handful of chemical companies with no interest in research and no medical staffs to a huge machine that discovered, developed, and marketed drugs of real use in treating disease." *Id.* Indeed, "rather than being merely a bureaucratic imposition on scientific progress, the FDA was arguably the co-inventor

of the clinical trial process . . . This is the process on which modern medicine founds most of its claims." Todd Seavey, *Regulation for Dummies: Is the FDA Necessary?*, Reason, Apr. 2004, at printed page 4.

2. Enforcement of Congressional Drug Regulations

Within a decade after passing the Pure Food and Drug Act, Congress passed the first federal drug enforcement law, the Harrison Narcotics Act, in 1914.[3] In 1970, Congress undertook a thorough revision of the federal narcotics laws, replacing them with the Controlled Substances Act (CSA), 21 U.S.C. 801 *et seq.* Although drafted in the form of a criminal statute, the CSA "concerns an obviously economic activity," *United States v. Genao*, 79 F.3d 1333, 1337 (2d Cir. 1996), namely the black market in illegal (or illegally diverted) drugs. Many of the CSA's provisions govern the registration, labeling and packaging, production quotas, and record-keeping of those wishing to manufacture, distribute or dispense controlled substances. 21 U.S.C. 822-827 (2004). It is the "enforcement" side of the regulatory framework initially established by the FDCA.

Without effective law enforcement by DEA and similar agencies, it would be impossible for Congress to ensure that only safe and effective drugs are available to the public, and that those drugs are not diverted to the illegal black market. The FDA is not, by itself, capable of effectively carrying out

[3] The Harrison Act and other early federal narcotics enforcement statutes were based on Congress' revenue powers. *See* Charles Doyle, Congressional Research Service, *Drug Smuggling, Drug Dealing and Drug Abuse: Background and Overview of the Sanctions Under the Federal Controlled Substances Act and Related Statutes*, Order Code 97-141 A, at CRS-1 and -2 (2003).

this enforcement role; instead, it relies on enforcement of the CSA by the DEA and other federal law enforcement agencies to defend the federal government's regulation of drugs. As a law enforcement agency, "DEA has the authority, expertise, and resources to interdict the illegal use of controlled substances." *See* Letter from Patrick Ronan, Assistant Commissioner for Legislation, U.S. Food and Drug Admin., to Rep. Mark E. Souder (July 1, 2004), at 3. Moreover, the CSA, as a statute primarily directed at criminal enforcement, is the more appropriate statute for enforcement actions, providing "greater penalties and requir[ing] proof of far fewer elements to establish a violation." *Id.*

Taken together, the FDCA and the CSA represent "a powerful 'social contract for drug use,' which established that potentially addictive (and abused) drugs would be available under a physician's prescription and only to treat illnesses other than addiction. . . . This approach to potentially abused medicines is now the standard throughout the world. It has served Americans admirably for most of the 20th century, separating medical from non-medical uses, labeling the contents of medicines, and subjecting medicines to scientific review for safety and efficacy." Robert L. DuPont, *Examining the Debate on the Use of Medical Marijuana*, 111 Proceedings of the Ass'n of American Physicians 166, 167 (Mar./Apr. 1999).[4]

[4] The fluid, global nature of the illicit drug market demands not simply a national strategy, but an international one. To that end, Congress has ratified a number of international narcotics treaties obligating signatory countries to take effective steps to control potentially dangerous drugs. *See, e.g.*, Multilateral Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407, T.I.A.S. 6298; Multilateral Amendment of the Single Convention on Narcotic Drugs, Mar. 25,

(Continued on following page)

3. Federal Drug Regulation and Marijuana

The history of marijuana in this country illustrates the efficacy of federal drug regulations – and the necessity of their full enforcement. Before the era of modern science, marijuana, like alcohol and tobacco, was used as a "folk remedy" for numerous ailments over the centuries. *See* DuPont, *supra* at 167. In the 19th century, marijuana was marketed as a medicine in the form of "tinctures, extracts, and elixirs," as a remedy for "asthma, bronchitis, migraine headaches, depression, gonorrhea, uterine hemorrhage, and dysmenorrhea." Andrea Barthwell, Deputy Director, Executive Office of the President, Office of National Drug Control Policy, *Marijuana as Medicine?*, Testimony before the New England Governors' Summit on Drug Use, Oct. 8, 2003. Quality controls were virtually non-existent. *Id.*

In the modern era, however, botanical marijuana has never been able to pass the strict scientific standards adopted by Congress; as a result, it has never been approved by the FDA as a safe and effective drug. *See* Response of Amit K. Sachdev, Associate Commissioner for Legislation, U.S. Food and Drug Admin., to Rep. Mark E. Souder, Sept. 25, 2003, at 1. This is because marijuana is fundamentally bad for human health. *See, e.g.*, *Marijuana and Medicine: The Need for a Science-Based Approach,*

1972, 26 U.S.T. 1439, T.I.A.S. 8118; Multilateral Convention on Narcotic Drugs: Psychotropic Substances, Feb. 21, 1971, 32 U.S.T. 543, T.I.A.S. 9725. Among other things, the 1961 Treaty requires signatories (including the U.S.) to establish a single national agency to license and control all supplies of marijuana for medical or research purposes. *See* 1961 Treaty, art. 23, 28; *see also* International Narcotics Control Board, United Nations, *Report of the International Narcotics Control Board for 2003*, at 24 (reminding signatory countries that the 1961 Treaty requires the creation of a "national cannabis agency").

Hearing Before the Subcomm. on Criminal Justice, Drug Policy & Human Resources of the House Comm. on Government Reform, 108th Cong., 2d Sess. (Apr. 1, 2004) (statement of Nora Volkow, Director, National Institute on Drug Abuse) (detailing research into negative impacts of marijuana use on the human body, and noting that the drug is addictive); Eric A. Voth, *A Peek into Pandora's Box: The Medical Excuse Marijuana Controversy*, 22 Journal of Addictive Diseases 27, 36-38 (2003) (listing negative health effects of marijuana, including brain damage, lung damage, and heart disease).

While some research does suggest that certain components of marijuana, most notably THC, may be useful to treat certain conditions, the Director of NIDA also recently testified that "there is greater promise in purifying the active constituents of marijuana and developing alternate delivery systems, such as inhalers, rather than studying smoked marijuana." *See* Volkow Statement, at 6. In fact, the FDA has already approved pure THC in pill form (called dronabinol, or "Marinol") for some indications. *See* Eric A. Voth and Richard A. Schwartz, *Medicinal Applications of Delta-9-Tetrahydrocannabinol and Marijuana*, 126 Annals of Internal Medicine 791, 791-4 (1997). Contrary to the claims made by some pro-marijuana activists, the federal government permits and supports research into the therapeutic potential of marijuana and its components. *See* Volkow Statement, at 6-9. Pharmaceutical companies are also actively developing new treatments made from marijuana. *See, e.g., Researcher working on medical patch to deliver marijuana-like chemicals*, Aug. 20, 2003, Assoc. Press State & Local Wire, *available in* LEXIS/NEXIS (describing efforts to create a medical treatment delivering THC through the skin); Eric Bailey, *British Firm Holds Hope for Users of Medical Pot*, Los Angeles Times, Feb. 1,

2004, at B1 (describing experimental marijuana derivative known as Sativex). In short, federal regulation of marijuana is serving the interest of public health.

Through state medical marijuana laws and lawsuits such as this one, however, pro-marijuana activists are seeking to do an end-run around these important regulatory safeguards. According to the FDA, state laws purporting to legalize medical marijuana "are inconsistent with [FDA's] efforts to ensure that approved medications have undergone rigorous scientific scrutiny and FDA's approval process." *See* FDA Statement Re: Marijuana Legislation, provided to Rep. Mark E. Souder on July 7, 2004. In opposing recent legislation that would have prohibited the U.S. Department of Justice from fully enforcing marijuana laws in states purporting to legalize the drug's "medicinal" use, the FDA further stated that "DEA is the Federal agency with primary jurisdiction regarding enforcement actions relating to the sale or distribution of marijuana. FDA will continue to cooperate with DEA in these actions. . . . We reiterate that any legislation that would prevent the Department of Justice or the DEA from enforcing the CSA with respect to marijuana either generally or in specified States would not serve the interests of public health." *Id.*

C. Exempting So-Called "Medical" Marijuana From Federal Drug Regulations Would Seriously Undermine Their Effectiveness

In its opinion below, the Ninth Circuit refused to look at the problem of marijuana trafficking as a whole, or the impact that local production, possession, and distribution have on the drug trade. Instead, the court narrowed its focus to "a *separate and distinct class of activities:* the

intrastate, noncommercial cultivation and possession of cannabis for personal medical purposes." *Raich*, 352 F.3d at 1228 (emphasis in original). By examining this "class of activities" in isolation from the overall marijuana trade, the court failed to see the effects that it might have on drug trafficking and law enforcement. The Ninth Circuit's error illustrates why this Court has warned against too narrow a focus on individual cases when examining a general regulatory statute. *See Lopez*, 514 U.S. at 558 ("where a general regulatory statute bears a substantial relation to commerce, the de minimum character of individual instances arising under that statute is of no consequence") (quoting *Maryland v. Wirtz*, 392 U.S. 183, 197 n. 27 (1968)) (italics and internal quote marks omitted). Individual courts can often underestimate or even fail to recognize what motivated Congressional action – namely, the importance of seemingly local phenomena to a national problem.

As reflected in its detailed findings in the CSA, Congress understood that to be effective, enforcement of drug regulations needs to reach all levels of the drug trade – including the initial production of the drug, and its "local" possession and distribution.[5] This policy is based on

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[5] "The Congress makes the following findings and declarations:

. . .

(3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because –

(A) after manufacture, many controlled substances are transported in interstate commerce,

(Continued on following page)

the fact that often the most effective drug enforcement is that which goes to the initial source of the narcotics. As this Court has held, the Commerce Clause power "permits Congress to attack an evil directly at its source, provided the evil bears a substantial relationship to interstate commerce." *North American Co. v. Securities & Exchange Comm'n*, 327 U.S. 686, 705 (1946).

Permitting even the limited marijuana cultivation and distribution allegedly at issue in this case would undermine drug regulation by (1) giving drug traffickers a new strategy to evade arrest; (2) creating geographic "safe havens" for drug dealers to base their operations; (3) increasing the risk of diversion from "medical" use to purely recreational trafficking; (4) increasing the supply and lowering the price of marijuana; and (5) potentially

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(B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and

(C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.

(4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.

(5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.

(6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic."

21 U.S.C. Sec. 801 (2004).

increasing the demand for the drug through reduced public perception of marijuana's harms. These practical considerations must be taken into account when evaluating Congress' power to deal with the narcotics trade. *See id.* ("And in using this great power, Congress is not bound by technical legal conceptions. Commerce itself is an intensely practical power. . . . To deal with it effectively, Congress must be able to act in terms of economic and financial realities.").

1. Creating a "Medical" Loophole for Marijuana Cultivation, Possession, and Distribution Would Give Drug Traffickers a New Strategem to Evade Arrest and Punishment

State medical marijuana laws undermine effective law enforcement, as drug traffickers can simply assert that their products are "medicinal" – forcing law enforcement authorities to prove otherwise. There is mounting evidence that current state medical marijuana laws are already being used as a cover for large-scale drug production and trafficking. In Oregon, for example, police discovered underground marijuana greenhouses with more than 3,500 plants, with room for 5,000 to 7,000 plants; the owners held state "medical marijuana cards" entitling them to possess the drug. *See* Beth Quinn, *Southern Oregon Police Raids Find 3,500 Marijuana Plants*, Portland Oregonian, Dec. 13, 2003, at C01. In Denver, Colorado, federal agents seized 800 marijuana plants from 3 homeowners, 2 of whom had state authorization to grow "medical" marijuana. Kirk Mitchell, *Feds Seize 800 Pot Plants*, Denver Post, June 3, 2004, at B-01. And just last month, the California Highway Patrol discovered a massive clandestine marijuana growing operation – with almost 2,000 plants

worth millions of dollars; medical marijuana activists, however, claimed that the marijuana was for "medical" purposes and was legal under Oakland city laws. Paul T. Rosynsky, *Big dispute in city pot bust*, Alameda Times Star, July 1, 2004, *available in* LEXIS/NEXIS. According to the U.S. Department of Justice, outlaw motorcycle gangs have applied for medical marijuana "caregiver" status, in an effort to legitimize their marijuana grow operations. *See* Letter from Robert F. Diegelman, Acting Assistant Attorney General for Administration, U.S. Dept. of Justice, to Paul Jones, Director, Justice Issues, General Accounting Office, dated Sept. 27, 2002, *reprinted in* General Accounting Office, *Marijuana: Early Experiences with Four States' Laws That Allow Use for Medical Purposes*, Report No. GAO-03-189, at 57 (2002). In Nevada, a convicted drug dealer obtained a state "medical marijuana" registration card (purportedly to treat his "bipolar" mental condition), and began growing the drug and "sell[ing] or giv[ing]" it to "about 20 other medical marijuana patients through his enterprise, Primary Caregivers and Consultants." Ed Vogel, *Medical Marijuana: Working to smoke out abusers*, Las Vegas Review-Journal, Apr. 12, 2004, at 1B.

Exemptions for "small" amounts of marijuana can also be a boon for drug traffickers. Three ounces of marijuana, for example, can make anywhere from 90 to over 250 marijuana cigarettes, or "joints" – enough to supply a so-called "medical marijuana user" for a month. *See* Dan Kulin, *Number of joints possible with 3 ounces of pot debated: Question 9 argument becomes food for commercial*, Las Vegas Sun, Oct. 15, 2002, 2002 WL 101210627. Where small amounts are presumed to be beyond the reach of the law, drug dealers will simply distribute drugs in those amounts so as to escape arrest. *See, e.g., Costa*

Rica: Review, Americas Review World of Information, Sept. 23, 2002, 2002 WL 100885937 (since Costa Ricans are allowed to possess small amounts of drugs, it makes it very difficult to stop dealing in drugs like crack cocaine).

2. Allowing Individual States To Immunize Marijuana Possession From Federal Regulation Would Create Geographic "Safe Havens" For Drug Traffickers

If certain states are permitted to simply "opt out" of federal drug regulation, they will quickly become a haven for drug traffickers. Drug trafficking organizations typically seek out venues where the drug laws, and/or the enforcement of those laws, are weaker; the drugs they manufacture or import in those areas can then be smuggled into areas where drug enforcement is more stringent. This has been especially obvious in the international arena. For example, when Congress passed stricter laws against the diversion of the precursor chemicals for methamphetamine production (such as pseudoephedrine), drug traffickers turned to Canada (where precursor chemical regulation was much weaker) as their source of supply. *See* Office of International Intelligence, U.S. Drug Enforcement Administration, and Criminal Intelligence Directorate, Royal Canadian Mounted Police, *Chemical Diversion and Synthetic Drug Manufacture*, at printed pages 1, 8. Similarly, lax Canadian laws and enforcement against marijuana growing have made the province of British Columbia a center of high-potency marijuana production. *See* Quentin Hardy, *Inside Dope*, Forbes, Nov. 10, 2003, at 146 (noting that in British Columbia only one-fifth of marijuana busts result in incarceration and the average sentence is only four months). This high-potency

marijuana is being smuggled into the U.S. *See* U.S. Department of State, *International Narcotics Control Strategy Report, 2003* (2004).

In Europe, lenient drug policies have made the Netherlands a haven for drug smuggling. *See, e.g.*, Justin Sparks, *Dutch Law Could Unleash Cocaine Flood In Britain*, London Times, Feb. 1, 2004, at 24; Ciarin McGuigan, *Mule be sorry; Dutch decision to 'let off' drug smugglers could lead to growth in trafficking here*, Belfast Telegraph Newspapers – Sunday Life, Mar. 14, 2004, *available in* LEXIS/NEXIS (Dutch policy of releasing drug smugglers at its airports carrying "normal" amounts of illegal drugs has sparked neighbors' fears that the Netherlands will become the preferred European Union gateway for narcotics). *See also* Anthony Browne, *Dutch drug café ban puts British noses out of joint*, London Times, Oct. 25, 2003, Overseas news section, at 5 (reporting on Dutch government's consideration of plan to forbid foreigners from accessing legal marijuana shops in the Netherlands, in part to stop cross-border trafficking by German drug dealers who purchase marijuana in the Netherlands and then drive it to Germany).

This problem is exacerbated by the fact that in states and localities that have attempted to legalize marijuana, state and local officials (facing local political pressures) are increasingly hostile to federal drug policies. For example, one California sheriff recently stated that he would, if necessary, actually remove seized marijuana from his department's evidence locker and give it to a friend in medical need. *See* Josh Richman, *Cops say feds' focus 'misplaced'*, Oakland Tribune, May 25, 2003, 2003 WL 8915341. According to the U.S. Department of Justice,

state officials are often refusing to prosecute obvious cases of drug dealing out of deference to state "medical marijuana" laws, and in one instance a local district attorney even ordered a county detective to arrest a DEA agent if the agent seized marijuana plants purportedly belonging to a "patient". *See* Diegelman Letter, *supra* at 56.

Furthermore, if drug production is permitted to take root in a community, that community can quickly become economically dependent on the drug – putting additional pressure on local governments to turn a blind eye to the problem. *See* Hardy, *supra* (reporting that marijuana has become Canada's most valuable agricultural crop, with even the legitimate British Columbian economy increasingly dependent on the profits from it). In fact, many so-called "medical" marijuana sellers now openly operate as businesses in California (which has the most permissive medical marijuana law). In Rosewood, California, a store sells strains of marijuana known as "Romulan," "White Rhino," "Acapulco Gold," and "Placer Gold" for $200-$320 per ounce, reportedly with the tacit approval of the local chief of police. *See* Art Campos and Jocelyn Wiener, *Store for medical pot opens in Roseville*, Sacramento Bee, Jan. 31, 2004, at A1. In Oakland, California, a dozen "cafes" selling purported medicinal marijuana (at least one owner claiming to serve 7,000 "patients") were in operation by the end of 2003, earning it the nickname "Oaksterdam"; in 2004, the city attempted to limit the number of stores by issuing marijuana "business permits" (in return for a $20,000 annual fee). *See* Jean Marbella, *Marijuana 'du jour' in Oakland*, Baltimore Sun, Nov. 28, 2003, at 1A; Laura Counts, *Medical marijuana merchant defies Oakland order to close*, Alameda Times-Star, June 2, 2004, *available in* LEXIS/NEXIS.

Nor can state medical boards in such states be relied on to provide effective regulation. As one commentator has observed, medical marijuana initiatives "have created serious regulatory dilemmas for state regulatory boards." Voth, *A Peek into Pandora's Box* at 27. Despite their mission to oversee the practice of medicine in their respective states, many of these boards disavow any responsibility to determine whether drugs are safe or effective. *See Marijuana and Medicine: The Need for a Science-Based Approach, Hearing Before the Subcomm. on Criminal Justice, Drug Policy & Human Resources of the House Comm. on Government Reform*, 108th Cong., 2d Sess. (Apr. 1, 2004) (statement of James D. Scott, Member and Past Chair, Oregon Board of Medical Examiners), at 2, ("No one representing the [Board] is prepared to give any testimony regarding the scientific or medicinal value of marijuana, or any sociopolitical issues regarding marijuana. These issues are beyond our jurisdiction."); Letter from Joan M. Jerzak, Chief of Enforcement, Medical Board of California, to Rep. Mark E. Souder, May 11, 2004, at 1, 2 ("The Board does not establish 'procedures' which physicians must follow, nor does it take a position with regard to specific medications. . . . [I]t is not for the Board to determine which medical conditions may be appropriately treated with marijuana.").

3. Legalizing "Medical" Marijuana Will Increase the Chances of Diversion to Purely Recreational Use

By increasing the amount of marijuana, and the number of "legitimate" uses for it, state medical marijuana laws increase the chance that the drug will be diverted to purely recreational uses. The more legally available any

drug is, the more indications it is approved for, and the greater the quantities of the drug in legitimate channels, the higher the rate of illegal diversion, trafficking and abuse will be. *See* Responses of Thomas W. Raffanello, Special Agent in Charge, Miami Division, Drug Enforcement Administration, to Questions from Rep. Mark E. Souder, May 24, 2004, at 2; Letter from Amit K. Sachdev, Associate Commissioner for Legislation, U.S. Food and Drug Admin., to Rep. Mark E. Souder, Apr. 26, 2004, at 2. The diversion of legal (but controlled) medical drugs into illegal uses is widespread, rivaling the market for strictly illegal drugs. For example, nationwide in 1993, people spent an estimated $25 billion on prescription drugs in the illegal market, compared with $31 billion on cocaine, including crack. *See* National Drug Strategy Network, *Prescription Drug Abuse Rivals Illicit Drug Abuse, Some See Double Standard in Law Enforcement*, New Briefs – Drug Use Trends (Oct. 1996). Abuse of legal prescription drugs, such as the opiate OxyContin, is on the rise; by 2001, prescription pain killers were second only to marijuana as the most abused category of drug. *See* National Survey on Drug Use and Health, *Nonmedical Use of Prescription Pain Relievers*, at 2 (2004).

Once a drug can be legally obtained, drug dealers and addicts have an increased number of avenues to obtain it – including prescription fraud (forging prescriptions; visiting multiple doctors to obtain prescriptions, often called "doctor shopping"; and altering prescriptions to increase the quantity); and outright theft or robbery from pharmacies (often performed by pharmacy workers themselves). *See* Julie Wartell and Nancy G. La Vigne, Office of Community Oriented Policing Services, U.S. Dept. of Justice, *Prescription Fraud* (2004), at 2-3. Those obtaining these drugs via fraud can, and do, ship them for profit to other

states. *See, e.g.*, Drug Enforcement Administration, *OxyContin: Pharmaceutical Diversion*, at printed page 5 (2002) (reporting DEA investigation into individual who took advantage of a severe medical condition to obtain legitimate prescriptions for OxyContin and other oxycodones from physicians in Arizona and California; he then shipped the pills – approximately 8,000 to 9,000 over the course of a year – via FedEx to another individual in Maryland for distribution).

The risk of "medical" marijuana being diverted is heightened by the fact that certain doctors have been consistently expanding their list of marijuana-treatable "conditions." One doctor, Frank H. Lucido, reports writing medical marijuana recommendations for 348 patients over a six-month period in 2002, for a wide range of conditions, including headaches, chronic anxiety, depression, insomnia, post-traumatic stress disorder, asthma, bipolar disorder, attention deficit disorder, vertigo, tinnitus, restless leg syndrome, phantom limb pain, and obsessive compulsive disorder. Frank H. Lucido and Mariavittoria Mangini, *Implementation of the Compassionate Use Act in a Family Medical Practice: Seven Years' Clinical Practice*, O'Shaughnessy's Journal of the California Cannabis Research Medical Group, Spring 2004, at 3. Claudia Jensen, a California pediatrician, has stated that she has recommended marijuana to teenagers with attention deficit disorder, despite acknowledging that "the science is lacking to justify some of her unorthodox uses." Daniel Costello, *Unorthodox uses for medical marijuana*, Los Angeles Times, Feb. 23, 2004, at F3; *see also Marijuana and Medicine: The Need for a Science-Based Approach, Hearing Before the Subcomm. on Criminal Justice, Drug Policy & Human Resources of the House Comm. on Government Reform*, 108th Cong., 2d Sess. (Apr. 1, 2004)

(statement of Claudia Jensen, M.D.), at 7-9. These cases are not isolated incidents. A 2003 study of AIDS patients using marijuana showed that less than one third smoked the drug even to relieve pain; 57 percent smoked to relieve anxiety or depression, while 33 percent admitted they smoked for "recreational" reasons. Sara Zaske, *Study: Many HIV patients use pot for mental health*, San Francisco Examiner, June 9, 2003, *available in* http://reform.house.gov/CJDPHR/Hearings/EventSingle.aspx?EventID=975. In Oregon, of the 10,196 patients registered with the state's medical marijuana program, only 335 were listed as suffering from cancer; only 221 with HIV/AIDS; only 198 with glaucoma; and only 438 with cachexia; by contrast, 8,711 patients listed "pain" as their reason for taking the drug. *See* Oregon Department of Human Services, *Oregon Medical Marijuana Program Statistics* (July 1, 2004).

Other pro-marijuana doctors are, moreover, also writing very large numbers of "recommendations" for marijuana. According to one estimate, as of spring 2004, 100,000 marijuana recommendations had been issued in California, almost half written by only 12 physicians in California – all associated with a group known as the California Cannabis Research Medical Group. Fred Gardner, *Encouraged by 9th Circuit's Conant Ruling, More California Doctors Approve Cannabis Use*, O'Shaughnessy's Journal of the California Cannabis Research Medical Group, Spring 2004, at 1. One doctor alone acknowledged writing approximately 8,000 such recommendations. *Id.* at 7. In Oregon, Dr. Phillip E. Leveque was recently suspended by the state medical board for writing 4,000 medical marijuana authorizations – approximately 40 percent of the total such authorizations in the state – often without conducting any physical examination or even personally meeting with his patients. *See* Kramer, Andrew, *Oregon doctor's license*

suspended for signing marijuana cards, Associated Press, Mar. 5, 2004, *available in* LEXIS/NEXIS.

4. The Aggregate Effect of Even Individual Cultivation of "Medical" Marijuana Justifies Federal Regulation

Even when marijuana never actually enters the immediate stream of commerce, it may still be regulated to prevent it from impacting the broader market. This Court has repeatedly held that Congress may look to the total, aggregate effect of many apparently small, local transactions on interstate commerce and federal regulations thereof. *See, e.g., Wickard*, 317 U.S. at 128-29 (aggregate effect of home-grown and personally consumed wheat); *Katzenbach v. McClung*, 379 U.S. 294, 301 (1964) (aggregate effect of many individual acts of racial discrimination at restaurants); *Perez*, 402 U.S. at 154-55 (aggregate effect of acts of loan sharking); *Fry*, 421 U.S. at 547 (aggregate effect of wage increases for state employees).

As was the case in *Wickard*, marijuana grown and consumed, even locally by purported "medical" users, can exert a significant effect on the traffic in the drug, by adding to the nation's marijuana supply while reducing demand on the immediate market. The result will be lower overall prices on the black market. *See Proyect v. United States*, 101 F.3d 11, 14 n. 1 (2d Cir. 1996) ("[T]he cultivation of marijuana for personal consumption most likely does substantially affect interstate commerce. This is so because 'it supplies a need of the man who grew it which would otherwise be reflected by purchases in the open market.'") (citing *Wickard*, 317 U.S. at 128); *see also* Drug Enforcement Administration, *Illegal Drug Price and Purity Report* (Apr. 2003) ("A decrease in drug price

typically indicates an increase in availability, and, conversely, a price increase usually indicates a decrease in supply."). This would undermine a key component of the federal government's anti-marijuana strategy, namely to increase the price of illicit drugs, resulting in a reduction in the demand. *See* Office of National Drug Control Policy, *National Drug Control Strategy 2004*, at 31 ("The main reason supply reduction matters to drug policy is that it makes drugs more expensive, less potent, and less available. Price, potency, and availability are significant drivers of both addicted use and casual use.").

5. Legitimizing "Medical" Use of Marijuana Will Potentially Increase the Demand For the Drug, by Reducing Public Perception of Marijuana's Harms

Repeated claims of marijuana's "medicinal" value, coupled with the apparent ratification of those claims by state medical marijuana laws, have lowered the public perception of marijuana's scientifically demonstrated harmfulness – particularly among young people. *See* Andrea Barthwell, Deputy Director, Office of National Drug Control Policy, *Marijuana Is Not Medicine*, Chicago Tribune, Feb. 17, 2004, at C19 ("Children entering drug abuse treatment routinely report that they heard that 'pot is medicine' and, therefore, believed it to be good for them."). These public perceptions can have a significant impact on marijuana usage rates. *See, e.g.*, Wilson M. Compton, et al., *Prevalence of Marijuana Use Disorders in the United States, 1991-1992 and 2001-2002*, 291 JAMA 2114, 2119 (2004) (reporting study demonstrating that decreases in the perceived risk of harmfulness and in

disapproval of marijuana use can explain the recent rise in marijuana use by young people).

D. If Congress Is Prevented From Regulating Local Production, Possession, and Distribution of Marijuana, Its Ability To Regulate Other Drugs Will Be Placed in Jeopardy

A ruling that the federal government may not regulate local production, possession, and distribution of "medical" marijuana would have far-reaching implications for the regulation of all drugs, both legal and illegal. A vast number of controlled substances may be produced in the home, including methamphetamine, GHB, and MDMA ("ecstasy"). *See* Drug Enforcement Administration, *Drug Trafficking in the United States* (2001). And virtually all drugs have at least some putative "medical" uses; for example, cocaine and heroin were long used as anaesthetics, methamphetamine as a stimulant, and for many years LSD and ecstasy were used in psychotherapy.

This scenario is not as unlikely as it may seem. In fact, many of the same proponents of medicinal marijuana have actively sought to force the approval of some of these other drugs as "medicines." *See, e.g., Grinspoon v. Drug Enforcement Admin.*, 828 F.2d 881 (1st Cir. 1987) (petition by pro-medical marijuana advocate Dr. Lester Grinspoon to remove ecstasy from Schedule I of CSA). In several foreign countries, physicians may now prescribe heroin to addicts as part of a medical practice known as "maintenance," and the same may soon be done for cocaine. *See, e.g.*, Dan Gardner, *Free junk for junkies*, Ottawa Citizen, Jan. 18, 2004, at C3; *Doctors push for cocaine prescription*, Swissinfo, June 3, 2004, *available at* http://www.swissinfo.org/sen/Swissinfo.html?siteSect=105&sid=4958011. If a

state were to attempt to approve these or any other currently controlled drugs for "medical" use, it would set up the same federal-state conflict present here.

CONCLUSION

Describing the 19th century age of "quack medicines," one historian writes that, "The market in medicines, without any regulation, was essentially the same as the only market today with no regulation – the trade in heroin, cocaine, and other drugs. The supply was unreliable, the purity suspect, the price high and variable, and the corrupted substances sometimes fatal." Hilts, *supra* at 27. Proponents of "medical" marijuana would take us full circle, "back to a time before the passage of the Pure Food and Drug Act." Barthwell, *Marijuana as Medicine?* Through its power to regulate the interstate commerce in medical drugs, Congress has the responsibility to protect the American public from such a foolish step backwards. That power, and that responsibility, are fully consistent with the Constitution and should not be denied. The decision of the Court of Appeals should be reversed.

Respectfully submitted,

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