U.S. REPRESENTATIVE MARK SOUDER (R-IN) HOLDS HEARING ON MEDICAL MARIJUANA - COMMITTEE HEARING

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HOUSE COMMITTEE ON GOVERNMENT REFORM: SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES HOLDS A HEARING ON MARIJUANA MEDICINE

APRIL 1, 2004

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[*] SOUDER: Subcommittee will now come to order.

Good afternoon, 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 also used by doctors.

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 1930s. Beginning in the 1970s, 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 safe, 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 supporting smoked marijuana, actually stated that, quote, "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.

SOUDER: 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 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 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, whether it 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 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 that I believe to be highly questionable.

For example, one of our witnesses, Dr. Philip 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.

SOUDER: 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 it be subjected 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 pain killers 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 of 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 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 responsibility for regulating medical drugs, we also welcome back Dr. Robert Meyer, director of FDA's Office of Drug Evaluation II, Center for the 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 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 and anticipate a frank and open discussion with her.

Dr. Leveque will not be able to be here, though he did not inform the committee. So, if he shows up, we'll include him in the second panel.

SOUDER: 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 testimonies.

Mr. Cummings?

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 Substances Act classifying all illegal and prescription drugs according to five schedules.

Marijuana was and remains classified as a schedule-one substance, meaning that it has a high potential for abuse, has no clearly accepted medical use and treatment in the United States and cannot be used in an acceptably safe manner under medical supervision.

Possession and the sale of schedule-one substances is generally prohibited and punishable by federal criminal statutes. Clinical trials involving schedule one 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 antidrug 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.

CUMMINGS: Beginning in the 1990s, 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 or 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 privates 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 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 three of 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.

CUMMINGS: 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.

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

Ms. Norton?

NORTON: Thank you, Mr. Chairman. I'm not going to be able to stay to hear the testimony, but I did want to come to 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 has led many steps to 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 federal authorities obviously understand 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 eight 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 have 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 the city.

And Initiative 59, 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 composed 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 officials that put it on the ballot. There is no official body that put it on the ballot.

An AIDS victim collected the signatures and put the matter on the ballot.

NORTON: That AIDS victim has since died. Essentially what he was seeking was 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 Columbia have been very clear that they want the two to be distinguished.

My own sense is that young people should lay off of the entire set of controlled substances, whether they are very harmful or terribly harmful, from marijuana to heroin.

And, by the way, heroin has become increasingly popular with young middle-class students.

And, for that matter, should lay off alcohol, which is, perhaps, the drug of choice for young people in college today.

You know, 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 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 county? 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 kids life by giving him a record for smoking pot.

NORTON: And to the credit of most of the states of the United States, they understand that. And there are very few such arrests made.

Nevertheless, as it stands, this 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 that you can't get educational grants 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.

SOUDER: Thank you. A couple of things for the record. I think it needs to be said that the 9th Circuit Court ruled and the Supreme Court didn't review -- which is a little different than the Supreme Court making the decision.

The Supreme Court -- and we're not going to debate today the preemption law, because Supreme Court has already ruled on preemption, in fact, fought a civil war over preemption. States do not have the right to pass laws contrary to federal law anymore than the states had referendums to pass and support slavery.

We fought a war and said federal law prevails. You don't have a right to nullification. Now, how we enforce those is another question.

SOUDER: One other thing on the record as the author of an amendment I did not, in the amendment, 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 and the Bush administration falsely continued that interpretation which we are about to appeal in the Higher Ed Act.

I also, before we start, I want to take a point of personal privilege because today is the last day for a longtime member of my staff, Nicole Garrett (ph). 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 staff of 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 in, 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 Narcotic 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 (ph) who was head of the Redwood City's Police Department's narcotics detail. He was killed in the line of duty on May 8th, 1981.

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

(APPLAUSE)

Now I'd like to ask unanimous consent that all members have five 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 hand, I need to give you each the oath. Do you swear and affirm the testimony you give today is the truth, the whole truth, and nothing but the truth so help you God?

Let the record show that each of the witnesses has answered in the affirmative. I want to welcome Dr. Volkow back and you're recognized four or five minutes.

VOLKOW: Good afternoon, Chairman Souder and members of the subcommittee. I am pleased to be here with my colleague, Dr. Robert Meyer from FDA and Patricia Goode (ph) 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 15 years to inform us about marijuana and its health consequences. Fact number one: Marijuana has been and continues to be the number one illegal drug in this country.

VOLKOW: Fact number two: 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 of the other illicit drugs put together.

It is also bringing more people to our emergency rooms. There has been 164 percent increase in emergency room visits involving marijuana since 1995.

Moreover, a recent study found that early exposure to marijuana increased the likelihood 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 is likely to contribute significantly to motor vehicle accidents.

Basically, marijuana can affect almost every organ and system in the body, including the lymph system, the heart and the lungs.

Because marijuana is typically rolled into a cigarette, or a joint, and smoked, and 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.

Tetrahydrocannabinol, or THC, is a primary ingredient in marijuana that causes an intoxicating effect, or "high."

While researchers were investigating why marijuana is abused and how it affects the brains, they discovered a new neuro-transmitter system.

VOLKOW: They found the brain has specific sites where marijuana finds (ph) 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 receptor, which is outside the brain, is involved in immune functions and in pain perception.

The discovery of these 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 (ph), 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 smoke marijuana on appetite, weight gain, and other behavioral and performance measures on 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 cover a range of medical conditions including pain, spasticity, nausea and HIV infections.

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.

VOLKOW: 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 exerts its effects offers a wide range of potential therapeutic applications. However, cannabinoid medications are being developed that optimize therapeutic properties and minimize adverse affects.

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

SOUDER: Thank you very much.

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

MEYER: Good afternoon, Mr. Chairman and members of the subcommittee. I am 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 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 biologics 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 to 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 subjects to the FDA in the form of an investigational new drug application, or an IND.

FDA reviews the IND for assurance that the proposed studies, generally refereed to as clinical trials, do not place human subjects at unreasonable risk of harm.

MEYER: FDA also verifies that there are adequate assurances of informed consent and human subject protection.

At that point, the first of three phases of studies in humans can begin.

Phase one studies primarily focus on the safety of the drug in humans.

Phase two studies are clinical studies involving a limited number of studies 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 three studies involving up to several thousand subjects. These studies firmly establish efficacy for a particular indication. It also provides further safety data.

Once the phase three 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, showed 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 Substances Act, or the CSA. The CSA separates controlled substances into five schedules depending upon their approved medical use and abuse potential. Schedule one controls substances such as marijuana or those deemed not to have any legitimate medical use, as well as a high potential for abuse.

The primary responsibility for enforcing the CSA, again, resides with the DEA.

MEYER: The criminal penalties related to Schedule One 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.

The 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 toxicity of the smoking, it is likely that any future approvals would not be of a 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 Kesimet (ph), for therapeutic use in the U.S., 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 risk 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'd like to thank the subcommittee again for this opportunity to testify on this important issue, and I'd be happy to take any questions the members of the subcommittee may have. Thank you.

SOUDER: Thank you very much. Ms. Good?

GOOD: Chairman Souder, Congressman Cummings, and distinguished members of the panel... SOUDER: Will you check to make sure your microphone is on? Or get in closer. Thank you.

GOOD: 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, known as the 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.

GOOD: And these considerations are applied to anyone who wishes to apply to manufacture a substance in schedules one or two of the Controlled Substances 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 applicants compliance with state and local law, the applicants 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 relating to the manufacture, distribution or dispensing of controlled substances.

We must also consider the applicants 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 interests.

In order to determine whether a proposed applicant will 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 expressly incorporated this principle into the CSA.

GOOD: The DEA regulations provide more detailed information on the process of obtaining registration to bulk manufacture of 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 one 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's 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're 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 sixty days to file written comments or objections to the proposed registration of this new applicant by filing a 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 treaty 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 a 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.

GOOD: Any applicant whose application is denied is then entitled to seek review of that decision to the U.S. Court of Appeals.

In conclusion, DEA will carefully consider any application for registration of the bulk manufacturer of marijuana consistent with the relevant statutory criteria.

Mr. Chairman, thank you for your opportunity to testify today. And I'll be happy to answer any questions.

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 an existing medical product to market and chose to bypass the FDA approval process by using ballot 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?

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.

SOUDER: Well, 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?

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

SOUDER: Would that not call into some degree the whole question of having an FDA and the scientific process that you described so thoroughly? In other words, what would be the point of having you and others do all this research if it can just be done by referendum?

MEYER: Right.

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

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's 200 ingredients inside marijuana and we're debating in -- just like heroin and cocaine and other narcotics that are dangerous have 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.

And when FDA was established -- and its funded by Congress -- it's to make sure that such confusion, in fact, doesn't 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, as just announced in the Washington Post, you're investigating walnuts. And the question is: Why hasn't this been more aggressively handled by FDA and will it consider imposing penalties as appropriate 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 approvals; if nothing else, false advertising.

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. And we agreed that it should remain in schedule one under the Controlled Substance Act, and should, therefore, be controlled and that should be enforced as a schedule one product meaning it has no known medical use and has substantial possibility for abuse.

The second things is I believe part of your question was directed to the FDA in a written form recently.

MEYER: And I believe that the preparation for answering that is under way, and I'll defer to that written answer for that.

SOUDER: OK, and I understand that when we bring a researcher in, you're not necessarily making the political policy level decision, but it's been a frustrating process, because as we read the FDA cracking down on other things -- and by the way, we had, 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.

And we have a similar number problem in Indiana. Number one, just exploded through a bunch of bank robberies, a bunch of kids, and the abuse of a legal drug. And as I understood Ms. Good's comment, one of the first criteria is: Can this be controlled and managed?

And what we learned at that hearing is the number one 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. And 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 wanted to, I'll actually go a second round here. Let me yield to Ms. Sanchez.

SANCHEZ: Thank you, Chairman. At this time, I actually have no questions for the first panel.

SOUDER: OK. I wanted to move to Dr. Volkow. What do you think -- you know you went through the research, you isolated pretty clearly what we're trying to find out in 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 thing that we're having with oxycontin, with heroin, with other types of derivatives, the opiates, that 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 addition and other things. VOLKOW: Yes and this, of course, is a difficult proposition because particularly, I think, in the case of opiates, drugs that you are referring, because we are faced now that the number two illegal drug in this country are prescription compounds.

The number two are opiates, are an algasics (ph) after marijuana -- and that also 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.

VOLKOW: So the number one issue, I think, is extremely important we know from research that one of the best strategies to combat drug addiction is prevention. And one of the best ways of addressing prevention is education. So in order to educate people, you have to have the information. So that is 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. And there are many studies that have shown that they have been adverse, but there have also been other studies that have shown it's not adverse. And so 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. And there is clear evidence to suggest that.

So our responsibility, the way that I view it, is to generate that knowledge such that that data will speak for itself. And it doesn't become, "I think this is a benign drug." It is the data that is going to state it.

And I mentioned two studies. I think they are quite impressive on what they are telling us.

There's one showing identical twins; the one that started taking marijuana before age 17 had significantly higher problems with drug abuse and addition. These are identical twins, same genetics. And another study shows that the chronic use of marijuana, and it wasn't whether it was 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, is the way that we do this is to prevention and the way that we do it is via education: education of lay public, education of policy-makers, education of officials (ph). So it's education across the different levels of society.

SOUDER: How would you, both Dr. Volkow and Dr. Meyer, if in balancing -- OK, you might get some good from doing something, but there are also 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 could 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'd approve it on those grounds.

VOLKOW: I am certain, I think that that's one of those answers that that is 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, number one.

Number two, there are many alternatives even if, in fact, it was shown -- it hasn't been shown -- that nicotine is an effective treatment for obesity, which it is not, but even if it were, for matter of argument, there are ways of delivering nicotine that, number one, 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?

VOLKOW: One of the things we've learned through the past 10 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 for drugs of abuse (ph), that's the group of administration that assures you the higher likelihood of abuse and addictiveness. It has to do with the rapidity at 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 from a patch. And that really 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 effects. That's why we have science. So that's why we're investing in institutes like the NIDA in order to be able to develop compounds that are safer and can help people.

MEYER: I think from my standpoint I would state that the safety and risk, as opposed to the efficacy, is wholly dependent upon what situation you're talking about. And 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 have 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.

SOUDER: So for example, if nicotine, a component of tobacco, I'm not arguing it is, but if nicotine had a side benefit such as -- who knows if you break out cigarettes and its components inside 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 justify to then refer to cigarettes that are smoked as medical cigarettes?

This is part of the political problem we're having here is you're saying there can be side things in the chemicals in marijuana and then people get away -- if it's taken in pill form. But then people refer to it as **medical marijuana**. Whereas we have other things that we take the chemicals and components out that 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 labelling? And why aren't you speaking out against it more aggressively in the public arena that this is not medical? It's a component inside it, just as there are components inside of all kinds of things that are terribly unhealthy. And then we come up with other names for them, but we don't call the primary, if it's dangerous, medical. That's the kind of baffling thing here which suggests a much broader agenda than a health agenda.

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 one 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, you know, we're clearly on record saying otherwise saying that it is not approved for any medical use, I think that's where we stand.

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 -- Marinol is one alternative. What are other alternatives to marijuana to treat some conditions?

VOLKOW: The conditions that have been brought forward in terms of research, apart from the issue of nausea and vomiting for cancer and increasing appetite of individuals that have (inaudible), that is they are not hungry like with HIV or cancer, there are other indications that are actually being investigated, particularly from California, and that is pain, neuropathic pain, pain that comes from the peripheral nerves. And marijuana appears to be effective in 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 ones are in the outside. And it's these, the cannabinoid receptors outside the body that are responsible for this pain-killing. So pharmaceutical companies 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. And 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, so 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. And there the stories are controversial because while effectively cannabinoids decrease the pressure in the eye, they also decrease blood pressure.

VOLKOW: And so there's concern that 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 just for marijuana -- nausea and vomiting -- they are several compounds that are now available. Kiketsia (ph) and the one -- Marinol -- appears to be useful in patients. And the one on analgesia is absolutely fascinating.

Now, there's the other area of research of developing drugs that antagonize the systems that are activated by marijuana, and those are ones that are being targeted for obesity, those are ones that are being targeted for smoking and for alcoholism.

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. And, in fact, Marinol is not particularly widespread in its use because there are alternatives. It's proved both as anti-nausea for chemotherapy patients and for kiketsia (ph) or for weight loss in the setting of AIDS. And there are a variety of drugs and 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 (inaudible), 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.

SOUDER: Let me see if I can summarize this. I'm not known for being kind of 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 is responding as to how to address people with AIDS or cancer who are in terrible pain, and we're so obsessed with the drug war on 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 than we are the concern.

Let me see if I understood your positions correctly -- and I'm going to try to say it precisely because you were both pretty precise -- that you do not believe that marijuana is medical. But there are components and chemicals in marijuana that you are actively researching in both agencies and 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 the Marinol, even as I understood it earlier -- that we always heard did not help in nausea cases in many cases -- has been improved and that while it may not treat all cases, you're continuing to try to make it more effective.

And in the minds of both your agencies, marijuana itself is not medical, but it does have components that you will continue to research, you've continued to have breakthroughs and will continue to improve the health of the United States.

Is that a fair statement? Is there anything I misspoke there or overstated?

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

SOUDER: Components within it can be used in other products when not smoked?

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 that there would be much more research needed to both explore the efficacy and to document the safety.

SOUDER: And it wouldn't be marijuana?

MEYER: Pardon?

SOUDER: And it wouldn't be marijuana? It would be some component inside the marijuana.

MEYER: Well, again, I think there are inherent toxicities to smoking anything. 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.

SOUDER: But it wouldn't, probably even if it was in dosage form, have all 200 -- did you say there were 200 chemicals?

VOLKOW: 400.

SOUDER: 400. Four hundred chemicals probably wouldn't be in it because you'd be isolating what you're treating. Is that correct, Dr. Volkow?

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

SOUDER: May I ask 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 find inside marijuana to make a more effective pill.

VOLKOW: Correct. And there are naturally occurring compounds that, for example, in the case of the amphetamines, which we used to treat children with ADHD. There are actually two really 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 it is believed to add in marijuana is the Delta-9 tetrahydrocannabinol, THC. But there is evidence that others are also having effects, but much less so.

Having said that, I do think that there's an element that is relevant in terms of research on marijuana and potential medical applications that help us on certain instances to identify areas where we say marijuana, for example, has this analgesic effect. Then we do the research and say what are the mechanisms by which marijuana lead to that analgesic effect, and then try to identify what the mechanisms are so then we can target compounds that go directly to it.

But that's a different perspective. That was the research that led to it. But we used it in order to get better intervention.

SOUDER: Dr. Meyer?

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 of a botanical product.

SOUDER: Do you have any smoked product that you've approved?

MEYER: I don't believe so. No.

SOUDER: Anything else that you want to add before we conclude the panel?

Thank you all for coming. We appreciate your testimony.

MEYER: You're welcome.

SOUDER: The next panel could 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, California; Mr. Robert Kampia, executive director of the Marijuana Policy Project; Dr. Robert DuPont, Institute For Behavior And Health of Rockville, Maryland.

I'm going to need to have you each stand.

Do you swear of affirm that the testimony you give today is the truth, the whole truth and nothing but the truth, so help you God?

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

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, also known...

SOUDER: Doctor, could you pull that just a little closer?

SCOTT: My name is Dr. James D. Scott, I'm an otolaryngologist, which is more easily known as an ear, nose, throat physician. I've practiced medicine in Roseberg, Oregon, 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 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 Practice 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 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 rule-making 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.

SCOTT: 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 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 scientific or medicinal value of marijuana or any social/political 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 patient's 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 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 medical 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.

SOUDER: Thank you for your testimony. We'll now move to, did I have your name, Dr. Jerzak, is that how you?

JERZAK: No. I'm no doctor. I'm Joan Jerzak, that's fine.

SOUDER: Joan Jerzak. And it's Jerzak is the correct?

JERZAK: Correct.

SOUDER: Well thank you for coming today, look forward to your testimony.

JERZAK: Chairman Sounder 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 physician 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 recommended 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.

At the 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 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 **medical 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 physician 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 physician 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 record keeping.

In July of 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 verses the federal level.

The immunity provision in the California act does not extend the violations of federal statute. And for that reason physicians recommending marijuana know that they may be vulnerable to actions by the federal government.

As you know, the traditional medical model flows from the presentation of ideas that lead to new emerging medicines. These typically include studies with positive trial outcomes. And physicians are traditionally introduced to these new methods through education 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 may 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 Passionate Use Act. And in October, 2003, the U.s. 9th 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, the opportunity to share this information with you.

SOUDER: By the way, once again, it was declined to be reviewed by the U.S. Supreme Court, which is different.

SOUDER: It was not overturned, which is different than being upheld.

JERZAK: I'm sorry.

SOUDER: Dr. Jensen?

JENSEN: Hi. Good afternoon, Congressman Souder and members of the committee. I am 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 am 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've 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 you 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, which I find very concerning that we treat adolescents who have authority issue problems with drugs that cause them to have mood swings and irritability and lack of appetite, which affects their nutritional status, reduces their ability to sleep properly and are well known to cause seizures, can trigger mental illness, et cetera.

JENSEN: Albeit small numbers of people are affected negatively by the amphetamines, but there are some.

There are other drugs to use from ADD, but they are off label. They have not been studied in children, for example, Wellbutrin 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 all over the years do that. In this country, we spend 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 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 government. And I really feel that with what you are doing today, perhaps we can rectify this. And I am here to answer any questions that you have that I could that might facilitate that process.

SOUDER: Thanks. And as I said in the beginning, your full statement will be in the record as well.

JENSEN: Thank you.

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

KAMPIA: Good to see you again. Thank you, Mr. Chairman.

And thank you in particular to Congresswoman Sanchez who's been such a strong supporter of the **medical marijuana** patients who are suffering in California.

I am Rob Kampia. I am 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 of that five 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. And there is 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. And

after three years of waiting, the DEA still has not given them an answer. And so consequently because there is no private source of marijuana in this country, no private sector industry is 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 a hold of a drug.

So there is 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, you know, Chairman Souder here criticized the state **medical marijuana** laws today as if it's some new discovery. Yet a couple of years ago, he asked GAO to do a comprehensive study of what's going on in the **medical marijuana** states.

And 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.

KAMPIA: Most of the patients are not abusing. The vast majority of the doctors are not abusing. And, in fact, GAO said that only one to three 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. And 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, the senior editor of the National Review, who could have told you about his **medical marijuana** use.

You could have invited Lyn Nofziger 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, 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 have 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, to you 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 sounds to me like the Dutch oppose **medical marijuana**.

Unfortunately this is not a scientific issue, but a political issue. And therefore, because of the obstruction of science, we are moving forward politically.

And we're going to keep passing state bills and state initiatives until the 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 one to schedule two. 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.

SOUDER: I want to appreciate you for at least being consistent (inaudible)

Dr. DuPont.

DUPONT: Thank you 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 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, and was the director from 1973 when the agency was started until 1978.

And I was also the White House drug czar as the head of Special Action Office under presidents Nixon and Ford. I served as head of NIDA also under president Carter.

And 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. And I was very interested in heroin in those days, so that was not a problem.

I had a flirtation with the decriminalization idea from 1975 to '78, and found myself in and interesting situation under president Carter when I changed my mind and no longer supported decriminalization and President Carter did support it.

DUPONT: So with two presidents I was restricted in 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. And 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. And 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 and to discuss issues with civility and respect and to contend vigorously in the marketplace of ideas.

And I am delighted to have this opportunity here.

The medical use of marijuana died, essentially, in the 19th century. And as modern pharmacology developed, it was totally left for dead. It was resurrected only in the 1970s as a stalking horse for decriminalization and legalization of marijuana. And it had a brief flurry of activity then that led to the publication of a book in 1976 called, "The Therapeutic Potential of Marijuana," edited by two of my friends, Sidney Cohen and Richard Stillman. And I just want to read one quote from this book.

I was head of NIDA, commissioned this book. This was 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 avoid the undesired ones will be preferred."

We haven't gone a long way since then in terms of our understanding of this. And I point out this was published -- it was actually the meeting 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 it's used much more intensely by much younger people than it was. In those days, it was primarily used by -- first used by people in their 20s and their late teens. And that is not the case now, it's used very early by very young people and often quite intensely.

Marijuana and the constituents in it is better understood from a biological point of view than any other chemical in the world. It has more research done on it. And you heard Dr. Volkow -- very proud that she is the fifth head of NIDA and is doing a wonderful job. And I support everything that she said today.

It is very well studied. And it may be that some of these chemicals will produce benefits. And I think she was eloquent in speaking about that. It is not conceivable that we're going to have smoking as a delivery system or 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. This is a toxic delivery system by definition. It is not scientific.

I was delighted to hear the FDA talk about -- Dr. Meyer talk about the FDA approval procedure and the fact that there is a procedure even for a botanical. But it would have to meet the standards of safety and efficacy to be approved. It has not met those. In my opinion it is not likely to meet those ever in the future.

This idea of **medical marijuana** is not a harmless idea.

DUPONT: 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 two years we have a downturn, and I am delighted to think about that. And 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.

SOUDER: I thank each of you for your testimony.

And I wanted to start with Dr. Scott and Ms. Jerzak. I am curious, because both of you are agents of your state government, and 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**.

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 is asking us to investigate FDA guidelines being violated because FDA would do those.

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

SOUDER: So you wouldn't take the FDA's position -- I mean, they said today there is no medicinal benefit to marijuana. There's 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? JERZAK: We would be looking at an individual case and not being proactively setting policy about FDA rules are being followed. The kind of complaints that we have got have not been characterized as your question would imply.

JERZAK: And certainly, we would 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.

SOUDER: How do you handle other non-FDA approved drugs? If somebody had -- you know, we had years ago, because I'm older -- laetrile was an argument. That do you have kind of random decisions if 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, then you look at it in the state context?

In other words, the FDA's standard of: This is not an approved drug, the federal standard this is an illegal drug, don't override state law?

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.

SOUDER: So there's a difference between a developing thing where there is not a stand and an illegal drug that the federal -- I mean, notification 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 local states didn't want to give minorities the right to vote. The local attorney generals and law enforcement people said: Well, our state law says blacks can't vote, so we're going to follow state law not federal, and we'll deprive them of the vote. But there is a federal law here. Furthermore, the health is clear. We just heard from the national researchers there's not a debate, that they are looking for ways to provide this.

And 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?

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 the pharmacy and get marijuana. You cannot buy it. You cannot sell it, OK.

The law was written that it allows the physician to discuss with the patient the use of marijuana that may be -- may be -- beneficial for their debilitating condition. And then the law went on to define what those specific debilitating conditions are.

And the law in Oregon says that this 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 physician has pain, for example, or nausea, for example, and then allows state law to do what it does.

And 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.

SOUDER: If the patient wants to get marijuana, does it have to be authorized by a doctor in Oregon?

SCOTT: That is correct.

SOUDER: So doctors do, in fact, have to authorize it.

SCOTT: They sign a -- it's written specifically this way. The physician signs a 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.

JERZAK: I would echo what Dr. Scott has said in terms of California.

JERZAK: 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 seriously ill to our licensed physicians to be the gatekeepers of describing that category of patients.

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?

JERZAK: Is that one of the what?

SOUDER: Is that an approved use?

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 a complaint about whether that was the appropriate care for those patients, what else has been tried? What did she explain as the risks and benefit ratio? What was the informed consent of those involved? What other treatment modality? How often they met in the context of medicine?

SOUDER: I'll come back.

Ms. Sanchez?

SANCHEZ: I thank the chair.

And before I ask questions, I just want to state that the reason I am here today is because the issue of **medical marijuana** use is very important issue to the people in my state. The voters of 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 am 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, raiding 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.

SANCHEZ: I'm thankful that this hearing has been called to explore science-based approached 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 in to my questions.

Dr. Jensen, is your testimony today that, under a physician's 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 or some other drug?

JENSEN: Well, as I said earlier, I only have a basis of two patients to discuss this issue with 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 Dexedrine, which is a very sophisticated form of amphetamine and very dangerous. I don't approve of Dexedrine, in general.

He had Ritalin. He had Adderall. 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; whereas this one particular boy who, by the way is 5-feet-11, 246 pounds 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 other medications for him.

JENSEN: But they don't have any desire to do it because of the side effects that he was suffering from the other medications. And now he is 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.

SANCHEZ: Thank you.

Dr. DuPont, I have a question for you. I am interested in knowing about 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.

DUPONT: I think it 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 it's going to be subjected to this FDA approval process. Should it go through that process, and I think it may very well successfully go through it, 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.

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 am interested in knowing specifically what the recommendations were that led to his suspension. And how did his recommendations adversely affect his patients?

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's available is that Dr. Leveque originally was disciplined by the Oregon Board of Medical Examiners approximately two years ago. And 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 a 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 two years ago.

SANCHEZ: Did any of the violations adversely affect the patients?

SCOTT: That's a matter that I can't answer.

SCOTT: His practice, quite honestly, was not as a primary care provider, but namely to sign these **medical marijuana** cards.

So he did not have an ongoing relationship with the patient. He was not monitoring the patients. And 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.

SANCHEZ: Thank you for your testimony.

SOUDER: Why don't you go ahead and finish your questions, and then I'll conclude.

SANCHEZ: OK, I thank the chair.

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

KAMPIA: Well, in the late '70s and early '80s, there were seven states, including California and New York, that did statewide research projects involving marijuana that came from the federal government. And 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 '82. And each of these states concluded their studies in '84 or '85, something like that. And they all issued reports.

And the reports showed that some patients benefited from Marinol pill. Some patients benefited from marijuana, but not the pill. And some patients benefited from neither, which is kind of what we see when we talk to patients, that 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. There's 10 or 11 studies going right now, I think, which was mentioned earlier today.

And there's been dozens of other studies done by private researchers here and there in the 1970s and early '80.

And those studies were all summarized by the Institute of Medicine, which released this comprehensive book in 1999. And 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. And 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, 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 turnaround if their physician and the patient decide that they need marijuana, that the federal government should give them the opportunity to use marijuana within 24 hours.

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

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

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

DUPONT: Well, the Institute of Medicine report -- I think there is some slippery words going on here. We talk about marijuana -- and you, Mr. Chairman, pointed this out. Much of the talk when you talk about **medical marijuana** is dealing with individual chemicals in it and not with the smoked marijuana.

And the IOM report specifically said with respect to smoked marijuana that smoking was a bad idea. And let me share this: "In summary, there are many reasons to worry that people who might choose to use marijuana as medicine, and 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 its the constituent chemicals like THC or others that are in there.

SOUDER: I thank you for clarifying that because it's something that we had some debates with the last administration who failed to note in some of their reports the correct distinctions.

And whether it is 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're trying to move ahead without smoked marijuana and in lower intensity even in the different pills and separate the components; in the Netherlands where a different government is in the process of trying to back up, which is now a mess in Amsterdam, they are attempting to isolate -- and don't get this confused with marijuana -- to say that there are substances in all kinds of things that have negative impacts on society.

And I appreciate you for clarifying that.

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

And that shows that their purpose is not medical. It's a way of influencing the country's policies toward marijuana. It's a stalking horse for legalization of marijuana.

DUPONT: The legitimization of smoking marijuana, you can see that very clearly, with how little interest they have in individual chemicals or any delivery system, any delivery system other than smoking. They're only interested in defending smoking.

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

(CROSSTALK)

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 hear, 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 to help people? Why are you mostly focussed on smoked marijuana?

KAMPIA: Alright, well, Dr. Dupont was wrong on two points. And this is answering your question, why has the IOM specifically recommended smoking marijuana, the word smoking marijuana is right among the word 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.

(CROSSTALK)

KAMPIA: I have a second part to my answer, which is that not all of our work actually has to do 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 its 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 prison.

Our position is: Let them do it while the research goes on, and do not arrest them.

JENSEN: Congressman, Senator, first of all, I wanted to leave this with you, if I might. This is a book from Dr. Mitch Earlywine. He is a clinical professor at University of Southern California, and he offered it to you. It's got some of the latest science on cannabinoids.

But 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 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, which 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 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.

SOUDER: Can I ask you a question? I hear your concern of the individual patients, but what's really hard for me to sort out in listening to this and 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 of whether people are saying a rolled joint or water pipe is most effective.

You're a doctor...

JENSEN: I want the science...

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

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

SOUDER: Note that they didn't...

JENSEN: He said so himself, that there are chronic pain, glaucoma -- there is proven evidence that it affects those conditions. By definition, it has medicinal value. It should not be schedule one.

SOUDER: By definition, there are 400 components of...

JENSEN: But the point is, why do you want to take and analyze out and define each component into a little pill that could be...

SOUDER: How about the...

JENSEN: ... sold from a pharmaceutical company when somebody can grow it themselves?

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.

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

JENSEN: Congressman Souder, and I am desperate for guidance from my peers. They are unwilling to give it to us.

In the absence of...

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

SOUDER: What you mean is you disagree with the experts who have done it, and you'd rather rely on people whose judgment you like better.

That is different.

JENSEN: The patients, Congressman Souder, I am a patient advocate. And even if one patient benefits from this drug, then it should never ever be schedule one, because schedule one means no medicinal uses.

And even if one patient is helped, we should help them.

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.

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

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

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 have abused marijuana and are driving and endangering other drivers.

It's more complicated because -- well, alcohol -- excess in alcohol has an immediate, devastating impact on impairing a driver. It also doesn't stay in the system as long, which is also why it doesn't have the same accumulative, negative effect.

My question -- and I don't know the answer to this, and it's dangerous to do 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 from the marijuana?

Because what I don't understand is if the marijuana stays in your system 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. And then 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 we're not going to do a hair follicle test.

DUPONT: Mr. Chairman, I mentioned that I'm the president of the Institute for Behavior and Health. And this is one of our two top priorities is to bring to bear testing and law enforcement in the drug driving field as we have in the last two decades with the drunk driving.

It is a major problem. Highway safety adverse effects of illegal drug use are equal to, or the same scale as, in some cases higher than associated with alcohol consumption. So this is a national problem that has not been addressed. And the drug testing technology does let us do that.

But there is a step here 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.

DUPONT: 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. And the technology is there to do that now.

And I am thrilled, delighted with your interest in this. It is extremely timely. It is going to make a huge difference of 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 workplace. That's what goes on now with people who do drug testing.

Millions of American workers are drug tested. 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.

SOUDER: Thank you. And I think that's the way we have it in Indiana. And I know there's 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. There's a case in Oregon that questioned whether it could be enforced if the person had a **medical marijuana** prescription.

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 in that, and that is a violation of the standard.

And so even if you have a medical certificate, it's a violation and you use you license and right to drive. That's my understanding of the law.

SOUDER: I think it was a local court that challenged that like in the last...

DUPONT: Well, but that has been the Department of Transportation standard. And the previous administration took that position. And this administration takes that position.

There may be something that has 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 Gore (ph) administration.

SOUDER: Yes. 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 that -- I'm very concerned about, because if you could have this medical waver and then be driving a truck, we have a huge loophole here unless we very tightly limit which I know that the state boards are trying to do to get to the abusive excesses of this.

At the same time, unless we radically control this and somehow get over this idea of states' rights nullifying federal law, we're in deep trouble in laws like that.

Well, I thank each of you for coming today. If you have any additional comments you want to put into the record, I appreciate us having a continuing debate. And I'm sure it won't have ended today.

With that, the subcommittee stands adjourned.

END

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