REP. ROBERT C. SCOTT HOLDS A HEARING ON THE DRUG ENFORCEMENT ADMINISTRATION'S REGULATION OF MEDICINE

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SPEAKER: REP. ROBERT C. SCOTT, CHAIRMAN

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WITNESSES:

- JOSEPH T. RANNAZZISI, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION, U.S. DEPARTMENT OF JUSTICE
- DAVID MURRAY, DIRECTOR, COUNTER DRUG TECHNOLOGY, WHITE HOUSE OFFICE OF NATIONAL DRUG CONTROL POLICY
- EDWARD J. HEIDEN, HEIDEN ASSOCIATES INC., WASHINGTON, DC
- VALERIE CORRAL, FOUNDER OF WAMM, WO/MEN'S ALLIANCE FOR MEDICAL MARIJUANA, DAVENPORT, CA
- SIOBHAN REYNOLDS, PRESIDENT, PAIN RELIEF NETWORK, SANTA FE, NM
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(CORRECTED COPY: CORRECTS SPEAKER LIST)

HOUSE JUDICIARY COMMITTEE, SUBCOMMITTEE ON CRIME, TERRORISM AND HOMELAND SECURITY HOLDS A HEARING ON THE DRUG ENFORCEMENT ADMINISTRATION'S REGULATION OF MEDICINE

JULY 12, 2007

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SCOTT: The subcommittee will now come to order, and I am pleased to welcome you today to the hearing before the Subcommittee on Crime, Terrorism and Homeland Security on the Drug Enforcement Administration's regulation of medicine.

The subcommittee has received numerous complaints about the Drug Enforcement Administration's regulatory hearings and at this hearing we will focus on three areas: OxyContin action plan, Operation Meth Merchant and prosecuting medical marijuana patients.

When it was first introduced, OxyContin abuse became rampant in such areas as Appalachia and rural New England. DEA responded by adopting the OxyContin action plan, which involved prosecuting medical doctors who prescribed high doses of painkillers.

The DEA claims that this policy was not intended to impact the availability of legitimate drugs necessary to treat patients, however, the evidence suggests that the DEA's decision to prosecute doctors has created a chilling effect within the medical community, so that some doctors are unwilling to prescribe pain medication in sufficiently high doses to treat their patients. The result is that many Americans live with chronic untreated pain.

The second issue is the DEA's Operation Meth Merchant, a campaign whose goal is to foreclose the sale of ephedrine in convenience stores and other small businesses, which the DEA refers to as gray markets. The DEA bases its policy on the belief that these businesses are the sources of material that is used to manufacture methamphetamines.

However, there is evidence that DEA's policy is based on faulty science and that the DEA may be engaging in racial targeting. For example, in 2003, the DEA charged 49 store clerks and owners with selling materials used to make methamphetamines. Surprisingly, 44 of the 49 defendants were Indian immigrants who spoke broken English.

The immigrants claimed know knowledge of the illicit drugs, including the methamphetamines.

Now, finally, the third issue is the DEA's policy of prosecuting medical marijuana users based on the scientific conclusion that marijuana has no known medical benefit. The federal government has a monopoly on growing marijuana for research purposes and this practice has discouraged research into the efficacy of medical marijuana, so that little progress has been made towards determining if medical marijuana could meet the FDA's approval standards.

Recently, a DEA administrative law judge ruled that it was in the public interest for researchers to be permitted to grow marijuana, and she recommended that the DEA grant a permit to a University of Massachusetts professor. The DEA has yet to decide whether it will follow the advice of the judge, which could open the area for beneficial medical research.

Lastly, the FDA has continued to federally prosecute people who use medical marijuana legally in their states, according to state law. A well-known case is that of Valerie Corral, who will be testifying before us today.

She and other patients at her hospice were arrested by armed DEA agents. Even if the law technically gives DEA the authority to investigate medical marijuana users, it is worth questioning whether targeting gravely ill people is the best use of federal resources.

There's been little or no oversight in the DEA during the last 12 years. In 1999, the GAO issued a report that was highly critical of the DEA. The report said that the agency had no measurable proof that it had reduced illegal drug supply in the country.

The DEA's use of heavy-handed tactics and its decisions to investigate and prosecute people for illegal but minor conduct is perhaps a response to that report.

Regardless, it is important that the agency have the opportunity to explain its decisionmaking process and we hope that this hearing will be the beginning of that dialogue.

And, with that said, it's my pleasure to recognize my colleague from Virginia, the ranking member of the subcommittee, the honorable J. Randy Forbes, who represents Virginia's fourth congressional district.

FORBES: Thank you, Mr. Chairman, and I appreciate your holding this oversight hearing on the Drug Enforcement Administration. Today's hearing will focus on implementation and enforcement of the combat methamphetamine act, which was passed as part of the PATRIOT Act Reauthorization and Improvement Act; medicinal marijuana; and pain-relief medication.

I understand that additional oversight hearings will be held so that we can focus on important issues, such as enforcement of the narcoterrorism and criminal prohibition, which was passed as part of the PATRIOT Act reauthorization; illegal drug-trafficking

activities along the Southwest border; and DEA enforcement against major drug-trafficking organizations and violent international and domestic gangs.

The combat meth act was a bipartisan measure to stem the growth and spread of meth across our country. From all accounts, the act has been successful in reducing the number of home-grown methamphetamine labs in our country.

However, as we have reduced domestic production of meth, Mexican super-labs have increased and illegal smuggling of meth has grown. This highlights two important points. Border security is needed, not only to reduce illegal immigration, but to protect our country from illegal drug traffickers who systematically smuggle large quantities of meth in our country. And new tools and resources are needed to improve enforcement against Mexican super-labs.

That is not the focus of today's hearings. While domestic enforcement against the precursor industries is important, I still think we need to address border security and drug-enforcement priorities.

On the two other topics of medicinal marijuana and pain-relief treatment, again, they are important topics, but they pale in comparison to...

(CROSSTALK)

SCOTT: The gentleman yields back his time, and I would respond by saying that I think just all of the hearings that you have suggested are on the agenda to be planned. One, you mentioned gangs. We'll be having a juvenile justice and joint (ph) committee prevention act (ph) oversight hearing with the Education and Labor Subcommittee this afternoon.

Having two committees on the same day is what we're having to do to try to get in all the appearances (ph).

(UNKNOWN): Mr. Chairman, this is kind of a break of order kind of thing, but apparently we're hearing some other hearing, which is distracting us...

SCOTT: They're working on it now.

(UNKNOWN): Because I wanted to be able to hear everything you said.

SCOTT: They're working on it from the seat of the chair. We're working on that now. I'll introduce the witnesses.

Without objection, the other opening statements will be included for the record.

We have a distinguished panel of witnesses before us today, and I want to apologize because I have another meeting that came up and I will be leaving and I'll be coming

back, and I did read everybody's testimony last night. So when I come back, I'll know what you have said.

The first witness is Joseph T. Rannazzisi. He holds a B.S. degree in pharmacy from Butler University and J.D. degree from the Detroit College of Law in Michigan state University, is a registered pharmacist in the state of Indiana, a member of the Michigan State Bar Association. He began his career with the U.S. Drug Enforcement Administration in 1986.

In 2006, he was appointed to the position of Deputy Assistant Administrator for the Office of Diversion and Control, where he's responsible for overseeing and coordinating major diversion investigations, among other duties.

The second witness is Dr. David Murray, who received an M.A. and Ph.D. from the University of Chicago, subsequently taught at Connecticut College, Brown University and Brandeis University before coming to Washington, where he has served as an adjunct professor in the Graduate School of Public Policy at Georgetown University.

He co-authored most recently the book, "It Ain't Necessarily So," how media remakes the scientific picture of reality. He has served as special assistant to the director of the ONDCP, the drug office in the White House, and currently is the director of Counterdrug Technology Assessment Center.

Next witness is Edward Heiden. He received his Ph.D. in economics from Washington University in St. Louis, specializing in industrial organization. He is also a Woodrow Wilson scholar at Harvard University. He is president of Heiden Associates, the Washington, DC, economic and product safety consulting firm, and he has directed studies on health, safety and environmental regulation and economic issues for numerous private and government clients. He testified as an expert witness before a number of courts and administrative and regulatory agencies.

Prior to becoming a consultant, he held a number of senior positions in federal government, including chief planning economist at the Federal Trade Commission and the White House Office of Consumer Affairs.

Next to testify will be Valerie Corral, founder of WAMM, the Wo/Men's Alliance for Medical Marijuana. For 14 years, WAMM has provided seriously and terminally ill patients with medical marijuana at no cost. It is the longest-running medical marijuana provider in the nation and for a time had the only legal garden in the nation.

It was instrumental in the passage of Proposition 215 and most recently was involved in the federal lawsuit Santa Cruz versus Gonzales. She is appointed by the California state attorney general to the medical marijuana task force and served on the commission for three years.

Next will be Siobhan Reynolds, who graduated with a B.A. in political science from Pitzer College and received her M.A. in liberal education from St. John's College in Santa Fe, New Mexico. She has a masters degree in fine arts from Actor's Studio Program in New York City.

In the mid-1990s, Ms. Reynolds became aware of the lack of available pain care in the United States, and after marrying Sean Greenwood, a man with an undiagnosed congenital connective tissue disorder. She discovered that it was impossible to secure treatment for her husband.

Following the eventual death of her husband in August of 2006, she organized the Pain Relief Network to redouble its efforts to help people suffering from chronic pain.

Lastly, John P. Flannery, who holds a bachelor's degree in physics from Fordham and bachelor's degree in industrial engineering from Columbia and a law degree from Columbia and master's degree in information science from George Washington graduate business school.

He is a former federal prosecutor from New York, has held a number of positions on Capitol Hill. His most recent position was chief of staff for Congresswoman Zoe Lofgren, a member of this committee.

After leaving Congress, he returned to practice law with Campbell Miller Zimmerman, where he has represented several doctors in cases involving prescription of pain medication. He is the author of the book, "Pain in America -- and how our government makes it worse!"

Each of our witnesses' written statements will be made part of the record in its entirety. I would ask that each witness summarize his or her testimony in five minutes or less.

And to help the witnesses stay within the time, there is a timing device just in front of us. The light will go from green to yellow with one minute let and, finally, to red when five minutes are up.

Administrator Rannazzisi.

RANNAZZISI: Thank you and good morning, Chairman Scott, Ranking Member Forbes and distinguished members of the House Subcommittee on Crime, Terrorism and Homeland Security.

On behalf of Administrator Karen P. Tandy and the men and the women of the Drug Enforcement Administration, I want to thank you for the opportunity it discuss and hopefully resolve some misconceptions about DEA's enforcement of its statutory obligations.

I would like to comment at the outset, that the title of this hearing, "DEA's Regulation of Medicine," is inaccurate. DEA does not regulate medicine or the practice of medicine.

DEA does investigate violations of the Controlled Substances Act, regardless of the source of the violation, be it a Columbian cocaine dealer, a marijuana trafficker or a doctor who abuses the authority to dispense controlled substances. DEA's mission statement is more than a cliche crafted to meet public relations need or strategy directive. It is the essence of the agency.

The statement begins, "The mission of DEA is to enforce the controlled substances laws and regulations of the United States of America." It is with that mission in mind that the agency conducts its work against methamphetamine manufacturers, illegal prescription drug suppliers, marijuana distributors and others who violate the Controlled Substances Act.

In the 1990s and early 21st century, America watched a home-grown epidemic in the form of methamphetamine spread across the nation. Unlike most other illicit drugs, methamphetamine is easy to make from inexpensive, readily obtainable chemicals.

Accessibility of precursor chemicals caused a boom in the number of small labs that fed a growing addict population. The need to control access to these chemicals resulted in the passage of the Combat Methamphetamine Epidemic Act. This law complemented similar efforts by states and provided tools for federal law enforcement and regulators to monitor precursor sales at the wholesale and retail levels.

Through these legislative efforts, DEA has seen a 58 percent drop in laboratory sites seized in 2006 over those of 2005. Equally important to this dramatic reduction in lab sites is the fact that agents and officers can now direct their law enforcement efforts elsewhere.

Investigations involving methamphetamines labs and their subsequent clean-ups have traditionally consumed a significant number of man hours and have caused considerable drain on governmental resources.

The increasing abuse of prescription drugs is one of the most significant challenges DEA is currently facing. As you know, one of the administration's goals is to reduce the abuse of prescription drugs by 15 percent between 2005 and 2008.

This requires DEA to prevent to the diversion of pharmaceutical drugs, while ensuring an adequate supply for legitimate needs. We know that the diversion of pharmaceuticals occurs from a number of sources, including a small number of unscrupulous doctors.

That said, doctors should not hesitate and should continue to provide their patients with whatever treatment they feel appropriate, as long as it's for a legitimate purpose and done in the usual course of medical practice.

Generally speaking, in any given year, DEA arrests less than 0.01 percent of the 750,000 doctors registered with DEA for a criminal violation. More often than not, those violations are egregious in nature and are acts clearly outside the usual course of accepted medical standards.

Examples of these acts include such things as trading drugs for sex, self-abuse of drugs and trading prescription drugs for crack cocaine. Illegal Internet sales, fraudulent prescriptions and outright theft are other ways that drug dealers are able to illegally provide prescription drugs to addicts.

No one should underestimate the potential damage that these substances can do when taken improperly. DEA has recently taken several steps to assist doctors in understanding the expectations of the law and aid them in meeting these requirements.

While there are always those on the fringe who think the laws should not apply to them, the steps that DEA has taken have generally been met with expressions of approval and even appreciation. Most medical practitioners, particularly those who specialize in the treatment of pain, are tired of a few bad physicians giving their entire profession a bad name.

DEA believes that the efforts it has made, including issuing a policy statement reiterating the requirements of the Controlled Substances Act and proposing a rule that would allow doctors to issue multiple schedule two prescriptions for up to a 90-day supply in a single office visit has significantly improved the medical community's understanding of what are and are not the legitimate ways to prescribe controlled substances.

We believe these efforts will assist the medical community to perform their responsibilities and understand the law.

Similarly, understanding DEA's activities regarding marijuana can also be traced back to our defined legal authorities. Like heroin and LSD, marijuana is listed by law as a schedule one controlled substance.

Approval to conduct research using any schedule one substance, including cannabis, is a process in which both DEA and the Food and Drug Administration play a role. The FDA reviews the merits of the protocol, qualifications and competency of the applicant, while DEA determines the adequacy of the necessary security arrangements.

Once these reviews are completed, DEA can issue a registration. DEA cannot make a judgment as to the legitimacy of the research, and DEA has never denied registration to a researcher whose application has been approved by the FDA and who has had adequate security to prevent diversion of controlled substances...

NADLER: Thank you.

I now recognize Dr. Murray for five minutes.

MURRAY: Thank you very much, Mr. Chairman, in absentia, Ranking Member Forbes and distinguished members of the House Judiciary...

NADLER: You need to speak up and speak to the microphone.

MURRAY: Indeed -- and Judiciary Subcommittee on Crime, Terrorism and Homeland Security. Thank you for the opportunity to appear before you today to discuss our national efforts to reduce drug use in America and to discuss federal drug policy regarding medical marijuana under state law, or so-called medical marijuana.

I do want to stress that their is good news out there. Let's not lose track of that, regarding the drug war. Youth use of all drugs is down by 23 percent over the last five years. Youth use of marijuana is down by 25 percent.

Youth use of specific drugs such as methamphetamine is down by over 40 percent. Yet, against this backdrop, we face a stubborn debate that is ongoing for quite a while regarding the status of claims that marijuana is somehow an acceptable medicine.

It is not the medical community, Mr. Chairman, who pushes this issue. It is not the medical community who identifies a need out there for a smoked weed to alleviate pain and suffering. Rather, this is an issue that is pushed overwhelmingly by legalization advocates for marijuana who fund initiatives and referenda in various states, trying to push through what we think is a troubling development.

First of all, let us reiterate, there is no evidence by the bodies that are charged with making this determination that marijuana is effective as a medicine for any medical condition and no evidence of marijuana's safety. That is why it remains in schedule one, as approved by the FDA and as judged by the DEA, as a substance without medical utility.

Moreover, there are superior substances already available in the medical community for treating the diseases for which marijuana purportedly is efficacious.

Secondly, the charge to medicine is first do no harm. There is increasing scientific evidence that marijuana actively is harmful to those for whom it was intended to be a healing device.

In fact, the evidence of smoked marijuana, a contaminated product of raw weed with carcinogens in it and the active ingredients themselves produce effects...

NADLER: Mr. Murray, do you think it's as harmful as nicotine.

MURRAY: Sir, if you're looking at the issue of an approved medicine that would be used -- excuse me, sir.

FORBES: Mr. Chairman, a point of order. Mr. Chairman, can the witness make his statement and then we...

NADLER: I just wanted to ask him that one question, because he was saying how harmful it is. I think he's correct...

FORBES: Can we not take away his time.

NADLER: I'm not going to take away his time. I just asked to answer that question, and we'll give you the time.

FORBES: Well, just I'd like to request regular order, Mr. Chairman. That's highly irregular.

MURRAY: Thank you, sir.

I believe they present different threats in different communities. There is no effort to say that nicotine should be treated as a medicine and dispensed for the cure of cancer. That's because, in its smoked form, it's quite virulent and quite troubling.

Marijuana, however, likewise, is a smoked weed that that is offered as though it were therapeutic and efficacious, as though it had healing powers. The active ingredient in marijuana, increasingly, science has shown, is a risk-producing substance that is an intoxicant, that produces dependency and withdrawal.

It's an addictive substance that has impact, particularly on the vulnerable. Those with psychotic predispositions, those with inclinations towards depression, towards schizophrenia, they are profoundly affected by this drug and it is risky to them actively.

It should not be treated as though it were benign. It is a dangerous substance that produces active harm to those for whom it would be offered.

Moreover, the presence of medical marijuana dispensaries in communities themselves turns out to be a harmful dimension. Increasingly, we are learning that these dispensaries are fronts for, increasingly, drug-dealing crime, that they are neighborhood nuisances, increasingly associated with high crime, with noise, with disruption, that communities increasingly are turning against and troubled by.

We are seeing evidence, moreover, from time to time, that the medical marijuana movement has not been driven by medicine but has been driven by politics and by many instances taken over by criminal elements that are quite dangerous.

We think that, basically, you're going to hear forms of argument that will anecdote. Tragic tales of suffering, no matter how genuinely believed in, no matter how emotionally laden they may be, that is not the way we make public policy decisions about what is an approved medicine -- by tragic tales or by accounts of suffering.

Rather, it is in a court of medicine and in a court of science that a drug is approved as being safe and effective and marijuana has never been able to successfully pass that test.

What we're going to hear will be arguments that somehow we should get out of the way and let marijuana be offered as medicine. We think this is a fraud. We think this is a misrepresentation.

The medical marijuana movement is at best a mistake, at worst, a deception, and it has another victim involved here, the integrity of the drug approval process in America, which is entrusted to the FDA, has kept America safe with regard to its medicines.

We should not bypass that. We should not political theater -- or political pressure groups try to approve medicines, which in fact damages the integrity of our drug approval process. If and when marijuana has substances in it that are shown to be efficacious, therapeutic, it will be done in the scientific community, and it will not be offered in the form of a raw, crude, smoked weed.

We know this from the scientific community. We know this from the medical community. And the people pushing for this are cynically manipulating tragic tales of suffering in such a way as to create -- and not win in a court of medicine and science.

I'll be happy to answer your questions, sir.

NADLER: I thank the gentleman.

I now recognize Dr. Heiden for five minutes.

HEIDEN: (OFF-MIKE) Homeland Security Subcommittee.

NADLER: Sir, could you speak to the mike, please?

HEIDEN: OK, is this better?

I appreciate the opportunity to appear before this subcommittee to present my views regarding various activities of the U.S. Drug Enforcement Administration.

My name is Edward J. Heiden. I'm president of Heiden Associates, an economic consulting firm specializing in health and safety issues and located in Washington, D.C.

Early this year, my firm and I were retained by the American Council on Regulatory Compliance, ACRC, an association that represents suppliers of pseudoephedrine and ephedrine-based products, such as over-the-counter cough and cold and asthma relief medications and whose members sell primarily to convenience stores and other non-mass merchandiser channels.

Our assignment was to help them respond to a DEA draft report published for comment in the Federal Register that contained DEA's 2007 national estimate of legitimate medical need and use for ephedrine and pseudoephedrine and prescription drug and over-the-counter products.

We were asked to examine two issues, the soundness of the data and methodology used by FDA to prepare the report and the estimate and whether the legitimate supply needs of ACRC member firms for ephedrine-based products to sell had been adequately taken into account by the DEA draft needs assessment.

ACRC members were seriously concerned that their needs were not being adequately considered, if at all. A few of them indicated that they had not been consulted -- many of them indicated they had not been consultant as the needs assessment was being prepared, and a few indicated, once they saw the assessment, that it was far less in total for the country as a whole than just their own sales to convenience stores and other non-mass merchandising channels.

Let me briefly summarize our work. DEA's assessment relied on a study by its contractor, IMS Health Government Solutions, to estimate medical needs for ephedrine and pseudoephedrine, based on data the company routinely collects on sales to retail establishments, patients and insurers.

The problem with this data is, and the report of DEA, that it was very sparse and provided very, very incomplete documentation as to its methodology, as to how the data was used. And, like much of the evidence that an interested and engaged analyst would need and expect to have to determine exactly how that methodology was applied, elementary materials such as key data files were not there, were missing. And, in one important instance, the agency refused to provide us and ACRC with access to a key set of spreadsheet data.

Likewise, DEA's treatment of how the needs of the convenience store market channel was treated in its national estimation process is vague and confusing. Even though convenience stores are mentioned by DEA as a channel that was included in the study, there is no way you can tell exactly how they were included.

In fact, as a starting point of data that we got, we obtained from DEA a copy of the product code listed by DEA's contractor for the study, IMS. Reviewed by industry numbers, it showed that not one of the ACRC member products was included in the initial DEA product inventory used to develop sales estimates for the ephedrine and pseudoephedrine needs assessment.

So none of the products was considered to be in scope for purposes of development of that needs assessment and not one of them, as I said, had been queried by DEA or its consultant as part of the needs assessment development process.

So we conducted our own study of ACRC needs and sales by working with industry members to give us such sales on a confidential basis and then consulting with the board members to determine what this was. ACRC member firms told us when we aggregated the data that, collectively, the products they sold to convenience stores and other channels represented a tremendously large amount more, seven times more, than the amount DEA proposed as its preliminary 2007 annual needs assessment.

How could something like this happen? How come the DEA study missed such a large part of the overall market for ephedrine-based products of convenience stores?

I think there are several possible reasons why DEA might have missed so much ephedrine-based products sold through non-mass market merchandising channels. First, many of the companies involved in making it and marketing it...

NADLER: The witness's time has expired.

Could you wrap up, please?

HEIDEN: Well, as I said, there are several reasons why this might have happened: technical, economic reasons. But, in conclusion, I would say that besides not documenting the procedures and denying access to data that could have indicated what was happening in this situation, it's quite obvious that this failure has caused DEA to propose an unrealistically low preliminary estimate for the amount of ephedrine required for legitimate needs.

If this estimate stands as the basis for DEA decisionmaking, substantial hardships are likely to result, not only for numerous suppliers in the distribution chain and those who are employed by them, but also for the many asthmatics and others in legitimate medical need who rely on convenience stores and small retailers in locations where other retail outlets, like mass merchandisers, Targets, et cetera, are nonexistent or are only open during daytime or early evening hours.

NADLER: Thank you very much.

I will now recognize Ms. Valerie Corral for five minutes.

CORRAL: Thank you.

NADLER: Talk a little louder, please.

CORRAL: Thanks to the honorable chair and distinguished -- it's not on. Thank you.

There we go, thanks.

Honorable Chair and distinguished committee members, I thank you for this opportunity to speak before you today. I am Valerie Corral and I am the co-founder of the Wo/Men's Alliance for Medical Marijuana, with my husband Mike Corral.

We reside in Santa Cruz, California. We run a medical marijuana hospice facility and we've done so since 1993. Following an automobile accident in which I happened to be in, with an airplane, my life changed dramatically.

I became an epileptic and suffered as many as up to five grand mal seizures a day. In the early '70s, under the Nixon administration, some research was being done. However, President Nixon's administration blocked that research.

But, prior to that, my husband had read in a medical journal that marijuana had been successfully used to treat laboratory-induced seizures in rats. It was really quite unbelievable that marijuana might control the seizures that I was experiencing, when FDA-approved medicines could not. In fact, I did not believe it, at first.

As time passed, our experience led us to quite a remarkable healing, if you will. I still experience some difficulty, neurological problems. However, I don't have seizures.

This also led us to work more broadly in our community. People who lived in our community contacted us about the possibility of working with them, and we began this small outreach program by growing a collective garden of medicine in which our members or their caregivers participated.

This is quite remarkable -- over the 14 years that we have conducted our operation, 189 of our members have passed. That gives me, while not the experience of dying, quite a remarkable experience, that which most people don't have the opportunity to participate in.

And what we found is that each of our members -- and not everybody that comes to WAMM finds marijuana to be a useful medicine. However, those that stay with us do.

These 189 people, of which I've been at the bedside of more than 100, tell us that it works. And while Dr. Murray has expressed in his testimony that patients say we feel better, I ask the committee, isn't that really what every doctor asks? Do you feel better? Is the medicine working? And when we say yes, doctors believe us. Why not with this medicine?

When I received confirmation that I'd be here today speaking before you, I was at the bedside of a dear friend of mine of more than 30 years. Little did I know that she would become a WAMM member.

She lay dying of ovarian cancer. She is the single mother of a 15-year-old daughter. That child grew up in our collective, respecting her mother's medicine, understanding the

difference between an abuse and a recreational drug and a very important, life-altering medicine, pain-relieving medicine.

In a word, I cannot call the members of my community liars. We have worked diligently since the early '90s on state law, on county law and on city law. We work very close with law enforcement. We're transparent in our work and we offer medicine at no cost.

We've changed the laws in each governing body, very slowly, but it has worked. We've convinced people of our truth by living in this transparent reality.

In 2002, the DEA raided our small collective, arresting both my husband and myself and this set our members into a panic, as you might imagine. Yet, while illness is a great enemy, fear is even greater. And we continued our work, as we do to this day.

It is not that we wish to break the law, for surely we do not. We've made every effort to change it.

I ask for a few things here today. One is that I realize that I can't change America. I know that. But there are simple things that we can do to relieve human suffering.

When you stand next to a person who's dying, and I suspect that all of you have had an experience, or will, that it changes you. You do what you can to relieve that suffering.

We use allopathic medicines, pharmaceuticals, of course. They are remarkable pain relievers and assist people in expanding their lives.

But what we ask here today is that you stop the aggressive antics of the DEA against sick and dying people, because that is what we are. Stop the raids. Allow research to continue. Allow the research to continue that the DEA is blocking in the Craker case, for instance, because only you can do that.

We offer you our testimony and we offer you the truth, and we ask that you allow us the opportunity to relieve our suffering, because only can do that.

Thank you.

NADLER: Time of the witness has expired. You may conclude.

CORRAL: That's it, and thank you so much.

NADLER: Thank you very much.

We'll now recognize...

REYNOLDS: Siobhan.

NADLER: Siobhan.

REYNOLDS: It's Siobhan.

NADLER: Ms. Siobhan Reynolds, for five minutes.

REYNOLDS: Thank you, Mr. Chairman, Mr. Ranking Member, members of the committee.

I'm not going to go into the really sad story of my husband's death and everything that we endured leading up to it. It's in my testimony, and I hope you'll read it.

What I am going to go into is how my community perceives the DEA's behavior over the last 12 years, specifically, really, though, since 2001, and ask you to intervene and to stop what we feel is an outrageous crackdown on the medical treatment of pain.

The DEA contends that they only prosecute 0.01 percent of registrants. However, that's a misleading figure, because a very small number of registrants prescribe opioid medicines and an even smaller number would prescribe in doses that would relieve serious pain.

So the actually number of doctors who are arrested is far greater, when you look at the correct denominator, which this leads me to my next point, which I think is really the most important point. This is a government agency that plays fast and loose with the facts, uses incredibly inflammatory rhetoric, talks about crime and addiction and dependence and puts them all together and maybe has no cognizance of the fact that this all ultimately falls on and stigmatizes very, very sick people. But that is in fact what happens.

So people go to their doctors or they go to their pharmacists. And the fear that physicians actually have toward the DEA is expressed as hostility and brutality toward patients. There are several articles that I could show you in medical journals, one in particular that I gave to the committee, called "Pitfalls in Pain Management," where it's very openly discussed that physicians who treat pain view their role as very much prison guards, or captors, of pain patients.

Now, Congressman Forbes, I just wanted to address the underlying assumption that you expressed, in that you think it's important to treat pain, but we have to not interfere with the underlying goals of drug control, or something like that.

I just want to say that I think that that fails to respect the idea that our country was founded on, which is that each individual matters and that the individual in this country is sovereign. And what's happening is that people are being sacrificed to this goal, which it seems to me to be illusory and un-winnable.

I don't know if you can imagine what it's like to have your husband or your wife or your son or your daughter sacrificed to an un- winnable goal. But, when you're an American,

at least for me, I thought that my individual existence and that of my loved ones and my countrymen really did reign supreme.

And so here I am, bringing you evidence that 10 million Americans live in out-of-control pain, and that was prior to the Bush administration crackdown, so we have no idea how bad it is now. And you have to realize that there are no suicide statistics kept in the United States for people who commit suicide as a result of untreated pain.

We see untreated pain pushing the assisted suicide agenda, we see untreated pain causing enormous costs to the medical community. We see physicians maybe unwittingly, but taking advantage of patients who would otherwise choose to treat their pain instead of, for instance, having extensive surgeries or what not.

So I just want to say that there are tremendous consequences to the actions that are taking by the Drug Enforcement Administration and I think that if we're going to take a responsible view and the country is going to look at what is genuinely going on here, that you will allow my community to speak out and to make what's happening known.

And that is that people who are in pain are being set upon by SWAT teams and we really need your support and we're asking you to put an end to it as soon as possible. Thank you very much.

NADLER: Thank you.

And we'll now recognize Mr. John Flannery for five minutes.

FLANNERY: Thank you, Chairman Nadler and Ranking Member Forbes and the rest of the committee and those in attendance today. I want to thank you for giving me an opportunity to address a critical issue.

I want to commend the committee and the Congress for showing oversight of DEA. For too long, the DEA and the department in which it serves has not been held accountable for its acts. And I want to commend you for taking a look at these very difficult issues.

The title of the hearing, which is the regulation of medicine by DEA is an apt one. Unfortunately, it is an apt one. And DEA has been regulating medicine, and for them to come here and say that they don't know it means that they either are consciously doing it or recklessly doing it. And I can't believe they're doing it recklessly, because we see the quality of people who work at the department.

And that means there's an ideological purpose in regulating medicine. They do not approve of certain medical practices. And, if that is it, they should bring it to the Congress and tell us why, with statistics and explanations, because then it should be a formal policy rather than the secret one that it is presently.

We had a comment earlier that we're not here to deal with compassion. Well, I do not understand what a democratic government does if its policies do not reflect policies that show compassion and fairness and justice. And the DEA has become the residual location of a place where it lacks compassion, has a very harsh policy and is compromising the health of Americans and has been doing so for years.

We have fewer physicians in this country who dare treat chronic pain than at any other time in the last 50 years. And we have a population that is living longer and more susceptible to pain and more in need of treatment and pain medication than at any other time, perhaps, in American history.

And, at this point in time, we have to look at the underlying enforcement structure. Because if the underlying enforcement structure is not addressing crime and it is addressing and compromising our health, then it has to be reformed or it has to be replaced, but it cannot be suffered any longer.

We have seen in this country, and the DEA doesn't recognize this, a paradigm shift in our medical treatment. We used to do it, if you want to compare it to the industrial age, we think of it in terms of mechanical things.

But, increasingly, it's become chemical. It's become digital. It is even more microscopic, which reflects a much more sophisticated kind of machinery. But we don't see a reflection of this in the acknowledgement in our enforcement mechanism.

There are studies from Sloan-Kettering that tell us that 98 percent of people who knock on the door of every physician are serious pain patients. They are not faking it.

Two percent of those patients may have a problem with addiction if they're not careful, but they also have pain. Physicians across this country, by nature and by practice, trust the people who come to them.

In other words, they can't tell and say 80 percent of the back pain cases that the person is faking it, because there is absolutely no identifiable way, by any imaging device, to tell that they are or are not in pain.

The government says that we have a standard and we're enforcing the law. Well, we have to look at the different between the words that they say they're enforcing and what they're actually doing. This is a bait and switch.

The bait is we have a statute that this Congress passed. Then we have a Supreme Court case of 1975, the United States against Moore, that says what the standard is, that you have to act outside the course of professional medical practice with the intent to push drugs, not treat.

Today, the DEA said to us outside the course of standards. Even today, the person charged with telling us what is the law and enforcing it can't state it, because they enforce

it as they stated it here today. They create these standards on a case-by-case basis. It tells you that they make it up.

The juries in this country get the most complicated instructions in this case and they are told there is no standard. We make it up case by case. And how do they do that? They bring a doctor into the courtroom that they pay, who travels around the country, and the standard is created on a case-by-case basis by the DEA doctor.

And take the case that I cited in my testimony. In the case of Dr. McIver, serving 30 years in prison because of an incompetent government doctor who says that the standard is an ever-changing modality. Whatever happened to criminal law?

In the first year of criminal law, we're taught strict construction, errors are in favor of releasing the guilty. We have an ever-changing modality and we have a doctor who based on his testimony -- we have a doctor who is, quote, "the expert," who says, "My doctor didn't look at charts," when he doesn't look at charts to give his opinion.

So let's examine what we have to do to look at the underlying enforcement structure. We have a failure give constitutional notice of the crime that we're enforcing. That's got to change.

We seize a person, a business and his property when the person has been innocent, has been charged, has not been convicted of anything. There's a presumption that we should punish him before we've proven a single thing.

We ambush the defendant at trial with prejudicial hearsay and experts who say whatever they have to do in each individual case. In short, we have a lot to do.

I refer you and commend you to review my testimony. I thank you for the opportunity to appear here today and I commend you for scrutinizing, finally, once and for all, the terrible, unaccountable behavior of the DEA.

NADLER: Perfect timing. I thank the witnesses for their testimony. It was perfect timing. The chairman has returned. I have to go to a TV interview.

I'll give the chairman back his chair to direct the questioning.

SCOTT: I want to thank the witnesses and apologize for my absence. I'll recognize myself for five minutes.

I'd like to ask, I guess, Dr. Murray, in terms of policy, what the public policy imperative it is to deny terminally ill patients the right to both marijuana, if they believe that it's going to help them, they believe that it reduces pain, terminally ill patients?

MURRAY: Thank you, Mr. Chairman.

The public policy imperative, actually, there are several. One of the first is the status of marijuana as the most widely abused medication claim in the United States.

It's a drug that's addictive. It is the leading prevalence rate drug for abuse and dependency, particularly for young people, causing more than 60 percent of treatment admissions for drug dependency.

Marijuana more readily available, marijuana, quote, "legitimized," as though it were a therapeutic medication, we fear would become more available and more used by young people who are already possessed of mistaken notions that somehow it's a miraculous cure, that it's good for you, that it can be used for medical conditions. So we think there would be a loss of deterrent effect.

Moreover, there's the realization that the scientific and medical bodies who have looked at this, who are charged with the responsibility of evaluating medical claims, have said there are too many risks to the use of the substance, that patients may be actively harming themselves. Though the intent there is to feel better, in the process of trying to feel better, they are not being better treated. They are not getting better.

The point of a therapeutic medication is to help the patient heal, not to provide to them a risky, contaminated, intoxicating substance that transiently gives them the impression they're getting better, when in fact it is doing active harm to their lungs, to their minds, to their susceptibility to depression and psychosis.

It is not the sort of thing that is going to be, in its raw, smoked form, an approved medication, according to the bodies charged with making that determination. Much to be lost and nothing to be gained by putting marijuana into the hands of people who are actively suffering.

SCOTT: Well, if they want it and they're terminally ill, what scientific studies have you had to show the effectiveness of marijuana? What scientific studies have you had? Do you have a list that you can supply to the committee?

MURRAY: Thank you, Mr. Chairman. I think there have been multiple claims and quite an extensive list of the purported conditions, medical conditions, that marijuana is supposed to actively treat.

But when each of these has been investigated in clinical trials situations, in animal studies, in active medical investigations, those claims have not been borne out.

SCOTT: Could you give us the list of those studies?

MURRAY: Yes, sir. The literature is quite replete with efforts to see whether marijuana is safe and effective, and it never has been able to satisfy the threshold, the requirement, that it demonstrates by medical science that it actually is useful and does do harm. And that's been repeated many, many times over.

SCOTT: What is the status of the study that the judge -- I believe it's University of Maryland -- Massachusetts. I'm sorry.

What is the status of that study?

MURRAY: Sir, I'm not quite sure I follow the question. If you are referring to the case of an applicant to be a marijuana provider, that is an active case and we obviously can make no comment nor weigh in no an active administrative matter that is being determined properly in the form of government now.

We have no intervention, nor any commentary, on the suitability of that application. It's in the hands of others. It is not a research project, as I understand it, sir.

SCOTT: Didn't the judge suggest that the permit should be awarded?

MURRAY: Sir, I think we are constrained from making any comment on a matter that is actively being considered by the administrative process of an agency, which I believe this matter is.

SCOTT: So you don't deny it was six years ago.

MURRAY: Sir, I think we are constrained at the White House from making comments or interventions with regard to actively ongoing cases.

SCOTT: Is the court order not public?

MURRAY: Sir, I don't wish to offer commentary, because I think it would be improper for us, and not our role, to step into an actively considered administrative process where an agency is doing the correct evaluation of oversight and determination with regard to this matter.

Sir, I have to defer and say it is not proper for us, I think, to make commentary on this case that is being actively considered by other agencies.

SCOTT: Mr. Flannery, there's a difference between criminal activity and malpractice.

FLANNERY: There certainly is.

SCOTT: And different medical theories about how to prescribe. Can you say a word about how impossible it is for a doctor to get in the middle of that?

FLANNERY: What's become so impossible is that the only crime that at doctor should be prosecuted for is pushing drugs and happening to be a doctor at that time. And the elements of that are that I know and I intend to traffic in some drug, and these are controlled substances. It would mean I'd be selling it to you or writing a prescription for you when you have no need for it, I know it, there's no question about it.

You haven't fooled me. You've said, "I'm going to give you $200 if you write a prescription for OxyContin 80-milligram tablets."

Now, malpractice, someone comes in and I don't spend enough time with them. Maybe I don't check all their records. I believe them, which the studies have shown doctors do believe their patients. They believe they come there with problems, and so they do believe them.

And I give them medication and say they get sick. They don't die, they get nauseous or something. And them I'm sued, because it leads to other things. I, the doctor, am sued. That would be malpractice.

SCOTT: Are these questions better for the DEA or the board of medicine in the different states to consider?

FLANNERY: They're better suited and historically and constitutionally suited for the several states by the boards of medicine. And there have been studies saying this for years. And the medical profession itself has become less able to articulate and advocate for itself for fear of being perceived in the current propaganda environment of being, quote, "soft on drugs," rather than strong on medicine.

We have deterred the best voices in America and the most capable physicians from speaking out on this issue, because they're terrified that they'll be targeted and they'll watch their family and their practice or the patients they can help with other medicines all compromised.

SCOTT: Mr. Forbes.

FORBES: Thank you, Mr. Chairman.

First of all, Dr. Murray, let me apologize to you for having your initial testimony interrupted. That is not normal order. I'm sorry that I was not able to stop that.

I also want to say that when we're talking about compassion, one of the things that we really -- it's really great to come in here and beat on the desk and yell compassion, but it's also compassionate when we try to curb teenage drinking so we stop people from ending up going to funerals where had people that were killed by drunken driving, when we stop the pharm parties that I know you guys have worked on so much. Because kids are taking drugs that they don't have any idea what the consequence is about.

We have to go the funerals and look at the parents and they're telling us, why didn't you do something? Why didn't you try to stop it? Or when we see suicides that take place because kids are addicted to drugs or other people are doing it.

So when we talk about compassionate, let's not suggest that anybody sitting at the table is not compassionate.

Ms. Corral, first of all, I thank you for being here and for your testimony to everybody. I want to ask you, and I only have five minutes, so I want to be kind of concise, but do you feel marijuana should be legalized?

CORRAL: Medical marijuana should be legalized.

FORBES: What about ecstasy, the drug, ecstasy?

CORRAL: I'm here to testify, sir, about medical marijuana.

(CROSSTALK)

FORBES: ... on that.

CORRAL: No, I'm just here to speak about medical marijuana.

FORBES: I appreciate that.

CORRAL: Thank you.

FORBES: Dr. Murray, let me ask you a question on Tylenol. Is Tylenol a good drug to relieve pain?

MURRAY: Yes, sir. I believe it is widely sold and offered.

FORBES: If you have an overuse of Tylenol -- I'm not talking about on a regular basis but a single or a couple of overuses of Tylenol, what's the impact?

MURRAY: Sir, it is my impression that it is a widely used and safe drug, taken appropriately, but as with all effective medicines, inappropriate use can be damaging.

FORBES: It can damage your liver if you have that.

MURRAY: Indeed.

FORBES: The question I'm raising, everybody's talking about, almost like what should be a controlled substance and shouldn't be, but doesn't Congress decide whether drugs are based on a schedule under the Controlled Substance Act? So isn't it true that Congress is the one who places things on the schedule one?

Mr. Rannazzisi, you can speak on that, too.

RANNAZZISI: A drug can be scheduled in one of two manners. Congress could place it on a schedule through legislation or it could go through the administrative process, a collaborative effort between FDA, who does a scientific evaluation, safety and efficacy of the drug, and then DEA scheduling recommendation.

FORBES: Once it's placed on that list, does DEA have the discretion to not enforce the drug laws.

RANNAZZISI: No, sir, it doesn't.

FORBES: So you can't just pick and say that you don't want to enforce this one, or you do want to enforce this one. You don't have that discretion, do you?

RANNAZZISI: No, sir, I don't.

FORBES: If a doctor is over-prescribing pain medication, even if done for a patient who is suffering, can the DEA just ignore this?

RANNAZZISI: No, sir. Many of these cases come from complaints, complaints from law enforcement agencies, other medical doctors, pharmacists. No, we can't ignore it.

FORBES: Do you eve have situations where suicides have taken place, or murders have taken place, as a result of some doctor over- prescribing medication to some individual that was taking it?

RANNAZZISI: We've had cases where there were deaths related to the prescription medication prescribed by the physician, yes.

FORBES: And if we had that, wouldn't we be in here pounding on you and saying, why didn't you try to stop that?

RANNAZZISI: Yes, sir, I believe that's...

FORBES: Let me ask you, are you familiar with this map that I believe was put out by Heritage. It's cannabis plants eradicated in 2006.

RANNAZZISI: It's the national drug intelligence -- yes.

FORBES: Can you explain what this represents to us?

RANNAZZISI: These are the outdoor plants and sites that were seized in California, by county, in 2006.

FORBES: And how widespread were they?

RANNAZZISI: Extremely widespread, almost the whole state.

FORBES: Is that the same math that is up here now with this chart up here?

RANNAZZISI: Yes, sir.

FORBES: Is there any concern that you have in some of these areas, some of those reports that we've looked at that talk about having armed guards, that they've conducted counter-surveillance. Are you familiar with any of that on any of these sites?

RANNAZZISI: Are we talking about the grow sites, the outdoor grow sites?

FORBES: Yes.

RANNAZZISI: Yes, absolutely. Currently, in addition to the grow sites, we're having problems with growing on public lands and we've just entered into a task force with the Park Service to address that.

FORBES: Dr. Murray, can you address that?

MURRAY: Yes, thank you, sir.

It's a huge problem in the United States. The domestic production of marijuana is an enormous danger. Criminal elements deeply moved in. States of Kentucky, Tennessee, California and Hawaii predominate, where public lands, national parks, off limits to people because of dangers of gangs, of undocumented aliens, cutting down forests to grow marijuana by the metric ton, spreading through the country.

It's quite a problem, and, moreover, the difficulty is connected to some of the compassionate care dispensaries, because some of the marijuana seized in episodes where the DEA has gotten involved, it was clear that it was not mom-and-pop locally grown marijuana from an herbal garden. It was criminal elements that moved into this country to generate indoor, hydroponically grown, high-potency and/or outdoor grow marijuana operations that were systematic and made thousands and thousands of dollars a day to distribute marijuana through the dispensaries to people for whom it was never intended.

So it is a public threat to have this production going on in the hinterland. It is moreover a criminal threat to have them have a readily available outlet. And it is clearly not the intention or the principle of the well-meaning people who tried to offer compassionate care for a few.

FORBES: My time's expired, but if the chairman would just allow for an additional question, for either Mr. Rannazzisi or Dr. Murray, can you tell us about the concept of pharm parties and how bad they're getting now and you're problems in trying to deal with Internet pharmacies.

RANNAZZISI: Currently, Internet pharmacies are one of the fastest-growing pharmaceutical diversion areas. What these kids are doing, basically, are acquiring drugs from either their medicine cabinets, their doctors or friends -- their doctors -- their relatives or their friends. And they're taking the drugs and they're coming to these parties where they throw the drugs into a bowl and then they systematically take the drugs out and take them.

They really don't know what they're taking. It could be a benzodiazepine. It could be a narcotic. It could be anything. And they just take them.

And so they don't know what they're ingesting, and this is a form of -- just a form of adolescent partying now.

FORBES: It's becoming a widespread concern?

RANNAZZISI: We've had several reports throughout the country, yes.

SCOTT: Thank you, and just one other. We're going to have a hearing on Internet pharmacy issues coming up.

I'd like to ask one other question. I guess, Dr. Heiden...

HEIDEN: Yes.

SCOTT: Do we know where ephedrine comes from that makes methamphetamines, where most of the people get it? And, if you closed one source, would other sources quickly sprout up?

HEIDEN: Yes, I think DEA has even addressed this, that I think Administrator Tandy in some recent testimony indicated that methamphetamine production, a major source is the Mexican super-labs, I guess you call them, in Mexico, controlled by drug kings are supplying the vast majority of the methamphetamine that is consumed in this country.

And the vast bulk of the products found in small methamphetamines are brand pseudoephedrine cough and cold products, such as Sudafed, and it's not the products distributed by ACRC members, which are the off-brand combination ephedrine asthma-relief products.

And it's those products that are being essentially targeted by the small allocation under the DEA needs assessment in the draft report that we reviewed and critiqued for ACRC, a report where there was absolutely no rationale given for the needs assessment of essentially 100,000 kilograms, essentially, of product, when the national estimate of the members of what indeed they sell for legitimate purposes is in the millions of products.

I'm here basically, and I didn't get to say it in my final remarks, to indicate that DEA just missed a very, very large portion of the ephedrine that is useful for products that are relied upon and needed by asthmatics for relief, particularly in low-income environments and others. And if it allows this very, very small allocation to go through, based on a study that completely draws an X through the needs of this ACRC sector -- if it allows that kind of allocation, this whole sector, it's my understanding, will be wiped out.

But it's not the major source of diversion. As I said, the major source here, according to DEA itself, is the super-labs and the small toxic labs, not the members of ACRC or small categories of suppliers.

SCOTT: Do those convenience stores have cost of compliance with the regulations?

HEIDEN: They certainly do have significant costs of compliance. I have heard nothing in discussing with the members of ACRC that their sales to convenience stores are anything but legitimate sales. But I do think the convenience stores have significant cost of compliance, although I haven't studied that issue.

RANNAZZISI: May I respond, Chairman?

SCOTT: Sure.

RANNAZZISI: First of all, the study, the initial needs assessment, was a proposed assessment. Our contract with IMS is a two-phase contract. We do the initial assessment by IMS. They give us the results and we publish them. The whole idea behind the deliberative process and notice and comment is that gives industry an opportunity to respond, and industry can give their comments and provide data that shows that we can be wrong.

And there are times in the past that we were wrong, and we made the corrections. Right now, we're in the deliberative process. I could tell you that we are looking at industry comments and that those numbers will not necessarily stand.

However, for us to do our job, we have to have a starting point, and that starting point was with our IMS contact. We appreciate the comments from industry and we take them under advisement. And a final needs assessment will be out shortly.

As far as the ACRC market, the people that are represented by ACRC, they're mostly small retail convenience stores and wholesalers, I believe, that distribute to them. The fact is that that sector of the market is a large avenue of diversion to small toxic labs.

Put aside the Mexican methamphetamine labs, which, incidentally, we didn't say a vast majority comes from Mexico. A vast majority of the methamphetamine produced by those organizations is produced in Mexico and the U.S., so we can't really tie it to either Mexico or the U.S., but we know it's tied to those organizations.

Well, put that aside for a second. Twenty percent of the meth on the street, currently, is coming from small labs. We believe that. And the fact is, is those small labs are obtaining their chemicals, their pseudoephedrine, or their ephedrine, products, from retail places.

Now, I noticed in Mr. Heiden's testimony, he says the products distributed by ACRC and other small distributors are off-brand combination ephedrine asthma relief products

which are not found in illicit labs as precursors to make methamphetamine. That's incorrect.

In 2006, we had 87 labs with brand names like BDI, Blue Label, Mini Thins, Bronchis (ph), Mini Ephedrine, Double Action Ephedrine, Rapid Ephedrine (ph), Fred's Private Label (ph), Ephedrine Extra (ph), Biotech, AM, BC Powder, Ultra Max Strength. Those are all off-brand, gray market, crypto-generic products. So I don't know where his information was coming from and I'd like to talk to him afterwards about it so I could clear it up on it.

Thank you.

MURRAY: Mr. Chairman, may I add one brief commentary as perspective, please, sir, with regard to methamphetamine issues.

The policy dilemma with regard to combat meth and somewhat restricting access to pseudoephedrine, ephedrine products and so forth was a cost-benefit equation. We had to make a balance, preserving legitimate access to needed medications, and we thought we did achieve that by making them still available in supplies that can still be had.

But, at the same time, we had to balance that with the diversion threat that was a very serious issue. While methamphetamine flow, already finished product from Mexico, continues to be a threat, we think we're taking effective action against that. We think it will be dramatically reduced in the future, which is a critical point that needs to be brought into the equation of cost and effect and the balancing here.

The methamphetamine laboratories that were small, toxic laboratories, that were fed by diverted pseudoephedrine, ephedrine products, from retail establishments, was not a small phenomenon in states in like Missouri and Tennessee, states like Arizona and Oregon and Oklahoma.

These were extraordinarily threatening circumstances that both produced meth use and the toxic laboratory residues from where people had cooked meth that left extraordinarily dangerous poisons in the atmosphere, on the walls, on the ground, on the furniture. That has been addressed.

In 2004, there were more than 17,000 such laboratory incidents reported across the United States. Today, in large measure due to the effective actions at restricting, not prohibiting, but narrowing the access to the precursor chemicals, there are between 6,000 and 7,000 laboratory incidents reported.

That dramatic drop has produced such a powerful beneficial consequence for these rural communities in particular that face the methamphetamine threat, including the lives of young, drug-endangered children, whose parents were exposing them to toxic environments, that retained that toxicity even after the first family moves out. Hotel rooms, trailer parks, barns, places where methamphetamine cooks take place, there is

leftover residues of poison that has respiratory consequences for children, neurological consequences for children, exposure for first responders and fire and police, that has been dramatically reduced.

That was the cost-benefit equation that we had to take into account of when we made the public policy choice, about not eliminating these medications, but restricting access in such a way where we retained the right for legitimate use and yet cut away the criminal dimension.

I think that's been a powerful success.

SCOTT: When all that was going on, did the cost of meth go up or down?

MURRAY: The cost of methamphetamine is measured somewhat indirectly by a complex system of drug reporting that the DEA maintains. We have seen both increases and decreases in the price of methamphetamine nationally over time.

We have also seen increases and decreases in purity, and the effects of the combat meth act in reducing the laboratory production has also been felt in reduced access and availability of methamphetamine itself that we can see in data such as workplace drug testing, where we've seen a steep tailing off of the use of methamphetamine of the work force, and by the survey reports we're getting from young people in particular, who are turning away from methamphetamine very strikingly.

Yet the drug importation from Mexico has also been a countervailing tendency to have purity pushed forward. But we believe that price and purity has been affected by the success of taking down the meth labs, that we've gotten success against the laboratory incidents and the toxic waste issue and also gotten better purchase on trying to control the use of methamphetamine.

It has been a successful and slow, but I think appropriate, process of curtailing access to these precursor chemicals. They used to come in from Canada, diverted in bulk form from Canada and fed super-labs in California, Nevada, Arizona.

We took action in conjunction with the government of Canada and effectively cut off that route. That's when people turned to the small toxic lab, pseudoephedrine diversion from the retail establishment. We took action against that.

Now we've got the third quadrant, the last piece of this down in Mexico. We are taking effective action in conjunction with the Mexican government to reduce their importation of pseudoephedrine and ephedrine products and to help them attack the methamphetamine laboratory production on their side of the border.

We're moving against this problem, sir.

SCOTT: Thank you, Dr. Murray.

We've been joined by the gentleman from North Carolina, Mr. Coble. And I understand you did not have questions, or you do you have questions?

COBLE: Mr. Chairman, my belated arrival was because of two conflicting hearings and I apologize. And I have no questions.

SCOTT: Thank you.

FORBES: I just have one additional statement to follow up with yours (OFF-MIKE).

I want to first of all say, based on your testimony, that the word "balance" is always one that we don't like to hear. A lot of times people don't like to talk about it, but that's what government's all about.

We're not perfect, but you're going to constantly see some of these criminals moving from one place to the other. They're going to come up with new technologies, new ways to do it. You have to work on it.

We thank you for the efforts that you have done, because one of the things that we were supposed (OFF-MIKE) with the meth problem is people (OFF-MIKE) and they would fill the walls of that room (OFF- MIKE).

SCOTT: Thank you.

As the gentleman from Texas is coming in, do any of the witnesses have any closing comments before I recognize the gentleman from Texas?

FLANNERY: I have one.

SCOTT: I'll start with Mr. Flannery.

FLANNERY: Compassionate seems to me when you have 40 to 75 million people in America how have chronic pain, which means that they have pain that's been living with them for longer than six months -- it's so bad they can't sleep at night. When they drive to work, they're falling asleep, they're irritable.

And, at first, it only bothers them a little bit, and then they start thinking about, should I commit suicide, because the pain is so great and I'm so worthless to the people I'm with and that I can't just put up with this anymore.

The ranking member appropriately noted that if one takes a Tylenol for pain, you can only take so much of it before your gastrointestinal tract is injured, before you literally bleed and you compromise your organs. And there is an answer to that, and it's a recent chemical answer, and it is the fact that the opioids we have are not sufficient to take car of the pain. And it is that oxycodone and other medications can help us.

And I don't think this argument is that dissimilar from the other issues that are before us today. So if we want to talk about compassion, and numbers matter, and we have 40 to 75 million people who are daily living in chronic pain, many of whom are contemplating suicide because they can't get medical attention and they can't get medical treatment because the physicians in this country are not going to risk going to jail and compromising their own lives and their other patients by doing so.

Then compassion means, in numbers and for this nation, changing how we do our business of law enforcement. It means changing our structure. It means not hiding behind some privilege when you're asked a question about a medical study.

It means actually having the medical study and examining it and then deciding what is the right policy. Thank you.

SCOTT: Ms. Reynolds?

REYNOLDS: Thank you. Just the thing I was thinking about as this was going on was that I just don't feel that the people are really getting their voices heard in this hearing.

I'm trying my hardest, and I know that you are, and several of us are, but I feel that we're being drowned out by a lot of sort of endless bureaucratic chatter about Mexico and appropriate procedures and what not. And we're talking about American citizens being denied medical treatment that they would afford, that they want, that they need to survive and take care of their families with.

I mean, it's so serious, and we have been working, my organization and I, for five years to get heard on this issue. And this is it. This is the culmination of those efforts. Two of us are here to speak about this.

So much more needs to be done. The platform needs to be so much bigger. I don't know how to describe it. It's just that what we need are you need to hear from doctors. You need to hear from patients. You need to hear about the science, which has been suppressed by the Drug Enforcement Administration.

Mr. Forbes just demonstrated a real misunderstanding of the science. Over-prescribing is a misnomer, sir. The doses can go as high as the sky, if they need to. That's the real anomaly of this medicine. And so if the medicine's being treated scientifically, it makes the doctor a target.

That's what I want you to understand, sir.

FORBES: Mr. Chairman, I'm just going to ask that we have regular order in the committee.

SCOTT: Regular order has been called for.

FORBES: We have not had it the whole committee meeting.

SCOTT: We will resort to regular order and recognize the gentleman.

(UNKNOWN): Including (ph) information, Mr. Chairman.

SCOTT: I'd like to recognize the gentleman...

(UNKNOWN): I just want to know, since I just walked in, what was the objection to lack of regular order just now? What was being violated?

SCOTT: My recognizing witnesses out of order for extended periods of time, which was in fact out of order and the gentleman made a good point. And recognizing the gentleman from Texas at this point.

GOHMERT: Thank you, Mr. Chairman. I do appreciate that. I appreciate your being here and I understand the frustration of not being heard. Actually, there's a majority of my district is not represented anywhere here, because the majority of my district does not want to see marijuana legalized for anything.

So I understand the frustration you have in feeling that you're not being heard, but there are also a lot of other sides to this that have not been heard.

REYNOLDS: Sir, I just don't represent marijuana. I just want you to know that. I'm talking about legal medications.

My name is Siobhan Reynolds, I'm with the...

(CROSSTALK)

GOHMERT: ... marijuana, right?

REYNOLDS: No, nothing to do with marijuana. We're here about schedule two substances, oxycodone, et cetera, supposedly legal medications that people can't get hold of.

GOHMERT: I thought you were speaking about marijuana (ph) on that. All right.

REYNOLDS: No, thank you, though.

GOHMERT: And I'm sorry I had to step out, momentarily. But I do want to go back very quickly to pseudoephedrine. I was one of the few that voted against making it so difficult to get it, because it works to decongest me, as so many Americans.

Pseudoephedrine P.E., my humble, non-medical opinion, is absolutely worthless for me. I can't speak for anybody else. It's anecdotal.

But, anyway, it's funny, not in a humorous, but ironic, way, this administration's been accused of sending jobs to Mexico, and apparently when we tightened up pseudoephedrine, that's exactly what we did. The job of making meth went to Mexico and the people I talk to in law enforcement back in Texas, having lots of contacts there, as a former judge, they say, man, it's coming in from Mexico. It's pure, there's more of it. We don't have the mom-and-pop labs in east Texas, which was once a real haven for them, because of the trees and whatnot, the rural areas.

So, anyway, I'm not sure -- I know we did a lot of good putting mom-and-pop labs out of operation, but from what law enforcement is telling me, including -- and I won't mention DEA agents, but some of them are telling me back home, man, it's coming in faster than ever from Mexico.

Perhaps if we got some border security instead of having National Guard troops that call in the fact, or radio in the fact, that there are armed drug smugglers coming in and then their SOP is to flee the area once they radio that in, maybe we could get some help there.

But I also want to bring to the DEA's attention, I mean, if the law is marijuana is illegal and it is, it has been. But I had a case as a judge where marijuana seeds were an issue. And we ended up having DEA come from the DEA lab up here back to my little courtroom in Tyler, Texas, and I didn't realize, but, apparently, if marijuana seeds are sterilized, then they're not illegal in Texas and most other places. And that's why they're included in so many birdseeds.

Well, we had a 50-pound bag of marijuana seeds that were legally bought from a feed seed place in Houston and they kept using it as an example, as a demonstrative aid in court. And I kept seeing hands go in and when they'd pour the seeds back in, there were green, leafy substances on their hands, of the prosecutor, the defense attorney, the witnesses.

And so at the end of the trial, I had it sent out for analysis and it turned out that 25 percent of that 50-pound bag would germinate, would produce marijuana plants, legally bought.

So, Ms. Corral, I don't know if you want to take note of that or not. But, anyway...

CORRAL: Well, I can address that, sir.

GOHMERT: You could buy it legally, and not only that, you buy a 50-pound bag of marijuana seed that's supposedly sterilized, 25 percent germinate and they had a plastic baggie full of marijuana as like a CrackerJack prize for buying the 50-pound bag.

So I provided that all to the FBI. I said, I know you all are under the same DOJ with Janet Reno, but this really needs to be looked into.

And it turned out, and we had testimony to this, that the DEA once in three or four years went to the single plant in New Jersey that actually does the sterilization. They said it was a complete surprise. They had no idea. So it was a really random survey.

Yet they met the ship at the doc, they were able to call in the people that worked for this company that the DEA was coming to watch them do the sterilization process. Unlike every agriculture department, which sticks a rod in and then opens, turns and gets seeds from every level of this huge vat. So you see how the DEA agent scooped a handful up.

They took those to the DEA plant. They were put in a petri dish to see if they would germinate. They were set on top of an oven, where the temperatures ranged 100 to 200 degrees. And after they were adequately cooked for seven days, the report was they didn't germinate, after we cooked them, which the Agriculture Department will tell you that's not the way to germinate.

I never got a report back on whether we were continuing to have such thorough investigations in the sterilization of marijuana. But we're apparently importing, or we were at the time of this trial in my court, carloads of marijuana seeds from China that were received at the dock and received that kind of really explicit study.

So, anyway, I bring that to your attention. I hope it's been looked into. If it's illegal, we ought to follow the law. Of course, we have laws on immigration that aren't followed either, but that's another matter.

Anyway, thank you.

SCOTT: The gentleman's time has expired.

The gentleman from New York.

NADLER: Dr. Murray, marijuana is the only controlled substance currently for which the federal government maintains a monopoly on the supply for use by scientists conducting research, even though federal law requires competition in the production of research-grade, schedule-one substances, such as research-grade heroin, LSD, ecstasy and cocaine.

Can you please tell us marijuana, as a comparatively harmless drug, compared to these other substances, is the only controlled substance for which the federal government maintains a monopoly on the supply made available to researchers?

In other words, why is it different than heroin, ecstasy, LSD, et cetera?

MURRAY: Thank you, Mr. Congressman.

NADLER: Quick and short, because I'm going to have a few more questions.

MURRAY: All right, sir.

We do not regard marijuana as a relatively benign schedule-one substance, sir...

NADLER: Why is it treated differently than these other harmful drugs?

MURRAY: Sir, I believe that we have international treaties and obligations that are specific to how we handle schedule-one controlled substances with regard to a single government source. And I believe that Mr. Rannazzisi can tell us even more about how that works.

NADLER: Mr. Rannazzisi, maybe you'll answer my question and not evade it the way Dr. Murray did.

The question is, why do we handle marijuana differently than other schedule-one drugs with respect to maintaining a monopoly of research on it?

RANNAZZISI: Because there's only one supplier, because that supplier basically handles the need for research. And that supplier is under a NIDA contract. We look at the NIDA contract...

NADLER: But why is that different from other drugs. There's more than one supplier for heroin?

RANNAZZISI: Because heroin poppies are not grown in the U.S. Cocaine, coca, is not grown in the U.S.

NADLER: And LSD isn't made in the U.S.

RANNAZZISI: LSD is manufactured for research, yes it is.

NADLER: But, again, I don't understand your answer. What has that got to do with the fact that for LSD, for heroin, there's not a monopoly for supply for use by scientists conducting research by the federal government, whereas for marijuana there is? Why?

RANNAZZISI: Well, first of all, the research that's conducted is approved by NIDA and FDA. NIDA and FDA make a determination -- NIDA makes a determination that that source of supply for that marijuana fits the needs of those researchers. We have no dog in that fight, really.

NADLER: Basically, they refused almost every researcher for marijuana.

RANNAZZISI: I'm sorry?

NADLER: They've refused the supply for basically every researcher. They've basically cut off medical research with respect to marijuana.

RANNAZZISI: I don't believe that's the case. If you look at my testimony...

NADLER: I won't debate that with you, because it's clearly the case. Let me go onto the next question.

RANNAZZISI: Well, I mean, would you like me to respond?

NADLER: I want to get the information I want to get.

RANNAZZISI: So you don't want -- OK.

NADLER: I heard your answer. I'm going to go from there.

Administrative Law Judge Mary Bittner recently recommended DEA grant a license to the University of Massachusetts professor Lyle Craker allowing him -- and I understand this may have been referred to -- allowing him to grow research-grade marijuana for use in FDA- approved studies that could evaluate whether marijuana meets the FDA safety and efficacy standards for approval of prescription medicine.

This application was submitted to DEA more than six years ago. Mister...

RANNAZZISI: Rannazzisi.

NADLER: Rannazzisi.

RANNAZZISI: Yes, sir.

NADLER: Can you please tell us within what time period can we expect the DEA will decide whether to accept Judge Bittner's ruling, before the expiration of the president's term?

RANNAZZISI: I can't give you a time period about when a ruling is...

NADLER: Would you expect it will be -- the president has a year and a half to go. Would you expect a decision whether to accept an administrative law judge's recommendation would be made within the next year and a half? Is that reasonable?

RANNAZZISI: Excuse me one second, please.

SCOTT: I would advise the committee that we'll have an opportunity to submit questions in writing, and I think this might be...

RANNAZZISI: That would be a question that we'd rather submit in writing. We would like to submit that...

NADLER: Well, let me ask you a different question.

RANNAZZISI: Yes, sir.

NADLER: Normally, how long does it take the FDA to agree or disagree with an administrative law judge's recommendation?

RANNAZZISI: The FDA would not...

NADLER: Not the FDA, the DEA.

RANNAZZISI: it just depends on the issue. It's a case-by-case basis.

NADLER: Well, does it normally take, on average, six months, on average six years?

RANNAZZISI: I wouldn't have that information handy, sir. I'd have to get back to you on that.

NADLER: Well, think of any instance where it's taken more than five years. Are there any?

RANNAZZISI: Well, that's erroneous. It's not been five years. If I'm not mistaken, the decision was handed down months ago.

NADLER: Are there any longer than two years?

RANNAZZISI: I don't know that information, sir.

NADLER: Are there any longer than one year?

RANNAZZISI: Sir, again, I'll have to get back to you. I will get back to you, and if you would like, I would...

NADLER: OK. I would like a commitment that the decision will be made within the lifetime of this administration. I think that's a minimum that we could ask.

Let me ask you the following question: does the DEA oppose or support efforts by scientists to resolve the controversy over medical marijuana by conducting FDA-approved clinical trials, yes or no?

RANNAZZISI: Well, the DEA does not oppose any clinical trials that have been accepted for trial by the FDA and NIDA. We've never done that.

In fact, in our process, the only thing DEA...

NADLER: The answer is, no, you do not oppose.

RANNAZZISI: No, we don't oppose any trials.

NADLER: Thank you, and let me ask you the following...

SCOTT: The gentleman's time has expired. We'll have just a few last questions.

NADLER: A company in England, GW Pharmaceuticals, has developed a marijuana-derived drug called Sativex that is already available for patients in Canada, England and Spain. I understand that GW Pharmaceuticals have now teamed with a major Japanese pharmaceutical company, Otsuka, to conduct Sativex trials in the U.S., which the FDA has approved.

Can you please tell the committee why the federal government is allowing foreign corporations to develop a monopoly on marijuana-based drugs in this country? Are we opposed to American economic development?

RANNAZZISI: Sir, I guess you've got to understand what DEA's role is, here. DEA doesn't approve studies.

All DEA does is issue registrations for controlled substance handlers and researchers. That's what we do. The studies are approved at NIDA and HHS, where studies have always been approved. That's not in our purview.

NADLER: Thank you.

SCOTT: Thank you.

The gentleman's time has expired. I'd like thank the witnesses for their testimony today.

CORRAL (?): May I just add something quickly?

SCOTT: Very quickly.

CORRAL (?): Very quickly. I just wanted to respond to Congressman Gohmert's assumption about the 50 pounds of marijuana seeds.

GOHMERT: It wasn't an assumption.

CORRAL (?): I beg your pardon.

GOHMERT: It was some factual testimony.

CORRAL (?): It's factual testimony. And, in fact, those seeds from sterilized plants, while they were germinate, will not render full-grown plants that actually sex out male or female and produce usable marijuana. They actually die after quite a short time.

I also wanted to mention that there's a great deal of scientific research. In 1992, the International Cannabinoid Research Society was founded, and there are numerous prestigious physicians and researchers throughout the world who are part of this.

SCOTT: I'm going to ask you to submit those studies to the committee.

CORRAL (?): Yes.

SCOTT: Dr. Murray is going to submit the studies he has, so we'll be able to review them all at the same time.

CORRAL (?): Yes, and I'd just like to mention that while the DEA does block research by not approving, throughout the world, other research, even in the face of these treaties, continues to provide and substantiate the medical value of marijuana.

Thank you for your time, and I'm sorry to go over.

SCOTT: Thank you very much.

And members may have additional written questions for our witnesses, which we will forward to you and ask you to answer as promptly as you can so they will be made a part of the record.

Without objection, the hearing will remain open for one week for submission of additional materials. And, without objection, the committee stands adjourned.

END

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