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DRUG ENFORCEMENT ADMINISTRATION'S REGULATION OF MEDICINE

HEARING

BEFORE THE

SUBCOMMITTEE ON CRIME, TERRORISM, AND HOMELAND SECURITY

OF THE

COMMITTEE ON THE JUDICIARY
HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

JULY 12, 2007

Serial No. 110–111

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DRUG ENFORCEMENT ADMINISTRATION'S REGULATION OF MEDICINE

THURSDAY, JULY 12, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIME, TERRORISM,
AND HOMELAND SECURITY
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to call, at 10:08 a.m., in Room 2237, Rayburn House Office Building, the Honorable Robert C. "Bobby" Scott (Chairman of the Subcommittee) presiding.

Present: Representatives Scott, Nadler, Forbes, Gohmert, and Coble.

Staff present: Bobby Vassar, Subcommittee Chief Counsel; Rachel King, Majority Counsel; Veronica Eligan, Professional Staff Member; Michael Volkov, Minority Counsel; Caroline Lynch, Minority Counsel; and Kelsey Whitlock, Minority Staff Assistant.

Mr. 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 no 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 toward 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 has 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 decision-making process and we hope that this hearing will be the beginning of that dialogue.

And, with that said, it is 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.

Mr. 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——

Mr. 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 will be having a Juvenile Justice and Delinquency Prevention Act oversight hearing with the Education and Labor Subcommittee this afternoon.

Having two Committees on the same day is what we are having to do to try to get in all the issues.

[Audio difficulties.]

Mr. SCOTT. They are working on it now. They are working on it from the seat of the Chair. We are working on that now.

I will 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 will be coming back, and I did read everybody's testimony last night. So when I come back, I will 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 is 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 be-

fore 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 3 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 master's degree in fine arts from Actor's Studio Program in New York City.

In the mid-1990's, 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 a 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 5 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 1 minute left and, finally, to red when 5 minutes are up.

Administrator Rannazzisi?

TESTIMONY OF MR. JOSEPH T. RANNAZZISI, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, U.S. DRUG ENFORCEMENT ADMINISTRATION, U.S. DEPARTMENT OF JUSTICE, WASHINGTON, DC

Mr. 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 1990's and early 21st century, America watched a homegrown 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 is 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——

[The prepared statement of Mr. Rannazzisi follows:]

PREPARED STATEMENT OF JOSEPH T. RANNAZZISI

Written Statement of

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration
United States Department of Justice

July 12, 2007

Introduction

Chairman Scott, Ranking Member Forbes, and distinguished members of the House of Representatives Judiciary Committee, Subcommittee on Crime, Terrorism and Homeland Security, thank you for the opportunity to appear today and discuss and clarify any misapprehensions the Subcommittee may have regarding the role the Drug Enforcement Administration (DEA) plays in enforcing the Combat Methamphetamine Epidemic Act, upholding the Supreme Court decision *Ashcroft vs. Raich*, supporting cannabis research, and the responsibilities doctors in prescribing scheduled medications.

The Investigation of Methamphetamine Precursor Distribution

Methamphetamine is unique from other illicit drugs of abuse in that it is an easy to make synthetic drug and its precursor chemicals have historically been easy to obtain and inexpensive to purchase. These factors have contributed to methamphetamine's rapid sweep across our nation. In March 2006, reacting to the devastating impact that the illicit manufacture of methamphetamine was having on our nation, Congress enacted the Combat Methamphetamine Epidemic Act of 2005 (Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005, P.L. 109-177) or CMEA. Among other things, the Act established a system to monitor and regulate the importation, production, and retail sales of non-prescription ephedrine, pseudoephedrine, and phenylpropanolamine products - common ingredients found in over-the-counter cough, cold, and allergy products. These chemicals and drugs were included in CMEA because they are key precursors used in the illicit manufacture of methamphetamine or amphetamine. This legislation provided law enforcement and regulators with tools invaluable to the containment of the drugs' production.

As a result of the CMEA, the ability of pseudoephedrine to be sold on the spot market was effectively taken away. These transactions, which were not regulated under prior law, are now treated as new imports or exports and, therefore, subject to 15 day advance notification during which the DEA verifies the legitimacy of each transaction. In addition, the Department of Justice now has the authority to establish production and import quotas for ephedrine, pseudoephedrine, and phenylpropanolamine. These quotas will allow for greater control of precursors that are imported into the United States.

Retail provisions of the CMEA became effective in September 2006 and include self-certification, employee training, product packaging and placement requirements, sales logbooks, and daily and 30-day sales/purchase limits. In order to purchase products containing ephedrine, pseudoephedrine, and phenylpropanolamine, an individual must now show identification and sign a log book at sales locations. Law enforcement is able to monitor these log books in order to identify any person purchasing more than 9 grams within a 30-day period. CMEA also created a national database of self-certification records available to state and local law enforcement agencies to document those retail sales locations that have complied with the requirements of this law. As a testament to the effectiveness of the CMEA (and similar predecessor laws passed by the states), DEA statistics show a 58% decrease in the number of methamphetamine laboratories in 2006 from the previous year.

Additional CMEA provisions include: requiring DEA to conduct an assessment of the annual need of ephedrine, pseudoephedrine, and phenylpropanolamine, establishing production and import limits, requiring DEA be noticed of transfers following importation or exportation of methamphetamine precursor chemicals, and removing previously established sales thresholds, among others.

DEA is committed to keeping our communities safe from the dangers of methamphetamine production and abuse. Preventing the use of these chemicals in clandestine methamphetamine labs and via enforcement of the CMEA is an important element in that effort.

Investigations of Physicians Who Over-Prescribe Scheduled Drugs

The abuse of prescription drugs is a serious and growing health problem in this country. According to the 2005 National Survey on Drug Use and Health, there were more than 6.4 million current non-medical users of psychotherapeutic drugs in the United States - more than the number of Americans abusing cocaine, heroin, hallucinogens, and inhalants, combined. If we look at the people who are just starting out as new drug users, prescription drugs have overtaken marijuana and cocaine as the gateway drug of choice.

One of the goals set forth in this Administration's *2006 Synthetic Drug Control Strategy* is to reduce the abuse, or non-medical use, of prescription drugs by 15 percent over the next three years. Consistent with that end, a primary role of the DEA is to prevent the diversion of pharmaceutical controlled substances while ensuring an adequate supply for legitimate medical and scientific needs.

Diversion of legitimate controlled substances occurs from a number of sources, including, the Internet, pharmacy theft, doctor shopping, prescription forgery, and other means. Unfortunately, a small number of unscrupulous doctors are also illegally supplying those drugs. Although there are very few of them, they can cause tremendous damage. One such doctor in Panama City, Florida, was diverting so many OxyContin pills to abusers and traffickers that after the DEA arrested him, the street price of

OxyContin nearly doubled in the area because of the significantly diminished availability of the drug.

In 2006, there were approximately 750,000 medical doctors and doctors of osteopathic medicine registered with DEA. In any given year, including this past year, less than one in every ten thousand physicians in the United States loses his controlled substance registration based on a DEA investigation for improper prescribing—that is less than .01 percent of all physicians. And far fewer of those physicians are criminally prosecuted for improper prescribing.

The longstanding requirement under the law that physicians may prescribe controlled substances only for legitimate medical purposes in the usual course of professional practice should in no way interfere with the legitimate practice of medicine or cause any physician to be reluctant to provide legitimate treatment. And the DEA's responsibility to enforce the law does not diminish our firm commitment to the balanced policy of promoting pain relief and preventing the abuse of pain medications. To help physicians meet the challenge of ensuring that people who medically need drugs get them, and that those who are diverting them don't, the DEA has developed several initiatives since last fall.

On September 6, 2006, we published in the Federal Register *Dispensing Controlled Substances for the Treatment of Pain*, a policy statement that reiterated the requirements of the Controlled Substances Act and the physician's long-standing responsibility to take reasonable steps to prevent diversion. The DEA also published a Notice of Proposed Rulemaking, which proposes to amend the DEA regulations to permit doctors to issue multiple Schedule II prescriptions during a single office visit, allowing patients to receive up to a 90-day supply of controlled substances according to the fill date that the doctor gives the pharmacist.

The DEA also launched a new section on its website to provide everyone with the facts on investigations against doctors who violate federal drug laws. It's called "Cases Against Doctors." So far, DEA has had more than 86,000 hits to the site. DEA created this site to provide the public with information about the scope of violations that cause DEA to investigate doctors.

In addition, the DEA also updated (and posted on its website) its Practitioner's Manual to aid doctors with their responsibility to take reasonable steps to prevent diversion and abuse. Before it finalized the Practitioner's Manual, the DEA asked a number of doctors to review its updates to the earlier 1990 edition, and they found the new edition helpful in understanding their legal obligations in prescribing drugs.

The DEA agrees that doctors can and should prescribe controlled substances under legitimate medical standards to treat patients in pain. The DEA knows that doctors overwhelmingly agree with what Congress mandates it do: enforce our nation's laws to ensure drugs are used only for the health and welfare of the public.

Cannabis Research

Approval to conduct clinical research involving Schedule I substances in the United States is a joint process involving both the DEA and the Food and Drug Administration (FDA). Clinical studies of a substance for use as a drug must be performed by well qualified applicants who meet the most rigorous of standards in order to conduct bona fide research.

Following the procedures described in Title 21 of the Code of Federal Regulations, new applicants submit their applications to the DEA with research protocols and individual qualifications (typically a resume or curriculum vitae). The DEA is responsible for evaluating whether effective measures to adequately safeguard against diversion are in place as well as assessing factors relating to public interest (See 21 U.S.C. 811(b)). After a preliminary review to ensure completeness of the application and accompanying material, the application package is sent to the Controlled Substances Staff of the FDA and the DEA field office in the area of the proposed research. FDA's role is to determine the qualifications and competency of the applicant, as well as the merits of the protocol. The DEA field office conducts an on-site, pre-registrant investigation, including a personal interview with the applicant, to ensure that security is adequate to prevent diversion or abuse of the controlled substance.

Upon receipt of favorable reports from both the FDA and the DEA field office, a certificate of registration is issued to the researcher. No research with a Schedule I controlled substance can be initiated until the DEA approves the application and a Schedule I research registration is assigned. The DEA has never denied an application to a researcher when FDA has determined that the qualifications and merits of the applicant (as well as of the research proposed) are acceptable, and that adequate security measures are in place.

At present 110 researchers are registered to perform studies within the drug category which includes marijuana, marijuana extracts and non-tetrahydrocannabinol marijuana derivatives that exist in the plant, such as cannabidiol and cannabinol. These studies include evaluation of abuse potential, physical/psychological effects, adverse effects, therapeutic potential, and detection. Nineteen researchers are currently approved to conduct research with smoked marijuana on human subjects.

Enforcing Federal Law in Light of Claims that Marijuana is "Medicine"

Marijuana is a Schedule I substance under Title 21 of the United States Code. As defined by law, a Schedule I substance is one that has *no currently accepted medical use in treatment in the United States,* no accepted safety for use under medical supervision and a high potential for abuse. Along with marijuana, other Schedule I controlled substances include heroin and LSD.

Under the Controlled Substances Act (CSA), DEA is required to act in consultation with the FDA in determining whether a controlled substance has a currently accepted medical use. Under the Federal Food, Drug, and Cosmetic Act (FDCA), it is unlawful to market a new drug in the United States unless FDA approves the drug as being both safe and effective for the treatment of disease or condition. To date, FDA has not found marijuana to be safe and effective for the treatment of any disease or condition. Given the absence of sound scientific evidence establishing that marijuana can be used safely and effectively as medicine, it remains a Schedule I controlled substance under the CSA and illegal under the FDCA to market as a drug. Reviews of the scientific evidence can be triggered by an application to the FDA for approval of marketing of a new drug, or for the new formulation of an existing drug. Reviews can also be triggered by rescheduling petition requests filed with the DEA.

DEA's efforts to enforce Federal law surrounding the possession and trafficking of marijuana have been hampered by the passage of laws in several states which inhibit State and local law enforcement from acting against individuals and organizations selling marijuana under the pretence that it has medicinal value.

Law enforcement has seen a growing list of ailments used by dealers, patients and physicians to justify smoking marijuana. It has become so exhaustive that anyone could claim "a medical need". That list includes ADD, headaches, arthritis, PMS, IBS, hepatitis, renal failure, hypertension, anxiety, depression, post-traumatic stress disorder, insomnia, paranoia, bipolar affective disorder, alcoholism, cocaine and amphetamine addiction, epilepsy, bronchitis, emphysema, osteoporosis, degenerative disc disease, polio, ulcers, stuttering, seizures, color blindness and various types of pain. In a *USA Today* article on March 8, 2007, Scott Imler, who co-wrote the California "medical" marijuana initiative in 1995 said, "What we set out to do was put something in the statutes that said medicine was a defense in case they got arrested using marijuana for medical reasons. What we got was a whole different thing, a big new industry." Imler added "I was pretty naïve, I thought people would act in good faith." Anecdotal information and data have suggested in Los Angeles the significant likelihood that the marijuana as medicine dispensaries affect crime in adjacent communities.

The authority of DEA to investigate those growing, selling, and possessing marijuana, irrespective of State law, was confirmed by recent rulings by the Supreme Court. In *United States v. Oakland Cannabis Buyers' Cooperative*, the Supreme Court held that the Controlled Substances Act contains no exception permitting the distribution of marijuana on the basis of "medical necessity." In *Gonzales v. Raich*, the Court stated that Congress's Commerce Clause authority includes the power to prohibit the intrastate and noncommercial manufacture and possession of marijuana for claimed medical purposes pursuant to state law and concluded that, "Congress had a rational basis for believing that failure to regulate the intrastate manufacture and possession of marijuana would leave a gaping hole in the Controlled Substances Act." These two cases made clear that Federal law prohibiting the manufacture, distribution, and possession of marijuana applies regardless of whether the person engaging in such activity claims to have a "medical necessity," claims to be acting in accordance with state law, or claims to

be acting in a wholly intrastate manner. Thus, DEA remains constitutionally obligated to enforce the Controlled Substances Act in all circumstances.

The DEA's role is one of enforcement. It is, after all, our middle name. We will continue to enforce the law as it stands and to investigate, indict, and arrest those who use the color of state law to possess and sell marijuana.

Conclusion

The Drug Enforcement Administration is a single mission agency. Our role is to enforce the provisions of the Controlled Substances Act, which is considered by Congress to be in the best interests of the people of this nation. The DEA does not discriminate in the application of the law, nor does it interpret the law's intent, a function left appropriately to the courts. The DEA applies the law to law breakers. Among other things, it does so through the Combat Methamphetamine Epidemic Act to prevent the spread of the bill's namesake drug, through the carefully application of its regulatory obligations or by investigating those who would use the color of state law to traffic in marijuana.

I thank you for the opportunity to testify here today, and would welcome any questions the Subcommittee might have.

Mr. NADLER. [Presiding.] Thank you.

I now recognize Dr. Murray for 5 minutes.

TESTIMONY OF DAVID MURRAY, DIRECTOR OF COUNTER-DRUG TECHNOLOGY, ONDCP, THE WHITE HOUSE, WASHINGTON, DC

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

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

Mr. MURRAT1 [CONTINUING]. 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 us not lose track of that, regarding the drug war. Youth use of all drugs is down by 23 percent over the last 5 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——

Mr. NADLER. Mr. Murray, do you think it is as harmful as nicotine?

Mr. MURRAY. Sir, if you are looking at the issue of an approved medicine that would be used—excuse me, sir.

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

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

Mr. FORBES. Can we not take away his time?

Mr. NADLER. I am not going to take away his time. I just asked to answer that question, and we will give you the time.

Mr. FORBES. Well, just I would like to request regular order, Mr. Chairman. That is highly irregular.

Mr. 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 is because, in its smoked form, it is 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 is an addictive substance that has impact, particularly on the vulnerable. Those with psychotic predispositions, those with inclinations toward depression, toward 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 are 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 are 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 will be happy to answer your questions, sir.

[The prepared statement of Mr. Murray follows:]

PREPARED STATEMENT OF DAVID MURRAY

Testimony of Dr. David Murray
Chief Scientist, Office of National Drug Control Policy
Before the Judiciary Subcommittee on Crime, Terrorism, and Homeland Security
"Hearing on the Drug Enforcement Administration's Regulation of Medicine"
July 12, 2007

Chairman Scott, Ranking Member Forbes and distinguished Members of the House 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 current Federal policy regarding so-called "medical" marijuana under state law.

Over the past several decades, there has been an ongoing national debate regarding the use of marijuana for medical purposes. While we all may agree that too many of our citizens suffer from pain and chronic illnesses, as a civilized society we must ensure that we base critical decisions regarding the health and safety of Americans on sound science and research. As Chief Scientist for the national agency tasked by Congress to evaluate, coordinate, and oversee drug policy, I look forward to providing the committee with the latest state of affairs regarding this important issue.

What is Wrong With Permitting the Use of Smoked Marijuana for Medical Purposes?

In order to provide the appropriate perspective regarding medical marijuana, we should examine our Nation's painful lessons from the past. At the beginning of the last century, America faced a serious medicinal challenge. Fly-by-night swindlers traveled from town to town hawking miracle medicines that claimed cures for everything from baldness to life-threatening diseases. While the tonics rarely cured what their proponents claimed, consumers often did report feeling better after taking them. In reality, people felt better because these "medicines" most often contained large amounts of alcohol, opium, or other "feel-good" agents. This chaotic medicinal marketplace, where legitimate medicine competed with unproven and often dangerous snake oils, compelled the U.S. Congress over 100 years ago to create the Food and Drug Administration (FDA), which is responsible for approving, regulating, and verifying the effectiveness and safety of medicines. More than making people "feel better," a core element of FDA's public health mission is to verify and ensure that medicines fulfill two critical principles: safety, and effectiveness in treating medical conditions.

The FDA's process for approving medicine has contributed to the United States having the world's finest medical system. In the century that the FDA has been approving medicines, it has shown an open willingness to evaluate and approve potentially harmful and addictive substances if it can be proven that the benefits of these substances provide outweigh the risks. For instance, medicinal derivatives of the opium poppy and the coca plant clearly demonstrate this principle. But smoked marijuana has never passed this test. Simply stated, the FDA has not found compelling scientific evidence that smoking marijuana relieves the myriad of ailments that its proponents

claim. Moreover, the medical community prescribes drugs that are safer and easier to administer and that have been scientifically proven to do a far more effective job at treating the ailments that marijuana proponents claim are relieved by smoking marijuana.

Funded by millions from those who want to legalize marijuana outright, marijuana lobbyists have now been deployed to Capitol Hill and to States across the Nation to employ their favored tactic of using Americans' natural compassion for the sick to garner support for a far different agenda. These modern-day snake oil proponents cite testimonials—not science—that smoked marijuana helps patients suffering from AIDS, cancer, and other painful diseases "feel better." Unfortunately for America's sick, the same scenario our Nation dealt with a century ago has returned, and a number of states have passed voter referenda or legislative actions making smoked marijuana available for a variety of medical conditions upon a doctor's recommendation under state law.

On April 20th, 2006, the Department of Health and Human Services (which includes FDA, the Substance Abuse and Mental Health Services Administration and the National Institute on Drug Abuse), the Drug Enforcement Administration, and the Office of National Drug Control Policy issued an advisory reinforcing the fact that no sound scientific studies have supported medical use of smoked marijuana for treatment in the United States, and no animal or human data support the safety or efficacy of smoked marijuana for general medical use. Additionally, the Institute of Medicine (IOM) has concluded that smoking marijuana is not recommended for any long-term medical use, and a subsequent IOM report (March 1, 1999) declared that, "marijuana is not modern medicine." These statements add to a substantial list of legitimate public health organizations that have already spoken out on this issue, including the American Medical Association, the National Cancer Institute, the American Cancer Society, and the National Multiple Sclerosis Society – all of which do not support the smoked form of marijuana as medicine.

Existing Legal Drugs Provide Superior Treatment for Medical Conditions

While the FDA has approved safe and effective medication for the treatment of glaucoma, nausea, wasting syndrome, cancer, neuropathic pain, and multiple sclerosis, it is also true that THC, the primary active chemical in marijuana and other cannabinoids in the plant might well be useful for treating certain medical problems. For example, the FDA approved synthetic THC, the main ingredient in Marinol, to control nausea in cancer chemotherapy patients and to stimulate appetite in people with AIDS. Marinol, in the oral form, is a legal prescription drug available on the market by prescription since 1985. It is currently classified as a Schedule III drug under the Comprehensive Drug Abuse Prevention and Control Act, meaning that the drug is widely available for patients who may need it.

In light of these scientifically proven medicinal alternatives, the idea of telling suffering patients that the best we can do for them is to encourage them to inhale the hot smoke of a burning weed, of unknown dose and purity, seems medieval at best. To resolve this whether science can demonstrate any conceivable medical benefit, NIH is

conducting controlled clinical trials of smoked marijuana. To date, the best available evidence points to the conclusion that the adverse effects of marijuana smoke on the respiratory system would almost certainly offset any possible benefit. As a result, marijuana remains as a Schedule I controlled substance under the Comprehensive Drug Abuse Prevention and Control Act of 1970. In other words, marijuana remains a dangerous drug that has no recognized medical value.

In fact, there is some evidence that suggests that prescribing smoking marijuana may actually harm the health of patients. The delicate immune systems of seriously ill patients, for example, may become compromised by the smoking of marijuana. Research has already demonstrated that the daily use of marijuana can compromise lung function and increase the risk for respiratory diseases, similar to those associated with nicotine cigarettes. Additionally, marijuana also has a high potential for abuse and can incur addiction. Research has also shown that frequent use of marijuana leads to tolerance of the psychoactive effects. Smokers may compensate by smoking more often or seeking higher potency marijuana.

Finally, in people with psychotic or other mental health problems, the use of marijuana can precipitate severe emotional disorders. Chronic use of marijuana may increase the risk of psychotic symptoms in people with a past history of schizophrenia. Marijuana smoking by young people may lead to impairment of higher brain function and neuropsychiatric disorders, as well as a higher risk for addiction and polydrug abuse problems.

Medical Marijuana Laws Do Not Work

Ten years of national experience with state-based voter referenda and legislative actions legalizing medical marijuana under state law also have bred abuse, confusion, and crime. An increasing number of reports have begun to illustrate this phenomenon. Consider the following:

- **Medical marijuana laws lead to drug-related violence**. Since the first medical marijuana law passed in the United States, as many as 20 "legal" medical marijuana providers have been killed around the country, mostly in robberies. (Killing Highlights Risk of Selling Marijuana. New York Times, March 2nd, 2007).
- **Medical marijuana laws protect drug dealers.** After Colorado legalized medical marijuana, a local CBS television station discovered that licensed medical marijuana providers were using medical marijuana laws to foster drug dealing. In one instance, a CBS reporter asked Ken Gorman, a licensed medical marijuana provider and user, how many people he had given marijuana to who weren't sick. He responded by saying, "Hundreds....When we passed the [medical marijuana] law we passed a great, great law...There are so many holes in it that for us, the patient, police can't do anything." Ken Gorman admitted he didn't have a medical condition and "just wanted to get high." Gorman was killed a month later in a marijuana-related robbery. (CBS Denver, February 11th, 2007, Glazer, Andrew. Medical Marijuana Clinics Face Crackdown, Associated Press, March 11th, 2007.)

- **Founding proponents of medical marijuana in the United States have reversed their key positions of support for medical marijuana**. Rev. Scott Imler, Co-founder of Prop 215, has lamented the passage of California's medical marijuana law stating that, "We created Prop. 215 so that patients would not have to deal with black market profiteers. But today it is all about the money. Most of the dispensaries operating in California are little more than dope dealers with store fronts." Imler also said that medical marijuana has "turned into a joke." Steve Kubby, another Co-founder of medical marijuana in California stated in a letter to supporters on April 14th, 2006 that "Marinol is an acceptable, if not ideal, substitute for whole cannabis in treating my otherwise fatal disease." (Alternatives magazine, Fall, 2006 Issue 39, San Gabriel Valley Tribune 2/07, Message from Steve Kubby, Steve Kubby Released After Serving 62 Days in Jail, April 14th, 2006)

Conclusion

Chairman Scott, Ranking Member Forbes, our investment in medical science is at risk if we do not defend the proven process by which medicines are brought to the market and to patient-physician relationships. All drugs must undergo rigorous clinical trials before a drug can be released for public use. The responsibilities of the public health system are to ensure the safety, efficacy, and effectiveness of contemporary drugs. This responsibility cannot be discharged where science-based knowledge is discarded in favor of misguided hearsay and uninformed pressure politics. I look forward to working with Congress to ensure that our nation's drug policies continue to work to make our national drug problem smaller and keep our citizens as safe and healthy as possible.

Thank you.

In Their Words: *What the Experts Say*:

The American Academy of Ophthalmology:

"Based on reviews by the National Eye Institute (NEI) and the Institute of Medicine and on available scientific evidence, the Task Force on Complementary Therapies believes that **no scientific evidence has been found that demonstrates increased benefits and/or diminished risks of marijuana use to treat glaucoma compared with the wide variety of pharmaceutical agents now available.**"
Complementary Therapy Assessment: Marijuana in the Treatment of Glaucoma, American Academy of Ophthalmology, May 2003

The American Medical Association:

"...AMA recommends that marijuana be retained in Schedule I of the Controlled Substances Act...AMA believes that the NIH should use its resources and influence to support the development of a smoke-free inhaled delivery system for marijuana or delta-9-tetrahydrocannabinol (THC) to reduce the health hazards associated with the combustion and inhalation of marijuana..."
Policy Statement H-95.952. American Medical Association, http://www.ama-assn.org

The National Multiple Sclerosis Society:

"Studies completed thus far have not provided convincing evidence that marijuana or its derivatives provide substantiated benefits for symptoms of MS."
The MS Information Sourcebook, Marijuana (Cannabis), National Multiple Sclerosis Society, September 18th, 2006

The Institute of Medicine (IOM):

"Because of the health risks associated with smoking, smoked marijuana should generally not be recommended for long-term medical use."
Marijuana and Medicine: Assessing the Science Base, Institute of Medicine, 1999

Mr. NADLER. I thank the gentleman.

I now recognize Dr. Heiden for 5 minutes.

TESTIMONY OF EDWARD J. HEIDEN, PH.D., HEIDEN ASSOCIATES, INC., WASHINGTON, DC

Mr. HEIDEN. Thank you. 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 am 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——

Mr. NADLER. The witness's time has expired.

Could you wrap up, please?

Mr. 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 is 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.

[The prepared statement of Mr. Heiden follows:]

PREPARED STATEMENT OF EDWARD J. HEIDEN

Good morning. My name is Dr. Edward J. Heiden. I am president of Heiden Associates, Inc., an economic consulting firm specializing in health and safety issues and located in Washington DC. For the past 26 years, Heiden Associates has been assisting companies and trade associations in examining the economic impact of government regulation. A statement of our corporate capabilities and my resume is attached.

Early this year my firm, Heiden Associates, and I were retained by the American Council on Regulatory Compliance (ACRC)—an association representing manufacturers, importers, and distributors of pseudoephedrine and ephedrine-based products such as over-the-counter cough and cold and asthma relief medications, whose members sell primarily to convenience stores and other non-mass-merchandiser

channels. Our assignment was to help them respond to a draft report, prepared by DEA and published for comment in the Federal Register, containing DEA's 2007 national estimate of legitimate medical need and use for ephedrine and pseudoephedrine in prescription drug and over-the-counter (OTC) products.

We were asked to examine two issues: (1) the soundness of the data and methodology used by DEA to prepare its report and estimate; and (2) 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 had not been adequately considered, if at all. For instance, members indicated they had never been consulted as the needs assessment was being prepared. A few also indicated, after initially examining the DEA analysis, that the entire estimate of national need for ephedrine contained in the report was far lower than the supply need represented just by what they knew to be their own sales to convenience stores and other non-mass-merchandising channels.

We briefly report below on the results of our work, and the conclusions and recommendations we have drawn from it.

SUMMARY OF OUR WORK

Analysis of DEA Methodology and Treatment of Ephedrine Needs for Product Sellers to Convenience Stores and Related Market Channels.

DEA's assessment relied on a study by its contractor, IMS Health Government Solutions (IMS), to estimate medical needs for ephedrine and pseudoephedrine based on data that the company routinely collects and offers annually to customers. IMS used several types of data for its study—sales to retail establishments (including pharmacies), sales by retail establishments to patients, and medical insurance claims. However, the DEA report itself provided very sparse and incomplete documentation as to how this data was used, and lacked much of the evidence that an interested and engaged professional analyst would need and expect to have in order to determine exactly how the methodology was actually applied. Elementary supporting materials, especially the data files and calculations that would show the key procedures used, were missing, and in one important instance the agency refused to provide us with access when we made a request.

Likewise, DEA's treatment of exactly how the needs of the convenience store market channel was treated in the national estimation process is vague, confusing, and even contradictory in several important respects. For example, even though convenience stores are mentioned by DEA as a market channel included in the study, there is no way that an analyst can tell how the major data sources used by DEA actually treat the sales of such stores in their role as suppliers of ephedrine and pseudoephedrine products for sale to the public. Without any documentation, explanation, or citation to source data, the report simply states that the convenience store channel had less than 0.1 million grams of legitimate OTC ephedrine-based product purchase needs.

Development of Independent Estimates of Ephedrine Needs for Convenience Store and Related Market Channels.

Because of this lack of documentation or explanation by DEA of its estimates, and the strong view by ACRC members that DEA's estimate of less than 0.1 million grams to convenience stores and other non-mass-merchandiser channels lacked foundation, Heiden Associates conducted an independent examination of the need for ephedrine-based products in these market sectors. As a starting point, we obtained from DEA, through the ACRC, a copy of the product code listing used by DEA's contractor for the study, IMS, to develop its estimates. Once we received this listing, we asked ACRC industry members to review it. **Review by industry members 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 pseudo-ephedrine needs assessment. This means that none of these products was considered to be "in scope" for purposes of development of the DEA needs assessment. Further, ACRC members indicated that not one of them had been interviewed or queried by DEA or its consultant as part of the needs assessment development process.**

Consequently, since it was clear that DEA and its consultant IMS were not adequately capturing the sales of legitimately marketed ephedrine-based products, we felt it was necessary to work directly with ACRC staff and member firms on a confidential reporting basis to develop preliminary estimates of ephedrine-based OTC products to convenience stores and related channels. Specifically, we asked individual participating manufacturers, importers, and distributors to provide 2005 esti-

mates of their total unit sales of ephedrine-based products for medical use and the channels through which they distributed these products. We also interviewed ACRC Board members to obtain their best assessments of the overall size of ephedrine-based product sales to convenience stores, the sector accounting for the largest portion of ACRC member industry sales. In addition, we consulted various extrinsic data sources to develop a profile of the economic importance of convenience stores and other non-mass-merchandising distribution channels that appeared not to have been adequately captured in the DEA consultant's study.

Eight ACRC member firms in all, of varying size and type (manufacturer, importer, and distributor) responded to our request for relevant sales data. In all, these eight firms sold more than 1.5 billion doses of 12.5 and 25 mg ephedrine-based products in 2005 to the public. About 80 percent of these sales were made through "bricks and mortar" outlets such as convenience stores and small independent grocers, with the remainder reported through mail order and online channels. Collectively, these products contained approximately 27,880 kilograms of ephedrine, or more than seven times the amount DEA proposed as its preliminary 2007 annual needs estimate.

In reviewing DEA's own statistical data, it has become clear to me that these products are not the major source of diversion for the production of methamphetamine. According to DEA Administrator Tandy's recent testimony before the Senate Foreign Relations Committee: ". . . super labs, which are primarily controlled by Mexican drug trafficking organizations . . . are supplying the majority of the methamphetamine consumed in this country." The vast bulk of the products found in small toxic methamphetamine laboratories are name brand pseudoephedrine cough and cold products, such as Sudafed, purchased in large chain pharmacies and mass merchandisers. The products distributed by the ACRC and other small distributors are off brand combination ephedrine asthma relief products, which are *not* found in these illicit laboratories as a precursor to make methamphetamine.

How is it possible that the DEA/IMS study missed such a large portion of the overall market for ephedrine-based products in its estimates? It is not as if the convenience store and online/mail-order market sectors are inconspicuous: according to the most recent source data available, convenience stores and online/mail order firms sold an estimated $644 million of non-prescription medicines in 2002, with more than 38,000 convenience stores selling non-prescription medicines.

There are several possible reasons why DEA might have missed so much ephedrine-based product sold through non-mass-merchandising channels.

First, many of the companies involved in manufacturing and marketing ephedrine-based asthma products are also in the business of producing and distributing dietary and nutritional supplements, sales of which are tracked under a separate product code than under the code for non-prescription medicines. It is very possible that retail establishments might bundle products distributed by ACRC members and other similar firms under a product code such as vitamins, minerals, and other dietary supplements, or even general merchandise, that is not defined as within the scope of the IMS study.

Second, many convenience stores and independent grocers, particularly smaller ones in center city and rural locations still do not have the ability to scan individual product purchases. Non-scanning convenience stores are not likely to have been included in the databases used for the DEA needs assessment, which rely heavily on scanned data.

Third, the participants in the DEA needs assessment data base used to track OTC drug purchases (Homescan) may have under-represented poorer, lower health status households in urban and rural areas, as is sometimes the case with national consumer market panels that we have worked with in past studies. In this connection, it is important to note that it is convenience stores and small retailers in these less completely-tracked locations who are most likely to make products available to asthmatics where other retailers are non-existent or are open only during daytime and early evening hours. IMS does not have the ability to accurately capture convenience store data.

CONCLUSION

The lack of access to data that serve as the foundation of the IMS study estimates and the sparse, non-transparent, confusing, and in some cases seemingly contradictory documentation of the procedures used to derive the annual needs assessment from these data make it difficult to determine whether the DEA has correctly characterized the volume of ephedrine requirements for prescription and non-prescription products sold in chain drug stores, large grocery chains, and mass merchandisers. However, it is obvious that the IMS study failed to incorporate any data on

ephedrine-based products lawfully marketed by a substantial and economically significant sector of manufacturers, importers, distributors, and retailers who market primarily through convenience stores and online/mail-order channels. This failure has caused the DEA to propose an unrealistically low preliminary estimate for the amount of ephedrine required for legitimate needs in 2007. Should this estimate stand as the basis for DEA decision-making, 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 (such as mass merchandisers) are non-existent or only open during daytime or early evening hours.

We encourage the DEA to revisit this issue and make the data and analysis that underpin the IMS study estimates available for review under appropriate restrictions to ensure confidentiality and limit the use of the data. With access to these materials, we are confident that we would be able to work with DEA and/or IMS analysts to develop a fuller and more complete picture of the market needs for ephedrine-based products.

Mr. NADLER. Thank you very much.

I will now recognize Ms. Valerie Corral for 5 minutes.

TESTIMONY OF VALERIE CORRAL, FOUNDER OF WAMM, WO/MEN'S ALLIANCE FOR MEDICAL MARIJUANA, DAVENPORT, CA

Ms. CORRAL. Thanks to the Honorable Chair and distinguished—it is 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 have 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 1970's, under the Nixon administration, some research on medical marijuana 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 have been at the bedside of more than 100, tell us that maijuana 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 would 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 1990's on State law, on county law and on city law. We work very close with law enforcement. We are transparent in our work and we offer medicine at no cost.

We have changed the laws in each governing body, very slowly, but it has worked. We have 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 have 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 is 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.

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

Ms. CORRAL. That is it, and thank you so much.

[The prepared statement of Ms. Corral follows:]

PREPARED STATEMENT OF VALERIE CORRAL

Mr. Chairman, distinguished members of the committee, I thank you for inviting me to speak today.

Upon receiving confirmation that I would have the privilege to appear before you, my elation was tempered only by exhaustion. For three nights I have had the honor of caring for my beloved friend, a member of WAMM, the medical marijuana hospice that I co-founded, and medical marijuana patient who is nearing the end of her struggle with ovarian cancer. She is the single mother of a 15-year-old daughter, and today she lays dying at her home in Santa Cruz. As I stood by her bedside, the impact struck me deeply, and the importance of this opportunity grew profoundly tangible. It is difficult to deny personal experience, and having repeatedly witnessed the relief of suffering in hundreds of my dying friends leaves little room for doubt.

Today, thousands of seriously ill Americans face arrest and prosecution at the hands of the federal government. Why? Because our doctors recommend a medicine that is condemned without evidence. Science does not form the basis of the irrational decision to hold this medicine hostage. Yet, sick and dying Americans are willing to risk imprisonment because suffering is a greater enemy than the fear of our own government. We rely on the medicinal properties unique to marijuana to help us cope with a variety of debilitating diseases, including AIDS, cancer, epilepsy and multiple sclerosis. Marijuana provides otherwise unattainable relief from an array of unbearable symptoms, such as chronic pain, intractable vomiting and muscle spasticity, as well as from the side effects of allopathic drugs, pharmaceuticals that cause addiction, nausea and confusion. This simple medicine allows seriously ill people to gain a measure of control over symptoms and, in turn, the ability to affect the circumstances of death.

Despite the testimony of thousands of patients and doctors, coupled with a tome of scientific research confirming marijuana's medical value, our government, specifically the Drug Enforcement Administration (DEA), remains married to subversion in its denial of a state's right to protect its seriously ill citizens. It is not the purpose of government to stymie medical science, but to avail itself to the gathering of knowledge as it seeks to create a compassionate response to the ills of a nation and its people. Devoid of scientific rationale, the federal intransigence toward medical marijuana appears to be rooted in the political calculations of the "War on Drugs." Can our elected officials ignore an ever-growing patient force that decries the callous antics of a government which puts politics before people's lives?

On March 23, 1973, at the age of 20, I suffered a severe closed head trauma in a serious automobile accident, and my life was changed forever. As a result of the accident, I began to suffer as many as five gran mal seizures a day. When I began to convulse, my parents would hold me on the floor while I foamed at the mouth and lost control of my bladder, urinating all over myself. During the seizures, I had no conscious control over my body, my mind or my being. Following the seizures, I typically slept for several hours and would wake up in tremendous pain with no memory of the seizures.

Doctors prescribed a myriad of anticonvulsants and pain medications. But the medications did not prevent the seizures and only minimally reduced my pain. Since phenobarbital and Dylantin offered little reprieve from the convulsions, my doctors added more prescription medications to my regimen. They prescribed a crippling anti-epileptic drug called Mysoline along with Percodan and Diazepam for pain. I did not fare any better with these medications. Each left me drunk with side effects and failed to alleviate my seizures. No medication or treatment offered me any hope.

These anti-convulsant and pain medications also sedated me to the point that I lived in a near vegetative state. My parents described me as "catatonic." I felt like I was living under water. I was wholly dysfunctional. Friends and family had to remind me to eat. I could not think clearly. I slept fitfully. My doctors changed my medications and tried different dosages, but the seizures continued to strike with little warning. The medications affected my vision, disabling my ability to read. They also affected my joints and connective tissue, my kidneys and liver, and they depleted my white blood cells, diminishing my immune system and rendering me vulnerable to viruses. I constantly battled ordinary colds and flus, which often resulted in hospitalization.

Eventually, I became physically dependent on my medications. I descended into a deep pharmaceutical darkness that paralyzed me. I could not work. I discovered that I could not even cross the street by myself after an incident where I walked into oncoming traffic. On another occasion, I nearly drowned while taking a bath. I could not complete the simplest of tasks. Family and friends would not leave me unattended, because at anytime I could have been overcome by a seizure and injure

myself. I spiraled into the isolation resulting from both the illness and the only drugs available to treat it. I survived this way for more than two years.

Meanwhile, my husband and caregiver, Mike Corral, scoured scientific and medical journals for a sign of some promising new therapy. His thorough research uncovered information that changed my life forever. He found an article published in a medical journal in the early 1970's, discussing marijuana's ability to control laboratory induced seizures in rats. This revelation, though hard at first for us to believe, offered a rare glimmer of hope. I yearned for any alternative to the powerful, debilitating prescription drugs and the ravages of the seizures and pain that consumed me. I obtained a small amount of marijuana and found that smoking it diminished my seizure activity almost immediately. Mike and I carefully figured out how much and with what frequency I should use medical marijuana to stave off my symptoms, and I adhered to that religiously. Whenever I felt an aura (the premonitory sensation that often precedes a seizure), I smoked a little more. To our amazement, it halted the onset of convulsions.

For the next two-and-a-half years, I slowly decreased the dosages of my various prescription drugs and finally stopped my anti-convulsants altogether. The only medication that I continue to rely on is marijuana. It controls my seizures and restores normalcy to my life. I can now do virtually everything that I did before my accident. I still experience neurological problems, but I live seizure-free because I use medical marijuana.

My personal experience with medical marijuana led me to share what I had learned with other patients, allowing me to again and again witness the benefits of medical marijuana firsthand. A particular patient, Harrold Allen, comes to mind. He was diagnosed with pancreatic cancer and given a prognosis of six months to live. His illness did not only devastate his health, it robbed him of his ability to provide for his family. Financially, he had to rely solely on state disability funding, which was not enough to pay for his prohibitively costly medication. Consequently, he lost everything, including his home, his automobile and family heirlooms. He reached a point where he was taking 42 Dilaudid per day. He substituted medical marijuana for the narcotics he was taking and within one day he ceased all narcotic use, without experiencing any withdrawal. His doctor once told me how astonished he was at the success of medical marijuana in Harrold's case and that he completely supported this alternative treatment. The miracle is that Harrold Allen lived six years beyond his prognosis.

It is because of just such experiences that, in the Spring of 1993, Mike and I cofounded the Wo/Men's Alliance for Medical Marijuana, WAMM, our hospice care community comprised of patients who rely on medical marijuana to quell the symptoms of grave illness. WAMM grew to a membership of 250 patients, mostly terminally ill. In the 14 years since our inception, 189 WAMM members have died—nearly one per month. Our collective serves as a critical support group for members and families who gather at our weekly meetings. Our members are as diverse as disease itself; still an intimate relationship with illness is the very thing that unites us. WAMM is committed to working in accordance with state law and in partnership with our local community and law enforcement agencies.

Unfortunately, the federal government seems to determined to sabotage our efforts. Both WAMM and the course of my own life were irrevocably changed the day the DEA focused its wrath on our small collective garden in Santa Cruz, California. Their target . . . Mike and me.

Early in the morning on September 5, 2002, Mike and I were awakened by the sound of approaching vehicles. With no warning, 20 to 30 armed DEA agents broke into our home with terrifying and overwhelming force. Yelling, with guns drawn, they commanded us to lie on the floor. They cuffed us and held guns to our heads. A paraplegic WAMM board member who sleeps with an assisted breathing device was staying at my home. She was awakened at gun-point by five agents, handcuffed, and ordered to stand, which she is physically incapable of doing. Officers brought me to the other house on the land, leaving my friend behind. Knowing the severity of her condition, I pleaded with them to remove her handcuffs and bring her to where we were being detained. Eventually they did so and I noticed that she was experiencing difficulty in breathing. She mentioned that she was also experiencing chest pain and her blood pressure was dangerously high.

The officers proceeded to our collective garden, used to cultivate medical marijuana, and tore from the ground and seized 160 of WAMM's marijuana plants and seven plants growing in my personal vegetable garden. They also seized numerous allotments of marijuana that had been pre-sorted for correct patient dosages and were kept in assigned envelopes. Additionally, they took various pieces of property including personal laptops, and photographs. The confiscation of WAMM's medicine has had a devastating effect on our ability to serve patients and to mitigate suf-

fering. In addition, WAMM members have expressed fear that our government will commit additional acts of reprisal against us because of our visibility. To date, neither Mike nor myself have been officially charged with any crimes stemming from the raid. It is worth noting that at the time of the raid all of WAMM's activities remained in full accordance with state law.

Following the DEA raid Santa Cruz County Supervisor Mardi Wormhoudt echoed the sentiments of our community when she said, "It is not reassuring to me to know that federal agents, instead of concentrating on issues of national security, are running around the mountains of Santa Cruz County disrupting the work of people who provide a valuable medical resource to the community."

In fact, both the City and the County of Santa Cruz County have signed on to our lawsuit against the federal government challenging the constitutionality of the DEA raid and seeking an injunction against future raids and arrests. The City of Santa Cruz has further enacted an ordinance establishing a mechanism for the provision of medical marijuana to qualified patients as an official government function. The ordinance becomes effective when federal sanctions are granted.

The situation in Santa Cruz offers a microcosm of the current tensions between the federal prohibition of medical marijuana and the will of the American people as expressed through mounting medical marijuana voter initiatives. Throughout our nation, patients and doctors, cities and states, are grappling with a means to provide medical marijuana to those in need. Twelve states have enacted legislation protecting qualified patients under state law, and more are destined to follow. But rather than allow the states to serve as laboratories for the federal system, current federal policy prevents states from establishing legitimate medical marijuana infrastructures—no matter how safe or secure such systems may prove. This leaves patients and state elected officials adrift in a legal morass—confident that medical marijuana is medicine, but blocked by federal law from following the recommendations of doctors and the will of voters. There is a solution to this dilemma provided by a piece of legislation soon to be considered by the House of Representatives: the Hinchey amendment.

The Hinchey medical marijuana amendment to the Commerce, Justice, Science Appropriations bill, sponsored by Congressman Maurice Hinchey (D-NY), would bar the Department of Justice, specifically the DEA from using funds to interfere with state medical marijuana laws. Under Hinchey, patients would no longer fear raids, arrests or prosecutions for using medical marijuana in compliance with state law. The Hinchey amendment would allow states to chart their own course on medical marijuana, instituting policies to best protect local patients and reflect the wishes of local communities.

A second, longer-term federal fix to the medical marijuana impasse was actually signaled by Supreme Court Justice Stephen Breyer during oral arguments in *Gonzales v. Raich*—a Supreme Court case challenging the federal prohibition on medical marijuana. Justice Breyer suggested that patients ask the Food and Drug Administration (FDA) to reclassify marijuana for medical use as "the obvious way to get what they want," adding, "Medicine by regulation is better than medicine by referendum." Unfortunately, the route suggested by Justice Breyer is currently closed.

For 40-years the federal government has maintained a monopoly on the supply of marijuana available for scientific research. Through this monopoly, the government has prevented any research aimed at taking marijuana through the established FDA regulatory system by simply denying marijuana to those attempting to conduct such studies. Efforts to develop marijuana as a legal, prescription medicine have been effectively hamstrung.

Incredibly, marijuana remains the only Schedule I drug that the DEA prohibits from being produced by private laboratories for scientific research. Other controlled substances, including LSD, MDMA (also known as "Ecstasy"), heroin and cocaine, are available to researchers from DEA-licensed private laboratories.

In contrast, the National Institute on Drug Abuse (NIDA) constitutes scientists' sole source of marijuana in the U.S. This monopoly exists despite NIDA's inherent conflict of interest due to its mission to study the harmful effects of drugs of abuse. Further undermining its position as marijuana gatekeeper, NIDA has been criticized for its repeated refusal to make marijuana available for privately funded FDA-approved research seeking to develop smoked or vaporized marijuana into an FDA-approved prescription medicine. Researchers also report that marijuana available through NIDA is of poor quality and variety and is not optimized to meet FDA standards for prescription drug development.

As the situation currently stands, due to an inability to secure marijuana to research its development as an FDA-approved prescription medicine, privately funded scientists in the U.S. are entirely blocked from conducting such research. Con-

sequently, pharmaceutical companies are effectively barred from the standard research path that would enable the FDA to determine whether marijuana should be brought to market as an approved prescription medicine.

This illogical arrangement is fundamentally responsible for muddying what would otherwise be a rather clear-cut discussion: If marijuana is an effective medicine for a variety of debilitating ailments, then why not simply develop it as a prescription medication through the accepted pharmaceutical regulatory framework? It is because this framework, available to all other substances, controlled or otherwise, is effectively closed to marijuana. The federal government has created a marijuana exception.

Thankfully, change is in the air. On May 15, DEA Administrative Law Judge Mary Ellen Bittner officially forwarded to DEA Deputy Administrator Michele Leonhart her final recommendation in support of University of Massachusetts-Amherst Professor Lyle Craker's almost six-year-old petition to cultivate marijuana for use in privately funded FDA-approved studies.

Simply put, Professor Craker is seeking a license from DEA to cultivate marijuana that would be used by other scientists in privately funded, FDA-approved studies aimed at developing marijuana as a legal, prescription medicine.

On February 12 of this year, following nine days of hearings, testimony and evidence from both sides, including from researchers who reported that the government denied their requests for marijuana for use in FDA-approved research protocols, Judge Bittner concluded that, "NIDA's system for evaluating requests for marijuana has resulted in some researchers who hold DEA registrations and requisite approval from [HHS and FDA] being unable to conduct their research because NIDA has refused to provide them with marijuana. I therefore find that the existing supply is not adequate." She added, "Respondent's registration to cultivate marijuana would be in the public interest."

Unfortunately, Judge Bittner is not the final arbiter. The Judge's opinion serves as a recommendation to DEA Deputy Administrator Michele Leonhart, who will make the final call. It is imperative that Deputy Administrator Leonhart be made aware of the need to follow the recommendation of the DEA's own judge and grant Professor Craker's application. After all, if marijuana is a legitimate medicine, would it not be logical that it be allowed within the FDA's established regulatory framework. If it's not, what's the harm in finding out through legitimate, unobstructed scientific studies?

And has not the federal government already acknowledged marijuana's medical efficacy? To this day, a federal program established in 1978 provides government grown marijuana to seven patients. This FDA-administered Investigational New Drug program was closed to new applicants in 1991 due to a massive influx of applications stemming from the AIDS crises, which the program was not designed to handle. In addition, the FDA has approved the cannabinoid drug Marinol. Marinol, which contains dronabinol, an analog of Delta 9-tetrahydrocannabinol (THC), is prescribed as an appetite stimulant, primarily for AIDS, chemotherapy and gastric bypass patients.

The fact is that marijuana is an extremely effective treatment for many serious ailments. As documented by a recent, rigorous and unassailable double-blind study conducted by Dr. Donald Abrams at the University of California at San Francisco that found smoked marijuana to be extremely effective at relieving the intense pain of a debilitating condition known as peripheral neuropathy, which often afflicts AIDS patients as well as those suffering with diabetes or multiple sclerosis. This study leaves no doubt that marijuana can safely ease this type of pain, which is often unresponsive to powerful narcotics like morphine and OxyContin. And of course, the study necessarily utilized government-supplied marijuana of notoriously poor quality—as all such research in the U.S. must currently do—and so likely underestimates marijuana's medical benefit.

As Lester Grinspoon, an emeritus professor of psychiatry at Harvard Medical School, recently wrote in the *Boston Globe,* "Marihuana is effective at relieving nausea and vomiting, spasticity, appetite loss, certain types of pain, and other debilitating symptoms. And it is extraordinarily safe—safer than most medicines prescribed every day. If marijuana were a new discovery rather than a well-known substance carrying cultural and political baggage, it would be hailed as a wonder drug."

It is unconscionable for federal agencies to continue to put politically expedient promotion of reefer madness before irrefutable medical science and the will and best interest of the American people. The well-being of thousands of seriously ill Americans backed by the opinion of the vast majority of their countrymen demands that medical marijuana be freed from federal interference.

Mr. NADLER. Thank you very much.

We will now recognize——

Ms. REYNOLDS. Siobhan.

Mr. NADLER. Siobhan.

Ms. REYNOLDS. It is Siobhan.

Mr. NADLER. Ms. Siobhan Reynolds, for 5 minutes.

TESTIMONY OF SIOBHAN REYNOLDS, PRESIDENT, PAIN RELIEF NETWORK, SANTA FE, NM

Ms. REYNOLDS. Thank you, Mr. Chairman, Mr. Ranking Member, Members of the Committee.

I am not going to go into the really sad story of my husband's death and everything that we endured leading up to it. It is in my testimony, and I hope you will 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 is 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 is 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 is 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 is 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 is like to have your husband or your wife or your son or your daughter sacrificed to an unwinnable goal. But, when you are 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 are 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 is 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 are asking you to put an end to it as soon as possible. Thank you very much.

[The prepared statement of Ms. Reynolds follows:]

PREPARED STATEMENT OF SIOBHAN REYNOLDS

Testimony of Siobhan Reynolds, Founder of Pain Relief Network
Before House Judiciary Committee on DEA Oversight
7/12/07

Mr. Chairman and members of the committee. Thank you for asking me to speak on the current situation facing patients in chronic pain. We come to you seeking your protection from the Drug Enforcement Administration, an agency out-of-control, an agency that has demonstrated no respect for the rights of ill Americans, nor for the rule of law itself.

My name is Siobhan Reynolds and I head the Pain Relief Network. My late husband Sean Greenwood and I founded PRN in order to oppose and speak out against the DEA's crackdown on pain treating physicians, a crackdown that kicked into high gear immediately following the tragic events of September 11th 2001.

While most Americans began to pull themselves together and readjust their thinking to a dangerous new world, we in the pain community, patients, their families, doctors and their families found ourselves set upon by the full force of the police powers of the Federal government, led in the main, by the DEA under administrator Karen Tandy. It is fair to say that we have, indeed, been the victims of a reign of terror, instigated and implemented by agents of our own government.

We have, until now, been unable to persuade our elected officials to listen to our grievance and have, as a result, suffered a constant and unrelenting onslaught; an onslaught, which has claimed many innocent and valuable, lives. Additionally, many of our nation's finest and most compassionate physicians have been sentenced to prison terms exceeding three decades. Yet all of this is merely the tip of the iceberg, for the most scandalous part of this shocking tale is that the DEA's actions have served to warn the rest of the medical community not to treat serious pain in all its forms.

Perhaps you think that if you, or a member of your family were to have a car accident, suffer ongoing pain after a surgery, or contract cancer, that doctors would be able to tell that you or your loved one really needed the medicine and that the medicine would be made available. The terrible truth is that you would be wrong. All the available evidence shows us that we are, in fact, living in an ongoing and worsening medical crisis as concerns the undertreatment of pain.

When Ms. Tandy brandished that bag of pills at a press conference in spite of the fact she had been warned of the dire consequences of her actions, she indeed sealed the fate of our most vulnerable citizens. Since then, Americans in pain have been subject to the excesses of a law enforcement free-for-all, Moreover, profiteering and exploitation are rampant: Patients are being forced to try new and dangerous drugs rather than being allowed to choose the safe and effective opioid medicine, the medicines in use for thousands of years to treat pain. Patients are rarely told that they will not find effective care, but are instead shuttled from clinic to clinic, in a kind of death march, their Medicare or insurance policy sucked dry of whatever benefits are available to the medical system, surgeons and physical therapists, psychologists and "addictionologists" along the way

In order for your to get the full picture of what has occurred and is occurring right now, I will offer you a brief synopsis of the history of pain care, or rather the lack thereof, under drug prohibition. For while the Harrison Narcotics Act and The Controlled Substances Act were promulgated with the stated, and I believe sincere intention of exempting medical pain treatment from Federal criminalization, our medical culture was perverted by enforcement actions taken against physicians and has been deeply and perhaps permanently damaged as a result.

After a major crackdown in the 1920's and 30's which put thousands of physicians in prison, the treatment of pain became something physicians simply didn't do; hospital corridors and emergency rooms rang out, and do to this day, with the anguished screams of people in pain whose plaintive wails fall on the deafened ears and hardened hearts of medical professionals.

Back in the late 1990's when the FDA and DEA collaborated with academic pain medicine to encourage American doctors to go ahead and treat pain, assuring them that the coast was clear, the climate began to change for the better and a few patients began to get care. Together, the DEA and the leadership of academic medicine codified an agreement called the FAQ, a document we have submitted as an exhibit to the committee. This document was introduced with much fanfare, to give physicians and DEA agents alike guidance about what does and does not constitute the treatment of pain under the new medical approach which allowed for high doses.

While the DEA reneged on this agreement once it became clear that physicians might rely on it in Federal courtrooms, pulling it off government and collaborating websites, the academic doctors were unable to recognize the agencies' apparent bad faith and change course to defend their patients against the government. Instead, they advocated the implementation of harsher and more onerous patient control and patient selection modalities that further enmeshed the practice of pain medicine with law enforcement imperatives.

Doctors who do continue to treat serious pain-and they are now very rare indeed-have been forced to collaborate with gun toting agents against the interests of their patient's privacy, health and dignity. Across America, a few tiny clinics dot our cities, the doctors quake in fear, and the patients in pain are being treated as sub-human, people without human or civil rights, always a hair's breadth away from losing care they need to work and take care of their families. With video cameras installed, and patients forced to sign contracts wherein they supposedly give their consent to doctors to withdraw treatment should the doctor find himself spooked, no matter the consequences to the patient's health, we are living in a country I do not recognize as my own.

We, the citizens of the United States of America, are suffering under the police state of medicine. And as all of this is happening within the doctor/patient relationship, under cover of the US War On Prescription Drug Abuse, the brutalization of our ill population is unseen, their weakened voices barely audible. However, their degradation is deeply

felt, indeed, many patients in pain have not survived. We are here from PRN, in the memory of those who have died, and most urgently on behalf of those who cling to life to ask, most sincerely, for your help in stopping this as soon s possible.

My husband, Sean and our entire family along with him, suffered under the medical culture of non-treatment for over ten years before we found Dr. William Hurwitz. Sean suffered with an extremely painful congenital connective tissue disorder that affected all of his joints. It was under Dr. Hurwitz's care that Sean, for the first time, was able to get his pain under actual control, so that he could function in anything like a normal capacity within our family. It wasn't long, however until Dr. Hurwitz's office was raided and all the records seized- the prosecutors claiming that the entire practice was, and I quote, "polluted" and that they would "root these doctors out like the Taliban."

General searches of private patient records began to take place all over the country, physician's assets were seized prior to trial, and physician after physician went down on drug trafficking convictions. It wasn't much later that the DEA actually published in the Federal Register that they were planning to investigate doctors who treated pain, merely to assure themselves that no crime was being committed. As a result, Sean and only God knows how many other patients nationwide were unable to get any other doctor to treat them with the dosages that worked for them. People needing orthopedic surgery, veterans, or children dying of cancer were and are increasingly shut out of care by doctors who were being conditioned, terrorized in fact, out of treating pain responsibly.

As you are undoubtedly aware, the Controlled Substances Act was not intended to usurp the regulation of medicine, but was, instead, supposed to be used to address those rare instances where a doctor used his prescription writing privileges to deal drugs as opposed to treat pain. Unfortunately, as government lawyers admitted early on in the Oregon vs. Ashcroft case, Department of Justice prosecutors have in fact been prosecuting doctors based on their subjective views as to how medicine out to be practiced, and appear to be quite un-conflicted about it. When District Court Judge Robert Jones asked the government to support their contention that they had the authority to regulate the practice of medicine in the state of Oregon using the criminal code, they offered the following:

"Although the Committee is concerned about the [in] appropriateness of federal prosecutors determining the appropriate method of the practice of medicine, it is necessary to recognize that for the last 50 years this is precisely what has happened, through criminal prosecution of physicians whose methods of prescribing narcotic drugs have not conformed to the opinions of federal prosecutors of what constitutes appropriate methods of professional practice. Defendants' Memorandum, pp. 16-17...." Oregon v. Ashcroft, 192 F. Supp.2d 1077 (2002)

Here, the Department of Justice admits that they enforce the law capriciously and without regard for the limits dictated by the requirements of Federalism. Gentlemen, I ask you, are these attorneys unaware that our country was designed with a Federalist structure in order to prevent precisely the kind of tyranny that we currently endure?

Under Attorney General Ashcroft and Attorney General Gonzales the entire Federal police apparatus got into the act, even going so far as to tout the number of Federal agencies involved in one case, as if this fact alone were validation of the heinousness of the "crime" that had been "committed". So that even while the Justice Department lawyers were being told by Federal courts all the way up to the United States Supreme Court that they did not possess the authority to regulate medical practice using the criminal code, they continued to pursue this policy of prosecuting doctors using so-called expert medical testimony to define the crime.

The situation got so bad, that the National Association of Attorney's General issued two letters asking the DEA to stop exacerbating the situation. But we never saw any official body hold a news conference to denounce what we all knew was going on. Academic medicine remained silent, as did the FDA and the addiction bureaucracies, the "medical ethicists" even the "pain foundations" that are really fronts for pharmaceutical companies refused to speak out: too many Federal dollars at stake, presumably.

It is a shocking but telling fact that our government does not keep track of the number of people who commit suicide because they can no longer endure their pain; this despite the fact that we know that prior to the Bush Administration crackdown, there were an estimated 10 million Americans struggling to live in out-of control pain. When we at PRN held press conferences and announced our outrageous predicament, introducing the press to patients and doctors, patients who had been labeled as "addicts" and refused care, doctors who had since been exonerated and who had joined together to speak out against this madness, the press remained silent. People in pain, and there are so very many of them, have become a silenced, desperate, and terrified minority.

This has all happened "under the radar" because the medical profession and the media have heretofore viewed SWAT raids on medical clinics as examples of law enforcement doing its job, rather than as evidence that their own government was systematically abusing a highly vulnerable population of patients. Nothing we said could cause the scales to fall from their eyes. And that appears to be due at least in part to the fact that as defined by the Controlled Substances Act, a pain patient crying out in need of more relief is virtually indistinguishable from a drug addict.

The term "addict" means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction. 21 USCS Section 802 (1996)

And so, as Justice Louis Brandeis so eloquently remarked on the inadvisability of witch-hunting, "Men feared witches and burnt women."

America was, and is, happily hunting addicts, but for the most part, we are actually hunting patients in pain.

My husband Sean died in a hotel room in Arkansas last August 23, 2006. He appears to have succumbed to a cerebral hemorrhage that resulted from out-of-control blood pressure due to the years he suffered in out-of- control pain. The paramedics who came to our room the evening before, refused to assure me that his pain would be treated were he taken to the hospital. They even told me that his dilated and fixed pupils were symptoms of drug addiction and that they planned to "detox" him at the hospital. As we had some pain medicine on hand, due to the heroism of Dr. Robert Kale, his final doctor, to whom we had driven a thousand miles in the August heat, Sean was at least comfortable. I decided, therefore, to let him die with us, and sent the supposed medical professionals on their way.

As he slipped ever further into a coma, he asked me to help him and I told him I was. But the truth was, I could not help him because there was no one left out there who would help.
After struggling for years to save him, spending all my family's resources to do it, I realized that I had come up short. My 15-year-old son Ronan, who sits behind me today, lost his father because his government had intimidated his father's doctors out of taking care of him. What do I tell him, has come of his country?

Gentlemen, we have no one to turn to but you. The community I represent desperately needs your intervention. People in pain and their families are being run to earth. I am happy to answer any questions you might have about this terrible crisis.

Siobhan Reynolds
July 9, 2007

Mr. NADLER. Thank you.

And we will now recognize Mr. John Flannery for 5 minutes.

TESTIMONY OF JOHN FLANNERY, ATTORNEY, CAMPBELL, MILLER, ZIMMERMAN, PC, AND AUTHOR OF "PAIN IN AMERICA—AND HOW THE GOVENMENT MAKES IT WORSE!", LEESBURG, VA

Mr. 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 this 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. 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 are doing it recklessly, because we see the quality of people who work at the department. And that means there is 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 are 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 resident location of a policy that lacks compassion, has a very harsh effect that 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 instead, 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 think of medicine, if you want to compare it to the industrial age, in terms of mechanical things. But, increasingly, it has become chemical. It has 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 acknowledgement of this 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 are 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, the physicians can't tell and say in 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 thee patients are or are not in pain.

The government says that we have a standard and we are enforcing the law. Well, we have to look at the difference between the words that they say they are enforcing and what they are 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 in 1975, 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 are 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 "the expert" who says, "My doctor didn't look at charts," when he doesn't look at charts to give his opinion.

So let us 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 are enforcing. That has got to change.

We seize a person, a business and his property when the person has been innocent, has been charged, but has not been convicted of anything. There is a presumption that we should punish him before we have 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 prepared 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.

[The prepared statement of Mr. Flannery follows:]

PREPARED STATEMENT OF JOHN P. FLANNERY, II

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STATEMENT

OF

JOHN P. FLANNERY, II, Esq.

[Former federal drug prosecutor (S.D.N.Y.), and former Special Counsel to the U.S. Senate and U. S. House Judiciary Committees; currently in private practice (www.CMZLaw.com)]

BEFORE THE

SUBCOMMITTEE ON CRIME, TERRORISM, AND HOMELAND SECURITY

OF THE

COMMITTEE ON THE JUDICIARY

U.S. HOUSE OF REPRESENTATIVES

CONCERNING

"THE DRUG ENFORCEMENT ADMINISTRATION'S

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PRESENTED ON

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Mr. Chairman, the Honorable Members of this Subcommittee, the Staff, respected members of this distinguished panel, and those attending this crucial hearing, I want to thank you for the opportunity to address this Crime Committee on an aspect of the "DEA's Regulation of Medicine" that I find among the most troubling incursions into our constitutional "right to be let alone" by our government.

There are 40 to 75 million patients across America (according to various statistical surveys) who suffer from terrible chronic pain that never leaves them, not even when they

sleep, and it has shattered the normal lives that they once enjoyed with their families at home and their colleagues at work.

The source of this pain should be well known as, with greater frequency, our friends and our family members suffer from this chronic non-malignant pain.

It's not the kind of pain that hurts for a day or so and heals itself. It abides and courses through your body like a raging fire, for six months or more, often for years, driven on by an unseen wind, stealing your sleep, your ability to stay awake during the day, and it replaces your even disposition with anger, and it tempts you to suicide. It is a Joycean nightmare from which one may not awake.

Surgery, therapies, various medicines may help for a time but the pain persists undiminished in many who consider alternative remedies. The modest amount of natural opioids that our bodies produce to block the pain receptors are overrun by the pain.

Congress specifically identified certain controlled substances in the Controlled Substances Act for the treatment of such pain. In recent years, physicians have discovered that by a combination of fast-acting and long release opioids that they can restore some semblance of normalcy to many patients who previously despaired at their suffering.

You might presume that the government was doing all that it could to redress this pandemic of pain.

Instead our government is daily making it worse, creating a public health crisis when it should be easing our pain.

Our Justice Department, and the DEA as its agent, is exceeding the authority granted by the U.S. Congress under Title 21, United States Code, Section 841(a)(1), that empowered the

Executive Branch to prosecute physicians for illicit drug dealing when the physicians acted with the specific intent to push drugs rather than to treat patients. *United States v. Moore,* 423 U.S. 122, 143, 96 S.Ct. 335 (1975); *see also* Title 21, United States Code, Section 802(21).

1. The Supreme Court created a standard in 1975

In 1975, the Supreme Court examined the Controlled Substances Act to decide whether it applied to physicians at all -- as the Act did not plainly include physicians who prescribed pain medication; indeed, it appeared to exempt physicians from its coverage.

The Supreme Court in *Moore* did the best that it could with a collection of imprecise statutory provisions and regulations to conclude that physicians are covered insofar as physicians may not push drugs.

The Supreme Court's formulation was that a physician had to act "outside the course of professional medical practice" with the "intent" to act as a drug pusher, rather than as a treating physician.

Congress has not re-visited the statute to clarify what conduct by physicians may be criminal – not since the Supreme Court in *Moore* cobbled together its holding.

Since *Moore*, much mischief has been done.

2. The Justice Department has been re-defining the standard

The Justice Department has been deciding on a case by case basis, by its charging documents, by its testifying experts at trial, by the extraneous evidence it offers, and by the wrong-headed jury instructions that it proposes to the court, what is permissible medical practice, and judges have been led into error by the Justice Department, allowing these prosecutions to modify and restrict pain medicine in this nation to a dangerous degree, and

according to a malpractice standard, that is civil in nature, although, in every respect, the consequences of these trials are criminal including the stigma of conviction, of mandatory sentences, levied fines, forfeited property, and confinement in federal prisons for decades – when not for life.

The Justice Department's impermissible re-definition of medicine, on a case by case basis, has so narrowed what is acceptable medical practice that it is fair to say that the Justice Department disapproves of a physician treating a patient with any substance containing an opioid component.

a. Constitutional Notice

We presume constitutional notice, say it's a necessary predicate, before we may hold anyone accountable for his bad acts. But the Justice Department has resisted all demands to state what precisely constitutes the offending misconduct. The Department prefers confusion over notice as this uncertainty effectively deters physicians from treating chronic pain.

b. the Department's varying "norm"

I represented a physician, Dr. Ron McIver of South Carolina, and the Justice Department prosecuted him for failing to conform with a "professional norm" that the Executive Branch defined for the first time at his trial after Dr. McIver had treated his pain patients.

Dr. McIver's case was so troubling that the ***New York Times Magazine*** featured a cover story, written by ***Times*** correspondent Tina Rosenberg, aptly titled, "When is a Pain Doctor a Drug Pusher?"

Dr. McIver's prosecution is illustrative of these prosecutions and underscores what's

gone awry. In McIver's case, the government insisted that Dr. McIver didn't do what the "average" physician might do when treating pain patients. Dr. McIver didn't conform to "the norm" - as defined by the Justice Department's paid expert at trial. But this "norm" was not the standard formulated by the Supreme Court in *Moore, supra.*

Dr. Stephen Storick, the Justice Department's expert at the McIver trial, conceded these norms were an "ever-changing modality" and that what Dr. McIver did as a treating physician, according to Dr. Storick, "[we] did it five years ago."

Dr. Storick explained that his "professional norms" were not "outside the bounds of professional conduct" but that "he [Dr. Storick] wouldn't do" what Dr. McIver did -- as it violated his "professional norms".

DEA Agent Rene Crowley conceded, for example, that neither Title 21, United States Code, Section 841, nor the Code of Federal Regulations, limited the number of pills a physician could prescribe. Dr. Storick also admitted that there was no maximum dosage for opioids that was prohibited. He acknowledged the finding of the University of Wisconsin Pain Management Study that "[o]pioids should be titrated by a percentage of the current dose based on the intensity of pain." Dr. Storick agreed that "titration" (increasing the dosage) was an apt approach for cancer patients, but he dismissed the study as "academic" and claimed to know better because, he said, "I work for a living." It wasn't outside the bounds of professional medical practice; but it didn't meet his standard.

Dr. Storick said that the highest daily dose that he would prescribe to a non-cancer patient with chronic pain was 160 mg OxyContin (80 mg OxyContin twice a day); Storick said

he was unfamiliar with the fact that Medicaid allows a daily dose of up to 960 mg of OxyContin (or eighty tablets).

Thus, you have some idea of the elusive norm applied to Dr. McIver.

c. The Department's jurisdictional competence – or authority.

The Department has been replacing its "judgment" of medical science without the lawful authority to do so.

The Supreme Court found that the Department exceeded its jurisdictional competence when it sought to defeat a state legislature's preference to allow assisted suicide. *Gonzales v. Oregon*, 546 U.S. 243, 126 S. Ct. 904, at 922 (2006). Justice Kennedy said, if the Attorney General enjoyed this authority to criminalize what it saw fit, then it would enjoy the unrestrained power to criminalize "the conduct of registered physicians whenever they engage[d] in conduct [that] he [the AG] deem[ed] illegitimate." *Id.*, at 920.

While our judicial branch decried the Department's unauthorized interference with assisted suicide, it has not yet seen fit to restrain the Department's interference with physicians who treat those in pain so that they may avoid suicide.

d. The Jury is not much help in protecting physicians.

You might presume that a jury could serve as a corrective for the government's excesses in these cases but you would be mistaken as the jurors' fear of addiction accommodates the government's prosecutions.

The Mayday Fund, in the 90's, asked Mellman Lazarus Lake, Inc., to conduct a public opinion poll of 1004 adults that would reflect the nation's views, so that we might "understand people's underlying assumptions about pain and its treatment." The research concluded that

Americans "would rather bear pain than take action to relieve it." Americans "withstand pain because they fear that too much medication will cause them to become addicted or dependent." When we select a jury, if there are more blue-collar workers or lower income Americans, the Mayday survey data indicates that they "are more likely to avoid medication than are professional or higher income Americans."

A high proportion of the population experience surgical pain (63%), or chronic back aches (49%). But Americans generally respond that they don't give in to pain. 92% say "it's a part of life". 71% wouldn't call the doctor when in pain. 66% said the last time they felt fairly serious pain, they withstood it. 46% tried to avoid medication unless the pain got "bad." 35% waited "until the pain [was] unbearable before they would take medication."

What explains this tolerance for pain?

It's our fear of medication and drug addiction.

87% believe "it is easy to become too reliant on pain medication." And Americans believe this to be true of any medicine, not just prescription drugs. 72% believe they will develop a tolerance to medication, if they use it, and it won't work when they need it. 41 % believe physicians give too much medication.

In an America, in which the citizens fear pain medication and addiction, and "tough it out," the Government is unconcerned about jury selection.

e. The jury doesn't have to find the physician "intended" to push drugs.

It is a bedrock principle that you may be held responsible for the natural consequences of what you intend to do.

But the Department does not prove in these pain cases that the defendant "knew" he was practicing "outside the course of professional medical practice" in order to push drugs, or that he did "intend" to push drugs.

In the McIver case, when it was on appeal before the U.S. Court of Appeals for the Fourth Circuit, the government said at oral argument that it was not sure that the government was required to prove "specific intent."

Circuit Judge James Harvie Wilkinson, III, pressed the prosecution, asking whether "specific intent was required" or whether, by adding it, was the court writing a "gloss" onto the statute?

The prosecution said, "I don't know."

Judge Wilkinson said, "Why not? That's part of the case!"

The prosecution then said, "The case did not go to the jury on specific intent."

Judge Wilkinson replied, "But he's now claiming [for Dr. McIver] it's an error, and I'm asking you, if we make this into a specific intent crime, are we adding or not to what Congress has set forth?"

Circuit Court Judge Allyson Kay Duncan asked the prosecution to explain what takes a malpractice claim to a criminal level and how was that dividing line articulated for the jury's consideration.

The prosecution said because the jury had been given an instruction that Dr. McIver could not be willfully blind as to what was happening, thus had the jury been instructed as to intent.

Judge Duncan then asked if that response meant the prosecution was then conceding that there was a specific intent standard?

In response, the prosecution said, "I do acknowledge there is an intent standard and it was proven and it was more than amply charged to the jury."

Judge Wilkinson expressed concern as to how the expert testimony and the jury instructions interlocked seamlessly around a violation of "professional norms" at the expense of criminal intent. Congress, Judge Wilkinson noted, did not express the critical element of proof for the jury as "a reasonable physician" standard or "a violation of professional norms" Congress had said "outside the course of professional practice."

Judge Wilkinson asked the prosecution if what Congress prescribed "wasn't something textually different from a 'norm of professional practice'." Judge Wilkinson asked, "doesn't 'outside the course' mean 'you just shuck professional practice to one side' and 'set yourself up as a drug dealer' and put all your medical training to one side?" Judge Wilkinson asked the prosecution if there wasn't a difference between "professional norms" and "outside the course of professional practice"?

The prosecution responded that there was "a difference."

But when the three-judge panel wrote its decision upholding Dr. McIver's conviction, the "difference" was considered as inconsequential as Dr. McIver's intent. (The colloquy is available on CD from the U.S. Court of Appeals for the Fourth Circuit.)

3. Few pain patients become addicted.

Dr. Mark Sullivan, Professor of Psychiatry and an Adjunct Professor of Medical History and Ethics at the University of Washington, confirmed that only 2% of chronic pain patients

may become addicted and that there is a 98% chance that a patient who claims that he has chronic pain is "on the level." *See* Pain, Opioids and Addiction: "An Urgent Problem for Doctors and Patients", 3/5/07, NIH Conference (http://videocast.nih.gov/PastEvents.asp?c=1.)

4. Detecting patients who are lying is difficult – if possible at all.

Knowing who is deceiving the physician is hard to uncover, according to a recent study conducted by Drs. Beth Jung and Marcus Reidenberg:

> "Physicians operate with what *Burgoon et al.* call a *truth bias.* That is, they presume that patients' presentation of themselves are true, complete and accurate. Their assessment of patients' pain complaints are based both on current information (obtained in the interview and physical examination) and on the starting point, or anchoring point for the assessment. Doctors assume that patients come to see them because they have a problem for which they want treatment. Law enforcement personnel appear to have a different assumption when they interview some people." *See* Jung G, Reidentbert M, DECEIVING PHYSICIANS, In Press (2006).

5. Nor is it easy to confirm a patient's pain.

It is good that patients are "on the level," according to Dr. Sullivan, because there is almost no way to confirm that a person has pain; the Center for Disease Control statistics reveal that "80% of lower back pain cannot be identified with imaging" whether it's an fMRI, PET, CT-scan or x-ray. *See* Pain, Opioids and Addiction: "An Urgent Problem for Doctors and Patients", *supra.*

Dr. Storick criticized Dr. McIver for not considering certain tests to confirm his diagnosis but also admitted that there are people who have pain who have a negative MRI. J.A. 564.

The medicial community is of one mind that "[i]t is sometimes a difficult medical judgment as to whether opioid therapy is indicated in patients complaining of pain because

objective signs are not always present." *See* "Rights and Responsibilities of Physicians in the Use of Opioids for the Treatment of Pain" (Public Policy Statement on the Rights and Responsibilities of Healthcare professionals in the use of Opioids for the Treatment of Pain – a consensus document of - the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine).

While cancer "is a symptom of a disease bearing a direct relationship predominantly with tissue pathology[,] ... there is only a *weak association* between reported pain and objective findings of disease in chronic pain not associated with cancer" (italics supplied). See Loeser, BONICA'S MANAGEMENT OF PAIN, 3rd ed., Lippincott Williams & Wilkins (2001).

Dr. Storick confirmed on cross-examination that "pain is a subjective amount of discomfort" and "there's no way to really measure it." Despite this observation, Dr. Storick, the government's expert, said he wouldn't prescribe opioids for any patient unless he could find objective signs of pain. In other words, he would purposefully fail to treat patients with lower back pain, migraine headaches, fibromyalgia, reflexive sympathetic dystrophy disorder (RSD), and various neuropathic disorders if he couldn't find "objective signs of pain". That was his "norm" or standard.

Incidentally, Dr. Storick couldn't know what Dr. McIver's patients had to say or how they presented themselves as patients as he never talked to or examined any of them.

6. Dependence is not addiction .

Physicians patiently explain that a dependence on a medical regimen that is an effective remedy to endless days of mind-altering pain is not an addiction, not some sort of obsession that is unrelated to medical need. It is indeed a medical remedy attacking a disease.

7. Physicians are discouraged from treating.

Physicians have made a decision, and are conducting the kind of triage that you might find in an emergency room, treating those that they can help as best as they can - but not going so far as to risk going to jail for treating a pain patient too aggressively – if at all.

Medical conferences in recent years add this issue -- "pain treatment" -- to their agendas to warn physicians against treating patients with controlled substances for fear of federal or state prosecution.

Unsurprisingly, given this direction by the leaders in their own medical profession, physicians are refusing to treat lest they be jailed.

With fewer physicians prescribing controlled substances, chronic pain patients daily consider the dilemma of choosing endless days of extraordinary pain without surcease or surrendering to suicide.

8. The bias of settled habits.

The federal government has wrongly and artfully cast the prosecutions of physicians as if it were a part of this nation's never-ending "war on drugs".

In this never-ending "war", that is never won either, the government invokes its drug speak, to mis-characterize physicians as "drug dealers", medicines as "drugs", and patients as "users" or "addicts".

Our critical faculties have failed to question the language we've grown accustomed to accepting. Thorsten Veblen called this the "bias of settled habit."

We must resolve to re-consider this "war" on physicians and patients, and the language we suffer in silence, because the extension from the street and "street drugs" to professional

medical offices and "prescriptions" is a quantum leap that has adversely affected the quality of debate and of our national health.

9. Stand-ins – red flags – that mislead.

The Justice Department has created an array of what they call "red flags" that are "stand-ins" for actual proof as to whether the physician did anything criminal. These flags are confounding in their logic. They consider how far a patient travels to see his physician, and the fact that the patient knows what prescriptions helps his condition. But, isn't it the case that a patient has to travel further because fewer physicians treat pain? Shouldn't we expect that a person in pain has the experience to know what makes a difference to ease his pain?

10. Why don't we limit ourselves to detecting crime, rather than creating it?

The Justice Department authorizes its agents to pretend to have pain, often lower back pain, and, if the physician doesn't catch on that they are pretending, then the Department may claim that the physician was drug dealing. No matter that you can't confirm back pain by any imaging device in 80% of the cases. No matter that physicians are by nature and necessity trusting of the patients they see.

11. We have lost our innocence – at least its presumption.

We have statutes in drug cases that presume guilt -- upon the government's say-so.

What follows upon the government's say-so, whether by indictment or search warrant, is the seizure of the physician's entire practice (taking his charts and the medical histories needed to practice), cutting off the patients, leaving patients to fend for themselves, denying the physician the right to write prescriptions, and maybe even confining the physician while he awaits trial.

Some physicians who have never gotten a traffic ticket before they run afoul of the government ask why they aren't presumed innocent. Is our answer really that the offense is so serious, you are just going to have to wait until you prove to us you are innocent?

12. We require more restraint in these prosecutions.

The media always knows more about these cases than the physician or his counsel when a search or indictment issues.

When the Accused gets to trial, the government offers a blizzard of information, an ambush, in an exercise that is less judicial and more like a political campaign.

The rules of evidence are applied without much rigor as all manner of prejudicial hearsay is offered in the jury's presence.

13. Confined pending sentencing and appeal.

If the physician is convicted, he is confined pending sentence, and, after sentence, he is confined pending his appeal.

This presumption is harsh when the physician was at large for years following the alleged misconduct, presented no danger to himself or his community, and always showed up at court.

But this denial of bail is presumed and hard to rebut.

The trial judge has to say that he made an error at law to justify releasing the defendant pending sentence or appeal.

Or the prosecutor has to agree that he doesn't expect the physician to receive any jail time.

This is as unjust and unfair as anything that is happening in modern criminal jurisprudence – and not just in these chronic pain cases. It diminishes the significance of any appeal.

14. The sentencing guidelines appear arbitrary.

When we sentence a physician for prescribing pain medication, we pretend that the pills that were prescribed are not oxycodone but that they were marijuana instead. There is no sentencing guideline for oxycodone itself. There is one, however, for marijuana. Why is that you might ask? There is no explanation. We treat as equivalent the medicine (oxycodone) and the substance (marijuana) that we insist has no medical use. We also multiply the weight of the oxcodone by 100s and 1000s, depending on when the offense occurred, to find an "equivalent" amount of marijuana and the corresponding offense level (for marijuana) under the sentencing guidelines. No one can give you any cogent reason for this bizarre and arbitrary sentencing exercise. It should be struck down.

15. The mandatory minimum is harsh and illogical.

If a patient has died, and this does happen in medical practice, and, if that patient was receiving an opioid, then it is presumed that the patient died as "a result" of the prescription and the physician faces a twenty year minimum up to a life sentence.

In the case of Dr. McIver, he had a patient, Lawrence Shealy, who had relentless chronic pain from crippling arthritis, back and knee pain, heart disease, depression, sleeplessness, and, unsurprisingly, he had tried to commit suicide.

At the time of his death, Mr. Shealy had an enlarged heart, an enlarged spleen and liver from congestive heart failure, severe coronary artery atherosclerosis, hardening of the arteries,

90% blockage of his left anterior descending artery, a 50% blockage of the left circumflex arterial branch, a scarred heart from an earlier heart attacks, and congested organs, meaning, that, as the blood backed up into the system, it backed up into the organs.

There is every reason to believe that Mr. Shealy died because of the complications involving his heart disease, having nothing to do with the medication that he was taking. Indeed, sudden death is the commonest presenting symptom of cardiovascular disease. *See* Zipes D.P., Wellens H.J.J., Sudden Cardiac Death. Circulation. 1998:98:2334-2351; available at http://circ.ahajournals.org/cgi/content/full/98/21/2334 .

While Mr. Shealy had various medications available to him at the time of his death, there was every indication that he had taken the appropriate medication that he had been prescribed for 16 days without suffering any adverse side effects. If the prescription was as harmful as the Department argued, then why hadn't the OxyContin caused Mr. Shealy's death sooner?

Yet, Dr. McIver was held responsible for the "resulting" death and was sentenced to 30 years, ten above the mandatory minimum of 20 years, and he is serving that sentence at the federal facility in Buttner, NC..

16. We have a right to be let alone.

We have a right to be "let alone", to enjoy our constitutional "right of privacy", the penumbral emanations of those basic rights enumerated in our Constitution.

The government may not muzzle a physician's unquestioned right to advise his patient confidentially or to write prescriptions or to associate with other physicians who seek to treat

chronic pain patients. That's violative of the right of free speech and to associate and to assemble guaranteed physicians and patients by the First Amendment.

The government may not compromise a physician's livelihood, by which it "takes" what is his property, in violation of the constitutional guarantee that no "taking" by the government of a person's property shall occur without due process, meaning unless it is fundamentally fair.

The government may not abridge the health and well-being of patients, for what could be more clearly an infringement of the constitutional guarantee of life and liberty?

The government may not set apart chronic pain patients as different than other patients, denigrate them in word and deed, stigmatize them as addicts when they should be healed, and thus deny patients the equal protection of our laws.

The government may not punish patients in violation of the constitutional prohibition against cruel and unusual punishment.

I represent Richard Paey, a chronic pain patient, who was the focus of a ***Sixty Minutes*** piece because he is serving a twenty-five year sentence in the state of Florida for possessing medicine – Percocets – to treat his chronic pain. Although he only "possessed" these medications, he was convicted of "trafficking." While in custody, Richard Paey is receiving more pain medication, a morphine pump, than was the subject of his alleged "trafficking." The State Court of Appeals agreed that the 25 year sentence was unjust but also said that only the Governor – by his clemency powers – may set the matter right in a clemency petition.

17. Congress must act!

Plainly, the "system" we have is not working well – if it can be said to be working at all..

For some, it may be tempting to think that chronic pain does not concern them.

But the difference between being pain-free today and being in chronic pain tomorrow may be a rush-hour rear-end collision at a congested intersection. Or a discovered illness that partners with chronic pain.

If we do not help those who are hurting today, there may be no one to help us tomorrow.

May this hearing commence a much-needed dialogue to clarify the law, and to improve the flawed process we have (if not to replace it entirely).

Thank you for your time and kind attention to my remarks.

# # #

Mr. NADLER. Perfect timing. I thank the witnesses for their testimony. It was perfect timing. The Chairman has returned. I have to go to a T.V. interview.

I will give the Chairman back his chair to direct the questioning.

Mr. SCOTT. [Presiding.] I want to thank the witnesses and apologize for my absence. I will recognize myself for 5 minutes.

I would 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 is going to help them, they believe that it reduces pain, terminally ill patients?

Mr. 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 is a drug that is 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 "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 is a miraculous cure, that it is good for you, that it can be used for medical conditions. So we think there would be a loss of deterrent effect.

Moreover, there is 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 are 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.

Mr. SCOTT. Well, if they want it and they are 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?

Mr. 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.

Mr. SCOTT. Could you give us the list of those studies?

Mr. 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 has been repeated many, many times over.

Mr. SCOTT. What is the status of the study that the judge—I believe it is University of Maryland—Massachusetts. I am sorry.

What is the status of that study?

Mr. MURRAY. Sir, I am 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 is in the hands of others. It is not a research project, as I understand it, sir.

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

Mr. 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.

Mr. SCOTT. So you don't deny it was 6 years ago.

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

Mr. SCOTT. Is the court order not public?

Mr. 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.

Mr. SCOTT. Mr. Flannery, there is a difference between criminal activity and malpractice.

Mr. FLANNERY. There certainly is.

Mr. 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?

Mr. FLANNERY. What has 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 crime are that, as a doctor, I know and I intend to traffic in some drug, and these are controlled substances. It would mean I would be selling it to you or writing a prescription for you when you have no need for it, I know it, there is no question about it.

You haven't fooled me. You have said, "I am 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 pa-

tients. 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 nauseas or something. And then I am sued, because it leads to other things. I, the doctor, am sued. That would be malpractice.

Mr. SCOTT. Are these questions better for the DEA or the board of medicine in the different States to consider?

Mr. FLANNERY. They are better suited to and historically and constitutionally suited to have the several States decide by their boards of medicine. And there have been studies saying this for years. 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 "soft on drugs" rather than strong on medicine.

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

Mr. SCOTT. Mr. Forbes?

Mr. 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 am sorry that I was not able to stop that.

I also want to say that when we are talking about compassion, one of the things that we really—it is really great to come in here and beat on the desk and yell compassion, but it is also compassionate when we try to curb teenage drinking so we stop people from ending up going to funerals. We 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 are 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 us 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 5 minutes, so I want to be kind of concise, but do you feel marijuana should be legalized?

Ms. CORRAL. Medical marijuana should be legalized.

Mr. FORBES. What about ecstasy, the drug, ecstasy?

Ms. CORRAL. I am here to testify, sir, about medical marijuana.

Mr. FORBES [continuing]. On that.

Ms. CORRAL. No, I am just here to speak about medical marijuana.

Mr. FORBES. I appreciate that.

Ms. CORRAL. Thank you.

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

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

Mr. FORBES. If you have an overuse of Tylenol—I am not talking about on a regular basis but a single or a couple of overuses of Tylenol, what is the impact?

Mr. 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.

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

Mr. MURRAY. Indeed.

Mr. FORBES. The question I am raising, everybody is 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.

Mr. 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.

Mr. FORBES. Once it is placed on that list, does DEA have the discretion to not enforce the drug laws?

Mr. RANNAZZISI. No, sir, it doesn't.

Mr. 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?

Mr. RANNAZZISI. No, sir, I don't.

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

Mr. 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.

Mr. FORBES. Do you ever 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?

Mr. RANNAZZISI. We have had cases where there were deaths related to the prescription medication prescribed by the physician, yes.

Mr. 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?

Mr. RANNAZZISI. Yes, sir, I believe that is——

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

Mr. RANNAZZISI. It is the national drug intelligence—yes.

Mr. FORBES. Can you explain what this represents to us?

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

Mr. FORBES. And how widespread were they?

Mr. RANNAZZISI. Extremely widespread, almost the whole State.

Mr. FORBES. Is that the same map that is up here now with this chart up here?

[The material referred to follows:]

Mr. RANNAZZISI. Yes, sir.

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

Mr. RANNAZZISI. Are we talking about the grow sites, the outdoor grow sites?

Mr. FORBES. Yes.

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

Mr. FORBES. Dr. Murray, can you address that?

Mr. MURRAY. Yes, thank you, sir.

It is 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 is 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.

Mr. FORBES. My time has 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 are getting now and you are problems in trying to deal with Internet pharmacies.

Mr. 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 are taking the drugs and they are 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 are 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 are ingesting, and this is a form of—just a form of adolescent partying now.

Mr. FORBES. It is becoming a widespread concern?

Mr. RANNAZZISI. We have had several reports throughout the country, yes.

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

I would like to ask one other question. I guess, Dr. Heiden——

Mr. HEIDEN. Yes.

Mr. 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?

Mr. 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 is not the products distributed by ACRC members, which are the off-brand combination ephedrine asthma-relief products.

And it is 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 am 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 is my understanding, will be wiped out.

But it is 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.

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

Mr. 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.

Mr. RANNAZZISI. May I respond, Chairman?

Mr. SCOTT. Sure.

Mr. 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 it 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 are 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 are mostly small retail convenience stores and whole-

salers, 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 is 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 is incorrect.

In 2006, we had 87 labs with brand names like BDI, Blue Label, Mini Thins, Bronchis, Mini Ephedrine, Double Action Ephedrine, Rapid Ephedrine, Fred's Private Label, Ephedrine Extra, 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 would like to talk to him afterwards about it so I could clear it up with him.

Thank you.

Mr. 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 are 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 has been a powerful success.

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

Mr. 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 have seen a steep tailing off of the use of methamphetamine of the work force, and by the survey reports we are 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 have 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 is when people turned to the small toxic lab, pseudoephedrine diversion from the retail establishment. We took action against that.

Now we have 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 are moving against this problem, sir.

Mr. SCOTT. Thank you, Dr. Murray.

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

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

Mr. SCOTT. Thank you.

Mr. FORBES. I just have one additional statement to follow up with yours.

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 is what government is all about.

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

Mr. 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?

Mr. FLANNERY. I have one.

Mr. SCOTT. I will start with Mr. Flannery.

Mr. FLANNERY. Compassionate seems to me to care when you have 40 million to 75 million people in America who have chronic pain, which means that they have pain that has been living with them for longer than 6 months—it is so bad they can't sleep at night. When they drive to work, they are falling asleep, they are 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 am so worthless to the people I am with and that I can't just put up with this pain 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 is a recent chemical answer, and it is the fact that the opioids we have in our bodies are not sufficient to take care of the pain. And it is that oxycodone and other medications can help us where our bodies fail 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, we have to look at the 40 million 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 are 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.

Mr. SCOTT. Ms. Reynolds?

Ms. 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 am trying my hardest, and I know that you are, and several of us are, but I feel that we are being drowned out by a lot of sort of endless bureaucratic chatter about Mexico and appropriate procedures and what not. And we are 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 is so serious, and we have been working, my organization and I, for 5 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 is just that what we need, for you 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 is the real anomaly of this medicine. And so if the medicine is being treated scientifically, it makes the doctor a target.

That is what I want you to understand, sir.

Mr. FORBES. Mr. Chairman, I am just going to ask that we have regular order in the Committee.

Mr. SCOTT. Regular order has been called for.

Mr. FORBES. We have not had it the whole Committee meeting.

Mr. SCOTT. We will resort to regular order and recognize the gentleman. I would like to recognize the gentleman——

Mr. NADLER. 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?

Mr. 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.

Mr. 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 is a majority of my district that 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 are not being heard, but there are also a lot of other sides to this that have not been heard.

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

My name is Siobhan Reynolds, I am with the——

Mr. GOHMERT [continuing]. Marijuana, right?

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

Mr. GOHMERT. I thought you were speaking about marijuana on that. All right.

Ms. REYNOLDS. No, thank you, though.

Mr. GOHMERT. And I am 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., in my humble, non-medical opinion, is absolutely worthless for me. I can't speak for anybody else. It is anecdotal.

But, anyway, it is funny, not in a humorous, but ironic, way, this Administration has been accused of sending jobs to Mexico, and apparently when we tightened up pseudoephedrine, that is 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 is coming in from Mexico. It is pure, there is 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 am 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 is 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, TX, and I didn't realize, but, apparently, if marijuana seeds are sterilized, then they are not illegal in Texas and most other places. And that is why they are 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 would 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——

Ms. CORRAL. Well, I can address that, sir.

Mr. GOHMERT. You could buy it legally, and not only that, you buy a 50-pound bag of marijuana seed that is 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 3 or 4 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 dock, 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 7 days, the report was they didn't germinate, after we cooked them, which the Agriculture Department will tell you that is 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 are 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 has been looked into. If it is illegal, we ought to follow the law. Of course, we have laws on immigration that aren't followed either, but that is another matter.

Anyway, thank you.

Mr. SCOTT. The gentleman's time has expired.

The gentleman from New York?

Mr. 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?

Mr. MURRAY. Thank you, Mr. Congressman.

Mr. NADLER. Quick and short, because I am going to have a few more questions.

Mr. MURRAY. All right, sir.

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

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

Mr. 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.

Mr. NADLER. Mr. Rannazzisi, maybe you will 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?

Mr. RANNAZZISI. Because there is 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——

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

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

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

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

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

Mr. RANNAZZISI. Well, first of all, the research that is 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.

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

Mr. RANNAZZISI. I am sorry?

Mr. NADLER. They have refused the supply for basically every researcher. They have basically cut off medical research with respect to marijuana.

Mr. RANNAZZISI. I don't believe that is the case. If you look at my testimony——

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

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

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

Mr. RANNAZZISI. So you don't want—okay.

Mr. NADLER. I heard your answer. I am 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 6 years ago. Mister——

Mr. RANNAZZISI. Rannazzisi.

Mr. NADLER. Rannazzisi.

Mr. RANNAZZISI. Yes, sir.

Mr. 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?

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

Mr. 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?

Mr. RANNAZZISI. Excuse me 1 second, please.

Mr. SCOTT. I would advise the Committee that we will have an opportunity to submit questions in writing, and I think this might be——

Mr. RANNAZZISI. That would be a question that we would rather submit in writing. We would like to submit that——

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

Mr. RANNAZZISI. Yes, sir.

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

Mr. RANNAZZISI. The FDA would not——

Mr. NADLER. Not the FDA, the DEA.

Mr. RANNAZZISI. It just depends on the issue. It is a case-by-case basis.

Mr. NADLER. Well, does it normally take, on average, 6 months, on average 6 years?

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

Mr. NADLER. Well, think of any instance where it has taken more than 5 years. Are there any?

Mr. RANNAZZISI. Well, that is erroneous. It has not been 5 years. If I am not mistaken, the decision was handed down months ago.

Mr. NADLER. Are there any longer than 2 years?

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

Mr. NADLER. Are there any longer than 1 year?

Mr. RANNAZZISI. Sir, again, I will have to get back to you. I will get back to you, and if you would like, I would——

Mr. NADLER. Okay. I would like a commitment that the decision will be made within the lifetime of this Administration. I think that is 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?

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

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

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

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

Mr. NADLER. Thank you, and let me ask you the following——

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

Mr. 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?

Mr. RANNAZZISI. Sir, I guess you have 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 is what we do. The studies are approved at NIDA and HHS, where studies have always been approved. That is not in our purview.

Mr. NADLER. Thank you.

Mr. SCOTT. Thank you.

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

Ms. CORRAL. May I just add something quickly?

Mr. SCOTT. Very quickly.

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

Mr. GOHMERT. It wasn't an assumption.

Ms. CORRAL. I beg your pardon.

Mr. GOHMERT. It was some factual testimony.

Ms. CORRAL. It is 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 is 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.

Mr. SCOTT. I am going to ask you to submit those studies to the Committee.

Ms. CORRAL. Yes.

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

Ms. CORRAL. Yes, and I would 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 am sorry to go over.

Mr. 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 1 week for submission of additional materials.

And, without objection, the Committee stands adjourned.

[Whereupon, at 11:44 a.m., the Subcommittee was adjourned.]

APPENDIX

MATERIAL SUBMITTED FOR THE HEARING RECORD

The War on Drugs, the War on Doctors, and the Pain

Alexander DeLuca, M.D., MPH; Senior Consultant, Pain Relief Network; 2004

Written Testimony submitted to the House Subcommittee on Crime, 2007-07-12

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References

Introduction

There is a Pain Crisis in America. Its primary manifestation is the routine and widespread under-treatment of pain, especially chronic, non-cancer pain. Other manifestations include a severe and growing shortage of physicians willing to prescribe morphine and related opioid analgesics, the widespread use of more toxic and less efficacious classes of medications in an effort to avoid opioids, and the profound distortion of medical education and of the doctor-patient relationship.

How large a problem is under-treated pain in America? In a 2001 article in the *Journal of the American Medical Society* (*JAMA*), Brian Vastag reports on the work of Richard Brown and colleagues who stated, at a National Institute on Drug Abuse (NIDA) symposium in April 2001, that there was widespread acknowledgment that both acute and chronic pain are undertreated. Brown estimated that more than 17% of Americans have serious chronic pain and that many go untreated and many more are undertreated. [Vastag, 2001] This is the pain crisis in America.

In an attempt to gauge the extent of the problem, these researchers developed a survey that measured the prescribing practices for benzodiazepines (Valium and related sedatives) and for opioid analgesics by different groups of physicians in response to variations of a single presented case. The physicians' prescribing decisions were then compared with recommendations from a panel of pain management experts. The findings were stark:

> While the expert panel recommended that virtually all patients with [common idiopathic back pain] who do not respond to other treatments be given an opioid analgesic, only 20% of physicians said they would actually write that prescription... "It suggests there's a lot of unnecessary suffering," said Brown. To combat the problem, he called for increasing the amount of medical school education devoted to pain management, from the typical 2 to 4 hours to 16 or 20. [Vastag, 2001]

None of this is new. For decades, researchers have noted this discrepancy between how chronic pain should be treated and the dismal state of the art as practiced in the U.S., and they commonly call for more and better education of physicians. But is the pain crisis in America simply a problem of the acquisition and application of medical knowledge? And if so, why have the impressive and consistent educational campaigns directed at this problem in recent decades failed to yield the expected changes in medical practice in the U.S.?

The historical record strongly suggests a deeper and far more disturbing root cause of our current pain management predicament. In the years after 1914, the Narcotics Division of the Treasury Department, progenitor of today's Drug Enforcement Agency (DEA), brought a series of test cases against physicians under the Harrison Act. Through the courts, drug prohibitionists achieved the criminalization of drug users and of the doctors who would treat them as patients and as human beings worthy of the same individualized medical care as any other sufferer in a free society. This wide scope of law enforcement responsibility was far beyond that legislated by Congress when it passed what appeared to be a tax act in 1914. [King, 1953]

This historical period marks the invention of a perpetual national drug crisis which has ever since been claimed as the special national interest justifying the regulation of opioid analgesic medications and other 'dangerous drugs' by a federal law enforcement agency. In so doing, this agency has usurped the right constitutionally reserved to the states to otherwise license and regulate medical practice in that most fundamental, archetypal, and timeless of all the medical arts: the skillful application of opioid analgesia towards the relief of human pain and suffering.

While opium and its derivatives are among the most ancient and well understood and safest pharmaceuticals mankind has ever developed, problematic use has been a source of personal tragedy in the lives of individuals throughout recorded history. However, before about 1920, there was no domestic 'drug subculture,' no 'drug problem,' no criminal black market, no drug cartels, no state-sponsored hounding and jailing of drug users and pain patients and of their physicians, no public outcry for the politicians of the day to "get tough on drugs." In fact, there is no credible record of a domestic drug problem prior to the perversion of the Harrison Act in the courts in the years after 1914 although there were many more opiate dependent people, both in absolute numbers and as a percentage of the population, than there are today. It has been estimated that in the 1880s some 4 per cent of the population of the United States used some kind of opiate for nonmedicinal purposes. [King, 1972a] For a sense of perspective, consider that modern heroin use *peaked* in the late 1980's at approximately 326,000 (past month) users, or about 0.1 percent of the population, according to National Household Survey on Drug Abuse data. It is notable that, in the decades around the end of the Nineteenth Century, America supported large and powerful popular social movements against alcohol and tobacco use which were widely (and correctly) perceived as true national public health scourges. There is no record of any anti-opioid movement or opioid prohibition movement of similar significance because this class of substance was not viewed (again correctly) to be a social scourge or significant public health menace. [Brecher, 1972a]

The root cause of the widespread undertreatment of pain can be traced directly to the systematic, nationally coordinated, relentless harassment, arrest, and prosecution of thousands of American physicians, many of whom had been engaged in nothing other than the standard care of pain and addiction of the day. This pogrom has continued, unabated, for almost ninety years.

The proximate cause of the pain crisis arises from what is known as the "chilling effect," a phrase which describes the grotesque distortion of the norms of medical practice and the violation of the doctor-patient relationship that results from the withdrawal of physicians from the appropriate treatment of pain due to fear of litigation, loss of livelihood, and incarceration.

Criminal prosecutions of physicians have increased under Attorney General John Ashcroft. Examples of recent important cases include those of Dr. William Hurwitz, a pioneer in the field of pain management in Virginia; Dr. Jeri Hassman, who had the largest pain practice in Tucson, and is being threatened with a 28-year prison term apparently because a small fraction of her patients used the prescriptions in unauthorized way; Dr. Robert Weitzel of Utah, who was convicted of negligent homicide and manslaughter but then acquitted in a new trial after the prosecutor was found to have concealed exculpatory evidence, and Dr. Deborah Bordeaux of South Carolina, who was convicted under a "drug kingpin" statute carrying a mandatory minimum sentence of 20 years, after working a mere two months in a locum tenems position at a clinic treating chronic pain among other ailments.

In a 2003 press release entitled "The Myth of the Chilling Effect," the DEA denied the possibility that its actions against physicians could have such an effect, arguing that DEA only brings actions against a miniscule proportion of doctors, therefore actions against doctors for violations of the Controlled Substances Act (CSA) cannot be causing other doctors to seek to avoid such actions by failing to use opioid analgesics appropriately or by refusing to prescribe them at all. [DEA, 2003] We will analyze this document very carefully later in this paper and reveal it to be so much dissembling gibberish.

What each of us as members of a free and democratic society, governed by our own consent under the Constitution and the Bill of Rights, with an understanding of the meaning of federalism, States rights, the Fourth Amendment right to privacy, and the separation of powers, has to decide is:

1. Was there ever, or is there now, a national problem caused by domestic licit and illicit drug use of such dire import and magnitude that it might justify placing medical doctors and researchers under the direct regulatory control of adversarial federal law enforcement officers with no medical training? Should the DEA, a federal law enforcement agency with a Fiscal Year 2004 Office of Management and Budget (OMB) rating of *ZERO* **[OMB, 2003]**, have the power to prescribe and proscribe the medical behavior of individual physicians, down to the level of judging individual patient medication regimens, and to grossly distort the norms of medical practice in entire specialties of medicine?

2. If there is a national drug problem that does warrant eighty years of a war on drugs / war on doctors and the systematic state sanctioned abuse of pain patients, drug users, and their families, what exactly is the nature of the problem and how severe is it? Compared to what?

3. Where do we go from here? Does the DEA have a legitimate role in making policy on issues which are considered to be medical and public health matters by the vast majority of the nations of the world? Is negotiating towards achieving consensus with such people possible? Is it strategically, morally and ethically advisable? There have been several 'Pain Summits' over the years and grand 'consensus documents' and 'clinical guidelines' have been proclaimed, and yet the war on doctors continues unabated. So we ask, does the DEA negotiate in good faith?

Historical Antecedents

A Tax Act Gone Terribly Wrong

The Food and Drug Act of 1906 was a basically good public health measure that required medicines containing opiates and certain other drugs must say so on their labels. Later amendments to the act also required that the quantity of each drug be truly stated on the label, and that the drugs meet official standards of identity and purity. The Harrison Act effectively withdrew the protection of the Food and Drug Act from the users of these drugs and precipitated the public health debacle that is the real drug crisis in America.

The nation would have an opportunity to learn this lesson again with alcohol Prohibition (1919 - 1933): prohibition equals social chaos, regulation equals social responsibility. Alcohol prohibition differed from drug prohibition in that the Volstead Act was passed in response to the very real problems caused by alcohol which is a far more destructive substance physiologically, behaviorally, and socially than are the opioids, stimulants or hallucinogens. The results of prohibition in both cases is strikingly similar. Alcohol prohibition was intended to lessen social problems, improve the public health, reduce crime and corruption and the costs of law enforcement and incarceration. It was an abject failure on all counts. **[Thornton, 1991]** Prohibition of reciprocally beneficial transactions is doomed to failure.

Matters of international diplomacy and international trade significantly impacted the development of U.S. domestic drug policy. In 1906, in response to domestic opposition to continued British opium sales to China and to America's own foreign opium problem in the Philippines, President Theodore Roosevelt called for an international opium conference to foster the development of international rather than just national controls. The Hague Convention of 1912, which focused mainly on the opium problems of the Far East, followed. Secretary of State William Jennings Bryan, a man famous and infamous in American history for his prohibitionist convictions, was the Harrison Act's primary proponent and he urged passage as a matter of international treaty obligation. [Brecher, 1972b]

The Harrison Narcotics Act was a tax act: "An Act To provide for the registration of, with collectors of internal revenue, and to impose a special tax on all persons who produce, import, manufacture, compound, deal in, dispense, sell, distribute, or give away opium or coca leaves, their salts, derivatives, or preparations, and for other purposes." [Harrison Act, 1914] The Act contained provisions for the licensure of physicians and pharmacists as well as manufactures and importers and set a modest excise tax of one cent per ounce on opium, coca leaves and their derivatives. Its passage was encouraged with some appeal to the early stirrings of the media-inspired hysteria with racist and xenophobic overtones that are a leitmotif in America's war on drugs and a driving force behind it. However, the Harrison Act was not a prohibition measure at the time of its enactment nor was fear of an impending domestic addiction problem its primary focus. [King, 1972a]

The Act was intended to measure and get a handle on what was an entirely unregulated and chaotic market. Physicians and patients in a doctor-patient relationship were specifically exempted with this language: "Nothing contained in this section shall apply . . . to the dispensing or distribution of any of the aforesaid drugs to a patient by a physician, dentist, or veterinary surgeon registered under this Act in the course of his professional practice only." [Harrison Act, 1914] The only burden placed on doctors was that they register for a fee and keep records of medications dispensed or prescribed.

Had the Harrison Act been left unchanged as initially passed by Congress, we might today be discussing it along with the Food and Drug Act of 1906 as examples of the United States' early and laudable public health efforts at addressing a small but potentially significant domestic substance abuse problem. Unfortunately, the Harrison Act is instead best remembered as a tax act gone terribly wrong, marking the beginning of drug prohibition as national policy. The very first cases brought to the Courts to test the Act and hone it through legal challenge were cases against practicing physicians, and so the Harrison Act marks the beginning of America's war on doctors making them the Acts first, and at the time only, targets. For a brief time, pain patients and drug users would have to wait their turn.

In the Course of His Professional Practice Only...

How did everything change, so abruptly and violently, in the wake of the Harrison Act? Enforcement was the responsibility of the Narcotics Division of the Treasury Department. The Division was merged into the Prohibition Unit of the Treasury Department when that was established in 1920 after passage of the Volstead Act in 1919, and later became the Federal Narcotics Bureau in 1930 as the era of alcohol prohibition was drawing to a close. The Division, seeking clarification and establishment of the scope of their powers under Harrison, brought a series of clever prosecutions to the court against the exemption for the doctor patient relationship. This was critical, for as long as doctors were taking care of addicts as they heretofore had, there was in fact no problem for our G-men-in-waiting to attack. Further, as long as doctors and

patients were shielded by the exemption from the Harrison Act, there could be no sizable market for illicit drugs and no way for law enforcement to get at addicts who turned to the medical profession for help. Quoting Rufus B. King from his 1953 Harvard Law Review article entitled, "The Harrison Narcotics Act - Jailing the Healers and the Sick":

> Our grievous error was in allowing the narcotics addict to be pushed out of society and relegated to the criminal community. He isn't a criminal. He never has been. And nobody looked on him as such until the furious blitzkrieg launched around 1918 in connection with the enforcement of the Harrison Act... Narcotics-users were "sufferers" or "patients" in those days; they could and did get relief from any reputable medical practitioner, and there is not the slightest suggestion that Congress intended to change this-beyond cutting off the disreputable "pushers" who were thriving outside the medical profession and along its peripheries. **[King, 1953]**

I will not review in great depth here the details of the three core cases through which the Bureau changed a benign tax act into a nightmare prohibition act. Interested readers are referred to detailed accounts by both King, in his 1953 Yale Law Review article **[King, 1953]** and in Chapters 3 and 6 of his 1972 book, *The Drug Hang-Up, America's Fifty-Year Folly* **[King, 1972b]** and by Brecher in Chapters 8 and 9 of his classic *Licit and Illicit Drugs* **[Brecher, 1972c]**, also published in 1972. The three key cases are *Webb* (1919), *Moy* (1920), and *Behrman* (1921). Rufus King portrays all three litigants as ne'er-do-wells. Dr. Webb "simply sold prescriptions by the thousands, indiscriminately, to all comers, for fifty cents apiece," Dr Moy was "an out and out peddler [who] prescribed morphine to strangers... 10 grams at a time for $1.00 a gram" and Behrman was "likewise a flagrant violator."

In *Webb,* the Attorney General posed a certified question to the Court:

> If a practicing and registered physician issues an order for morphine to an habitual user thereof, the order not being issued by him in the course of professional treatment in the attempted cure of the habit, but being issued for the purpose of providing the user with morphine sufficient to keep him comfortable by maintaining his custom use, is such order a physician's prescription under exception (b) of s.2? **[King, 1953]**

The Court, offended by the facts of the Dr. Webb's outright peddling responded: "to call such order for the use of morphine a physician's prescription would be so plain a perversion of meaning that no discussion of the subject is required." The problem here is that the phrase, "sufficient to keep him comfortable by maintaining his customary use" is not a merely a description of the egregious facts of *Webb* but also encompasses the dispensing of opioids for the relief and prevention of withdrawal that is clearly bona-fide medical treatment of opioid dependence.

The wedge between "the appropriate bounds of medical practice" and the bona-fide medical treatment of opioid dependence was widened in *Moy* in which the Court rendered the opinion:

> Manifestly the phrases "to a patient" and "in the course of his professional practice only" are intended to confine the immunity of a registered physician, in dispensing the narcotic drugs mentioned in the act, strictly within the appropriate bounds of a physician's professional practice, and-not to extend it to include a

> sale to a dealer or a distribution intended to cater to the appetite or satisfy. the craving of one addicted to the use of the drug. [King, 1972c]

Which brings us to *Behrman*, a name made infamous in succeeding years when medical doctors were rounded up in large numbers by means of what came to be known as the "Behrman indictment." [King, 1972c] Behrman was arrested for prescribing at one time 150 grains of heroin, 360 grains of morphine and 210 grains of cocaine. **[See also "*Flash Trash*" in Appendix Two for an analysis of this dosing regimen.]** The trick here is that the indictment was not drawn as an accusation that Behrman's prescriptions were not "in the course of his professional practice only," but "instead alleging that, in effect, the drugs were given in a good faith attempt to cure the addict." [King, 1953] This is the birth of what we might call the "doctor's dilemma," that it is a federal offense to administer opiates to an opiate addict for the purposes of treating their opiate addiction though to administer opiates to an opiate addict in pain for the purposes of analgesia is OK. Now, if only the distinction between the two could be reliably made...

The Doctor's Dilemma

While opioid medications are relatively safe and effective, there can be complications. Doctors commonly bring both legitimate medical concerns and well-founded fear of regulation to the table. An aura of unease surrounds medical training in the use of opioid analgesia. Perhaps to put a psychologically more palatable medical face on what was really painful historically experience with federal harassment and persecution, the clinical dangers of opioid use are exaggerated. Physicians are taught that morphine and its relatives are dangerous, difficult to use substances; that they are highly addictive and can easily cause respiratory depression and death. But even when the safety and efficacy of opioid therapy is recognized and taught, the reality of the DEA war on doctors need not be taught; it is on the news and in the trade journals and happening all the time around physicians in communities across America.

In 2002, then DEA Director Asa Hutchinson, in an address to the American Pain Society, attempted to reassure the medical community:

> I'm here to tell you that we trust your judgment... The DEA does not intend to play the role of doctor... We will not prevent practitioners acting in the usual course of their medical practice from prescribing OxyContin for patients with legitimate medical needs. We never want to deny deserving patients access to drugs that relieve suffering and improve the quality of life. [Orient, 2003]

Soothing words perhaps, but the medical community can be forgiven for paying more attention to the escalation of the war on doctors this agency has undertaken under Bush / Ashcroft. The unfortunate reality is that it is impossible on clinical grounds to reliably distinguish the "deserving" chronic pain patient from the presumably undeserving drug addict who is not otherwise in pain. The pain management physician employs functional criteria to monitor the course of chronic opioid therapy. That is, the patient is regularly assessed in the areas of his ability to perform "activities of daily living" and to meet family obligations and social norms, and the patient who meets expectations in these areas is presumed to be a chronic pain patient rather than an addict. However, any opioid dependent person on an adequate regular dosage regimen, for example, a successful methadone maintenance patient, is physiologically and socially indistinguishable from a chronic pain patient whose pain is controlled by chronic opioid therapy, or indeed, from a well person.

We have reviewed the Harrison Act and its aftermath as the historical crux of the war on drugs, the war on doctors, from which the pain crisis in America directly stems. In short, the drug prohibitionists succeeded in creating, through deceptive legal challenges, a very broad scope of power criminalizing doctors and drug users as well as drug importers and peddlers, instead of the very small scope that Congress had intended (the smuggler and the peddler) when it exempted the doctor-patient relationship under Harrison. [King, 1953] Millions of law-abiding American opioid users became criminals by legislative fiat while at the same time being cut off from legal supply of the medication they needed to function in society and with no effective public health measures employed to mitigate the predictable physical, emotional and spiritual sickness and suffering unleashed across the nation.

Big Lies and Bullies Trump Research in the War on Drugs

In a scientific society we might expect that good epidemiological and medical research would, over time, dissolve myths and prejudices and generate basic scientific answers on which rational policy might be based. It is a sad, recurrent theme in the war on drugs that law enforcement repeatedly tried to limit what research is undertaken by denying permits to possess and use drugs for studies, and by vilifying and threatening the professional lives of those courageous researchers who do the necessary work despite the obstacles. What research is accomplished is manipulated and spun by various governmental agencies to suit predetermined national drug policy.

The LaGuardia Commission

A classic and well documented example of law enforcement misinformation and shameless bullying of politicians, doctors, and scientists is the story of NY Mayor Fiorello LaGuardia and his 1939 blue-ribbon commission which was established under the auspices of the NY Academy of Medicine to examine the absurd claims of Narcotics Bureau Commissioner Anslinger expressed in hysterical press suggestions that New York City children were on the brink of launching "marijuana-induced orgies of theft, sex, and murder." **[Anslinger, as quoted in [King, 1972d]]**

The Academy did excellent work documenting the physiological and psychological effects of marijuana including careful tests of IQ, memory, and learning which failed to reveal any significant pathological pattern. Further, the Mayor's investigators found virtually no use of marijuana in high schools or junior high schools, and no observable association between juvenile delinquency and such marijuana use as they did find.

Alas, the LaGuardia Report was to be a case of winning the battle and losing the war. Anslinger did not challenge the findings but rather attacked the researchers for publishing them. "From [the enforcement] point of view it is very unfortunate that Doctors Allentuck and Bowman should have stated so unqualifiedly that the use of marijuana does not lead to physical, mental or moral deterioration." **[Anslinger in a 1942 letter published in the *American Journal of Psychiatry*, as quoted in [King, 1972d]]**

The Narcotics Bureau's attack on the final release of the LaGuardia Report was far more insidious and damaging. Consider the following excerpt from an editorial in *JAMA*:

> [A] book called "Marijuana Problems" by the Mayor's Committee on Marijuana submits an analysis [which] minimizes the harmfulness of marijuana. Already the book has done harm. One investigator has described some tearful parents who

> brought their 16 year old son to a physician after he had been detected in the act of smoking marijuana. A noticeable mental deterioration had been evident for some time... The boy said he had read an account of the La Guardia Committee report and that this was his justification for using marijuana. **[Excerpt from AMA editorial, as quoted in [King, 1972d]]**

King reminds us that "this nonsensical frothing, which could not conceivably have come from anywhere but the Bureau," was published under the prestigious AMA masthead. The message to doctors and to researchers was clear. Expect to be attacked by federal law enforcement and abandoned by your peers in the powerful AMA for your professional efforts and honesty.

The ultimate outcome of this brouhaha was devastating. Few reputable doctors and scientists would risk their professional lives in this sort of environment and law enforcement officials in the Bureau unhesitatingly denounced even the facilities of major hospitals and leading universities as inadequate for the conducting of responsible experiments, and hence unworthy of a Treasury license required for studying controlled substances. [King, 1972d] Treasury-approved research projects dropped from 87 in 1948, to 18 in 1953, to 6 in 1958.

The Dissembling DEA and the Myth of the "Chilling Effect"

A 2003 Drug Enforcement Agency DEA press release entitled "The Myth of the Chilling Effect" [DEA, 2003] is a very interesting document. It is brief, a mere 182 words in seven sentences formed into four paragraphs, and contains a table and six pie charts. Every sentence is entirely true, and the text as a whole is odd only in that the content of the first three paragraphs make no particular point regarding the "chilling effect" the document purports to debunk. The overall message is: "DEA only brings actions against a miniscule proportion of doctors, therefore actions against doctors for violations of the Controlled Substances Act (CSA) cannot be causing other doctors to seek to avoid such actions by failing to use opioid analgesics appropriately or by refusing to prescribe them at all."

Let's start with the title. What is a "chilling effect"? The phrase does not exist in most dictionaries as such. "Chilling" is an adjective meaning 'so scary as to cause chills and shudders,' and as a verb "chill" can mean 'to depress or discourage.' Let me propose the following working definition of a "chilling effect" that is consistent with what the DEA is addressing in its press release:

The "chilling effect" is the withdrawal, for fear of litigation, by physicians from the appropriate treatment of pain.

It is important to note that much of the public health damage here is caused not by the doctors accused of wrongdoing, rather it is caused by doctors-in-good-standing who, faced with a patient in pain and therefore at risk of being targeted by the DEA, modify their treatment in an attempt to avoid regulatory attention. This distortion of the doctor-patient relationship is complex and can be gross or subtle. Examples include a blanket refusal to prescribe controlled substances even when clearly indicated, or selecting less effective and more toxic non-controlled medications when a trial of opioid analgesics would be in the best interests of a particular patient. At the very least, some degree of suspicion and mistrust will surely arise in any medical relationship involving controlled substances.

There is very little a well-intentioned physician can do to mitigate this risk, to correct these distortions in medical values, ethics, and in the doctor-patient relationship that always arise in the course of treatment for pain and/or substance abuse problems. Even experts in the medical

treatment of addiction and pain cannot make the crucial distinction, the identification of the 'legitimate pain patient,' with confidence. **[PAIN_CHEM_DEP listServ, 2003]** Quite simply, the core presumption, that the states-of-being: 'legitimate pain patient,' 'drug abuser,' 'diverter,' 'frequent flyer,' etc., are mutually exclusive and dichotomous is, medically, false.

The legal punishment for mistaking a drug abuser for a pain patient can be extremely severe; doctors are being threatened with 28-year prison terms (Dr. Hasman), have been likened to "crack dealers" (Dr. Hurwitz) and tried as "drug kingpins" (Dr. Bordeaux). **[Orient, 2003];[White & Kaufman, 2003]** On the other hand, mistaking a pain patient for a drug addict, and thereby committing the error of failure to appropriately treat pain, is highly unlikely to have any legal consequences at all. This set of legal and psychological imperatives with their attendant severe punishments has created a near ideal environment for manifestation of a "chilling effect," which inexorably leads to the under-treatment and non-treatment of pain in America.

The Controlled Substances Act (CSA) of 1972, which supersedes and replaces the Harrison Act and all intervening federal drug legislation, makes it a federal offence to prescribe controlled substances to a drug addict for the purposes of treating or maintaining their addiction, except where the physician holds a separate DEA license to provide methadone maintenance. This is what defines the "bounds of accepted medical practice" referred to in the subtitle of the DEA press release under consideration. Defining the medical treatment of addiction as 'outside the bounds of accepted medical practice' is a legacy of the Harrison Narcotics Tax Act of 1914 as discussed earlier in this paper.

The one table contains the only comprehensible data in the DEA press release and makes, somewhat obliquely, the point as stated in the beginning of this analysis. Here is the table which presents partial Fiscal Year (FY) 2003 data:

Total registrants = 963,385	**Number**	**% Total Registrants**
Investigations Initiated:	557	0.06
Actions Against MDs:	441	0.05
Arrests of MDs:	34	0.01

The table is presented without caption or discussion except what is contained in paragraph four:

> Since FY 1999 the DEA registrant population has continually increased reaching almost 1 million doctors (as of June 30, 2003). During this same time, DEA has pursued sanctions on less than one tenth of one percent of the registered doctors..." **[DEA, 2003]**

We are talking about risk here and the appropriate statistic is a rate. The **Numbers** in the table above can correctly be used as numerators to compute this statistic, however, **Total registrants** *is not* the appropriate denominator because the denominator used must include only physicians who could possibly come to DEA attention. I call this misleading use of an incorrectly computed rate ***Denominator Abuse.***

Having a DEA license is necessary but not sufficient to put a physician at risk of investigation, loss of license and arrest. The other requirement for being a physician-at-risk, thereby earning a rightful place in the denominator, is prescribing controlled substances in regimens that DEA finds

questionable, and this number is far, far smaller. It should be noted in this regard, that DEA licensure is commonly required for hospital employment or privileges regardless of whether a physician ever intends to prescribe controlled substances or even possesses the special prescription pad necessary to do so.

Exactly how much smaller is the appropriate denominator? The answer is open to interpretation and affected by assumptions; only the DEA could provide the precise number and they do not publish this datum. For example, using the full year's numbers from the same 2002 data set, 622 physicians were investigated, charges were brought against 586, and in 426 cases medical licenses were revoked "for cause." **[Hochman, 2003]** Dr. Hochman, a pain specialist and the Executive Director of the National Foundation of the Treatment of Pain, estimates that the number of physicians practicing "chronic opioid therapy" was 5000 in 2002. This estimate is somewhat close to the "3000 pain specialists" estimated by Eric Chevlen. **[Chevlen, 2001]** If we use Hochman's "5000 doctors practicing chronic opioid therapy" number to compute the rate statistic (and assuming that all in the numerator are also members of the denominator): 622/5000 = 0.1244 = a DEA investigation-or-action rate of 12.44 percent, ***orders of magnitude higher than the incorrectly computed DEA rate statistic*** of "less than one tenth of one percent of the registered doctors." The comparable rate using Chevlen's "3000 pain specialists in the U.S." is 20.73 percent of at-risk physicians had DEA action initiated against them in 2002.

I do not know exactly how either Hochman or Chevlen arrived at that their estimates. If reasonably derived, either estimate could be a statistically appropriate denominator to compute a rate statistic. On the other hand, the DEA's choice for the denominator is most certainly wrong. I am trying here to give a sense of how important it is to be explicit about one's assumptions in these matters and of how difficult it is, given the available DEA data, to construct even simple rates that are more enlightening than misleading. Regardless of how the rate statistic is computed, a "chilling effect," as operationally defined in this paper, is not a solely a function of risk as defined by an appropriate rate; severity of risk, highly publicized trials of prominent physicians, and the perceived rationality or irrationality of the DEA criteria used to set the "bounds of accepted medical practice" also play a significant role in how physicians react to the fear of litigation.

Finally, as Dr. William Hurwitz pointed out in a December 7, 2003 message to the PAIN_CHEM_DEP listServ, the DEA presents statistics relating only to their actions against doctors and not the consequent distortion of medical practice that is the 'chilling effect' they are claiming to examine. "The same purportedly low rate of disciplinary action cannot logically serve as an index of both cause and effect. How can one determine if there has been a chilling effect without looking at what doctors really do? There has been no attempt by the DEA to do so." **[Hurwitz, 2003]** I call this misleading confusion of outcome for index event, "***Outcome Obfuscation***." (See Appendix Two)

One can only conclude that *"The Myth of the Chilling Effect"* DEA press release is grossly and purposefully misleading, and statistically childish.

Before we turn to a consideration of the nature and relative severity of the "drug problem" which is the justification for the regulation of opioid analgesic medications by federal law enforcement, let me point out that the above examples of the triumph of big lies and bullies over medical and social rationalism are more than just amusing historical anecdotes. It is beyond the scope of this paper to thoroughly consider the "Findings of Congress" that are written into the Drug-Free Workplace Act of 1998 **[Drug-free Workplace Act, 1998]** and interested readers are referred to

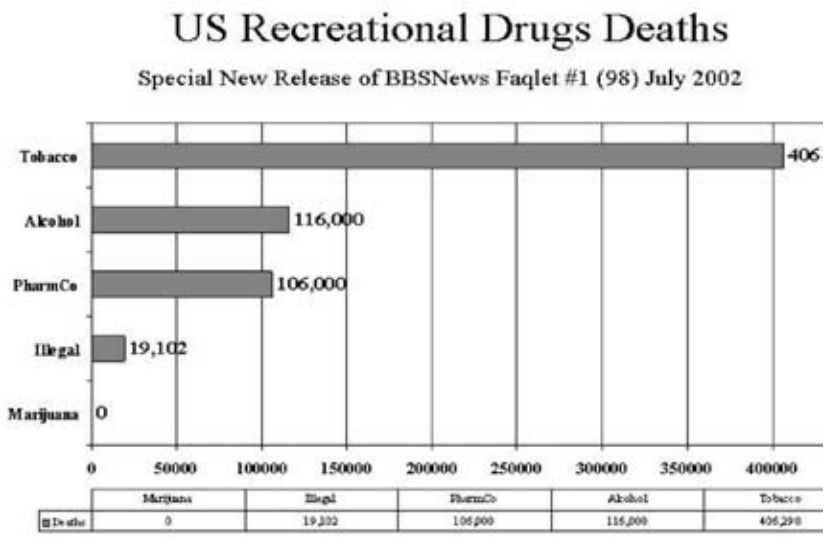
"A critical assessment of the impact of drug testing programs on the American workplace." [DeLuca, 2002] Let it suffice to say here the major "Finding," that "employees who use and abuse addictive drugs and alcohol increase costs for business" was publicly debunked by research sponsored by the governments' own National Institute of Drug Abuse and published in 1994 in a book entitled *"Under the Influence? Drugs and the American Workforce"* by Normand et. al. [Normand et. al., 1994] Regarding the minor "Finding" that "health benefit utilization is 300 percent higher among drug users" these same authors found studies on this question equivocal at best.

It is particularly dismaying to find this same old tired litany of discredited information written, without attribution, directly into major U.S. drug policy legislation.

Drugs are Bad. Compared to What?

America does have a large substance-related public health problem, but it is very difficult to make a serious case that the substances we should be most concerned about are the illicit drugs and licit prescription controlled substances. Figure 1 compares deaths related to the "recreational" use of tobacco, alcohol, illicit drugs, and cannabis to deaths related to fatal adverse drug reactions (ADRs) which are captioned "PharmCo." Note that deaths related to illicit drugs are an order of magnitude lower than deaths related to the legal recreational substances tobacco and alcohol. Note also that deaths related to cannabis use are zero.

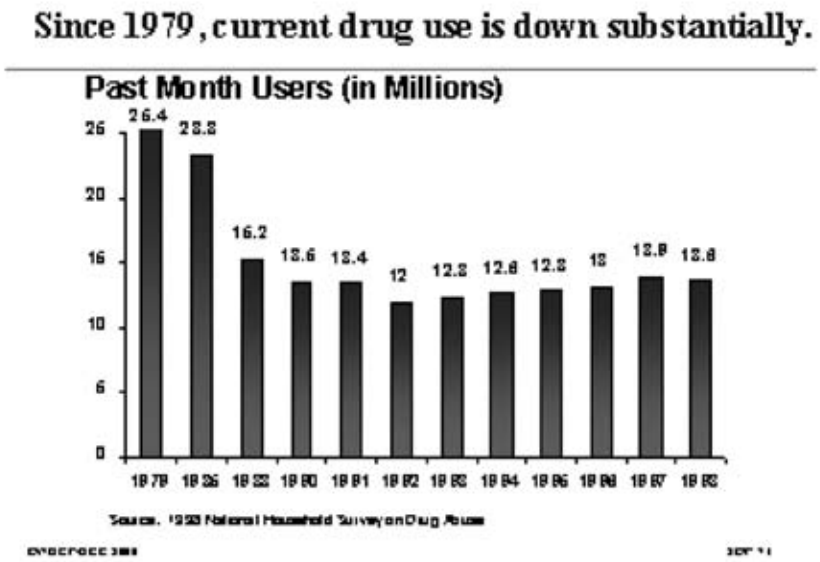
Figure 1 [From: http://bbsnews.net/drug-deaths.html]



America's problem with ADRs is truly startling in that it is a far more common cause of morbidity and mortality than illicit drugs and occurs under direct medical auspices. Lazarou et. al., in their 1998 meta-analysis of prospective studies, published in *JAMA*, calculated the overall incidence of serious ADRs to be 6.7 percent, and fatal ADRs to be 0.32 percent, of hospitalized patients in the U.S. [Lazarou et. al, 1998] Focusing on analgesic medication, in 2000 approximately 16,000 Americans died from direct complications of NSAIDs (non-steroidal anti-inflammatory medications like Motrin and Naprosyn). In that year only some 200 died from OxyContin, usually in combination with alcohol or other drug. [Chevlen, 2001]

Figure 2 was composed from National Household Survey data, obtained from the Office of National Drug Control Policy (ONDCP), to show drug use trends since 1979. While the government is correct that "since 1979 current drug use is down substantially," the data also clearly show that the percentage of Americans who used illicit drugs in the past month is essentially unchanged since 1988.

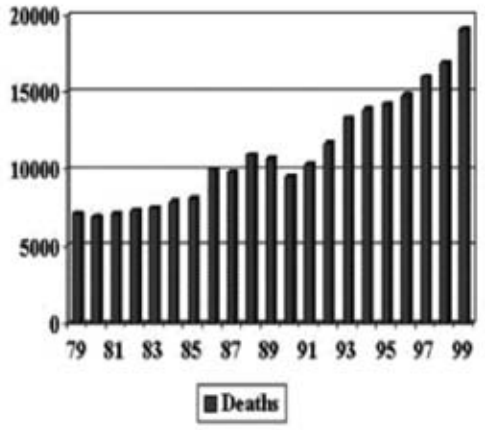
Figure 2 [Scherlen & Robinson, 2003]



While the war on drugs / war on doctors has not resulted in decreased regular drug use, it is making that use increasingly deadly. The goal of minimizing the harm to addicts, frequently proclaimed by the ONDCP, appears to be a dismal failure. These figures lend support to the argument of the drug reformers that drug prohibition does significantly more harm than good.

Figure 3 shows that over the same period of time that current drug use is essentially unchanged, deaths related to illicit drug use climbed continuously and dramatically. This is the opposite of a sane public health policy of harm reduction: our national policy creates conditions under which more and more drug users get sick and die.

Figure 3 [Scherlen & Robinson, 2003]



Source: Sourcebook on Criminal Justice Statistics (2003)

The Pain Crisis in America

On October 2, 2003, the Association of American Physicians and Surgeons (AAPS) issued a statement entitled, "Doctors say U.S. drug policy forces pain patients to extreme measures, turns doctors into criminals." [Serkes, 2003] In a country where there is no shortage of physicians qualified to prescribe opiate analgesics, which are relatively safer than alternative classes of medications commonly used in the treatment of chronic pain (antidepressants, NSAIDs, and anticonvulsants), they noted that the 48 million odd people suffering from chronic pain in the U.S. were having difficulty finding doctors to treat them, and that this was the result of a tragically misguided, politically driven national drug policy, defacto law enforcement regulation

of medical practice, and overzealous federal prosecutors. "The 'war on drugs' has turned into a war on doctors and [on] the legal drugs they prescribe and the suffering patients who need the drugs to attempt anything approaching a normal life," said Kathryn Serkes, public affairs counsel for the AAPS. Referring to an review of thirty recent cases of prosecutions against physicians [AAPS, 2004] involving physician loss of livelihood, loss of license, and imprisonment and the abandonment of literally thousands of their patients, Serkes issued this stark and frightening statement to AAPS members:

> If you're thinking about getting into pain management using opioids as appropriate -- DON'T. Forget what you learned in medical school -- drug agents now set medical standards. [Serkes, 2003]

Magnitude and Nature of the Problem

How big a problem is pain in America? Stewart et. al., in a 2003 cross-sectional study using 2001 - 2002 data from the American Productivity Audit on 28,902 working adults, revealed that thirteen percent experienced a loss in productive time during a 2-week period due to a common pain condition. (Most, 76.6 percent, of the lost productive time was explained by reduced performance while at work and not work absence). Lost productive time was estimated to cost $61.2 billion per year. They concluded that pain "is an inordinately common and disabling condition in the US workforce..." [Stewart et. al, 2003]

Reports and statements from government, regulatory and academic bodies attesting to a massive problem of untreated and undertreated pain abound. In 2004 Robert Meyer, Director of the FDA's Center for Drug Evaluation and Research, in testimony to the House Subcommittee on Criminal Justice, Drug Policy and Human Resources reminded legislators of a Consensus Statement from the National Cancer Institute Workshop on Cancer Pain over a decade earlier (1990) which indicated that the "undertreatment of pain... is a serious and neglected public health problem." [Meyer, 2004] The Agency for Healthcare Research and Quality reported in 1992 that, "half of all patients given conveutional therapy for their pain...do not get adequate relief." **[Carr, 1992]** In 1999 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued a press release noting that unrelieved pain had huge physical and psychological effects on patients and increased health care costs. JCAHO at that time officially declared pain to be the "fifth vital sign," henceforth regarding the evaluation of pain a routine requirement of proper patient care as important and basic as the assessment and management of temperature, blood pressure, respiratory rate, and pulse rate. **[JCAHO, 1999]**

Roadblocks to Relief

What is the impact of chronic pain on quality of life? Are there barriers and stigma related to pain treatment and especially to mainstay opioid medications? Most importantly, do those afflicted with chronic pain in fact have their pain under control? Does treatment goes far enough particularly in more difficult cases where first line therapies have failed? These questions about the effect of chronic pain on individual sufferers and about their experiences seeking relief were investigated in a study commissioned by the American Pain Society (APS), the American Academy of Pain Medicine (AAPM) and Janssen Pharmaceutical and conducted by Roper Starch Worldwide, which was published in 1999 as, "*Chronic Pain in America: Roadblocks to Relief*." [Roper Starch Worldwide, 1999] Of a mail panel of over 500,000 households representative of all households in the U.S., a total of 35,000 screening questionnaires were sent to a random cross-section and 805 individuals with moderate to severe non-cancer pain were interviewed. The findings are thus representative of all such suffers in the U.S.:

- An estimated 9% of the U.S. adult population suffers from moderate to severe non-cancer related pain.

- Approximately one third describe their pain as being almost the worst pain one could possibly imagine and two thirds have been living with it for over five years.

- Just over one-half say their pain is pretty much under control, however, the majority with the most severe pain do not have it under control and of those who do, it took most over a year to reach that state.

- Uncontrolled pain has a significant impact on quality of life, affecting the ability to concentrate, work, socialize, sleep, exercise, and engage in sexual activity.

- Controlled pain is associated with significant improvement in function and mood, however, those with severe pain still have a significantly lower quality of life and emotional well being compared to moderate pain suffers.

- Overall 40 percent are not currently seeing a physician for pain relief believing that there is nothing more a doctor can do and that they can deal with it. Of severe chronic pain suffers, 70 percent are under current medical treatment and are significantly more likely to require emergency room visits, hospitalization, and psychological therapy in pursuit of adequate pain relief.

- Difficulty finding a doctor willing and competent to treat pain is the rule and not the exception. Approximately one half of the entire sample have changed physicians since the onset of the pain condition and over on fourth have made at least three changes because doctors did not take their pain seriously enough, or were unwilling to treat it aggressively, or seemed to lack knowledge about pain.

- Among the subset with severe pain, the level of frustration with the availability of adequate medical care was truly disturbing. The majority had changed doctors and almost one third had made three or more changes primarily because of persistent intolerable pain despite treatment.

- Opiate analgesics are rated significantly more effective than non-opiate pain relievers among those who had ever tried them, though fears about addiction and side effects limited wider usage. A small percentage had turned to alcohol at one time or another for relief, and this was most common in those middle aged and in men.

Etiology of the Undertreatment of Chronic Pain in America

In 1929 Alexander Fleming published his discovery of penicillin, the first antibiotic. Prior to this time, all the way back to ancient Greece, physicians could be relied on for little else beyond the skillful administration of opium preparations and later morphine, which was isolated by German pharmacists at the turn of the century, towards the effective relief of pain. Just as there is no historical record of a national drug abuse problem in the first decade of the 20th century, a pervasive problem of the undertreatment of pain was likewise unheard of. Indeed, especially after the invention of a practical hypodermic syringe by Alexander Wood in 1845, rampant undertreatment of pain such are we are experiencing in the early 21st

century would probably have been unimaginable to medical practitioners in the early decades of the Twentieth Century.

Recognizing the efficacy of opioids in relieving pain and in improving the mood and functioning of the majority of chronic pain patients many experts have urged that such medications not be denied to sufferers. Portenoy, among others, has thoroughly studied and reviewed chronic opioid therapy and the consensus is clearly that long-term opioid treatment is safe, efficacious, and is widely perceived to improve functioning and quality of life. **[Portenoy, 1996];[Portenoy & Foley, 1986]**

How then can we explain the shortage of American physicians willing to prescribe appropriately potent opioids in appropriate doses on an ongoing basis to achieve such results? One reason is a persistent belief in the medical community that opioids are dangerous and difficulty to use and that in high doses commonly cause respiratory depression and death. In fact, respiratory depression is often seen in studies when opiate-naive subjects who are not in pain are given acute doses in the range commonly used to treat pain. The same doses given to opiate-naïve patients in pain do not cause respiratory depression. An explanation is that painful stimuli affect the respiratory center of the brain counteracting the respiratory depressant potential of the opioid. This is why opioids can and should be titrated to effect against pain. **[McQuay, 1999]** Further, respiratory depression and death from overdose are so rarely seen in pain populations receiving chronic opioid therapy because while tolerance to the analgesic effect of the drugs develops very slowly if at all, tolerance to the respiratory depressant and euphoric effects develops relatively rapidly.

A second persistent erroneous belief is that addiction is a common outcome of chronic opioid therapy. There is no research evidence of any quality that chronic opioid therapy is associated with any significant level of addiction outcomes. This is consistent finding over decades.

- In 1981, Medina and Diamond reviewed their experience with 2,369 patients treated in the 1970's at the Diamond Headache Clinic in Chicago for a NIDA Research Monograph: only two of 2,369 patients showed signs of psychological dependence (addiction) consequent to their receiving opioid or other pharmacotherapy. **[Medina & Diamond, 1981];[Medina & Diamond, 1977]**

- Moulin et. al. (1996) employed a randomized double-blind crossover study design to investigate whether oral morphine effectively relieved pain and improved quality of life in a group of chronic pain patients who had failed other therapies. Their findings: "[The] morphine group showed a reduction in pain intensity relative to placebo in period I ($p=0.01$) and this group also fared better in a crossover analysis of the sum of pain intensity differences from baseline ($p=0.02$). *No other significant differences [including psychological symptoms, functional status, and cognition] were detected.*" **[Moulin et. al., 1996]** (emphasis mine)

- In a 2003 review article in the *New England Journal of Medicine*, Ballantyne and Mao thoroughly examined the literature on opioid therapy. In none of the 37 articles reviewed by these authors was addiction as a consequence of opioid therapy found to be a major, or even significant, problem. **[Ballantyne & Mao, 2003]**

A corollary of the belief that opioid therapy commonly causes addiction is that modern potent opioid formulations favored by expert practitioners, for example sufentanil and Oxycontin, are

especially dangerous in this regard. This is entirely incorrect and suggests a failure to understand the basic pharmacology of opioids and of substance abuse. Sufentanil is 1000 times more potent than morphine but it's therapeutic index, the ratio of the dose necessary stop breathing to the dose necessary to stop pain, is similar to that of morphine. The addictiveness of a substance, more accurately how neurophysiologically reinforcing a substance is, depends on the interaction of host, substance, dose, rapidity of onset of action, duration of effective blood levels after ingestion, and pattern of ingestion (daily regimen). Transdermal fentanyl and Oxycontin were designed in part to decrease abuse liability by producing a gradual onset of effects and prolonged steady state blood levels. This is distinctly different from the "drugs of choice" of substance users and abusers which are uniformly rapid in onset and of short duration, for example, caffeine, alcohol, amphetamine, methylphenidate, cocaine, short and intermediate acting barbiturates, alprazolam (Xanax), heroin, morphine, and short-acting oxycodone.

The third persistent erroneous belief widely held by the American medical community is that opioid drugs should be avoided because increasing medical use will lead to a corresponding rise in diversion to illicit recreational use. It is this "problem" that is the "drug crisis" that is the target of America's peculiarly intense regulation of controlled substances. Joranson et. al., in an important 2000 *JAMA* article, measured the proportion of opioid abuse (as opposed to mere non-medical use or emergency room "mentions" of opioid use) as well as overall trends in the medical use and abuse as a result of medicinal opioid therapy for severe pain. The results:

> Conventional wisdom suggests that the abuse potential of opioid analgesics is such that increases in medical use of these drugs will lead inevitably to increases in their abuse. The data from this study with respect to the opioids in the class of morphine provide no support for this hypothesis. The present trend of increasing medical use of opioid analgesics to treat pain does not appear to be contributing to increases in the health consequences of opioid analgesic abuse. [**Joranson, 2000**]

The Distortion of Medical Practice

The persistence and power of these beliefs, which are quite simply wrong, over the medical community is remarkable. This, I believe, is a consequence of basing national drug policy on the given that opioids are bad because the policeman says they are and are therefore dangerous for physicians who would prescribe them - but that is an uncomfortable thing for the medical community to admit. So we hold on to half truths and false beliefs which more acceptably bolster the legislatively encouraged behavior which is the avoidance, fear and loathing of opioid therapy. Jacob Sullum refers to this as *opiophobia*:

> Torture, despair, agony, and death are the symptoms of "opiophobia," a well-documented medical syndrome fed by fear, superstition, and the war on drugs. Doctors suffer the syndrome. Patients suffer the consequences. [**Sullum, 1997**]

Society sanctions these beliefs and doctors are punished for acting otherwise by regulatory structure and function. The authority lies in state health practice acts and in the federal CSA and at both of these levels the war on drugs, war on doctors is unquestioned policy. It is this authority so directed that informs "the standard of medical practice" by which physicians are then judged, at least as much as the current state of medical understanding does. The various guidelines produced by clinicians in negotiation with various state and federal the boards and agencies also incorporate these erroneous beliefs and in fact reinforce and legitimize them. Often referred to as embodying the "principle of balance," in fact such activities are examples of the pitfalls and

consequences of negotiating with people whose mission and values rest on a belief that addicts are criminals who belong in jail, and in drugs with the power to render citizens soulless, amoral, ghouls.

Even authors who ably explain the power relationships underlying the pain crisis in America conclude by calling for more physician education or for the inclusion of more clinical expertise in consensus building with law enforcement. They are wrong.

If the problem were one of physician knowledge or of the dissemination of clinical expertise, and not state and federal regulatory behavior guided by a war on drugs policy and mentality, then we would expect that medical knowledge and the current state of the practice of pain management would be substantially the same in countries where the regulatory balance struck is far less determined by anti-diversionary law enforcement. Let us consider two recent studies of doctors' medical knowledge and attitudes about basic aspects of pain management and about the deficiencies in the treatment of patients suffering from chronic non-malignant pain.

Rothstein et. al. 1998, using a questionnaire to investigate a sample of Germany physicians, found that the "[treatment] of pain with strong opioid analgesics was seen as beneficial for the patients [and the] use of strong opioids for long-term treatment was recommended, and psychological addiction was regarded as non-existent." **[Rothstein et. al., 1998]** The results of a similar survey administered to a group of Texas physicians in 2000 by Weinstein et. al. are starkly different. "Overall, a significant number of physicians in this survey revealed opiophobia (prejudice against the use of opioid analgesics), displayed lack of knowledge about pain and its treatment, and had negative views about patients with chronic pain." **[Weinstein et. al, 2000]**

Conclusion

In 1918, a mere four years after initial passage of the Harrison Tax/Prohibition Act, a high level commission was appointed by the Secretary of the Treasury to examine the drug problem. It reported that an illegal black market approximately equal to the legitimate medical trade in these substances had come into existence. It also noted that some twenty cities including San Francisco and New York were reporting increasing addict populations, suggesting migration and the beginnings of a drug subculture. **[Brecher, 1972b]** And so in 1918 the Treasury Department documented the birth of "the drug problem" in America. The committee noted that "the wrongful use of narcotic drugs had increased" since Harrison, but it is also simply and tragically true that the Narcotics Division of the Treasury Department in their legal challenging of Harrison and highly aggressive police actions directly brought these problems into being. Before prohibition there were no "wrongful users," no "illegal black market," no migration of addicts to form an incipient drug subculture and black market in major cities. We made these problems.

The committee's recommendation? Stricter law enforcement and the passage of State legislation patterned on the Harrison Act to stem the apparently rising tide of drug abuse. **[Brecher, 1972b]** And so the pattern was set. The perpetual drug crisis was brought into existence between 1914 and 1918. We have compounded the problem with decades of criminalization and imprisonment of drug users, collateral damage to generations of pain patients, and over eighty years of ongoing harassment of caring physicians and distortion of medical ethics and practice, and of the constitutional right reserved to the States to regulate medicine. The emperor has no clothes.

The Solution...

***Is Not* More Education of Physicians**
As we have noted, calls for more and better education for physicians have been frequently offered as the solution to the pain crisis, and at one level, who could be against education? Educational campaigns regarding modern techniques of optimizing chronic opioid therapy in the treatment of non-cancer chronic pain, are in fact highly successful in countries where the chilling effect does not hold sway, but they are not effective in addressing the chilling effect itself, which is the problem in the United States. The point of the comparison between physician education in Germany vs. the U.S. (above) is not that German physicians better learned chronic opioid therapy, but that the U.S. doctors have also been taught an opiophobic worldview that places them squarely in a therapeutic double bind.

***Is Not* More "Research" in Thrall to Governmental Policy**
The American taxpayer deserves a lot more for the money they spend on supposedly "scientific" federally supported research from the likes of the Substance Abuse and Mental Health Administration, the Centers for Substance Abuse Treatment and indeed from the Congress of the United States. What we get is the endless spinning of data to suit drug war policy objectives and, as we have discussed in this paper, the knowing incorporation of nonsense and bad science into Congressional legislation such as the Drug Free Workplace Act of 1998. [DeLuca, 2002] If there is a real drug problem in this country let physicians and public health researchers rigorously define it and propose rational solutions instead of decade after decade of crisis declaration, denominator abuse, flash trash and shock schlock (see Appendix Two).

***Is Not* More Negotiation with Law Enforcement**
Appeasement is a strategy that groups of clinicians and policy-makers have used in an attempt to work with the DEA to agree on common guidelines for prescribing for pain patients, for example. Appeasement is also a strategy or understanding employed by individual clinicians and policy makers as they justify their actions to themselves and others. For example, the clinician who declines to treat a patient for pain because that patient might be considered an "addict" by regulatory and law enforcement bodies is practicing appeasement.

What is common and what defines appeasement is a tacit agreement with the DEA core belief in magic substances that turn some users into criminal addicts requiring long term incarceration to be distinguished from deserving pain patients who may morph into criminal drug addicts at any moment. This is gibberish and nonsense, of course, promulgated by the very same police forces that invented and that perpetuate the real drug problem in America.

Law enforcement *does not* deserve a place at the table where scientists and clinicians and politicians of good faith should meet to honestly assess the harm that has been done to criminalized drug users, pain patients and physicians and earnestly seek ways to undue the public health crisis stemming from our disastrous drug war juggernaut.

***Is* to Let Doctors Treat Pain, Let Doctors Treat Substance Use Disorders**
The solution to this awful societal dilemma is to once again allow doctors treat patients respectfully, as whole and complex human beings. Some of these patients have simple medical problems; others complex conditions involving overlapping emotional problems and substance use disorders. Let doctors freely treat pain and addiction just as they do the other chronic public health problems of major importance and consequence in our society, such as alcoholism, asthma

and chronic obstructive pulmonary disease, HIV, chronic liver disease, and hepatitis C. These are medical and public health matters, and are treated primarily as such by all Western nations except the U.S.

Dr. Jerome H. Jaffe, a psychiatrist who became head of President Nixon's drug programs and established a network of methadone treatment centers for heroin addicts, remarked in the 1965 edition of Goodman and Gilman's textbook, *The Basis of Therapeutics*:

> Much of the ill health, crime, degeneracy, and low standard of living are the result not of drug effects, but of the social structure that makes it a criminal act to obtain or to use opiates for their subjective effects... It seems reasonable to wonder if providing addicts with a legitimate source of drugs might not be worthwhile, even if it did not make them our most productive citizens and did not completely eliminate the illicit market but resulted merely in a marked reduction in crime, disease, social degradation, and human misery. **[Jaffee, 1965]**

The Real Enemy is the Big Lie

In 1962 the United States Supreme Court described the addict as "one of the walking dead," and one could no doubt find isolated persons superficially fitting this description among addicts living under modern prohibition-caused conditions of high opiate prices, vigorous law enforcement, draconian penalties, and ostracism. The court erred, both in presenting its ghoulish description as the norm and by attributing this "addict" state of being to the drugs themselves rather than to the laws and to the social conditions which largely determine the how modern addicts live.

The US tries, through its drug policy, to keep drugs out of the hands of addicts; most countries, like the UK, Denmark, and the Netherlands, put their resources into trying to keep drugs out of the hands of the as-of-yet unaddicted. Addicts are treated, with various forms of opiate maintenance including methadone, heroin, and buprenorphine, *by community physicians*, individually. In the European model, addicts don't 'clump up,' and a drug subculture is less likely to form and less likely to be strong. In the American model, we interfere with the community treatment of addiction, instead segregating suffers into 'treatment centers' including drug-free inpatient, drug-free outpatient, methadone maintenance, and jail. Under conditions of prohibition this breeds subculture and crime-culture which is then misleadingly called "a drug problem." Accurately, these are drug prohibition problems.

It is argued here that prescription drug abuse is a trivial problem compared to under-treated chronic pain in this society, and one that would largely disappear were doctors permitted to freely treat addiction and pain. Instead, American physicians daily face the demoralizing and futile task of distinguishing between chronic pain and addiction, to the satisfaction not of the patient or medical peers, but of federal policemen who have the power to crush their livelihoods and jail them as drug dealers or murderers.

The myths of the criminal addict, of the perpetual drug crisis, and of a significant prescription drug problem caused by venal pill-pushing physicians in the guise of pain doctors are deeply intertwined in our national law, social values, prejudices about pain, poverty, and race, and have severely distorted our public health research systems and medical practice. This genie will not be put back in the bottle in anything like the four years (1914 - 1918) it took to unleash it. Administration after administration, Congress after Congress, generation after generation of physicians, and an entrenched and often reactionary substance abuse research and treatment industry, have all bought into and amplified the Big Lie.

We can start by looking to Western Europe and Australia where a policy of harm reduction has gone a long way in mitigating the worst abuses of the war on drugs, including supporting vastly more enlightened medical attitudes and of modern pain management practices. And we can stop negotiating with and attempting to appease law enforcement who brought this scourge upon us toward the accumulation and maintenance of their ever increasing power over the citizenry.

Let honest public health research and enlightened citizens groups and political leaders finally lead the way towards championing expert pain management for all, compassionate medical care for the sick and disabled among us, and universal respect for every individual as a human being who potentially suffers.

Appendix One

Fooling most of the people all of the time

Declare a perpetual crisis...
The historical existence of a "drug abuse crisis" that justifies the extreme financial and social expenditures of a decades long "war on drugs," and the bizarre result that the practice of medicine is defacto regulated by federal law enforcement, is an article of faith among the drug warriors and one that has been so often repeated that it shocks many to hear that evidence for the existence of a problem for which the war on drugs is the solution is very scarce while evidence of the awful cost of the war itself abounds.

History aside, it is extremely difficult, I think, to make a rational argument that there exists a continuing drug abuse crisis complete with periodically declared "epidemics." Nonetheless, the relentless dirge and dire warnings of the drug warriors continues into the present. **[Leshner, 2001];[Vastag, 2001]** It is crucial that one thoroughly grasp the most robust trend in addiction epidemiology: drug use has dramatically declined over thirty years. Past month use rates are literally half of what they were in the 1970's, and there has been virtually no change in past-month drug use for over a decade. The declining trend was clearly established for a decade before workplace drug testing became routine. **[Maltby, 1999]** In 2000, Quest Diagnostics reported that positive urine drug tests were at historic lows, down some 66 percent in eleven years. **[Quest, 1999]** In that report, 62% of the positives were for marijuana - a group particularly *unlikely* to cause workplace problems. **[DeLuca, 2002]**

It's Orwellian: thirty years of steady decline in national drug use but drug abuse somehow remains a "crisis" and an "epidemic" justifying a brutal war on doctors and pain patients.

Appendix Two
Statistical Tricks of the Drug Warriors

Outcome Obfuscation
A sort of statistical sleight of hand, *Outcome Obfuscation* is a misleading confusion of outcome and index event. For example, in their 2003 press release "The Myth of the 'Chilling Effect'" the DEA (see "**The Dissembling DEA and the 'Chilling Effect'**" above) the index event is the rate of actions against physicians, which they incorrectly calculate. The outcome would be some measure of effect on physician behavior resulting from the index prosecutions, which the DEA ignores.

Outcome Obfuscation commonly turns up in statements like the following, in which drug use is correctly identified as an index event, but is also incorrectly identified as the (problem) outcome.

- "In 2001 it is estimated that 94 million people had used an illegal drug at some point in their lives. Today, some 16 million people are using illicit drugs at least once a month -- about seven percent of the population."

- "The National Household Survey on Drug Abuse reports a significant increase in "past month, non-medical use" of pain relievers among those age 18-25 when comparing 2001 data with that for 2000."

The misleading message is: use = abuse = problem = national crisis demanding federal action. More accurately and honestly we might say, for example, that a teenage alcohol use rate of X (index event) resulted in Y motor vehicle accidents (outcome).

Denominator Abuse
Denominator Abuse is the misleading use of an incorrectly computed rate statistic.
(See "**The Dissembling DEA and the 'Chilling Effect'**" above.)

Flash Trash
The use of suggestive of provocative numbers or statistics, usually presented as true prima facie, which when analyzed using algebra, do not in fact support the implied conclusion.

A famous example of *Flash Trash* is contained in the *Behrman* case discussed in the "**Historical Antecedents**" section of this paper. Behrman was arrested for prescribing at one time 150 grains of heroin, 360 grains of morphine and 210 grains of cocaine. These amounts are not as outrageous as they might seem. Just to put the dosing in perspective, and considering for the moment only the morphine component of the medication regimen, 360 grains represents near ideal outpatient maintenance dosing for an opiate dependent person based on a *modern* understanding of methadone dose-effectiveness research.

- 1 grain = 64.8 milligrams (mg).

- Outcomes for MMTP (methadone is equipotent with morphine) are best in the dose range of 100-200 mg a day; chronic pain patients sometimes require doses in the *grams* /day range.

- 360 grains X 64.8 mg / grain = 19,440 mg / 150 mg/day = 129.6 days = approximately 4 months supply = a script for one month with 3 refills with a little left over = medically appropriate ambulatory treatment of opiate dependence.

I have no knowledge of Dr. Behrman other than what is written about him in the document by Rufus King in his "The Narcotics Bureau and the Harrison Act: Jailing the Healers and the Sick" article [King, 1953] and 1972 book, *The Drug Hang-Up, America's Fifty Year Folly* [King, 1972b] and in Brecher's 1972 *Licit and Illicit Drugs,* [Brecher, 1972c] and I do not know what his intentions were. Assuming for the sake of argument that he was acting as a legitimate physician, we could hypothesize that the morphine / heroin / cocaine regimen was part of a detoxification-to-abstinence regimen starting with morphine at, say, 200 mg /day decreasing the dose on a weekly basis, faster at first slower towards the end, switching at some point to heroin (believed at the time to be an effective 'cure' for morphine dependence) and ultimately tapering to abstinence using the cocaine, in the accepted manner of the day, to mitigate the depression and ennui known to accompany detoxification from opiates. This detoxification regimen could be accomplished, given the amounts of the medications involved, in six to twelve months depending of the patients' progress.

For another example of *Flash Trash*, consider the following sentence from a DEA document entitled, "A Closer Look At State Prescription Monitoring Programs" in the "Scope of the Problem" section by Susan Peine, DEA Program Analyst: "In the last five years of her life, Renee obtained at least 469 prescriptions—11,684 doses of pills—from 43 Treasure Valley pharmacies under the names of 110 doctors." [Peine, 2003] (Presumable there were many forgeries or did she see two docs a month for 5 yrs?)

- 5 years X 365 days = 1825 days

- 11,684 "doses of pills" / 1825 days = 6.4 doses / day as in the very commonly written, "Take 1 dose every 4-6 hours as needed for pain." This would be a pharmacologically correct script for the low potency, combination-opiate formulations such as Tylenol #3, Vicodin 7.5/325, Percocet, etc, etc.

If the patient were taking such most commonly prescribed opiates, the number of pills she had to work incredibly hard to obtain is the amount of medication, daily, commonly prescribed for toothache.

Shock Schlock

Shock Schlock is the presentation of lurid or otherwise shocking anecdotes in lieu of meaningful data and sober statistical analysis.

Consider again the "Scope of the Problem" section of the DEA's "A Closer Look At State Prescription Monitoring Programs" [Peine, 2003] which, after all, was written by a DEA 'Program Analyst:'

> Kentucky is a hotbed of prescription drug abuse. The reasons are many—drug seeking patients, pill-pushing doctors, no-questions-asked pharmacists, and lax oversight and enforcement." Two examples cited: During a 15-month period, a woman visited 10 doctors a total of 45 times, went to three hospitals' emergency rooms at total of 43 times, visited four dentists, had 30 prescribers of medicine, filled 159 prescriptions in 103 visits to eight drugstores. Cost to the state

> $14,508; after she was restricted, her treatment for one year dropped to $3,091. During a 15-month period, a man visited five doctors a total of 56 times, went to two hospitals' emergency rooms a total of 18 times, had 224 prescriptions filled in 114 visits to 15 drugstores. Cost to the state $32,130; after he was restricted, his care for one year dropped to $5,604." **[Peine, 2003]**

One might expect to find data and analysis demonstrating, minimally, a mastery of the real situation and a reasonable plan of action and a plausible connection between the two. Instead, the taxpayer is treated to anecdotes worthy of tabloid journalism.

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[END]

PREPARED STATEMENT OF MARTIN E. WAUGH, D.O.

From the time I was little, I had always dreamed of becoming a doctor. Though I grew up on a farm, my folks always encouraged me to pursue my dream, even though that meant not following in my father's footsteps as a farmer in western Kansas.

I had always pictured myself in the healing profession, sharing the forgiveness and healing power of Christ to those who were hurting in body, mind, and spirit.

In 1982, I graduated from Oral Roberts University in Tulsa, Oklahoma, a body, mind, and spirit university. I met my wife, April, there, and in May of 1982, we were married. I subsequently attended Oklahoma State University in Tulsa, where I received my D.O. degree. I was well on my way to living out my dream as a physician. While living in Tulsa I entered the Army Reserve, and with that took an oath to uphold and defend the Constitution of the United States against all enemies. This was a very proud moment for me, as my father had served in the Marines in the Korean Conflict.

In the late 80's and early 90's, I was very concerned about the spread of HIV, and I pursued an opportunity at Yale University after graduating from medical school. I managed an outpatient clinic whereby heroin addicts received detoxification on an outpatient basis that I helped to develop. This population was, of course, at risk for the spread of AIDS.

After a two year substance abuse fellowship, our clinic's published success rate won several million dollars of federal grant monies. At that time, my mentors encouraged me to pursue a specialty in Psychiatry at Yale. So, I entered and completed the Yale Psychiatry Residency program in 1995, which added another three years to my postdoctoral studies.

During my time at Yale, I became aware of the use of brain scans and its application in diagnosing impulses that addicts and other patients had. Studying brain scans in the university setting was difficult, mostly due to the fact that we had only one functional brain scan machine, and many others competed for time on that machine. So, when the opportunity presented itself in 1996 of joining a Neuropsychiatric private practice in Northern California with 3,000 brain scans on file with the latest brain scan machine available, I accepted a position there. I was also able to continue to publish studies on substance abuse and brain scans.

After a year of working for Dr. Daniel Amen in Fairfield, California, I opened up my own practice in Davis, California, while continuing to collaborate with him on using his excellent brain scan machine for my patients. My practice grew very quickly, mostly from referrals from other physicians due to my substance abuse fellowship and Psychiatric training. Many patients who had been problematic to others were also given to me by the clinic.

My patients were typically people whose diagnoses were lost in the chasm between Neurology and Psychiatry, proper. This can occur when a temporal lobe seizure disorder creates a constellation of symptoms that resemble ADHD, but must be treated primarily with anticonvulsants, before considering a stimulant for any residual ADHD. Many of them had tremendously complex medical needs and some of them needed daily supervision. These were the ones that moved to houses in Davis, CA.

I would typically make rounds early in the morning, sometime dispensing medications to those who had been unable to manage their medications on their own. This dramatically cut down the abuse potential of a medication like Ritalin, and since this was similar to making house calls in New Haven, CT, as I did throughout my Substance Abuse Fellowship, and Psychiatric residency, I thought that it was or should be the standard of care. It certainly was the standard of care when I was at Yale, so I thought this should be acceptable in Davis, CA. I did not realize that without the protective arms of Yale around me, however, this behavior, which was helpful to my patients, became suspect to the town authorities.

Throughout our married life, my wife and I had always shared extra rooms in our home with others. Some were patients, some fellow physicians. Now that we were in California, when the needy presented themselves for treatment, and we found that they had neither safe housing nor ability to afford medications, sometimes we would intervene by offering them a room at the boys house, or even a temporary respite in our house.

I have been deeply ingrained with the oath I took, the Osteopathic version of the Hippocratic Oath, which states that we will treat our patients as friends, and the religious command I had to care for how I treated the least of these, in matters of hunger or medicine. They had been put in my path; I could not turn them away.

While at Yale, the treatment and medications were given free to the patients, paid for by grants. While training at Walter Reed on active duty in the Army, medica-

tions were paid for by the Army. In California, this was the first time I had ever encountered patients who needed life saving medicine, who sometimes could not afford to buy it. So, since my practice was successful, I used up to $5,000 a month to buy medicines for patients, while we were getting them on State services. In retrospect, in the town of Davis CA, this was not a wise move.

As I was used to the rigorous, thorough practice of medicine at Yale, I was shocked to encounter a substandard practice of it in California. We began to sense that what had been praised and well-funded on the East Coast, with in-house treatment and outpatient detoxes, was now scorned, mocked and put under surveillance in California. The authorities could not accept that I was a Christian doctor, treating some of my live-in patients for free. They thought otherwise and after spending quite a bit of time and money investigating me, they finally resorted to actions below the law. I was always fully cooperative with any questions they or the State had about the care I was giving.

Fully mindful of the penalties of perjury to Congress, I shall now describe what happened on the day that my world turned upside down. I will only state facts that can be independently verified.

On the morning of May 29, 1999, I was arrested for the unlawful distribution of a controlled substance.

At 7:15 a.m., our home was raided by a SWAT team. My wife awoke to five policemen breaking open our bedroom door, guns drawn, screaming at her to get out of bed and down on the floor. They handcuffed her for several hours—saying that she was not being arrested but being "detained" for questioning. I had already left the house to make my morning rounds. When my wife asked to see a search warrant, she was told that one would be forthcoming, (since they didn't have one until the courts opened at 9 a.m.). The three other people who were staying with us had their seizure disorder medication taken from them, their pain medicine (one patient had a few Vicoden for her Fibromyalgia) and their stimulant medications taken. They also took all of the empty bottles that my wife had saved in the garage of all of the people we had bought medication for that she was saving for tax purposes. Most of these prescriptions were antidepressant or anticonvulsant medications, not controlled substances.

At the same time across town, my office was being broken into. Many patients charts were taken, including all of my back copies of triplicate prescriptions that I was required by State law to save, and most importantly my computer system that had a custom program to keep track of all patients' medications, serial numbers of the triplicate prescriptions, and dates that they were prescribed. When the prosecutor's office gave me back this computer 1½ years later, they said that there was no medical data on it. It had been erased while in their custody, but since I had a back-up copy of the data on a disk that they didn't find, I was able to bring the computer back with all of its lost data.

The worst thing they did that day was to take my triplicate prescriptions which had just been issued for that month. Even though the DEA were also present at the time of my arrest, and at my house raid, they told me and the town police that they had no problem with my triplicate prescriptions, the town of Davis police force said they did have a problem with them and were still taking them from me, in direct violation of State law that mandates a hearing must be conducted before triplicate prescriptions are confiscated.

So, I now had 100 patients that I had to refer immediately, with no court hearing and no recourse. These patients were children entering into summer school, needing their Ritalin, and some were patients with chronic pain. Thankfully, all the physicians to whom I referred these 100 patients kept them on the same doses as had worked for them in the past.

All—except for one patient who was on a higher dose of stimulant, and other doctors initially didn't want to take on his care due to his complex medical needs. These higher doses of stimulant medications had literally brought him back from a serious depression in which he had made a serious attempt at suicide before I took him as a patient.

With his parent's desperate pleas and the fact that I had treated him for three years, I felt responsible to make sure he had a smooth transition to another doctor's care. Since I still had legal authority to issue white prescriptions, I gave him a white prescription and told him that until we could find another doctor to take him, he could fill it in Nevada as they had no requirement for a triplicate form for controlled substances. This action earned me a second arrest, and my bail was set at $500,000 dollars, clearly an attempt to financially deplete me. The judge even said that "we couldn't even hold you for a day, so money doesn't appear to be a problem."

In desperation, we hired a San Jose attorney, who told me that he taught at Stanford. With $25,000 given just for the preliminary hearing, and $50,000 given to him

up front to prepare to fight a trial, he dragged out my case for 1½ years, ultimately calling my parents in Kansas without my permission or knowledge, and told them that he thought I could get up to 27 years in jail. This prompted them to drive 24 hours straight to Davis, to plead with me to take a no contest plea to one count of improper distribution of a controlled substance, and to get out of California. They said they might die and I would not be able to be with them at that crucial time. They also reminded me that without my computer records, and the files that had not been given to my defense lawyer, how could I expect to get a fair trial on my memory and word of proper diagnoses and treatment of my patients. So, I plead no contest to a felony count of an unlawful prescription. I did not want to do this, but my wife and my parents did not want to risk a trial with a potential outcome of state prison time for the maximum sentence of 27 years. So, I gave in. In exchange for pleading no contest to something I did not do, I spent 4 months in county jail and worst of all, accepted a felony on my record. I was devastated.

When the Osteopathic medical board investigated this, they refused to accept my backup copies of computer records for all my triplicates for the past three years, stating that since the police said that they were not there in my computer at the time of the arrest. They stated that I must have made these records up from memory. There is no way that I could remember all the data including serial numbers of three years of triplicate prescriptions. When I asked them if I could just go back to the Army, their reply was no, because they did not trust the Army to properly supervise me. They ultimately revoked my CA license. I never got past the administrative section of the CA medical board to the doctors on the board. I felt that if they could just see what had been done, and hear on a case by case basis the tremendous gains that patients had made under my care, that they would rule differently.

During my earlier years of training, I had previously been licensed in New York where I had moonlighted in various ER's. When the State of New York reviewed my case, they had a three doctor panel. They listened for hours and reviewed all of my back copies of my recovered records from the computer, and most notably said that they thought I should be able to have my license renewed, since I had suffered "legal malfeasance," in California. Their carefully considered ruling was overturned by an administrative lawyer from the New York Department of Health, and it has been stated that until CA says that I can practice again, they will take no further action, other than to suspend my New York license. The thought of me going back to CA puts my family into such fear and depression, that I cannot bring myself to put them through further trauma.

My hope now resides with my expired license in Connecticut or even Oklahoma where I have had good records of training. Once I get a state to license me, I will go straight to the Army, where I served honorably for 10 years; the Army has already said that they could use me here at Walter Reed. I would even prefer a tour overseas, so that the returning wounded could see that I have a combat patch and would relate to me better. I believe I know something personally about how to rebuild your life after great trauma. I simply want to discharge the skills that I have spent so many years getting and desire to be in an institution where the Constitution of the United States is still revered and followed.

Since there are two cases that highlight the type of patient care that I gave in Davis, and these folks don't have the honor of having their voices heard by Congress, I feel that I should briefly describe their stories:

Suzanne was a 57 year old woman who was known in Davis as the town's worst drunk. She had lost her housing years before when she lost her disability due to her alcoholism. Her case was made more complicated by a Temporal Lobe Seizure disorder and Fibromyalgia. I sent her to the town's local ER, when she showed up in my office one day with early signs of potentially life threatening alcohol withdrawal seizures. The hospital accepted her referral from me over the phone, but when they saw it was Suzanne, whom they knew had no way to pay for her care, they did no treatments other than to give her cab fare, with instructions to get out of the county. No other treatment facility would take her, either. So, I took her into my home where she successfully completed her alcohol detox.

Over the next 6 months, she cleared up all her many public court cases for public drunkenness, and the court even ordered her as a part of her probation to continue treatment with me. She was also on a low dose of opioids for her Fibromyalgia and anticonvulsants for her seizure disorder. She progressed from barely being able to think straight, to six months later being able to play the piano again and recite the Night before Christmas from memory. She was also reconciled with her daughter. When I asked the police how they could explain her progress on the day I was arrested, they said that they could not.

Judy was a 37 year old heroin addict from the next town over in Woodward, CA. I had been treating her daughter for ADHD and when I asked her grandparents where the mother was, they shook their heads and said she was a heroin addict and prostitute, and that they could not even acknowledge her when they saw her on the street. I told them that we could find her and detox her because I felt that this would go a long way in helping her daughter with her anger and ADHD. We found her and since there was no treatment facility that would take her either, she also moved into our house while she was working on reintegrating with her parents and daughter. She was on parole and when she was approached after my arrest, she was given a choice by the police—to either say that I had been sexually inappropriate with her or had given her medications for sale. If she chose neither, she faced going back to prison to serve out her time. She chose the latter and served 11 months in a CA state prison. She told them and us that she could not lie just to make it easy for herself.

My office secretary was also a recovering alcoholic whose children I was treating for ADHD. Court records of her divorce showed that the police came to her after she sent her children to school with an afternoon dose of Ritalin in their pocket. They told her that unless she said that I gave them Ritalin without even properly diagnosing them, they would file child endangerment charges. Since she was afraid they would be returned to their father's custody, she agreed to lie. Her divorce records in Suisun, CA, record these facts about what choices the police had offered her. This was the charge that I plead no contest to—since their records had been confiscated, and I had only my word as proof. I do understand and forgive why she buckled under such tactics by the Davis police.

While the DEA did not object to my practice, they did nothing to stop the town police from illegally seizing my triplicates. The fact that one county over they had one month before employed similar tactics in the prosecution and arrest of Dr Frank Fisher, from which he was eventually exonerated, is something that the town police could have taken a page from the same playbook. I am afraid that the war on drugs has been turned into a war on doctors and patients.

My seventh great grandfather, John Waugh, came to Virginia to serve as a Church of England parson in 1660. During that time, he got into trouble with an English court, controlled by powerful few for such offenses as taking in pregnant, unwed girls cast out from their homes from Maryland and performing marriage ceremonies for young couples who were in love without parental consent. He was even thrown in jail in Jamestown.

When he was elected from Stafford County to the House of Burgesses in 1699, they denied him his seat, saying that a member of the clergy could not serve in the House due to having two masters, the King and the people he would represent. His wife was Elizabeth Madison. His progeny helped to craft this government of a more perfect union, with a Constitution and Bill of Rights.

It is a terrible irony that the Bill of Rights has been turned into a "Bill of Wishes"—only for those wealthy enough to prosecute when it is violated. I hope that this House Judiciary Subcommittee on Crime, Terrorism and Homeland Security, which has oversight supervision of the DEA, will consider my testimony when thinking about how the tactics used in the war on drugs in spilling over into local town cops' attitudes about dealing with doctors with whom they disagree.

I don't seek revenge, because that will cripple me. I don't even seek justice, because no amount of money could compensate me for the pain I saw my patients and family put through. I only seek remembrance, so that this won't continue to happen to others, and that the practice of medicine be freed from fear of intimidation for treating patients in good faith. Thank you for your time and attention. I will be happy to respond to any questions you might have about my testimony.

STATE ATTORNEYS GENERAL

A Communication From the Chief Legal Officers of the Following States:

Arizona • Arkansas • California • Connecticut • District of Columbia • Georgia Illinois • Iowa • Kentucky • Louisiana • Maine • Maryland • Massachusetts Minnesota • Mississippi • Missouri • Montana • Nevada • New Mexico • North Dakota Northern Marianna Islands • Ohio • Oklahoma • Oregon • Pennsylvania • Puerto Rico Rhode Island • South Carolina • Vermont • Washington • Wisconsin • Wyoming

March 21, 2005

Deputy Administrator
Drug Enforcement Administration
Washington, DC 20537
Attention: DEA Federal Register Representative/CCD

RE: Docket No. DEA-261
Comment on Dispensing of Controlled Substances for the Treatment of Pain

Dear Ms. Leonhart,

We, the undersigned Attorneys General, write to comment on "Dispensing of Controlled Substances for the Treatment of Pain", pursuant to the Solicitation of Comments published on January 18, 2005. As the chief legal officers of our respective states, many Attorneys General investigate and prosecute drug-related offenses ranging from diversion and trafficking of prescription drugs to Medicaid fraud and abuse. In our consumer protection role, working to remove barriers to quality care for citizens of our states at the end of life, we have learned that adequate pain management is often difficult to obtain. One key contributor to this problem is that **many physicians fear investigations and enforcement actions if they prescribe adequate levels of opioids or have many patients with prescriptions for pain medications**. We are working to address these concerns while ensuring that individuals who do divert or abuse drugs are prosecuted. There are many nuances of the interactions of medical practice, end of life concerns, definitions of abuse and addiction, policy-making and enforcement considerations that make balance difficult in practice. However, we believe this balance is very important to our citizens, who deserve the best pain relief available to alleviate suffering, particularly at the end of life.

This comment acknowledges the past efforts of the Drug Enforcement Administration (DEA) to support the dual goals of preventing drug abuse and diversion and ensuring the availability of prescription pain medications to those who are legitimately in need of them. The undersigned have strived to maintain the delicate balance between these two goals in carrying out our own legal mandates. We are concerned that **recent DEA actions** send mixed messages to the medical community and **are likely to discourage appropriate prescribing for the management of pain.** Those actions also put DEA at odds with advances in state policies

regarding prescription pain medication. The undersigned are committed to working with the DEA to develop a balanced policy that supports both goals and hope that the following comments will assist in the realization of such policy.

This comment also addresses several specific issues raised in the November 16 Interim Policy Statement on Dispensing of Controlled Substances for the Treatment of Pain.[1] These include commencement of investigations, preparation of multiple prescriptions on the same day with instructions to fill on different dates, concerns of family members, and the issue of how to treat pain in former or current addicts. Finally, we address changes in the realities of health care and prevalence of pain over the past 80 years that suggest a reconsideration of how law from 80 years ago should be applied today.

Our recommendations include the following:

1. We urge DEA to clearly restate its commitment to the balance policy released in 2001 and commit to balance in all public communications. We also recommend that DEA consider appointing an Advisory Committee both to reassure all major groups (health care professionals, consumers, state and federal law enforcement officers) that are affected by DEA's actions and to assist DEA in translating balance policy into practice;
2. In commencing investigations, focus on factors that distinguish the criminal trafficking and diversion of pain medications from the legitimate and responsible practice of medicine and other health professions;
3. Develop a clear statement of policy that the preparation of multiple prescriptions on the same day with instructions to fill on different dates can be a legitimate practice;
4. Allow health care professionals to determine how to interpret communications by family members consistent with the requirements of their professions and licensing boards;
5. Develop an Advisory Committee or commission an Institute of Medicine study to consider in depth the medical, ethical, law enforcement and policy issues involved in prescribing pain medications to former and current addicts for the treatment of pain and to report recommendations;
6. Consider the changing realities of health care and the patient population in the United States, in addition to changes in the nature of drug abuse, as policy regarding prescription pain medication is developed.

1. DEA's Commitment to Balancing the Importance of Ensuring Patient Access to Prescription Pain Medications with Preventing Abuse of Those Medications.

Subsequent to DEA endorsement of the 2001 Joint Statement from the DEA and 42 Health Organizations[2] supporting balance between the treatment of pain and enforcement against diversion and abuse of prescription pain medications, the National Association of Attorneys General (NAAG) in 2003 adopted a Resolution Calling for a Balanced Approach to Promoting

[1] Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. 67,170 (November 16, 2004).
[2] Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act – A Joint Statement from the DEA and 42 Health Organizations, *available at* http://www.ampainsoc.org/advocacy/pdf/consensus_1.pdf.

Pain Relief and Preventing Abuse of Pain Medications.[3] Both these documents reflected a consensus among law enforcement agencies, health care practitioners, and patient advocates that the prevention of drug abuse is an important societal goal that can and should be pursued without hindering proper patient care.

In an October 23, 2001 press release,[4] DEA Administrator Asa Hutchinson urged a policy that protects the appropriate use of opioid pain relievers for patients who need them, while also preventing abuse and diversion of drugs. "We don't want to cause patients who have legitimate needs for these medications, to be discouraged or afraid to use them. And we don't want to restrict doctors or pharmacists from providing these medications when appropriate," Hutchinson said. "At the same time, we must take all reasonable steps to ensure that these powerful medications don't end up in the wrong hands and lead to abuse. We want a balanced approach that addresses the abuse problem without keeping patients from getting the care they need and deserve."[5]

On March 14, 2002, DEA Administrator Asa Hutchinson presented a speech to the annual scientific conference of the American Pain Society entitled "DEA and Doctors: Cooperation for the Public Good."[6] He said, "It was critical that we let the public know [that] law enforcement and the health of the community are working together. We are not at odds. We have a shared goal of making sure that controlled substances are used only for the health and welfare of the American public. **We made a commitment at that press conference to achieving a balanced approach to the prescribing and regulating of opioids. My message to you tonight is that we stand by that commitment.**"[7] (emphasis added).

More recent DEA Statements.

The Frequently Asked Questions (FAQ)[8] document, which we understand to be an effort to educate law enforcement and health care personnel about advances in knowledge concerning the medical treatment of pain and the meaning of "balance," was released on August 11, 2004 following development with DEA involvement. In an August 11 Frequently Asked Questions (FAQ) Press Release by DEA, Administrator Karen Tandy said, "The medical and law enforcement communities continue to work together to carefully balance the needs of legitimate patients for pain medications against the equally compelling need to protect the public from the risk of addiction and even possible death from these medications."[9]

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[3] Resolution Calling for a Balanced Approach to Promoting Pain Relief and Preventing Abuse of Pain Medications, National Association of Attorneys General (March 17-20, 2003).
[4] Press Release, DEA, 21 Health Groups Call for Balanced Policy on Prescription Pain Medications like OxyContin (October 23, 2001), http://www.usdoj.gov/dea/pubs/pressrel/pr102301.html.
[5] *Id.*
[6] DEA Administrator Asa Hutchinson, DEA and Doctors: Cooperation for the Public Good, Address Before the American Pain Society (March 14, 2002), http://www.usdoj.gov/dea/speeches/s031402.html (prepared remarks).
[7] *Id.*
[8] Drug Enforcement Administration, Last Acts Partnership & University of Wisconsin Pain and Policy Studies Group, Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel, August, 2004.
[9] Press Release, DEA, DEA and Major Pain Groups Release Consensus Document on the Use and Abuse of Prescription Pain Medications (August 11, 2004), http://sollaires.net/prn/press_release.dea.guides.pdf.

There was a period of over a month between the October withdrawal of the FAQ from the DEA and other websites[10] and the November 16, 2004 publication in the Federal Register of the DEA Interim Policy Statement.[11] During and after that time, we and the health organizations originally involved in the 2001 Joint Statement with DEA wondered what this withdrawal meant about current DEA policy with respect to dispensing pain medications and the practice of medicine. The Interim Policy Statement addressed "a few of the significant misstatements" contained in the FAQ, leaving the interested community wondering what other aspects of the FAQ were likely to be considered "misstatements" later. This type of uncertainty alone is detrimental to the practice of medicine because **physicians tend to practice conservatively to avoid even the possibility of legal involvement.** Such practice is not primarily concerned with the best interests of patients, but is instead concerned with protecting physicians from liability. Whenever possible, physicians and other health care providers should not be put in the position of having to choose between protecting themselves and providing the best possible care for the patients who need their services.

The November 16 Interim Policy Statement did state that "It is crucial that physicians who are engaged in legitimate pain treatment not be discouraged from providing proper medication to patients as medically justified. DEA recognizes that the overwhelming majority of physicians dispense controlled substances lawfully for legitimate medical reasons, including the treatment of pain."[12] However, physicians and others did not find this document reassuring. It is likely that this is in part because the document, citing *U.S v. Morton Salt Co.*[13], also stated that "It is a longstanding legal principle that the Government 'can investigate merely on suspicion that the law is being violated or even just because it wants assurances that it is not.'"[14] While the FAQ was an effort to provide explanations of how to implement balance policy in practice, to provide some guidance on how to practice pain management responsibly and to avoid investigation and prosecution of legitimate and responsible practitioners, the Interim Policy Statement made it clear that DEA now felt it necessary to state that any physician (or other health care provider) could be investigated at any time for any reason.

If DEA is serious about promoting a balanced approach to enforcement without hindering the availability and use of prescription pain medications for those who need them for legitimate medical purposes, we recommend that the DEA begin by clearly restating its commitment to the balance policy released in 2001 and also commit to balance in every public communication. That would mean describing what constitutes legitimate use and what advantages accrue to such use in addition to identifying the dangers associated with abuse, rather than focusing solely on the dangers. Our understanding is that the FAQ were intended in part to make such communication easier, but in view of the uncertainty since the withdrawal of the FAQ, this should be a consideration in all public DEA communications. We also recommend that DEA consider developing an Advisory Committee comprised of physicians, pain experts, consumers

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[10] Letter from William J. Walker, Deputy Assistant Administrator, Office of Diversion Control, DEA, to David B. Joranson, Director, Pain and Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, http://www.medsch.wisc.edu/painpolicy/DEA/Mr.%20David%20Joranson.PDF).
[11] Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. 67, 170.
[12] *Id.* at 67,170.
[13] United States v. Morton Salt Corp., 338 U.S. 632, 642-643 (1950).
[14] Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. at 67, 171.

(pain patients), and state and federal prosecutors to evaluate potential consequences of DEA actions on the various communities and to reassure prescribing professionals, law enforcement officials and consumers of prescription pain medications that their needs are being taken seriously.

2. Commencement of Investigations.

The November 16 Interim Policy Statement identified the following statement from the FAQ as a "misstatement":

> The number of patients in a practice who receive opioids, the number of tablets prescribed for each patient, and the duration of therapy with these drugs do not, by themselves indicate a problem, and they should not be used as the sole basis for an investigation by regulators or law enforcement.[15]

DEA stated, "In fact, each of the foregoing factors – though not necessarily determinative– may indeed be indicative of diversion." The Interim Policy Statement goes on to cite factors from *United States v. Rosen*[16] as support for that position.

While we do not question the legal authority for such an investigation, this position presents a problem for consumers, particularly at the end of life. It discourages physicians from treating those with severe pain or those who might need high doses, multiple medications, or long term palliative care with opioids. Those physicians who are willing to treat such vulnerable patients are likely to see many because their colleagues are often afraid to do so[17] (or treat the patients, but treat the pain inadequately, resulting in many cases of unrelieved pain and concomitant suffering). The undertreatment of pain is a significant problem and led the Federation of State Medical Boards (FSMB), in 2004, to promulgate new model policy to emphasize that undertreatment of pain, like overtreatment, constitutes poor practice.[18] Several states have already adopted all or part of the FSMB Model Policy.[19] Because good practice may involve precisely the factors that DEA believes might be indicative of diversion, DEA is creating a climate that puts legitimate medical practitioners in danger of investigation and discourages good practice.

We do not believe that either the Controlled Substances Act or *Rosen* must be read to require this result. A number of previous communications from DEA have stated that quantity of

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[15] Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. at 67, 171.
[16] United States v. Rosen, 582 F.2d 1032, 1035-1036 (5th Cir. 1978).
[17] For more information on the relationship between the fear of regulatory scrutiny and the undertreatment of pain, see New York Public Health Council, *Breaking down the barriers to effective pain management: recommendations to improve the assessment and treatment of pain in New York State*, New York State Department of Health (1998); Federation of State Medical Boards of the United States Inc., *Model guidelines for the use of controlled substances for the treatment of pain* (1998); Prescriptions for Terminally Ill Patients, Cal Health & Safety § 11159.2; Pain & Policy Studies Group, *Achieving balance in federal and state pain policy: A guide to evaluation,* Second Edition, University of Wisconsin Comprehensive Cancer Center (2003).
[18] FSMB, Model Policy for the Use of Controlled Substances for the Treatment of Pain (May, 2004), http://www.fsmb.org/Policy%20Documents%20and%20White%20Papers/2004_model_pain_policy.asp.
[19] According to the FSMB, as of March 8, 2005, Colorado, Nevada, Massachusetts, Missouri, Minnesota, Virginia, West Virginia, and Wisconsin have all adopted or endorsed the 2004 FSMB Model Policy.

drugs prescribed and frequency of prescriptions filled alone are not indicators of fraud or improper prescribing.[20] The facts of *Rosen* itself make clear that it was not a single factor, but a host of factors inconsistent with good medical practice that resulted in the affirmation of Dr. Rosen's conviction. The *Rosen* court derived the list of behaviors presented in the Interim Policy Statement from a number of cases, most if not all of which involved multiple behaviors. At least some of those behaviors were more indicative of acting outside a legitimate medical purpose than are the number of patients, number of tablets or duration of treatment. In addition, the population of patients and practice of medicine have changed considerably since *Rosen* was decided in 1978 (and since some of the cases cited therein, which date back as far as 1919 and 1922).[21] This is reflected in the updating of the FSMB policies and should also be reflected in DEA policy.

Diversion is a serious problem and we must be serious about stopping it. As law enforcement agents, we should concentrate on drugs that are illegally on the streets and work back to see how they got there. An undue focus on potentially misleading factors like the number of prescriptions written or number of patients seen in a practice would serve neither the goals of law enforcement nor the needs of suffering patients. We need indicators that distinguish the small number of physicians and other DEA registrants engaging in criminal behavior from responsible practitioners of legitimate health professions. Perhaps research is needed to better identify those indicators. In the meantime, we cannot cast a broad net over all health care practitioners hoping that a few criminals will be caught while the other cases are thrown out. It is precisely this approach that leads to the problem of inadequate availability of prescription pain medications to consumers who need them.

DEA could assist in ensuring the responsible practice of medicine and pain management. Physicians need to be confident that good practices will not be investigated by DEA. Good patient workups, good record-keeping, following practice guidelines, seeking and documenting consultations for necessary departures from such guidelines, and other aspects of the responsible practice of medicine as required by state medical boards should be sufficient.

3. Preparation of Multiple Prescriptions on the Same Day with Instructions to Fill on Different Dates.

The Interim Policy Statement states:

> For a physician to prepare multiple prescriptions on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a schedule II controlled substance. To do so conflicts with one of the fundamental purposes of section 829(a). [W]riting multiple prescriptions on the same day with instructions to fill on different dates is a recurring tactic

[20] *See e.g.* DEA Administrator Asa Hutchinson, DEA and Doctors: Cooperation for the Public Good, Address Before the American Pain Society (March 14, 2002), http://www.usdoj.gov/dea/speeches/s031402.html (prepared remarks); *Pharmacist's Manual: An Information Outline of the Controlled Substances Act of 1970,* DEA Office of Diversion Control, Apr. 2004, at 55, http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/2pharm_manual.pdf.
[21] This will be described further in section six *infra*.

> among physicians who seek to avoid detection when dispensing controlled substances for unlawful (nonmedical) purposes.[22]

This appears to be a change of DEA position[23] and is already causing hardships for physicians, pharmacists and consumers in the states.[24] The preparation of multiple prescriptions on the same day with instructions to fill on different dates is a way of making it unnecessary for patients with chronic conditions to have to schedule, travel to, and pay for physician appointments for the sole purpose of renewing prescriptions. This is particularly important for patients in severe pain or near the end of life, for whom travel may be very difficult, and for patients in rural areas who may live hours away from an appropriate physician.

The preparation of multiple prescriptions on the same day with instructions to fill on different days is an area in which DEA's current position, as expressed in the Interim Policy statement, is at odds with practices permitted by state licensing boards.[25] As described above, we do not believe that single aspects of the responsible practice of medicine or pharmacy should be used to commence investigations and do not believe that *Rosen* is dispositive on this issue. The current DEA position is not consistent with the responsible practice of medicine and does not seem to be a necessary or useful position with respect to drug abuse and diversion control. We believe the risk of drug abuse and diversion is greater if physicians are forced to prescribe more medication at one time in order to balance DEA's new requirement with the needs of their patients than if they are allowed to write multiple prescriptions with instructions to pharmacists to fill on different dates.

If DEA now intends to prohibit writing predated prescriptions, it should promulgate new regulations, allowing for appropriate public comment. However, we urge DEA to communicate a balanced policy on this issue by clearly stating a position consistent with DEA's communications prior to the Interim Policy Statement.

4. <u>Potential Significance of Concerns of a Family Member or Friend.</u>

Question # 11 of the August, 2005 FAQ document was "What kinds of problems might patients encounter when obtaining opioid prescriptions, in having them filled, or in taking the medications properly?" The last bulleted item under that heading was:

> Family and friends, or health care providers who are not directly involved in the therapy, may express concerns about the use of opioids. These concerns may result from a poor understanding of the role of this therapy in pain management or from an unfounded

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[22] Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. at 67, 171.
[23] *See* Howard A. Heit, Edward Covington & Patricia M. Good, *Dear DEA*, Pain Medicine, Sept. 2004 at 303; Letter from G. Thomas Gitchel, Chief Liaison and Policy Section, Office of Diversion Control, DEA to Patrick Gavin, R. PhD., Vice President, Pharmacy Operations, Meijer, Inc. (June 8, 1995), http://pharmacy.ohio.gov/DEA_to_Meijer_060895.pdf.
[24] *See e.g.* Letter from William T. Winsley, Executive Director, Ohio State Board of Pharmacy to Karen P. Tandy, Administrative Director, Drug Enforcement Administration (Dec. 16, 2004), http://pharmacy.ohio.gov/BOP_to_DEA_121604.pdf).
[25] *See Id.*

> fear of addiction; they may be exacerbated by widespread, sometimes inaccurate, media coverage of opioid pain medications.

DEA, in the Interim Policy Statement, states that the FAQ "incorrectly minimized the potential significance of a family member or friend expressing concern to the physician that the patient may be abusing the medication" and went on to say that the FAQ "statement is incorrect to the extent that it implies that physicians may simply disregard such concerns expressed to them by family members or friends."[26]

This appears to us to be a misunderstanding by DEA of what was stated in the FAQ. It is true that many potential patients, families and practitioners are afraid of opioids because they have heard largely about the abuse potential and less about the medical use and benefits of such drugs. If not addressed, this can result in non-compliance problems – patients trying not to use the opioids or to use less of them. Such deviation from physicians' or pharmacists' instructions can lead to undertreated pain or even to opioid abuse as the pain continues when the drugs are taken improperly.

A later section of the FAQ, Question #20 is "What behaviors are potential indicators of problems for patients on long-term opioid therapy?" "Deterioration in functioning at work, in the family, or socially" is listed as the first point in a list of behaviors that are "egregious" and are more probably indicators of abuse, addiction, or diversion than a list of other possibly problematic behaviors listed on an earlier page.

Health care professionals are often called upon to make judgments about the extent to which family involvement is beneficial or detrimental to patient care – this is an important aspect of professional practice. It would be difficult for DEA to direct appropriate doctor/patient/family communication without unintended consequences because so many variables are involved. We do not believe the Interim Policy Statement strikes the correct balance on this issue.

5. <u>Prescribing Pain Medications to Former or Current Addicts for the Treatment of Pain.</u>

This is perhaps the most difficult area in which to balance law enforcement and medical considerations because the stakes are high and perhaps not enough is known.

We agree with the Interim Policy Statement that if a physician is aware that a pain patient is a drug addict or has re-sold prescription narcotics, the physician has a responsibility to exercise a much greater degree of oversight than with other patients in order to protect society and to take appropriate precautions with respect to care of the patient.

In practice, prescribing pain medications to former or current addicts for the treatment of pain is a very difficult area. An important perspective is reflected in the following statement, which is paraphrased from testimony to the Health, Education, Labor and Pensions Committee by Maine Attorney General G. Steven Rowe.

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[26] Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. at 67, 171.

> People with chronic pain are no different from the general population. Some are more susceptible than others to addiction and substance abuse. When pain patients become dependent upon prescribed drugs, sometimes their doctors don't react appropriately. Some physicians suddenly cut patients from narcotic medications without appropriate referral to substance abuse treatment or to medical detoxification and without an adequate pain management plan. These patients may try to secure drugs illegally. These patients are different from those who abuse narcotic drugs because they are seeking to get high. They are patients whose dependency is the product of an area of medical treatment that is still, in many ways, in its infancy. Such addictions are preventable, but not in an environment where doctors are scared to treat pain because of fear and threat of prosecution. The answer to preventing this type of addiction is an environment where doctors are comfortable and knowledgeable treating pain and have adequate resources for referrals to substance abuse prevention and treatment programs. When doctors are confident in their knowledge and ability to actively manage their patient's pain, we will see fewer medical problems transformed into law enforcement problems[27].

It is essential that we seek to develop workable guidelines and policy in this area, which is where the most difficult questions reside. Drug-addicted people in pain represent the toughest case in which to put the general principles of balance into practice. How will we, as law enforcement officers, regulators and policy-makers, balance the need for alleviation of the suffering of people in severe pain with the need to protect individuals and society from the devastating effects of drug abuse and trafficking? How can we simultaneously respect the important ethical and professional decisions health care professionals must make on behalf of individual patients?

We recommend that DEA convene an advisory committee or ask the Institute of Medicine to develop a study committee to consider these issues in depth and to develop recommendations for policy and for the practice of law enforcement, medicine, pharmacy and other health care professions. We would be happy to participate in such an endeavor.

6. <u>Changes in the realities of health care and the prevalence of pain.</u>

The Interim Policy Statement concludes that none of the principles summarized in it are new, but that they have been incorporated for more than 80 years into federal laws and regulations governing drugs of abuse. Whether or not we agree with that characterization, what has changed during the past century and is expected to continue to change in the future, is that improvements in health sciences and health care have not only allowed people to live longer, but have also prolonged the process of dying for most people in the United States.[28] Not only are

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[27] Paraphrased from Testimony of Attorney General G. Steven Rowe before the Health, Education, Labor & Pensions Committee, United States Senate, September 20, 2001.

[28] *See* National Institute of Nursing Research, NIH & Office of Medical Applications of Research, NIH, National Institutes of Health State-of-the-Science Conference Statement (2004), http://consensus.nih.gov/ta/024/EoLfinal011805pdf.pdf; Joan Teno, *Measuring Outcomes Retrospectively,* NIH State-of-the-Science Conference on Improving End-of-Life Care at 39-41, http://consensus.nih.gov/ta/024/ImprovingEndoOfLifeProgramandAbstractBook.pdf.

more people suffering from chronic diseases than in the past, when death was earlier and quicker, but many are dying following prolonged suffering in pain[29]. Medical practice and pain management have changed and will probably continue to change as a result. These realities make it imperative that DEA consider the impact of its policies on the legitimate treatment of pain.

CONCLUSION

The undersigned Attorneys General respectfully submit these comments and offer our assistance in analyzing and resolving these issues. We urge the Drug Enforcement Administration to (1) clearly restate its commitment to the balance policy released in 2001, commit to balance in all public communications, and to consider creation of an Advisory Committee composed of state and federal law enforcement officers, health professionals (including specialists in pain management) and legitimate consumers of prescription pain medications; (2) in commencing investigations, focus on factors that distinguish the criminal trafficking and diversion of pain medications from the legitimate and responsible practice of medicine and other health professions; (3) develop a clear statement of policy that the preparation of multiple prescriptions on the same day with instructions to fill on different dates can be a legitimate practice; (4) allow health care professionals to determine how to interpret communications by family members consistent with the requirements of their professions and licensing boards; (5) develop an Advisory Committee or commission an Institute of Medicine study to consider in depth the medical, ethical, law enforcement and policy issues involved in prescribing pain medications to former and current addicts for the treatment of pain and to report recommendations; (6) consider the changing realities of health care and the patient population in the United States, in addition to changes in the nature of drug abuse, as policy regarding prescription pain medications is developed.

Thank you for considering our views.

Sincerely,

Attorney General W.A. Drew Edmondson
Attorney General of Oklahoma

Attorney General G. Steven Rowe
Attorney General of Maine

[29] Joan Teno, The Prevalence and Treatment of Pain in U.S. Nursing Homes, Brown University Center for Gerontology and Health Care Research, www.chcr.brown.edu/dying/factsondying.htm.

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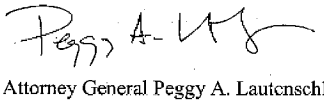
Attorney General Roberto Sánchez Ramos
Attorney General of Puerto Rico

Attorney General Patrick C. Lynch
Attorney General of Rhode Island

Attorney General Henry McMaster
Attorney General of South Carolina

Attorney General William H. Sorrell
Attorney General of Vermont

Attorney General Rob McKenna
Attorney General of Washington



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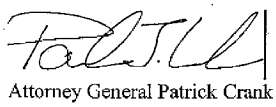

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2007-03-05
Dear Doctors Lester and Reese,

As I think both of you know, I am a friend of James Fernandez Retired USMC. James was initially injured in a series of helicopter accidents in the first gulf war. He has received continuous medical care from the VA until he became a patient of yours, Dr. Reese, earlier this year. From what I can tell, Mr. Fernandez's pain was never adequately controlled by his VA clinic doctors, nor did he ever get a simple titration to effect of chronic opioid therapy, nor were the basic principles of chronic opioid therapy including the concept of and proper use of breakthrough meds ever explained to him. Mr. Fernandez, like most patients, believed and trusted his doctors; he trusted that if they could being doing more for his pain, they would be.

Finally Mr. Fernandez was referred to Dr. Lester at the ? Pain Clinic. Noting that he was taking all of what was supposed to be breakthrough medication, and was still in significant pain, Dr. Lester did the completely correct medical thing and increased the long acting component of the treatment. With his MSContin now QID instead of TID, and still taking the full complement of shorting meds, the patient experience a wonderful decrease in his pain and increase in functioning and significant weight loss. James and I were very happy. We thought this was the first step of a proper titration to effect. Unfortunately the VA clinic failed to continue James on Dr. Lester's new regimen, instead cutting the short acting component of his therapy, negating the positive changes Dr. Lester had made. So in the end, there was no net gain – Mr. Fernandez is still in chronic pain severe enough to make his life mostly miserable most of the time. It was at this point that James lost faith in his providers at the VA clinic; we are both extremely grateful to Dr. Reese for stepping up at this point to take on James as a private medical patient.

Currently Mr. Fernandez is on MSContin 130mg QID plus oxycodone 2ml = 40mg TID. On this regimen he is in unacceptable pain all day long EXCEPT for 60-90 minutes of good pain relief after he takes the oxycodone. Clearly this calls for an increase in the long-acting component of the therapy with close follow-up toward the ultimate goal that the patient require an average of zero to one dose of short-acting to remain functional and mostly comfortable all day long. This is always the goal of simple opioid titration to effect for chronic severe pain.

James and I are frustrated. We seemed to be so close to ending this nightmare of entirely preventable daily severe pain only to experience that the process seems to never be

continued to completion. I can not imagine, literally, a more appropriate candidate to get this most basic pain treatment than a disabled combat vet with continuous medical care from the VA, with ZERO drug related aberrant behaviors (like doctor shopping or forged scripts or taking meds other than as prescribed), ZERO history of symptoms of alcohol or substance abuse, and complete compliance with all requirements placed upon him by his providers. James Fernandez, USMC Retired is clearly a legitimate and deserving chronic pain patient. He is one of the lowest risk patients (from the doctors perspective) that I can imagine.

My understanding is that Dr. Reese is willing to provide general medical care including writing the routine pain medication prescriptions once a satisfactory regimen is achieved by Dr. Lester and the Pain Clinic, and with periodic follow up by Dr. Lester for any minor regimen adjustments and to continue the therapy. This sounds to me like an excellent team approach to the case, with an internist and a pain specialist both monitoring the patient's progress and able to consult with each other in an ongoing manner.

So, as I see it, all we need now is for Dr. Lester and the Pain Clinic to complete the titration to effect procedure. For example, raise his MSContin from 130mg to 160mg QID, continue the short acting oxy, and then see the patient again in about 2 weeks. If his need for short acting is reduced – that is, if an adjustment like this resulted in good round the clock pain relief without the need to take every single dose of short acting, then we are making progress! Some docs aim for the patient to require zero to one breakthrough dose a day, most are satisfied if the patient requires on average one to two doses of breakthrough a day; both of these outcomes are correct and acceptable and would be a significant improvement over the current state of affairs.

James experienced much improved pain relief after the changes made by Dr. Lester in her first visit with him and this confirms that this man responds well to adequate doses of opioids without significant side effects, and that significant improvement in his health and quality of life can be easily accomplished with minor adjustments these medications. We have the ongoing care in place. We have an internist and pain specialist in communication and both monitoring progress. We have a near ideal patient. Can we finally finish this simple medical job and get this man out of pain and on with his life?

Dr. Lester, I honestly believe that James' titration could be completed in 2 – 3 visits over 1-2 months. As you both know, Mr. Fernandez is exceedingly nice, honest, and compliant with medical orders – this is not a difficult patient, but a rather pleasant one, it seems to me. Once his pain is adequately and properly controlled it will be a pleasure for all of us to look forward to improved exercise tolerance and weight loss, improved general quality of life, improved mood, and less stress and strain on his wife who has had to live for so many, many years with a man in chronic pain that can easily be medically treated.

Again let me sincerely thank you both, Dr. Lester and Dr. Reese. James and I both feel so much less isolated and abandoned having doctors we trust and can talk to in charge of his case. If we can just achieve and maintain an adequate dosing regimen, and fully

coordinate his team care, then I think James can look forward to many years of virtually pain free life – something he has not experienced in over 30 years.

Together we can do this. I urge both of you to work together to make this happen as soon as possible. Mr. Fernandez has suffered enough; he has proven his trustworthiness, honesty, and willingness to comply with medical instructions. He is an ideal candidate for optimal chronic opioid therapy. Please help us achieve our goals of a reasonably pain free and productive life.

Thank you for hearing me out. Sincerely and respectfully,

Alexander DeLuca, M.D., MPH

The Treatment of Chronic Pain in Veterans - a Brief Review

Testimony Submitted to the House Subcommittee on Crime

Alexander DeLuca, M.D., MPH; Senior Consultant, Pain Relief Network; 2007-07-12.

Two very similar articles were published in the first full week of June, 2007. On June 4, the cover story in Newsweek was, "*The Changing Science of Pain*" by Mary Carmichael.[1] Three days later on June 7, the Associated Press (AP) published, "*Doctors Urge Better Pain Care for Troops*" by Lauran Neegaard.[2] Both articles seem prompted by Lt. Col. Trip Buckenmaier, M.D., an anesthesiologist described in Newsweek as "sort of a pain czar for the Army" who is doing exciting research on battlefield placement of peripheral nerve blocking devices and on whether blocking acute pain early and continuously might decrease the incidence of the development of chronic pain later on. Hundreds of soldiers have so far received the battlefield block treatment, and preliminary results are expected over the next few years.

Both articles use a focus on this novel application of nerve block technology to quite aptly explain the modern understanding of the etiology of chronic pain, which truly represents a paradigm shift in pain management that is changing the medical standard of care (see: "*A Modern Understanding of Chronic Pain*," below). Newsweek does an especially good job at this, employing well produced graphics to explain the medical-technical details clearly.

Medical and Lay Opiophobia and Opioignorance [3]

Unfortunately both Carmichael and Neegaard perpetuate the popularly held opiophobic, war-on-drugs, worldview aggressively promoted by federal law enforcement for ninety years and currently enshrined in federal drug control policy based on the legislative foundation of the Controlled Substances Act,[4] as promulgated and disseminated by the Office of National Drug

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[1] Carmichael, M. The Changing Science of Pain. Newsweek; p 40; 2007-06-04. Available: http://www.msnbc.msn.com/id/18881802/site/newsweek/; accessed: 2007-07-08.

[2] Neegaard, L. Doctors Urge Better Pain Care for Troops. Associated Press; 2007-07-07. Available (excerpts): http://doctordeluca.com/wordpress/index.php/archive/pain-care-for-troops/122/; accessed: 2007-07-08.

[3] Brennan F., Carr D.B., and, Cousins, M. Medical and Lay Opiophobia and Opioignorance. Anesth Analg;105:205-221; 2007. Available: http://www.anesthesia-analgesia.org/cgi/content/full/105/1/205?ijkey=ccd0d3492131b3b9927c13f13c9040108add48cb; accessed: 2007-07-08. "Principal among the attitudinal barriers of health care professionals to pain relief are misconceptions [collectively known as opiophobia] about [opioid] medications... [There exists] considerable [physician anxiety and] concern about opioid addiction, tolerance and hyperalgesia, including dose escalation and dependence [and] with side effects [and] about precipitating adverse side effects... There is also an unfounded assumption among physicians and patients that chronic opioid treatment necessarily impairs quality of life [and] belief that at least some pain is inevitable, and that opioid doses should be related to the severity of the disease rather than the intensity of the pain. These attitudes [do not reflect the standard of care and] recur in surveys of clinicians and patients about analgesia... Opiophobia among health care providers is compounded by opioignorance. Repeatedly, survey respondents acknowledge that they have received insufficient training in, or exposure to, pain management."

[4] Food and Drug Administration (FDA). Controlled Substances Act: Title 21 - Food and Drugs, Chapter 13 - Drug Abuse Prevention and Control, Subchapter I - Control And Enforcement.FDA; 1970. Available: http://www.fda.gov/opacom/laws/cntrlsub/ctlsbtoc.htm; accessed: 2007-07-08.

Control Policy (ONDCP),[5] also known as the Office of the Drug Czar. These errors, especially when reinforced by experienced and prominent journalist like Carmichael and Neegaard, are important to examine as they underlie extensively documented barriers to pain relief faced daily by the majority of chronic pain sufferers.[6]

The real life consequences of opiophobia and opioignorance to pain sufferers are horrific; studies have repeatedly shown the pain management customs and practice of physicians, even in cases of end-stage cancer, is extremely conservative and below the medical standard of care.[7] [8] This disturbing reality in which the medical community standard of care (what most reputable doctors do) is dramatically and widely below the medical standard of care (what the textbook say doctors should do) is the primary manifestation of the distortion of medical ethics and practice in response to defacto regulation of Pain Medicine by adversarial federal law enforcement.

I will use Ms. Carmichael's Newsweek article for two examples of common opioid myths and misconceptions.

> "Morphine, [used] in the Civil War, is still the Army's most commonly used painkilling drug. It works, but compared with more-modern options, it's one step above chloroform and two above biting the bullet."

Yes, opioids have been used by mankind, mostly to good effect, since recorded history. But the implication that they are crude or primitive is entirely false. Morphine, plain morphine, delivered according to modern, commonly taught medical principles, remains the most widely applicable and best treatment for a large majority of pain types, far more than any other class of medication or any interventional procedure. Opioids are the gold standard therapy. "Although there is currently no ideal analgesic for chronic pain, medications that act on μ-opioid receptors are the closest thing that we have." [9] It is interesting that later in the article Ms. Carmichael describes at length a patient with fibromyalgia doing very well on a combination of powerful opioids where all other treatments had failed. She also describes recent alternatives to opioid therapy for chronic pain in these terms:

> "Some of the most promising pain treatments of the past decade have turned out to be disappointments. Studies of some radiofrequency therapies show they work no better than placebos. Spinal-fusion surgery, a recent review found, has 'no acceptable evidence' to support it. And if a treatment does work, says Edward Covington, a pain specialist at the Cleveland Clinic, 'for most people, the effect is temporary.'"

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[5] Regarding legislative authority for ONDCP, see also: Office of National Drug Control Policy Reauthorization Act of 1998. Available: http://www.whitehousedrugpolicy.gov/about/legislation%5Fc.html; accessed: 2007-07-08.

[6] Rich, B.A. An Ethical Analysis of the Barriers to Effective Pain Management; Cambridge Quarterly of Healthcare Ethics; 9: 27-39; 2005; p. 66. Discusses 5 major impediments to pain relief: 1. The failure of clinicians to identify pain relief as a priority; 2. Insufficient knowledge among clinicians; 3. Fear of regulatory scrutiny; 4. Failure to hold clinicians accountable for pain relief; 5.Irrational beliefs and fears about addiction, tolerance, dependence, and adverse side effects.

[7] SUPPORT Principle Investigators. A Controlled Trial to Improve Care for Seriously Ill Patients.; JAMA; 274: 1591-1598; 1995.

[8] Marks,R.M., Sachar,E.J. Undertreatment of medical inpatients with narcotic analgesics; Archives of Internal Medicine; 78:173-181; 1997.

[9] Brookoff D. Chronic Pain: Part 2. The Case for Opiates; *Hospital Practice*. 2000.

This next example from the Newsweek article is more subtle, but no less wrong and no less damaging:

> "The military is pioneering its own new approaches. Since 2003, a small but growing number of soldiers in Iraq have been treated at the front with high-tech nerve-blocking devices that are effective but not addictive."

First, there are many types of pain not susceptible to local, peripheral nerve blockade; the military's experimental treatment will never replace opioids as the mainstay treatment for pain. The implication here, that opioids administered for severe traumatic pain under battlefield or MASH conditions are inherently 'addictive' is nonsense. This is the error of conflating the phenomenon of physical dependence on an opioid analgesic prescribed for pain with that of 'drug addiction.' Soldiers exposed to opioids under these conditions who become addicts[10] because of such exposure are very, very rare. Even in non-veteran, non-cancer related, chronic pain populations exposed to high dosages of opioid analgesics continuously for many years, unexpected dose escalation and the development of substance use disorders by DSM-IV criteria is uncommon.[11 12 13] Pain patients responsive to opioid therapy need those medications every day in order to function in the world with any degree of comfort and efficacy. If they suddenly discontinue the medication the underlying pain returns, in some cases worsened by withdrawal symptoms; this is physical dependence. Most chronic pain patients on adequate, stable daily opioid therapy are not groggy or otherwise cognitively impaired, not sedated, are more alert, more active, more engaged in the world around them, are able to drive automobiles without impairment, and appear and feel well.

A Modern Understanding of the Etiology of Chronic Pain

Research into pathophysiology and natural history of chronic pain have dramatically altered our understanding of what chronic pain is, what causes it, and the changes in spinal cord and brain structure and function that mediate the disease process of chronic pain, which is generally progressive and neurodegenerative.[14] Simply put, a continuous flow of pain signals into the pain mediating pathways of the dorsal horn of the spinal cord alters those pathways through physiological processes described as central sensitization, and neuroplasticity.[15 16 17]

The end result is the disease of chronic pain in which a damaged nervous system becomes the pain source generator dissociated from whatever the initial pain source was. This understanding

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[10] Addiction, for the purposes of this paper, is continued, compulsive drug use despite direct negative impact on more than one major life-area: physical / psychological health, relationships, work-life, social-life; globally, quality of life decreases with persisting use.

[11] Savage SR. Long-term opioid therapy: assessment of consequences and risks. J Pain Symptom Manage;11:274-286; 1996.

[12] Portenoy RK, Foley KM. Chronic use of opioid analgesics in non-malignant pain: report of 38 cases. Pain. 1986;25:171-186.

[13] Portenoy RK, Dole V, Herman J, et al; Pain Management and Chemical Dependency Working Group. Commentary: pain management and chemical dependency: evolving perspectives. JAMA;278:592-593; 1997.

[14] Argoff C.E. Managing Neuropathic Pain: New Approaches for Today's Clnical Practice; *Medscape*. (Available at: http://www.medscape.com/viewarticle/453496_1)

[15] Gudin J. Expanding Our Understanding of Central Sensitization. Medscape Neurology & Neurosurgery; Pharmacologic Management of Pain Expert Column; 2004. (Available at: http://www.medscape.com/viewarticle/481798)

[16] Brookoff D. Chronic Pain: Part 1. A New Disease?; *Hospital Practice*. 2000.

[17] Brookoff; The Case for Opiates; 2000.

explains many clinical observations in chronic pain patients, such as phantom limb syndrome, that the pain spreads to new areas of the body not involved in the initiating injury, and that it generally worsens if not aggressively treated. The progressive, neurodegenerational nature of chronic pain was recently demonstrated in several imaging studies showing significant losses of neocortical grey matter in the prefrontal lobes and thalamus.[18] [19]

The implications for how acute and early chronic pain should be treated, the medical standard of care, are very serious. The analgesic effects of opioids are primarily mediated in the dorsal horn of spinal cord where they bind with receptors blocking pain transmission and thereby protecting the dorsal horn from being bombarded with pain signals which is believed to be the pathophysiological mechanism underlying the development of chronic pain, as just discussed. Dr. Buckenmaier's experimental technique would protect the dorsal horn by another mechanism, but preliminary results are a year or two away and controlled studies of efficacy and outcome against an appropriate 'gold standard' regimen of opioid therapy will probably be several years in coming. Non-steroidal anti-inflammatory drugs (NSAIDs – for example: aspirin, ibuprofen, Vioxx), antidepressants, anticonvulsants and other commonly used non-opioid analgesics do not have this protective property, and treatment of persistent acute pain with these non-opioid classes of medications would not be expected to prevent the central nervous system damage understood to underlie the development of chronic pain.

Based on a modern, scientific understanding of the pathophysiology of chronic pain, delaying aggressive opioid therapy in favor of trying everything else first is not rational and is therefore not the standard of care. Delaying opioid therapy resulting in continuous pain signals overwhelming the dorsal horn, would be expected to promote the development of chronic pain and making the patient's illness progressively more difficult to treat. This is why opioid analgesics are the cornerstone, and the gold standard against which all other analgesic medications are measured, in the treatment of chronic pain.[20]

Evidence Regarding the Risk of Addiction in Chronic Opioid Therapy
Overwhelmingly, research has failed to show that chronic opioid therapy is associated with any significant level of addiction outcomes. This is consistent finding over decades.

1. In 1981, Medina and Diamond reviewed their experience with 2,369 patients treated in the 1970's at the Diamond Headache Clinic in Chicago for a NIDA Research Monograph: only two of 2,369 patients showed signs of psychological dependence (addiction) consequent to their receiving opioid or other pharmacotherapy.[21] [22]

2. Moulin et. al. (1996) employed a randomized double-blind crossover study design to investigate whether oral morphine effectively relieved pain and improved quality of life in a group of chronic pain patients who had failed other therapies. Their findings: "[The] morphine group showed a reduction in pain intensity relative to placebo in period I

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[18] Apkarian,A. et al. Chronic Back Pain Is Associated with Decreased Prefrontal and Thalamic Gray Matter Density; The Journal of Neuroscience; 24(46):10410-10415; 2004.
[19] Schmidt-Wilcke,T. et al. Affective components and intensity of pain correlate with structural differences in gray matter in chronic back pain patients. Pain; 125(1-2):89-97; 2006.
[20] Brookoff; The Case for Opiates; 2000.
[21] Medina JL, Diamond S. Drug dependency in patients with chronic headaches. Headache; 17(1):12-14; 1977
[22] Medina JL, Diamond S. A headache clinic's experience: Diamond Headache Clinic, Ltd. NIDA Res Monogr; 36:130-136; 1981.

(p=0.01) and this group also fared better in a crossover analysis of the sum of pain intensity differences from baseline (p=0.02). *No other significant differences [including psychological symptoms, functional status, and cognition] were detected.*" [23] (emphasis mine)

3. In a 2003 review article in the *New England Journal of Medicine*, Ballantyne and Mao thoroughly examined the literature on opioid therapy. In none of the 37 articles reviewed by these authors was addiction as a consequence of opioid therapy a significant outcome.[24]

Treatment and Outcomes of Veterans with Chronic Pain
What about the rank and file? What about the thousands and thousands of injured veterans with painful conditions who don't get the experimental nerve block? What treatment are they receiving?

Consider "Long-term Oxycodone/Acetaminophen Prescriptions in Veteran Patients" by Gagnon et al., published in 2004 in the Archives of Internal Medicine. It is an interesting article. The authors went looking for prescription drug abuse in a large sample of chronic pain patients, but found dose-stability rather than dose-escalation, and acknowledge, "the apparent long-term dose stability that we have demonstrated supports previous observations from both VA and non-VA settings" citing six references that together are overwhelming evidence that dose-stability is the rule in opioid therapy for chronic pain, and prescription drug addiction is uncommon in this population.

But along the way, this study of did turn up this highly revealing datum:

> "In aggregate, 2195 patients (31% with cancer diagnoses) received oxycodone/acetaminophen for more than 9 months at a **mean prescribed daily dose of 3.9 tablets per day** (range, 0.5-13.0 tablets per day) with minimal changes in daily prescribed mean dose over time." (emphasis added)

This is quite remarkable. Veterans in chronic pain are prescribed an average of four oxycodone/acetaminophen pills, for example, Percocet, daily from VA medical providers; and 31 percent of this sample had cancer-related pain. "Oxycodone/acetaminophen" means low potency opioid compounded with acetaminophen (Tylenol). Assuming 7.5mg of oxycodone per tablet (the larger commonly available formulation of this medication), four pills daily = 30mg oxycodone daily, which is the analgesic equivalent of approximately 45mg of morphine, **a day**. Patients with chronic severe pain commonly require dosages 25 times as high - over a 1000mg morphine equivalent daily, and some require and tolerate three to four grams a day.

Low potency compound opioids are properly prescribed for mild to moderate acute pain. They are not very useful in severe pain because the total daily dose is limited by the liver toxicity of the acetaminophen part of the compound, to about 10 pills a day (less in drinkers and patients with liver disease), which in total contain 75mg of oxycodone, the analgesic equivalent of

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[23] Moulin DE, Amireh R, Sharpe WKJ, Boyd D, Merskey H, Iezzi A. Randomized trial of oral morphine for chronic non-cancer pain. The Lancet; 347(8995):143-146; 1996.
[24] Ballantyne JC, Mao J. Medical Progress: Opioid Therapy for Chronic Pain. New England Journal of Medicine 2003; 349[20], 1943-1953. (Available: http://www.doctordeluca.com/Library/Pain/OpioidRxChronicPain03NEMJ.htm).

approximately 112 mg of morphine daily, meaning the maximum analgesia achievable is some 10 times lower than that commonly required by patients in moderate to severe chronic pain. Low potency compounded opioids are likewise a poor choice for chronic moderate pain, again due to acetaminophen toxicity.

Four pills a day of oxycodone/acetaminophen is a low, not moderate, not adequate, dosage. Oxycodone is a short acting opioid in this preparation, with an effective duration of action of about three hours. One pill every six hours of oxycodone/acetaminophen for chronic pain guarantees that the patient will be in unacceptable pain 50 percent of the time, *at best*. That's not treatment, its mis-treatment; it could not possibly be adequate.

How are our injured veterans with chronic pain faring under medical VA auspices? Not too well if you ask them. From a 2005 study of 348 patients entitled, "*Prevalence And Characteristics Of Chronic Pain in Veterans with Spinal Cord Injury*" we learn that **75 percent of this population reports pain, 83 percent of which is round-the-clock daily, of average intensity of 6.7** out of 10, and two thirds of which interfered with daily activities. The pain was most commonly described as "aching," "sharp," "hot-burning," and "tiring-exhausting." The authors' conclusion is darkly humorous: "More research is needed to identify better ways to prevent, assess, and treat chronic pain in the veteran SCI population." I suggest we start by researching whether the veterans would have less pain and higher quality of life if their pain medication were simply titrated to analgesic effect, which is the standard of care for the treatment of chronic pain.

A 2007 article from the Journal of Rehabilitation Research and Development, published by the Department of Veteran Affairs, entitled "*A Closer Look at Pain and Hepatitis C: Preliminary Data from a Veteran Population*" reviews the literature on the relationship between HCV and pain, and presents preliminary findings from a survey conducted at two Department of Veterans Affairs facilities to assess the scope and impact of pain on functioning in veterans with HCV.[25]

The prevalence of hepatitis C virus (HCV), a leading cause of cirrhosis and hepatocellular carcinoma and death from liver disease, among veterans who use Veterans Health Administration (VHA) facilities are more than double that of the general population, and affect 5.4 to 6.6 percent of veterans.[26] Treatment for HCV is a rigorous 6-month to 1-year regimen of pegylated interferon and ribavirin which, unfortunately, is expensive, often poorly tolerated and painful in its own right, and is only successful in 54 to 61 percent of patients. Symptoms of HCV include weakness, fatigue and general malaise, muscle, joint and abdominal pain, and anorexia. HCV infection is associated with immunological manifestations, psychiatric disorders, and negative changes in self-perception that have pronounced implications for quality of life, psychological health, and mortality.

> "Preliminary results from this study demonstrate that **82.7 percent reported pain** symptoms… **Even on their "good" pain days, patients with HCV and pain symptoms reported pain intensity levels that met VHA criteria for comprehensive pain assessment and intervention**. Patients with HCV reported that their pain symptoms interfered with their daily activities and relationships. [These] preliminary data strongly

[25] Silberbogen, A.K., Janke, E.A., Hebenstreit, C. A closer look at pain and hepatitis C: Preliminary data from a veteran population. Journal of Rehabilitation Research and Development; 44(2): 231-244; 2007.
[26] Silberbogen; Pain and HCV in Vets; 2007.

> suggest that pain is highly prevalent and significantly affects patients' functioning and experience of HCV." [27] (emphasis mine)

Moving from spinal cord injury and hepatitis C, conditions known to be commonly associated with chronic pain, to a general medical population, consider a 2006 study undertaken to determine the prevalence, morbidity, and pervasiveness, of pain in a random sample of veterans registered at a VA primary care clinic, entitled "*Survey of Pain among Veterans in Western New York.*" The results in this population are startling:

> "... **71% reported having pain.** The average number of body parts affected was 4.4 of a possible 11. **The average intensity of pain was moderate; 35% reported constant pain**, and 85% reported the pain to be occurring for years. Seventy-nine respondents [53%] described their pain to be interfering with their life and well-being. Medication was the primary treatment approach and was reported as ineffective by 48%." [28]

The finding that pain medication was reported ineffective by 48 percent of those in the NY primary care study does not surprise me. Opioid analgesics work well if prescribed in proper dosages at proper intervals and titrated to analgesic effect, as discussed above, otherwise not so well. More importantly, the percentage of patients in chronic moderate to severe pain in these three very different VA populations ranges from 71 to 82.7 percent. This is very high. In normative healthcare-seeking populations, directly comparable to the NY general-medical VA sample, persistent pain is among the most commonly reported health problems with an estimated prevalence of 22 percent.[29]

Rampant Undertreatment of Pain is a National Scourge

Four surveys of various VA population samples, two of them quite small, are conclusive of nothing. However, these four studies, taken together with an awareness that pain management exists in a cultural and political environment of opiophobia and opioignorance, *strongly suggest* that such unnecessarily poor treatment and unnecessarily bad outcomes might very well be endemic in the VA. Unfortunately, this should not surprise us. Rampant undertreatment of pain is a national scourge exacting a terrific toll on both the public health and on our national financial health:

1. Stewart et. al., in a 2003 cross-sectional study using 2001 - 2002 data from the American Productivity Audit on 28,902 working adults, revealed that thirteen percent experienced a loss in productive time during a 2-week period due to a common pain condition. (Most, 76.6 percent, of the lost productive time was explained by reduced performance while at work and not work absence). Lost productive time was estimated to cost $61.2 billion per year. They concluded that pain "is an inordinately common and disabling condition in the US workforce..." [30]

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[27] Silberbogen; Pain and HCV in Vets; 2007.

[28] Crosby,F.E.; Colestro,J.; Ventura,M.R.; Graham,K. Survey of Pain Among Veterans in Western New York; Pain Manag.Nurs.; 7(1): 12-22; 2006.

[29] Gureje O, Von Korff M, Simon GE, Gater R. Persistent pain and well-being: A World Health Organization Study in Primary Care. JAMA; 280(2):147-51; 1998. Erratum in: JAMA;280(13):1142; 1998.

[30] Stewart WF, Ricci JA, Chee E, Morganstein D, Lipton R. Lost productive time and cost due to common pain conditions in the US workforce. JAMA; 290(18):2443-2454; 2003. (Available: http://www.doctordeluca.com/Library/Pain/LostProductivity2ndPain03.htm).

2. Reports and statements from government, regulatory and academic bodies attesting to a massive problem of untreated and undertreated pain abound. In 2004 Robert Meyer, Director of the FDA's Center for Drug Evaluation and Research, in testimony to the House Subcommittee on Criminal Justice, Drug Policy and Human Resources reminded legislators of a Consensus Statement from the National Cancer Institute Workshop on Cancer Pain over a decade earlier (1990) which indicated that the "undertreatment of pain... is a serious and neglected public health problem." [31]

3. The Agency for Healthcare Research and Quality (AHRQ) reported in 1992 that, "half of all patients given conventional therapy for their pain [are not getting] adequate relief." [32]

4. In 1999 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued a press release noting that unrelieved pain had huge physical and psychological effects on patients and increased health care costs. JCAHO at that time officially declared pain to be the "fifth vital sign" henceforth regarding the evaluation of pain a routine requirement of proper patient care as important and basic as the assessment and management of temperature, blood pressure, respiratory rate, and heart rate.[33]

Disturbing as these academic findings are, at the level of the doctor-patient relationship opiophobia leads to unnecessary personal suffering and family tragedy for men and women who served their government and gave everything when called upon. Mr. James Fernandez, a marine helicopter door-gunner in the first Gulf War, involved in two helicopter crashes, resulting in well documented disabling back injuries and chronic severe pain, has submitted testimony to this committee. Mr. Fernandez, under continuous medical care of the VA, has been utterly compliant with that care, has exhibited no "ref-flag" or aberrant drug-related behaviors suggesting substance abuse and has no history of alcohol or drug problems. Yet Mr. Fernandez, an uncomplicated case of chronic pain, has been allow to remain in agony, for decades, physically deteriorating from immobility due to pain, all under the watchful eyes of his VA providers. He believed VA doctors could do nothing more to help him, when the documented truth is that even fractional dosage increases make a significant positive difference in his life.

Mr. Fernandez was abandoned to his pain by his physicians and his government because they were more concerned about a prescription drug abuse problem, that had NOTHING to do with him or his combat acquired medical conditions, than they were about the obvious suffering and deterioration of the obviously deserving patient before them. This is medically very wrong, and a national disgrace.

Mr. Fernandez, and thousands of veterans like him, and millions of their fellow citizens, have their lives destroyed for lack of a couple of hundred milligrams of morphine-equivalent analgesic medication because federal drug control regulations and DEA enforcement imperatives have changed pain management physicians into deputy lawmen whose primary obligation is to catch

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[31] Meyer RJ. The Need for Effective Pain Relief - Statement by Robert J. Meyer, Director, Center for Drug Evaluation and Research, Food And Drug Administration. Before the U.S. House of Representatives Committee on Government Reform, Subcommittee on Criminal Justice, Drug Policy and Human Resources; 2004. (Available: http://www.fda.gov/ola/2004/oxycontin0209.html).
[32] Carr DB, Jacox A. Acute Pain Management: Operative or Medical Procedures and Trauma - a Clinical Practice Guideline. Report of the Agency of Healthcare Quality and Research, Washington DC, 1992.
[33] JCAHO. Joint Commission Focuses on Pain Management. Report of the Joint Commission on Accreditation of Healthcare Organizations, Washington DC, 1999.

vaguely defined "addicts," and whose concept of pain treatment is to prescribe the weakest opioids in the lowest possible dosages so as not to incur the wrath of federal law enforcement.

If Mr. Fernandez is denied basic compassionate medical care, what chance is there for the rest of us when our time of need comes? Mr. Fernandez was at least inadequately medicated. How much worse would his life have been if he had not been a marine, if his injuries were due to an auto crash instead of a military helicopter crash, if he didn't have access to VA medical resources? What if he were alone, and poor and uninsured; or black, or a 20 year old recent immigrant whose English was poor?

Congress has the power to get DEA, a police agency of the Executive branch of government, out of the medical decision-making process. The authority to license and regulate medical practice is constitutionally reserved to the states who maintain the standard of care through state medical boards and whose enforcement powers rest with the state Attorney General. That system is in place. I urge you to return this authority and this power back to these more democratic institutions which are responsive to the will of the people, and which could function as laboratories of progress and change if freed to do so. Until this is done, the pain crisis in America will worsen.

I want to thank the House Subcommittee on Crime, and its staffers, for considering my testimony.

Respectfully submitted,

..alex...
Alexander DeLuca, M.D., MPH

Gregg & Son Distributors

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Fax (865)938-3335
Cell Ph. (865)776-2271

July 11, 2007

The Honorable Robert C. Scott, Chairman
Subcommittee on Crime, Terrorism, and Homeland Security
Committee on the Judiciary
B-370 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Scott:

Enclosed herein is my statement for the record for your July 12, 2007, hearing entitled "The Drug Enforcement Administration's Regulation of Medicine."

I would appreciate it if the statement could be included in the record of the hearing.

Sincerely,

Dennis Gregg

Dennis Gregg

Enclosure

ATTENTION
RETAIL STORE EMPLOYEES
Certain People are Cooking Methamphetamine
Using Common Household Items Sold in Your Store
Cold Tablets
(Containing ephedrine
or pseudoephedrine)
Acetone
Alcohol
Camp Fuel
Coffee Filters
Brake Cleaner (Ether)
Iodine
Hydrogen Peroxide
Lye
Book Matches
Muriatic Acid
Sulfuric Acid
Mason Jars
Propane Tanks
Gas Line Anti-Freeze
Aluminum Foil
Anhydrous Ammonia
Lithium Batteries
Plastic Tubing
ACTIFED
SUDAFED
DELUXE MATCH BOOKS
Acetone
DIAMOND
10 Years of Methamphetamine use
IF YOU HAVE INFORMATION ABOUT SUSPECTED ILLEGAL ACTIVITY
PLEASE CALL 1-866-RID-METH OR LOCAL LAW ENFORCEMENT

EXHIBIT
1

ATTENTION EMPLOYEES!

Methamphetamine manufacturing is on the rise

Items to watch for:

- Common cold pills containing ephedrine or pseudoephedrine
- Acetone
- Rubbing alcohol
- Gasoline additives
- Brake cleaner (toluene)
- Engine starter (ether)
- Drain cleaner (sulfuric acid)
- Coffee filters
- Iodine
- Salt (table/rock)
- Lithium batteries
- Lye
- Propane Tanks
- Matches (red phosphorus)
- Muriatic acid

Take a look at these common household items. Many of our valued customers buy these products on a regular basis and for the intended use.

Some people, however, see something quite different. Their intent is to make illegal drugs such as methamphetamine or "meth." Frequent or large-quantity purchases of these and similar products may be a sign of illegal drug manufacturing.

Help, but be smart. Don't take matters into your own hands. Don't confront the purchaser. Inform your manager of suspicious activity, or call 1-877-TNN-METH.

A partnership between law enforcement and the retail industry:
TBI, Tennessee Sheriffs Association, Tennessee Association of Chiefs of Police, and the Tennessee Retail Marketers Association.

GREGG & SON DISTRIBUTORS
P.O. BOX 368
POWELL, TN 37849-0368

TENNESSEE METH WATCH

Report suspicious activity to the TBI Drug Investigation Division at **1-877-TNN-METH**

GG & SON DISTRIBUTORS

EXHIBIT
Deposition Exhibit
1 page
Date: 1-21-09

EXHIBIT
2

****

UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

****

In the Matter of	:	Docket No. 05-43
Gregg & Son Distributors	:	Administrative Law Judge Gail A. Randall
	:	**AFFIDAVIT OF DENISE GREGG**

****

STATE OF TENNESSEE :
COUNTY OF Knox : SS: 409-78-8204

Denise Gregg, being first duly sworn, affirms and states as follows:

1. I am over 18 years of age and otherwise competent to testify as to the matters in this affidavit.

2. The following statements are based upon my personal knowledge.

3. I am the bookkeeper and records custodian for Gregg & Son Distributors ("Gregg & Son").

4. On March 15, 2005, Drug Enforcement Administration ("DEA") investigators performed an inspection at Gregg & Son's registered premises located at 8329 Sharp Road, Powell, Tennessee, 37849.

5. As part of the DEA's inspection, it performed an audit of Gregg & Son's

purchases and sales of pseudoephedrine and combination ephedrine products from December 27, 2003, through March 15, 2005. As part of that audit, the DEA investigators seized virtually all of Gregg & Son's packing slips and sales invoices from December 27, 2003, through March 15, 2005.

6. The DEA seized Greg & Son's only copies of these documents.

7. The documents seized by the DEA at the time of the March 15, 2005, investigation and audit were only recently returned, and received by our attorneys on March 31, 2006.

8. Our attorneys placed Bates Numbers 00103G&S through 01089G&S on these documents, and mailed them to us on April 3, 2006.

9. Greg & Son received the documents at approximately 11:40 a.m. on April 7, 2006.

10. Upon receipt, I began to review these documents.

11. During my initial review, I observed that customer sales invoices from December 27, 2003 through March 15, 2005, for approximately 21 of Gregg & Sons customers, which the DEA seized on March 15, 2005, were missing from the DEA's March 31, 2006, document production.

12. I also noted that there were additional sales invoices and packing slips missing for other Gregg & Son customers.

13. I estimate that approximately 800-1000 pages of sales invoices that were seized on March 15, 2005, were not returned or produced as part of the DEA's March 31, 2006, document production.

14. Since DEA seized the originals of virtually all of Gregg & Son's packing slips and sales invoices, we have no way of knowing the total number of documents seized by the DEA at the time of the March 15, 2005, investigation and audit.

Further affiant sayeth naught.

Denise Gregg

Denise Gregg

Sworn to and subscribed in my presence this 11th day of April, 2006.

Janet Caughorn

Notary Public 10-13-09

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JANET CAUGHORN
STATE OF TENNESSEE NOTARY PUBLIC
KNOX COUNTY

Statement of Dennis Gregg

Before the

Subcommittee on Crime, Terrorism, and Homeland Security

Committee on the Judiciary

Chairman Robert C. Scott

on

Oversight Hearing on the Drug Enforcement Administration

July 12, 2007

Mr. Chairman and Members of the Subcommittee, my name is Dennis Gregg, and I am the owner of Gregg & Son Distributors. Gregg & Son is a wholesaler distributor which primarily services convenience stores and other similar entities in the Knoxville, Tennessee area. Gregg & Son also services a limited number of customers in the bordering areas of North Carolina and Virginia.

I have been involved in the distributing business since 1973. Gregg & Son is a family run business which employs four individuals: myself, my wife Denise Gregg, my son Jeremy Gregg, and a family friend. This business is our sole source of income. Gregg & Son sells items such as automobile equipment, fishing tackle, gloves, soft drinks, cigarette lighters and other novelty items to its customers. Gregg & Son also sells List I medications such as two-pack dosage of pseudoephedrine products, and multi-count over-the-counter ("OTC") combination ephedrine-medications[1] to its customers.

Gregg & Son has distributed List I OTC products to its customers since it first became licensed with the DEA in 1998. None of Gregg & Son's customers purchase solely List I OTC products. It is authorized under its DEA Registration to distribute pseudoephedrine and ephedrine OTC products. It is important to the continued operation of Gregg & Son's business to maintain its DEA certificate of registration because it allows Gregg & Son to serve as our customer's one-stop supplier in those circumstances. If Gregg & Son does not retain its DEA Registration, competitors able to distribute List I OTC products will have a competitive advantage over Gregg & Son, which will be difficult for Gregg & Son to overcome and remain competitive. Gregg & Son's DEA registration was renewed annually by the DEA through 1998 through 2005.

[1] These ephedrine-based OTC products also contain guaifenesin.

From 1998 through 2005, Gregg & Son carried two-pack dosages of pseudoephedrine products and multi-count combination OTC ephedrine products in table form. The packaging count was determined primarily by the manufacturer for distribution and sale to retail customers. Since enactment of the Tennessee Free Meth Act in 2005, Gregg & Son has carried List I OTC ephedrine-gel capsule products for sale and distribution to its Tennessee customers. Gregg & Son also distributes List I OTC ephedrine-gel capsule products in bordering states to comply with their methamphetamine precursor legislation as well. In order to comply with the 2005 Combat Methamphetamine Epidemic Act ("CMEA"), Gregg & Son also limits sale of List I OTC ephedrine-gel capsules to those packaged in blister packs. Gregg & Son supplies its customers with log books required under the CMEA and instructs its customers to comply with the sales limitations and restrictions of the CMEA. Gregg & Son only distributes List 1 product to those customers who "self certify" with the DEA under the CMEA. Gregg & Son has also advised its customers of the sales limitations imposed by the CMEA and instructed them to comply with those limitations. Gregg & Son also stamped this limitation on each customer's sales invoices, and placed small signs in each of the acrylic cases to remind the retail clerk of these limitations.

In 1999, and again in 2003, the DEA investigators performed administrative inspections of Gregg & Son's registered premises and reviewed Gregg & Son's sale information. From 1998 through present, Gregg & Son's business has not changed significantly. Gregg & Son was never notified of any problems or DEA regulatory violations. Gregg & Son has never received a "warning letter" from the DEA indicating that any of the List I OTC products sold by Gregg & Son have ever been discovered in the methamphetamine manufacturing process or dump sites, or traced back via lot number to a distribution by Gregg & Son. There have been no allegations

that any customer of Gregg & Son has been convicted of a crime relating to the manufacture or distribution of methamphetamine. No employee of Gregg & Son has ever been convicted of a crime relating to a controlled substance or Listed Chemical.

Throughout its time as a List I Distributor, Gregg & Son has shared concerns over the reported methamphetamine problem in Tennessee, and has undertaken steps to help make customers aware of the potential for methamphetamine abuse, and to guard against the theft and diversion of List I OTC product sold by Gregg & Son to its customers. Over the past four years, Gregg & Son has voluntarily provided its customers with posters for display in their facilities from an organization called "Tennessee Free Meth."[2] The posters provide a list of methamphetamine precursor materials, which can be purchased in most retail establishments and combined to produce methamphetamine. The posters also contain a "law enforcement hotline" for retailers to call if they believe the products in their establishment are being diverted into methamphetamine production. I have placed these posters for display in many of Gregg & Son's customers' facilities.

For the past 10 to 12 years, Gregg & Son has been providing its customers selling List I OTC products with acrylic display cases to sell and display their List I product from. The acrylic case is closed in the front and prevents the customers from obtaining the product out of the case without the assistance of the retail clerk. The case is typically placed behind the counter or somewhere else out of the reach of the customer. The purpose of these cases is to help guard against theft of the product and diversion into illegitimate channels. This is a form of "behind-the-counter placement" which is required under the CMEA. Gregg & Son put this procedure in place to assist its customers and guard against diversion well before it was required under the CMEA. For those few customers who, due to the recent changes in packaging size, do not place

[2] Copies of these posters are attached hereto as Exhibit 1.

the product in these acrylic cases, I have verified that they place and store the OTC product in a means and manners sufficient to comply with the behind-the-counter placement requirements of the CMEA. I have not been told by any of my customers that there are repeat customers purchasing List I OTC products on a daily basis. I believe the List I OTC products sold by Gregg & Son are not being diverted into illegitimate channels.

On March 15, 2005, the DEA performed an administrative inspection at Gregg & Son's registered premises. DEA investigators questioned me about Gregg & Son sales of List I OTC products. At that time, I did not know the percentage of sales that List I OTC products comprised of Gregg & Son's total annual sales. I later reviewed Gregg & Son's sales records and determined sales of List I OTC products comprised approximately 20% of Gregg & Son's overall sales. I never indicated to DEA that sales of List I OTC products comprised 50% of Gregg & Son's annual sales. However, DEA Diversion Investigators later claimed that I stated sales of List I OTC products comprised 50% of Gregg & Son's annual sales. This was a lie.

Also, as part of the DEA's March 15, 2005, investigation, the DEA investigators allegedly performed an "audit" of Gregg & Son's List I chemicals. At that time, the investigators seized the originals of all of my List I OTC sales and receiving invoices to my customers. These seized copies were Gregg & Son's only copies of these documents. The audit was performed off site of Gregg & Son's premises, and Gregg & Son was not advised of the results of this audit. DEA investigators also did not leave or return copies of these documents to me following the inspection. DEA later issued a Show Cause Order to Gregg & Son after performing its March 15, 2005 inspection.

In the Show Cause Order, the DEA alleged the results of the "audit" of Gregg & Son's List I OTC product revealed "substantial underages and overages" of List I products. The DEA alleged these results were indicative of diversion.

During the prehearing process in Gregg & Son's administrative DEA license revocation proceedings, my attorney demanded that the DEA return the invoices seized at the time of the March 15, 2005 audit investigation so that I could attempt to recreate the DEA's audit. However DEA was reluctant to turn these documents over to me. Finally, on or about March 30, 2006, DEA produced a stack of invoices which it had seized at the time of the March 15, 2005 administrative inspection.

DEA initially claimed it produced all of the documents seized at the time of the March 15, 2005 inspection. However, my wife Denise observed that there were hundreds of pages of invoices missing from production which were taken by the DEA on March 15, 2005. During my wife's review of the documents produced by the DEA, she noticed there were sales invoices for approximately 21 of Gregg &Son's customers missing from the DEA's document production. She also observed that there were additional invoices missing for other Gregg &Son customers. She estimated that approximately 800 to 1,000 pages of invoices which were seized on March 15, 2005 by the DEA were not returned or produced to Gregg & Son.[3] As such, there was no possible way for us to reconstruct the DEA's allegations of alleged substantial overages and underages in its Show Cause Order. Gregg & Son is confident in its recordkeeping processes and maintains that any audit of its List I OTC product would in fact reveal no overages or underages. I believe that the DEA had reached a predetermined result of the audit of Gregg & Son's List I OTC product before even beginning its review of the invoices.

[3] See Affidavit of Denise Gregg attached hereto as Ex. 2.

Moreover, during Gregg & Son's administrative hearing, DEA Diversion Investigator David Graham, who was the lead investigator performing the March 15, 2005 inspection of Gregg & Son, admitted the DEA has adopted a policy that the sale of List I generic OTC combination-ephedrine products (such as those sold by Gregg & Son) to convenient stores and related entities [which the DEA has coined "gray market entities"] is sufficient grounds for the DEA to revoke a DEA registrant's registration. Diversion Investigator Graham testified it is the DEA policy and practice that regardless of whether or not the registrant complies with all other DEA rules and regulations, the act of selling to these "gray market entities" automatically subjects the registrant to license revocation. This testimony was echoed by DEA Diversion Investigator Darryl Meador as well. Investigator Graham testified that it was DEA's intentions to revoke Gregg & Son's DEA registration based upon Gregg & Son's sale of generic-combination ephedrine OTC product to its customers.

Gregg & Son has always conducted business with integrity and committed to maintaining compliance with the changes in state and federal regulations relating to the handling of List I chemicals. I believe that our business was wrongfully targeted by the DEA for license revocation because we are a small business and do not have significant resources to oppose the DEA. The unfounded allegations in the Show Cause Order, and the administrative process in general, have been a difficult and overwhelming process for my wife and I to deal with. Gregg & Son has been forced to incur significant legal fees in defending its DEA registration. I have done so while also battling a bout of kidney cancer. But because we do not believe that we have done anything wrong, we continue to maintain that Gregg &Son is entitled to maintain its DEA registration.

It is my hope that by sharing our circumstances with this Committee, detailing discriminatory and abusive treatment of Gregg & Son at the hands of the DEA, that the Committee will take necessary action to ensure that no other small business will be subjugated to similar treatment by the DEA.

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*CERTIFIED BY NATIONAL BOARD OF TRIAL ADVOCACY AS A CIVIL TRIAL ADVOCATE

July 11, 2007

The Honorable Robert C. Scott, Chairman
Subcommittee on Crime, Terrorism, and Homeland Security
Committee on the Judiciary
B-370 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Scott:

Enclosed herein is my client's, Buddy Poole, Poole Marketing, statement for the record for your July 12, 2007, hearing entitled "The Drug Enforcement Administration's Regulation of Medicine."

I would appreciate it if the statement could be included in the record of the hearing.

Sincerely,

Jason A. Hill

Enclosure
cc: Mr. Buddy Poole

Statement of Buddy Poole, Poole Marketing

Before the

Subcommittee on Crime, Terrorism, and Homeland Security

Committee on the Judiciary

Chairman Robert C. Scott

on

Oversight Hearing on the Drug Enforcement Administration

July 12, 2007

Mr. Chairman and Members of the Subcommittee, my name is Buddy Poole, and I am the owner of Poole Marketing, which is located at 458 Peggy Drive, Fort Valley, Georgia 31030. Poole Marketing is a small wholesaler distributor which distributes novelty products and merchandise, including snacks, candies, lighters, to a customer base which is made up of convenient stores and similar entities. Poole Marketing services convenience stores and other similar entities in the state of Georgia. Poole Marketing also distributes generic brands of List I combination-ephedrine, over-the counter medications to its customers.

Poole Marketing obtained the necessary DEA registration which permits it to distribute List I combination-ephedrine products. Poole Marketing is authorized under its DEA registration to distribute ephedrine and pseudoephedrine based combination products. Poole Marketing no longer distributes pseudoephedrine products, such as single packaged dosages of cold medications, because it is not permitted to do so under Georgia's recent enactment of its methamphetamine precursor legislation

Poole Marketing first received its DEA Certificate of Registration in 1999. Its registration was renewed by the DEA annually through March 31, 2006. Poole Marketing has never been advised by DEA that it is operating in violation of DEA regulations. To my knowledge, no employees of Poole Marketing have been convicted of a crime involving the manufacture of distribution of Controlled Substances or Listed Chemicals. I also have not been advised by the DEA that any of Poole Marketing's customers have been convicted of crimes relating to the manufacture or distribution of methamphetamine.

On February 19, 2006, Poole Marketing submitted its application to renew its DEA registration. Poole Marketing's DEA registration was set to expire on March 31, 2007. After a few weeks, I began to contact the DEA office in Arlington, Virginia to check on the status of

Poole Marketing's registration. Each time, I was told by the DEA representative I spoke to that the Poole Marketing's renewal application had not yet been processed.

On April 20, 2006, I then contacted the Atlanta DEA Regional Office and was told that the office had no record of my applying for Poole Marketing's registration renewal. The person I spoke with advised me to reapply online, and to retain confirmation number. I followed these instructions.

A few weeks later, I called back to the Atlanta DEA Regional Office to follow-up on the status of Poole Marketing's registration renewal. I was connected to someone whom I was told to be the office supervisor, "Mr. Shortas." Mr. Shortas' first question to me was, "Who are your customers?" I told him that I service convenience stores. Mr. Shortas then stated my DEA license would not be renewed. He said, "Convenience stores don't need to sell ephedrine products. If a person needs ephedrine products, they should go to the drug store."

On May 18, 2006, Investigators Linder and Jones came to my facility to perform an administrative investigation. After the investigation, they visited several of Poole Marketing's customers. At that time, I not told that any problems existed with Poole Marketing's operations. It was my understanding that no problems existed with Poole Marketing's operations. No hard copy of Poole Marketing's DEA license was issued, but I received several extension letters[1], indicating that Poole Marketing's registration would continue to be valid until March 31, 2007. During that time, I received no written confirmation that my DEA license had expired or had been revoked. No Show Cause Order was issued to Poole Marketing.

The latest extension letter I received indicated that Poole Marketing's license expired on March 31, 2007. At that time, I called Investigator Linder to find out what action I should take. He did not return my phone calls. On March 12, 2007, I called the Washington DEA office and

[1] Copies of these letters are attached hereto collectively as Ex. 1.

was informed that my license had "been retired" on October 31, 2006 and that I needed to contact Atlanta. I called Atlanta DEA Regional Office that day. I was informed that Investigator Linder was no longer assigned to my case.

DEA Investigator) Green contacted me on Tuesday, March 13, 2007. He stated I was selling "non-traditional products to a non-traditional outlet." He indicated that based on this, Washington would likely not renew Poole Marketing's DEA Registration. Investigator Green said that the DEA had met its obligation to Poole Marketing and that no further letters of extension would be issued. I told Investigator Green that there were several companies operating in the wholesale distributor business that distributed OTC combination-ephedrine medication. Investigator Green stated that DEA had simply not gotten to them yet.

When I asked Investigator Green what to do about my inventory of combination-ephedrine medication, he told me that I needed to have it destroyed or that I needed to send it back to the people that I bought it from "before the license expires." Investigator Green asked if I would surrender my license. I told him no. I then also timely filed for the renewal of my DEA registration in advance of the alleged March 31, 2007 registration termination date.

After speaking with Diversion Investigator Green, I retained Attorney Jason A. Hill of the law firm of Connelly, Jackson & Collier LLP to represent Poole Marketing with respect to its DEA registration renewal matters with the DEA. Mr. Hill prepared a letter dated March 19, 2007, copies of which were sent to Investigator Green by facsimile and ordinary mail. In that letter, Mr. Hill indicated that since Poole Marketing had timely sought renewal of its DEA registration, and no final decision had been rendered approving or denying that registration renewal request, the DEA was obligated by law to permit Poole Marketing to continue

distributing combination-ephedrine products.[2] Mr. Hill sought written and/or oral confirmation that Poole Marketing would be entitled to continue operating under its existing DEA registration until such time as a final decision was made with respect Poole Marketing's registration-renewal request. Investigator Green never responded to this letter. I was also advised that Investigator Green failed to return several phone calls from my attorney.

My attorney was advised by another member of the DEA Atlanta Regional Office to contact Linden Barber, Esquire, Office of DEA's Chief Counsel's Office. My attorney provided Mr. Barber a copy of the March 19, 2007 correspondence sent to Investigator Green. After reviewing the March 19, 2007 correspondence, Mr. Barber advised that pursuant to the DEA Deputy Administrator's decision in *In Re: Wild West Wholesale*, Fed.R. Vol. 72, No. 18, 4042, 4043-44, because Poole Marketing had timely submitted its registration-renewal request, it was permitted to continue distributing combination-ephedrine products until such time that a final order (after issuance of a Show Cause Order) from the DEA Deputy Administrator was issued revoking Poole Marketing's registration.

After my attorney spoke with Mr. Barber, I then spoke to my distributor of List I combination-ephedrine products, C.B. Distributors, and provided C.B. with a copy of the *Wild West Wholesale* decision. I told my C.B. that Mr. Barber advised that Poole Marketing was permitted to continue operating under its existing DEA registration. C.B. then contacted Investigators Green and Jones to confirm that Poole Marketing was permitted to continue operating under its existing DEA registration. Investigators Green and Jones advised C.B. that it was not permitted to ship combination-ephedrine products to Poole Marketing because its registration "allegedly expired" or "been revoked." CB advised Poole Marketing that any

[2] A copy of this letter is attached hereto as Exhibit 2.

distributions of combination-ephedrine products to Poole Marketing would have to be approved by Investigator Green before shipment.

As a result of this conversation, on or about April 10, 2007, my attorney Mr. Hill again wrote Investigators Green and Jones requesting that the DEA provide written confirmation with respect to its position that Poole Marketing was not permitted to operate under its existing registration. Mr. Hill also advised the investigators that he spoken with Mr. Barber, and provided investigators with a copy of the decision *In Re: Wild West Wholesale,* which expressly stated that because Poole Marketing had timely submitted its registration-renewal request, it was permitted to continue operating under its existing DEA registration. Mr. Hill also advised that if the DEA did not respond to this request, that he would advise Poole Marketing to file suit and sue for injunctive relief.[3]

The DEA did not respond to Mr. Hill's April 10, 2007 request and hence forth, Poole Marketing has been unable to obtain additional combination-ephedrine products from C.B. Distributor, even though it retains an existing DEA registration. This has caused both financial and irreparable harm to Poole Marketing's good will and its customer base. I find the DEA's refusal to respond to any of Poole Marketing's requests that the DEA advise Poole Marketing in writing of its position with respect to Poole Marketing's DEA registration to be disingenuous and deceitful.

Due to the damage to my business, financial and otherwise, Poole Marketing does not have the funds to file suit to enjoin DEA's wrongful actions. The DEA has maliciously and intentionally violated my due process, and that of Poole Marketing, and continues to do so.

H:\Cases\Poole Marketing\Pleading\statement-jah.doc

[3] A copy of this April 10, 2007 letter is attached hereto as Ex. 3.

FROM : FAX NO. : Mar. 13 2007 01:47PM P5
01/31/2007 16:07 4048937095 REGISTRATION PAGE 01/01

U. S. Department of Justice
Drug Enforcement Administration
Atlanta Division
75 Spring Street, SW
Suite 800
Atlanta, GA 30303

www.dea.gov

TO: Buddy Poole
FAX: 478 825 5381

Dear Sir/ Madam: Poole Workentins 458 Peggy Drive P.O Box 197 Fort Valley, GA 31030

This letter confirms that your Drug Enforcement Administration (DEA) registration number 004320PAY remains current and valid beyond its expiration date, pending the processing of your renewal application. This notice is valid until March 31, 2007

This letter will serve as proof of your registration status until your application is processed.

If you require further assistance, please call toll free (888-869-9935). A directory of DEA offices is available on the internet at the Diversion Control Program site at www.deadiversion.usdoj.gov.

Date: Jan 31 2007
Initials: G.S.W.

DRUG ENFORCEMENT ADMIN.
ATTN: REGISTRATION FOR GA.
75 SPRING ST., SW, ROOM 800
ATLANTA, GA 30303
PH (888) 869-9935

EXHIBIT
1

U. S. Department of Justice
Drug Enforcement Administration
Atlanta Division
75 Spring Street, SW
Suite 800
Atlanta, GA 30303

www.dea.gov

TO: Pools Marketing

FAX: 478-825-5361

Dear Sir/Madam:

This letter confirms that your Drug Enforcement Administration (DEA) registration number 00432DZAY remains current and valid beyond its expiration date, pending the processing of your renewal application. This notice is valid until February 1, 2007.

This letter will serve as proof of your registration status until your application is processed.

If you require further assistance, please call toll free (888-869-9935). A directory of DEA offices is available on the internet at the Diversion Control Program site at www.deadiversion.usdoj.gov.

Date: November 30, 2006

Initials: GH

U. S. Department of Justice
Drug Enforcement Administration
Atlanta Division
75 Spring Street, SW
Suite 800
Atlanta, GA 30303

www.dea.gov

TO: Poole Marketing

FAX: 478-825-5381

Dear Sir/ Madam:

This letter confirms that your Drug Enforcement Administration (DEA) registration number 004320PAY remains current and valid beyond its expiration date, pending the processing of your renewal application. This notice is valid until December 1, 2006.

This letter will serve as proof of your registration status until your application is processed.

If you require further assistance, please call toll free (888-869-9935). A directory of DEA offices is available on the internet at the Diversion Control Program site at www.deadiversion.usdoj.gov.

Date: September 19, 2006

Initials: SG

U. S. Department of Justice
Drug Enforcement Administration
Atlanta Division
75 Spring Street, SW
Suite 800
Atlanta, GA 30303

www.dea.gov

TO: Poole Marketing

FAX: 478-825-5381

Dear Sir/ Madam:

This letter confirms that your Drug Enforcement Administration (DEA) registration number 0043208AV remains current and valid beyond its expiration date, pending the processing of your renewal application. This notice is valid until September 20, 2006.

This letter will serve as proof of your registration status until your application is processed.

If you require further assistance, please call toll free (888-869-9935). A directory of DEA offices is available on the internet at the Diversion Control Program site at www.deadiversion.usdoj.gov.

Date: July 20, 2006

Initials: SA

U. S. Department of Justice
Drug Enforcement Administration
Atlanta Division
75 Spring Street, SW
Suite 800
Atlanta, GA 30303

www.dea.gov

TO: Pole Marketing
FAX: 478 825 5381

Dear Sir/ Madam:

This letter confirms that your Drug Enforcement Administration (DEA) registration number 00620PAN remains current and valid beyond its expiration date, pending the processing of your renewal application. This notice is valid until July 22, 2006.

This letter will serve as proof of your registration status until your application is processed.

If you require further assistance, please call toll free (888-869-9935). A directory of DEA offices is available on the internet at the Diversion Control Program site at www.deadiversion.usdoj.gov.

Date: 5/23/06
Initials: SEL

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REGINALD S. JACKSON, JR.*
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TIMOTHY P. NACKOWICZ
KATHERINE E. KING

*CERTIFIED BY NATIONAL BOARD OF TRIAL ADVOCACY AS A CIVIL TRIAL ADVOCATE

March 19, 2007

VIA FACSIMILE NO. 404-893-7096
AND ORDINARY MAIL

Diversion Investigator Green
U.S. Department of Justice
Drug Enforcement Administration
Atlanta Division
Office of Diversion Control
75 Spring St., SW, Suite 800
Atlanta, GA 30303

Re: **Poole Marketing -- D.E.A. Registration No. 004320PAY**

Dear Diversion Investigator Green:

Please be advised that our office has been retained to represent Poole Marketing with respect to the DEA's processing of Poole Marketing's DEA registration-renewal request. Please direct all future communication and correspondence concerning this matter to my attention. As you know, Poole Marketing is registered with, and authorized by, the DEA to distribute List I chemicals. Our client distributes generic combination-ephedrine products to its customer base, which includes convenient-store type entities.

Poole Marketing's DEA registration was set to expire on March 31, 2006. Poole Marketing timely submitted its 2006 registration renewal. Prior to that time the DEA renewed Poole Marketing's registration annually, since inception in 1999. The DEA did not issue a decision denying or approving Poole Marketing's registration-renewal request prior to the expiration of this deadline. Instead, the DEA issued a series of letters confirming that Poole Marketing's registration would remain valid until such time that the DEA issued a decision approving or denying Poole Marketing's registration. These letters purported to extend Poole Marketing's registration by a period of 60 days. The most recent of these letters is set to expire March 31, 2007.[1] To date, the DEA has not issued a decision either approving or denying Poole Marketing's 2006 registration-renewal request.

[1] Copies of these letters are attached hereto as Ex. 1.

EXHIBIT
2

It is my understanding that you spoke with Mr. Poole on March 13, 2007, and advised him that while the DEA had not yet reached a decision approving or denying Poole Marketing's pending-registration renewal, the DEA *would not* be issuing any additional letters confirming that Poole Marketing would be entitled to continue operating under its existing registration until such time that a decision is reached approving or denying Poole Marketing's registration renewal. This represents a significant variance from past DEA policy and practice. You apparently indicated to Mr. Poole that this decision was based upon Poole Marketing's sales of generic combination-ephedrine products to its customer base, which the DEA has termed "non-traditional" or "gray market" entities.

Poole Marketing operates its distribution and sales practices within the applicable law. While Poole Marketing distributes List I chemicals, it does so within the parameters of the 2005 Combat Methamphetamine Epidemic Act. Poole Marketing has also proactively sought to ensure its ongoing compliance with the changes in Federal and State law.

Moreover, based upon Mr. Poole's conversations with you and other DEA Diversion Investigators, Mr. Poole was left with the distinct impression that DEA as an agency is attempting to abolish sales of generic List I combination-ephedrine products to the "gray market" by revoking the DEA registrations of all similarly-situated distributors who distribute generic List I combination-ephedrine products to convenient stores and related entities. It is our understanding that the DEA is taking a position that the sale of List I generic combination-ephedrine products to "gray market entities" in anything other than minimal quantities automatically subjects a registrant to registration revocation. Such a policy and enforcement practice amounts to a violation of the Administrative Procedures Act.

The DEA has renewed Poole Marketing's DEA registration annually since the time it became registered. Neither its customer base, nor its business practices have changed significantly during this time. The DEA's policy and practice of abolishing the "gray market" and revoking List I registrants' registration for sales of generic combination-ephedrine products to "gray market" customers, is as a practical matter a "rule" within the meaning of 5 U.S.C. § 551(4). However, this "rule" by the DEA has not been subjected to the notice and comment rule making requirements of 5 U.S.C. § 553(b). Thus, any agency enforcement practice in this regard constitutes a violation of the Administrative Procedures Act and Poole Marketing's due process rights under the Fifth Amendment.

Poole Marketing has a record of ongoing commitment to complying with its obligations under State and Federal law. It has a history of DEA regulatory compliance as exhibited by DEA's continued registration renewals. We believe that there is no direct evidence that Poole Marketing's List I products are actively being diverted into illegitimate diversion.

Based upon the foregoing, we would request that the DEA confirm that Poole Marketing will be entitled to continue operating under its existing DEA registration until such time as a decision is issued with respect to its request for registration renewal. Given DEA's impending March 31, 2007 deadline, I would appreciate you providing us with the DEA's position with respect to this issue as soon as possible. As always, Poole Marketing will continue to cooperate with any ongoing DEA investigation. If you have any questions, please feel free to contact me at the above number.

Very truly yours,

Jason A. Hill

JAH/clm
cc: Mr. Buddy Poole
Enclosure

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FROM : FAX NO. : Mar. 13 2007 01:47PM P6

U. S. Department of Justice
Drug Enforcement Administration
Atlanta Division
75 Spring Street, SW
Suite 800
Atlanta, GA 30303

www.dea.gov

TO: Poole Marketing

FAX: 478-825-5301

Dear Sir/Madam:

This letter confirms that your Drug Enforcement Administration (DEA) registration number 004320FAY remains current and valid beyond its expiration date, pending the processing of your renewal application. This notice is valid until February 1, 2007.

This letter will serve as proof of your registration status until your application is processed.

If you require further assistance, please call toll free (888-869-9935). A directory of DEA offices is available on the Internet at the Diversion Control Program site at www.deadiversion.usdoj.gov.

Date: November 30, 2006

Initials: GH

EXHIBIT 1

U. S. Department of Justice
Drug Enforcement Administration
Atlanta Division
75 Spring Street, SW
Suite 800
Atlanta, GA 30303

www.dea.gov

TO: Poole Marketing

FAX: 478-825-5381

Dear Sir/ Madam:

This letter confirms that your Drug Enforcement Administration (DEA) registration number 004320PAY remains current and valid beyond its expiration date, pending the processing of your renewal application. This notice is valid until December 1, 2006.

This letter will serve as proof of your registration status until your application is processed.

If you require further assistance, please call toll free (888-869-9935). A directory of DEA offices is available on the internet at the Diversion Control Program site at www.deadiversion.usdoj.gov.

Date: September 19, 2006

Initials: SG

U. S. Department of Justice
Drug Enforcement Administration
Atlanta Division
75 Spring Street, SW
Suite 800
Atlanta, GA 30303

www.dea.gov

TO: Poole Marketing

FAX: 478-825-5381

Dear Sir/ Madam:

This letter confirms that your Drug Enforcement Administration (DEA) registration number 004320PAY remains current and valid beyond its expiration date, pending the processing of your renewal application. This notice is valid until September 20, 2006.

This letter will serve as proof of your registration status until your application is processed.

If you require further assistance, please call toll free (888-869-9935). A directory of DEA offices is available on the internet at the Diversion Control Program site at www.deadiversion.usdoj.gov

Date: July 20, 2006

Initials: SA

U. S. Department of Justice
Drug Enforcement Administration
Atlanta Division
75 Spring Street, SW
Suite 800
Atlanta, GA 30303

www.dea.gov

TO: Pole Marketing
FAX: 478 825 5381

Dear Sir/ Madam:

This letter confirms that your Drug Enforcement Administration (DEA) registration number [illegible] remains current and valid beyond its expiration date, pending the processing of your renewal application. This notice is valid until July 22, 2006.

This letter will serve as proof of your registration status until your application is processed.

If you require further assistance, please call toll free (888-869-9935). A directory of DEA offices is available on the internet at the Diversion Control Program site at www.deadiversion.usdoj.gov.

Date: 5/23/06
Initials: [illegible]

FROM : FAX NO. : Mar. 13 2007 01:47PM P5
01/31/2007 15:07 4046...085 REGISTRATION PAGE 01/01

U. S. Department of Justice
Drug Enforcement Administration
Atlanta Division
75 Spring Street, SW
Suite 800
Atlanta, GA 30303

www.dea.gov

TO: Buddy Poole
FAX: 478 825 5381

Dear Sir/ Madam: Poole Wilkerson P.O Box 197
458 Peggy Drive Fort Valley, GA. 31030

This letter confirms that your Drug Enforcement Administration (DEA) registration number 004320PAY remains current and valid beyond its expiration date, pending the processing of your renewal application. This notice is valid until March 31, 2007

This letter will serve as proof of your registration status until your application is processed.

If you require further assistance, please call toll free (888-869-9935). A directory of DEA offices is available on the internet at the Diversion Control Program site at www.deadiversion.usdoj.gov.

Date: Jan 31 2007
Initials: G.S.W.

DRUG ENFORCEMENT ADMIN.
ATTN: REGISTRATION FOR GA.
75 SPRING ST., SW, ROOM 800
ATLANTA, GA 30303
PH (888) 869-9935

EXHIBIT
3

CONNELLY, JACKSON & COLLIER LLP
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TIMOTHY P. NACKOWICZ
KATHERINE E. KING

*CERTIFIED BY NATIONAL BOARD OF TRIAL ADVOCACY AS A CIVIL TRIAL ADVOCATE

April 10, 2007

VIA FACSIMILE AND OVERNIGHT MAIL
Diversion Investigators Green and Jones
U.S. Department of Justice
Drug Enforcement Administration
Atlanta Division
Office of Diversion Control
75 Spring Street, SW
Suite 800
Atlanta, GA 30303

Re: Poole Marketing
DEA Registration No. 004320PAY

Dear Diversion Investigator Green and Jones:

I am writing in response to my March 19, 2007 letter to Diversion Investigator Green, as well the various voice messages to him that have gone unreturned. I have contacted Diversion Investigator Green on multiple occasions on behalf of my client Poole Marketing over the past three weeks, to which he has provided no response. I am told that Diversion Investigator Green is the investigator handling my client Poole Marketing's registration matters.

Today, my client Poole Marketing was informed by CB Distributors that according to Diversion Investigator Jones, CB Distributors was not permitted to ship List I combination-ephedrine products to my client Poole Marketing because its registration had allegedly "expired" or been "revoked." CB Distributors reported to Poole Marketing that any distributions to Poole Marketing would have to be approved by Diversion Investigator Green.

Demand is hereby made that the DEA cease its wrongful interference with Poole Marketing's right to continue to lawfully distribute List I combination-ephedrine products as a DEA registrant. My client timely submitted its DEA renewal application in 2006; DEA still has not issued a decision approving or revoking its DEA registration. There has been no show cause order issued revoking its right to distribute List I combination-ephedrine products. Diversion Investigator Green has instructed my client verbally on multiple occasions that Poole Marketing is not to continue distributing List I products beyond March 31, 2007. *However, DEA has refused to provide any written confirmation indicating the grounds or basis for its position.* Thus, I underscore the fact that while my client has inquired in good faith with Diversion

Investigator Green, he and DEA have refused or otherwise failed to provide written explanation or confirmation of DEA's position with respect to Poole Marketing's continued registration.

That being the case, I was instructed to contact DEA Chief Counsel Lyndon Barber to discuss this matter. During the course of our discussions, we discussed the recent case of *In Re Wild West Wholesale*, Federal Register Volume 72, Number 18, Page 404-405, which *expressly recognized* that pursuant to 21 CFR 1309.31 (b), as long as a registrant submits a renewal application *in advance of its registration expiration*, that DEA registration *remains valid and in full effect until* a final revocation order is issued by the DEA deputy administrator. I have attached a copy of this decision for your review. Thus, there having been no final order of revocation issued in this matter, *Poole Marketing's registration renewal was timely and it retains a valid and existing DEA registration* until such time that a final order revoking that registration is issued by the deputy administrator.

Therefore, DEA's continued instruction to CB Distributors not to sell List I product to Poole Marketing is groundless, outside the scope of DEA's authority, and continues to deprive Poole Marketing of its due process. As a result, we are demanding DEA provide written confirmation to both myself and CB Distributors that Poole Marketing retains a valid and existing DEA registration.

Upon DEA's failure to do so within 48 hours, I will instruct my client to take all necessary action including, but not limited to, filing suit in federal court to enjoin DEA's wrongful activities, and for monetary damages and attorneys fees incurred as a result of DEA's wrongful actions. If DEA is insistent upon failing to comply with Poole Marketing's request, I would ask that you please provide a copy of this letter to the civil division of your local United States Attorneys branch so that I may discuss this matter further with them, and if need be, have a contact in the office to provide and serve courtesy copies of any injunctive relief papers that need be filed.

Thank you for your anticipated prompt attention to this matter. I look forward to hearing from you.

Very truly yours,

Jason A. Hill

JAH/jks
Enclosure
cc: Mr. Lydon Barber
Mr. Buddy Poole
Mr. Jeff Pifer, CB Distributors, Inc.

H:\Cases\Poole Marketing\Correspo\DIGreen-02-jah.doc

U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
OFFICE OF DIVERSION CONTROL

HOME PRIVACY POLICY CONTACT US WHAT'S NEW HOT ITEMS SITEMAP SEARCH

DIVERSION PROGRAMS
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QUOTAS
REGISTRATION SUPPORT
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e-COMMERCE INITIATIVES
FEDERAL REGISTER NOTICES
MEETINGS & EVENTS
OFFICES & DIRECTORIES
PROGRAM DESCRIPTION
PUBLICATIONS
QUESTIONS & ANSWERS
REGULATIONS & CODIFIED CSA

LINKS
FEDERAL AGENCIES & RELATED
INDUSTRY RELATED
PUBLIC INTEREST

REGISTRATION VALIDATION
CASES AGAINST DOCTORS
REGULATIONS.GOV

Registrant Actions - 2007

FR Doc E7-1316 [Federal Register: January 29, 2007 (Volume 72, Number 18)] [Notices] [Page 4042-4045] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr29ja07-65]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Wild West Wholesale Revocation of Registration

On August 18, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Wild West Wholesale (Respondent) of Cedaredge, Co. The Show Cause Order proposed to revoke Respondent's DEA Certificate of Registration, 005516WWY, as a distributor of list I chemicals, and to deny any pending applications for renewal or modification of the registration, on the ground that Respondent's continued registration is inconsistent with the public interest. Show Cause Order at 1.

The Show Cause Order specifically alleged that Respondent distributed list I chemical products containing ephedrine, a precursor chemical used to manufacture methamphetamine, a Schedule II controlled substance. See id. at 1-2. The Show Cause Order alleged that Respondent distributed combination ephedrine products to gas stations and convenience stores, which are non-traditional retailers of these products. Id. at 2. The Show Cause Order further alleged that Respondent was distributing "approximately five or more case of various ephedrine products to its 45 customers each month," id., and that only a very small percentage of the licit retail market for these products is sold in convenience stores and gas stations. Id. 2-3. Finally, the Show Cause Order alleged that Colorado and adjacent states "have experienced a proliferation of small methamphetamine laboratories" and that "[l]aw enforcement officials have observed that a substantial proportion of precursors found at illicit methamphetamine sites have involved non-traditional brands sold through convenience stores." Id.

On September 26, 2005, the Show Cause Order was served on Respondent by first class mail.\1\ On October 14, 2005, Respondent, through its counsel, requested a hearing. The case was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner, who ordered the parties to prepare pre-hearing statements. However, on February 22, 2006, Respondent withdrew its request for a hearing. The ALJ then ordered that the proceeding be terminated so that the investigative file could be forwarded to me for final agency action.

\1\ The Show Cause Order was initially sent by certified mail to the street address of Respondent's registered location but was returned with a notation indicating that Respondent's owner had moved and that the time for forwarding mail had lapsed. This address was also used by Respondent's owner when she submitted a renewal application in April 2005. In May 2004, Respondent's owner had submitted a request for a change of its registered location to the address at which Respondent was eventually served.

www.DEAecom.gov

To view PDF documents Adobe Reader

External links included in this website should not be construed as an official endorsement of the views contained therein.

I find that Respondent has waived its right to a hearing. I therefore enter this final order without a hearing based on information contained in the investigative file.

Findings

Respondent is a supplier of sundry items to approximately forty- five convenience stores and gas stations in western Colorado. Among the items

[[Page 4043]]

which Respondent distributes are products containing the list I chemicals pseudoephedrine and ephedrine. Respondent is owned by Ms. Brenda Garcia and operated out of her home in Cedaredge, Co.

While ephedrine and pseudoephedrine have therapeutic uses, they are easily extracted from lawful over-the-counter products and are used in the illicit manufacture of methamphetamine, a schedule II controlled substance. See 21 U.S.C. 802(34). Methamphetamine is a powerful and addictive central nervous system stimulant. See Gregg Brothers Wholesale Co., 71 FR 59630 (2006). The illegal manufacture and abuse of methamphetamine pose a grave threat to this county. Methamphetamine abuse has destroyed numerous lives and families and ravaged communities. Moreover, because of the toxic nature of the chemicals used to make methamphetamine, its manufacture causes serious environment harms. Id.

Respondent holds Certificate of Registration, 005516WWY, which authorizes it to distribute pseudoephedrine and ephedrine at the registered location of 224 SW 13th Circle, Cedaredge, Co. Respondent's registration expired on May 31, 2005, and was subsequently retired on December 31, 2005. Respondent did, however, file a renewal application on April 28, 2005, which was received by DEA on May 5, 2005.

On May 12, 2004, Respondent's owner requested a modification of Wild West's registration seeking to change its registered location from the SW 13th Circle address to her home. Thereafter, on May 24, 2004, Respondent's owner submitted additional information. Included in this information was a sales report from one of Respondent's suppliers, Proactive Labs, Inc., which documented the firm's purchase of combination ephedrine products on various dates between December 12, 2002, and March 3, 2004. These records showed that during this period, Respondent purchased from Proactive Labs a total of 426,912 dosage units of combination ephedrine products. As noted in previous decisions, DEA has issued numerous warning letters to Proactive Labs because its products have been found repeatedly at illegal methamphetamine labs. See D & S Sales, 71 FR 37607, 37608 (2006).

Thereafter, on July 14, 2004, two Diversion Investigators (DIs) went to Respondent's new location to interview its owner and conduct a security inspection. During the interview, Respondent's owner told the DIs that list I chemicals comprised five to ten percent of its sales. She also informed them that Respondent obtained list I products from two additional suppliers. Respondent further provided the DIs with a customer list.

Several months later, one of the DIs contacted twelve of Respondent's customers. Most of the customers claimed either that they did not purchase, or purchased only small amounts of, list I products from Respondent.

On July 13, 2005, the DIs conducted an additional interview of Respondent's owner. During the interview, Respondent's owner told the DIs that Proactive Labs had been her exclusive supplier of ephedrine products since February 2005. Respondent's owner further told the DIs that the company had notified her that effective July 1, 2005, it was selling its products lines to Advantage Healthcare.

Respondent's owner informed the DIs that prior to July 1, 2005, when Colorado law changed to require that pseudoephedrine and ephedrine products be sold in blister packaging, she had sold 48-count bottles of Bronch-eze Asthma Relief, a combination ephedrine product. Respondent's owner stated that she paid $1.26 per bottle and that the bottles sold at retail for $5.99. Respondent's owner told the DIs that a 48-count blister package cost $1.49 per box and sold at retail for $6.99. She also informed the DIs that the six-count combination ephedrine blister packs cost $.25 each and sold at retail for $.99.

Respondent's owner provided the DIs with twelve invoices documenting its purchases of combination ephedrine products from Proactive Labs/Advantage Healthcare between January 31, 2005, and July 19, 2005. The invoices showed that Respondent had purchased $7003.80

worth of 48-count bottles and $2837.53 worth of six-count packets between January 31, 2005, and June 9, 2005. The two invoices for July 2005 showed that Respondent had purchased $1712.96 worth of 48-count blister pack boxes. Relatedly, at the time of the inspection, Respondent had on hand 543 bottles (48-count), which were to be returned following the change in Colorado law.

Based on the retail price information provided to the DIs, Respondent distributed combination ephedrine products with a retail sales value of $40,916.76,\2\ over the approximately six-month period or $6819.46 per month. On a per store basis, the estimated average monthly retail sale of the products was $191.54.

\2\ This figure was calculated based on the invoice amounts minus the inventory that was being returned.

In numerous cases, DEA has established through expert testimony the monthly expected sales of combination ephedrine products by non- traditional retailers such as convenience stores and gas stations to meet legitimate demand, i.e., the purchase of the products for their medically approved use as a bronchodilator to treat asthma. See, e.g., T. Young Associates, Inc., 71 FR 60557, 60567 n.2 & 60568 (2006); Tri- County Bait Distributors, 71 FR 52160, 52161-62 (2006); D & S Sales, 71 FR 37607, 37608-09 (2006). In these cases, DEA has proved by substantial evidence that the monthly expected retail sales range for combination ephedrine products by non-traditional retailers is between $0 and $25, with an average of $12.58. See T. Young, 71 FR at 60568; Tri-County Bait, 71 FR at 52162; D & S, 71 FR at 37609. DEA has also established that a monthly retail sale of $60 of ephedrine products "would occur about once in a million times in random sampling." T. Young, 71 FR at 60588 (int. quotations and citations omitted).

Respondent's owner also provided the DIs with a customer list. Using the customer list, a DI visited twenty-one of the stores and interviewed their managers regarding whether they sold list I products and, if so, the volume sold. At fifteen of the stores, the managers estimated that they were selling $60 or more per month of combination ephedrine products. Indeed, at ten of the stores, the managers estimated that they were selling $100 or more per month of the products, and at eight of the stores, the managers estimated that they were selling $300 or more per month.

Discussion

As an initial matter, the scope of this proceeding must be determined. According to the investigative file, Respondent's registration expired on May 31, 2005. On April 28, 2005, however, Respondent's owner submitted a renewal application. DEA received the application on May 5, 2005, and charged the application fee to its owner's credit card.

Under the Administrative Procedure Act (APA), "[w]hen [a] licensee has made timely and sufficient application for a renewal or a new license in accordance with agency rules, a license with reference to an activity of a continuing nature does not expire until the application has been finally determined by the agency." 5 U.S.C. 558(c). DEA's regulation which addresses renewal applications merely

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states that "[a]ny person who is registered may apply to be reregistered not more than 60 days before the expiration date of [her] registration." 21 CFR 1309.31(b). This regulation does not specify a date by which DEA must received a renewal application in order for an existing registration to be continued in accordance with the APA.

Another DEA regulation addresses the renewal of an existing registration when Show Cause Proceedings are pending. See 21 CFR 1309.45 ("Extension of registration pending final order"). This regulation provides that:

[i]n the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least 45 days before the date on which the existing registration is due to expire, and the Administrator has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Administrator issues his order. The Administrator may extend

any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for reregistration at least 45 days before expiration of the existing registration, with or without request by the registrant, if the Administrator finds that such extension is not inconsistent with the public health and safety.

Id.

As demonstrated by its text, this regulation clearly contemplates that a Show Cause proceeding must be ongoing in order to trigger the requirement that a registrant submit a renewal at least 45 days in advance of the registration's expiration date in order to continue the registration. Here, however, Respondent's renewal was submitted four months before the Show Cause Order was issued and thus this regulation is not applicable. Instead, the timeliness of Respondent's renewal application is governed by 1309.31, which imposes no deadline by which the application must be filed. Therefore, I conclude that Respondent submitted a timely renewal application, and that under the APA, her registration has remained in effect pending the final order in this proceeding.

The Public Interest Analysis

Section 304(a) of the Controlled Substances Act provides that a registration to distribute a list I chemical "may be suspended or revoked * * * upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a)(4). In making this determination, Congress directed that I consider the following factors:

> (1) Maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;
>
> (2) compliance by the applicant with applicable Federal, State, and local law;
>
> (3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;
>
> (4) any past experience of the applicant in the manufacture and distribution of chemicals; and
>
> (5) such other factors as are relevant to and consistent with the public health and safety.

Id. section 823(h).

"These factors are considered in the dis|unctive." Joy's Ideas, 70 FR 33195, 33197 (2005). I may rely on any one or a combination of factors, and may give each factor the weight I deem appropriate in determining whether a registration should be revoked or an application for a modification of a registration should be denied. See, e.g., David M. Starr, 71 FR 39367, 39368 (2006); Energy Outlet, 64 FR 14269 (1999). Moreover, I am "not required to make findings as to all of the factors." Hoxie v. DEA, 419 F.3d 477, 482 (6th Cir. 2005); Morall v. DEA, 412 F.3d 165, 173-74 (D.C. Cir. 2005). In this case, I conclude that Factors Four and Five establish that Respondent's continued registration would be "inconsistent with the public interest," 21 U.S.C. 823(h), and that Respondent's registration should be revoked and its pending application for renewal should be denied.

Factors Four and Five--The Registrant's Past Experience in the Distribution of Chemicals and Other Factors Relevant to and Consistent With Public Health and Safety

As found above, the illicit manufacture and abuse of methamphetamine have had pernicious effects on families and communities throughout the nation. Cutting off the supply source of methamphetamine traffickers is of critical importance in protecting the public from the devastation wreaked by this drug.

While combination ephedrine products have a legitimate medical use as a bronchodilator to treat asthma, DEA orders have established that convenience stores and gas stations constitute the non-traditional retail market for legitimate consumers of products containing ephedrine. See, e.g., Tri-County Bait Distributors, 71 FR at 52161; D & S Sales, 71 FR at 37609; Branex, Inc., 69 FR 8682, 8690-92 (2004). DEA has further found that there is a substantial risk of diversion of list I chemicals into the illicit manufacture of methamphetamine when these products are sold by non-traditional retailers. See, e.g., Joy's Ideas, 70 FR at 33199 (finding

that the risk of diversion was "real, substantial and compelling"); Jay Enterprises, 70 FR 24620, 24621 (2005) (noting "heightened risk of diversion" should application be granted)

DEA orders thus establish that the sale of certain list I chemical products by non-traditional retailers is an area of particular concern in preventing diversion of these products into the illicit manufacture of methamphetamine. See, e.g., Joey Enterprises, 70 FR 76865, 76857 (2005). As Joey Enterprises explains, "[w]hile there are no specific prohibitions under the Controlled Substances Act regarding the sale of listed chemical products to [gas stations and convenience stores], DEA has nevertheless found that [these entities] constitute sources for the diversion of listed chemical products." Id. See also TNT Distributors, 70 FR 12729, 12730 (2005) (special agent testified that "80 to 90 percent of ephedrine and pseudoephedrine being used [in Tennessee] to manufacture methamphetamine was being obtained from convenience stores"); OTC Distribution Co., 68 FR 70538, 70541 (2003) (noting "over 20 different seizures of [gray market distributor's] pseudoephedrine product at clandestine sites," and that in eight month period distributor's product "was seized at clandestine laboratories in eight states, with over 2 million dosage units seized in Oklahoma alone."); MDI Pharmaceuticals, 68 FR 4233, 4238 (2003) (finding that "pseudoephedrine products distributed by [gray market distributor] have been uncovered at numerous clandestine methamphetamine settings throughout the United States and/or discovered in the possession of individuals apparently involved in the illicit manufacture of methamphetamine").

Here, nearly all of Respondent's customers are convenience stores and gas stations, which are non-traditional retailers of list I chemical products. Most significantly, the investigative file establishes that the combination ephedrine products distributed by Respondent were not being sold to meet legitimate consumer demand but rather were being diverted to supply the illicit manufacturers of methamphetamine. As found above, the average monthly retail sales value of the combination ephedrine products distributed by Respondent was $151.54 per store. This

[[Page 4045]]

figure grossly exceeds the monthly expected sales range of $0 to $25 (with an average of $12.55) by convenience stores to meet legitimate demand for these products as an asthma treatment. See T. Young, 71 FR at 60568; D & S Sales, 71 FR at 37609.

Indeed, a monthly retail sale of $60 of ephedrine products at a convenience store should "occur about once in a million times in random sampling." T. Young, 71 FR at 60566. The $151.54 average retail sale value of Respondent's products is 2.5 times this amount. Moreover, this figure is an average for all forty-five stores serviced by Respondent over a seven-month period. It is thus even more improbable than a one in a million probability that Respondent's products were being purchased to meet legitimate demand.

I therefore conclude that a substantial portion of Respondent's products were diverted into the illicit manufacture of methamphetamine. See T. Young, 71 FR at 60572; D & S Sales, 71 FR at 37611 (finding diversion occurred "[g]iven the near impossibility that * * * sales were the result of legitimate demand"); Joy's Ideas, 70 FR at 33198 (finding diversion occurred in the absence of "a plausible explanation in the record for this deviation from the expected norm").\3\ Moreover, "the diversion of list I chemicals into the illicit manufacture of methamphetamine poses the same threat to public health and safety whether a registrant sells the products knowing they will be diverted, sells them with a reckless disregard for the diversion, or sells them being totally unaware that the products were being diverted." T. Young, 71 FR at 60572 (citing D & S Sales, 71 FR at 37610-12, & Joy's Ideas, 70 FR at 33198). In short, the statutory text does not require that the Government prove that a registrant acted with any particular mens rea to sustain a public interest revocation. T. Young, 71 FR at 60572. Accordingly, adverse findings are warranted under these factors even if Respondent's owner was unaware that its products were being diverted.

\3\ This finding is also supported by the customer verifications. At nearly half of the twenty-one stores visited, the managers told the OIs they were selling quantities of combination ephedrine products that would sell for $100 or more per month; at eight of the stores, the managers estimated that they were selling quantities of $300 or more per month.

Here, while Respondent (and its owner lacks a criminal record) and the file does not establish that Respondent has failed to comply with applicable laws or lacks effective controls.\4\ I nonetheless conclude that Factors Four and Five compel the conclusion that Respondent's continued registration would be inconsistent with the public interest.

[4] The Government bears the burden of proof on each factor even when a registrant waives its right to a hearing. In this case, the investigative file contains no evidence to support a finding that Respondent does not maintain effective controls because it was aware of diversion occurring at the retail level and failed to act.

Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. 823(h) & section 824(a), as well as 28 CFR 0.100(b) & 0.104, I order that DEA Certificate of Registration, 005516WWY, issued to Wild West Wholesale be, and it hereby is, revoked. I further order that Wild West Wholesale's pending applications for modification and/or renewal of its registration be, and they hereby are, denied. This order is effective February 28, 2007.

Dated: January 20, 2007.

Michele M. Leonhart,
Deputy Administrator.

[FR Doc. E7-1316 Filed 1-26-07; 8:45 am]

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Telephone: (419) 243-2100
FAX: (419) 243-7119

To: Diversion Investigators
Green and Jones
U.S. Department of Justice
Drug Enforcement Administration

Date: April 10, 2007

Fax #: 404-893-7096

Pages: 9, including this cover sheet.

From: Jason A. Hill, Esquire

Subject: Poole Marketing

MESSAGE:

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CONNELLY, JACKSON & COLLIER LLP
405 Madison Avenue, Suite 1600
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Telephone: (419) 243-2100
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To: Mr. Jeff Pifer
CB Distributors, Inc.

Date: April 10, 2007

Fax #: 608-368-9919

Pages: 9, including this cover sheet.

From: Jason A. Hill, Esquire

Subject: Poole Marketing

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Fax #: 202-307-4946 **Pages:** 9, including this cover sheet.

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Subject: Poole Marketing

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Fax #: 202-307-4946 **Pages:** 9, including this cover sheet.

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To: Mr. Buddy Poole
Poole Marketing

Date: April 10, 2007

Fax #: 478-825-5381

Pages: 9, including this cover sheet.

From: Jason A. Hill, Esquire

Subject: Poole Marketing
DEA Registration No: 004320PAY

MESSAGE:

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Telephone: (419) 243-2100
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To: Mr. Buddy Poole
Poole Marketing

Date: April 10, 2007

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"Standing up for patients in pain, and the physicians who treat them"

Karen Tandy
Administrator
Drug Enforcement Administration
Mail Stop AXS
2401 Jefferson Davis Highway
Alexandria, VA 22301

November 26, 2004

Dear Ms. Tandy,

As US v Hurwitz draws to a close, I call upon you to rethink your approach to this important matter and to weigh the implications for the American people, should your agency secure a conviction.

Our system for regulating medical practice was set up so that medical conduct would be evaluated by physicians, in the context of state medical boards. Instead, the Controlled Substances Act (CSA), combined with your agency's interpretation of this legislation has produced a different result. What began as an effort to address those rare instances where a physician departed the practice of medicine and instead dealt drugs, has evolved into a travesty of justice. Over the years, case law has moved the issue argued in court so far from what was originally intended, that a physician's allegedly negligent errors in medical judgment have become admissible as circumstantial evidence of criminal intent. As a practical matter, the practice of pain management is currently regulated by US attorneys, under the threat of federal criminal prosecution, a troubling outcome that lawmakers who enacted the CSA could not have foreseen.

Evidence presented by the government has revealed beyond a shadow of a doubt that Dr. Hurwitz was set upon, and victimized by a gang of criminal predators whom he treated in good faith for their well-documented complaints of chronic pain. What the government has not produced is even a shred of direct evidence that Dr. Hurwitz intended to deal drugs.

In essence, the government's charges, as they now stand, accuse Dr. Hurwitz of doing a poor job of policing his practice against the criminal diversion of drugs. Effectively, the charges state that he was a bad law enforcement officer who failed to detect the criminal

activity of a ring of career criminals acting entirely without his knowledge or consent. How this set of facts could ever be construed as criminal conduct on his part sheds light on the fundamental unfairness of the proceedings against him, particularly in view of the fact that your agency was aware of the criminal activities of a sub segment of his patient population, and could have put a stop to it at any time.

Nevertheless, Dr. Hurwitz is now forced to prove his innocence concerning complex and socially controversial medical judgments, before a lay jury, a jury which has been privy to the most prejudicial kinds of evidence imaginable. Whether a jury of lay people can process all of this inappropriate testimony and still keep their minds open to the legal question at hand remains to be seen. The situation represents a dilemma for all concerned.

Primary care physicians play an essential role in the management of chronic pain. As you are aware there are not nearly enough experts to deal even with the challenging patients for whom specialist referral is appropriate. As a result of your agency's recent enforcement efforts, prescribing by primary care physicians is already substantially impeded. In many parts of the country, pain care is unobtainable. How are the primary care physicians, practicing on the front lines of medical care to approach this humanitarian, and public health disaster?

My concern is this. Should you achieve a conviction against Dr. Hurwitz, a distinguished physician whom the medical community holds in high regard, you will have established beyond a shadow of a doubt, your agency's power to characterize as criminal, a physician's well-intended, and compassionate care of suffering patients, and you will have done so entirely on the basis of evidence that should only have been brought before a state medical board, if there. Should your agency succeed in burning Dr. Hurwitz at the stake, I am gravely concerned that the entire field of pain management will shut down forthwith. Certainly no primary care physician in his right mind will be willing to risk the chance that your agents might arrest some of his patients, and then proceed to influence them to testify against him in federal court.

Ms. Tandy, the entire pain community has recently become aware of the methods through which your agency secures the convictions of well-intentioned primary care physicians. These include the beggaring of providers, the polluting of jury pools through prejudicial media stories characterizing well-intentioned physicians as "crack dealers in white coats", and most alarmingly, the purchasing of corrupt and misleading expert testimony, offered by anti-opioid zealots, who lurk at the fringes of the discipline of pain management.

If under these circumstances you succeed in convicting this compassionate and skilled physician, you will have succeeded only in condemning our nation's most vulnerable population, those who suffer from severe chronic pain, to vastly shortened lives, without care, and without hope. If Dr. Hurwitz is acquitted, the result will be only slightly better, as the medical profession will still remain in a state of panic. Neither outcome is even

close to acceptable, and surely not what you, or anyone else wishes.

The time has come to end this madness. We at Pain Relief Network implore you to pursue the only sensible and humane course of action. Withdraw the charges against Dr. Hurwitz, and join with us in our call for a Commission on Pain, which will look for solutions to the terrible problem of under treated chronic pain in the United States. It is our fervent hope that in evaluating this request, that you will place a priority on the needs of suffering Americans.

Sincerely,

Siobhan Reynolds
President
Pain Relief Network

P.O. Box 231054
New York, NY 10023
(212) 873-5848

JAMES D. FERNANDEZ - 28 791 003
11801 Highland Oaks Drive
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July 11, 20076

Mike Phaup, Director Hunter Holmes McGuire VA Medical Center /
McGuire Satellite Clinic Fredericksburg
1201 Broad Rock Blvd
Richmond Virginia 23249

Dear Mr. Phaup,

I am a retired U.S. Marine with combat injuries resulting in service connected disability and chronic pain. I have been under continuous medical care from the Veteran's Administration (VA) since the Summer of 1997. I initially suffered an L4-L5 disc hernia ion in a helicopter accident in 1977. These injuries were exacerbated in another helicopter accident in 1988. During the Gulf War I flew 54 combat hours and logged over 3,500 total hours in my military career. In 2005, My Primary Care, Dr. Abdullah, referred me to the McGuire pain clinic. My pain had become unmanageable on that medication regimen, which remained unchanged as my condition worsened. My quality of life had become dismal, all under the watchful eyes of my V.A. primary care clinicians. At the McGuire Pain Clinic, after a thorough evaluation and examination by Dr. Denise Lester, the frequency of my long-acting pain medication dose was increased from three times a day to four times a day. I had so much relief, it was astonishing. I was bathing every day, dressing, going to the mail box â€" simple daily activities I had long been unable to do regularly or with confidence. I lost twenty-five lbs in six months. I am, to this day, much better.

In February 2006 I was returned to my primary care physician with a letter stating I was considered stable on the adjusted medication regimen, and that no further treatment was required from the pain clinic. This should have been the end of the story. And if the story ended here it would be just another example of a chronic pain patient suffering needlessly for years for lack of a simple dose adjustment, one of the most basic and obvious medical interventions conceivable.

I did not receive my 30 day supply for February 2006 through the Fredericksburg Clinic for 35 days. When I ordered my pain medication in March 2006, I was told it was processed. It was not! My prescriptions were simply ignored and not filled. Assuming clerical error, I called the clinic and re-submitted the prescriptions for March 2006. On about March 17th, I was contacted by a nurse identified as Linda to come into the clinic "to have blood drawn." I was happy to immediately go to the clinic and told the nurses on arrival that I welcomed blood tests because I had been feeling ill lately and that I thought I might have a fever. When asked what I thought it might be, I responded I was concerned I might have an acute infection that lab tests might detect. My medical complaints and stated concerns were completely ignored by the medical staff. I was told that the blood tests were only to determine "if there was anything in your system that is not permitted."

It was further demanded that I sign a "narcotics agreement" or my medications would be reduced or stopped. I was informed that this "agreement" would include weight-loss targets in addition to a pledge "not to use any other drugs." I protested. I reminded the nurse that I had always done my best to comply with medical recommendations, that I had been in the first smoking cessation group offered by the clinic and was currently it's only continuously smoke-free member. I also informed her that I had already lost 25 lbs on my own, partially a result of the increased exercise tolerance I had achieved subsequent to the dose adjustment and stabilization accomplished by Dr. Lester at the McGuire pain clinic, whom Dr. Abdullah had ordered me to see due to my very high pain level. I agreed to sign a letter to not use "other drugs" because I had never taken medication other than exactly as prescribed, but I felt the weight stipulations were 1) threatening, 2) unfair in failing to acknowledge my lack of any substance abuse history and my progress in losing weight on my own, and 3) disingenuous if not hypocritical in that it was this clinic's under-treatment of my pain that most likely exacerbated my weight problem in the first place. In response to this the nurse again informed me, in no uncertain terms, that I would sign the "agreement" presented or else my pain medications would be reduced, period.
By this time I was feeling very embarrassed because the entire encounter had occurred in the presence of several other patients who were watching and hearing everything, and I returned home feeling shaky and sick to await the blood test results that would shed no light on my current illness. My medical complaints had been neither acknowledged or addressed, my confidentiality rights under HIPPA trampled, and my expectation of common decency and professional

medical behavior dashed.

Several days later I was called back to the clinic to sign the "agreement." When Pharmacist Stanley put the agreement in front of me, I began to sign my name. She said, "You have to read it." I asked, "Why? Didn't you say if I don't sign it you would reduce the medications I need?" She acknowledged that was true. I said, "Then I have no choice!" I signed the agreement.

I asked why they were using medications to threaten me! She said the clinic had failed some sort of administrative 'JAYCO' inspection and not to take it personally. I objected that medical decisions not in my best interest were being made without my advice and consent, by a physician I'd never met and who was not my doctor (they said a 'Dr. George' was the physician responsible for my case), Ms. Stanley remarked in an offhand manner that my breakthrough medications were being, summarily, reduced by half effective immediately.

I protested again, again reminding this Ms. Stanley that VA pain specialist Dr. Lester, in consultation with my VA primary care physician, Dr. Abdullah, had established my current medication regimen and asked on what medical authority my medications were being altered. I received no answer to this question. I stated that it was unfair and medically unethical to punish me just because the clinic had regulatory problems that had nothing to do with my behavior or the particulars of my case. My protest fell on deaf ears. Still, I reminded this Fredericksburg Satellite clinician, to no avail, that my medications had been prescribed for me by Dr. Abdullah at this clinic in stable doses, and that this regimen had been evaluated and confirmed and re-recommended as proper therapy by VA Pain Specialist Dr. Lester, whom I had been ordered to consult by Dr. Abdullah.

I asked why, since I had signed the "agreement," were my medications being reduced? Ms. Stanley told me the reason for the abrupt dose decrease was that I didn't have a recent MRI in the chart. I told her I was claustrophobic and that Dr. Abdullah had discussed this with me and that Dr. Abdullah felt that more MRI studies were not needed. I further reminded Ms. Stanley that the McGuire pain clinic, whose consultation I had so recently received, had also not seen any medical point in performing MRI studies at this time.

Ms. Stanley told me that my new doctor was "Dr. George" who "did not see how I needed so many drugs." I, to this day, have never met this physician, nor has she called me or invited me in for an appointment to review my medical history. To this day no explanation of Dr. Abdullah's removal as my physician been offered me by anyone. Since my return from the McGuire pain consultation, no physician at the Fredericksburg Satellite clinic has examined me, or reviewed the records and recommendations from the McGuire Pain clinic evaluation with me, despite medical complaints and concerns clearly expressed by me to clinical staff onsite. Yet my medical regimen, adjusted so recently by VA specialists and finally adequate, was abruptly changed by a physician with whom I do not have a legitimate doctor-patient relationship.

This feels to me more like assault than medical care. I no longer feel my well being is important at the Fredericksburg Satellite, rather I believe the treatment I am receiving is substandard and unethical medical care that has directly harmed me and threatens to entirely ruin me.

After March 17th embarrassment at the clinic and the alteration of my medication regimen, I decided to try and go back to the military for my primary care needs, because I was not being treated professionally or with respect by my VA primary care clinic. I scheduled an appointment for around the first week in April with a military physician, Dr. Golden, at the Quantico Medical Clinic. When he saw my medication regimen, I could tell by the look on his face he did not want anything to do with me. He said, "I do not want to write a prescription for the pain medications you need each month. If I did the DEA would 'red flag' me each month."

Dr. Golden recommended I have a "morphine pump" surgically implanted. If I did so, he said, then I would not "face hardship" getting my meds each month. I understood that if I got a morphine pump, not for medical reasons as I was stable and doing well on oral medications after Dr. Lester's dose adjustment, and despite the small but real surgical risks (for a device I did not medically need) - that if I got 'the pump' for the reason that it made the doctor feel less vulnerable to DEA scrutiny - then, and only then, would he take on the role of my primary care physician.

Dr. Golden offered a referral for the morphine pump procedure. He then asked if there was anything else he might do to help me. I mentioned that I felt ill as though I might have a infection and could he do some tests and check. He asked me to submit blood and urine for testing, which I did. I never heard back from Dr. Golden. I have yet to discuss this encounter with State medical licensing authorities, but I doubt they will find this acceptable or ethical medical practice, or that it meets the standard of care for management of chronic pain adequately treated by oral doses of medication without side effects or complications in a well known and stable patient.

Over the next several days I felt progressively weak and ill, developed a temperature of 104 degrees, and went to the Mary Washington Hospital ER where I was diagnosed with a urinary tract infection and started on antibiotics. My condition improved slightly on the antibiotics prescribed, but then worsened again. I returned to the ER on April 25, 2006, with fever and tremendous pain, and was diagnosis with a kidney infection (pyelonephritis). Currently, I am home, bedridden and in worse pain than usual, trying to recuperate. Almost certainly these complications of the lack of medical care I received from the VA could have been avoided if the Fredericksburg clinic had, on March 17th, treated me with professional respect and paid attention to my medical complaints and examined me instead of threatening me to cover for their own clinical and administrative inadequacies and regulatory problems.

In Conclusion:
I have become a victim of unethical, substandard, frankly abusive 'medical' care at the hands of the Veteran Administration's Fredericksburg Satellite Clinic where I have received my primary care, uncomplicated by substance abuse or any medical non-compliance.

1) Mr. Phaup, I formally request you investigate the events I have related to you. I formally request that you review my entire VA medical record, including the records from the McGuire pain clinic consultations. I expect a detailed explanation of how such medically irresponsible and humiliating treatment of myself, complete with flagrant disregard to my confidentiality, occurred under VA auspices. And I want to know what administrative changes you will be making to ensure this sort of thing ceases immediately. And I specifically want to know what measures will be taken regarding Dr. George. And I expect an apology.

2) I need comprehensive medical care now! The medical negligence I have experienced has rendered me acutely ill on top of my longstanding, well documented, chronic medical conditions. I insist that you immediately assign me a new physician at the Fredericksburg Satellite clinic; one who will pay more attention to my medical problems than to your internal administrative problems, one who will reinstate the medication regimen on which I was stabilized by VA physicians Dr. Lester and Dr. Abdullah, and one who is competent to manage uncomplicated chronic opioid therapy and who will treat me in a medically professional and ethical manner and with the respect I deserve and have earned in service of this country,

3) It seems to me, in light of my experience at McGuire, that my course of treatment by VA physicians in response to worsening pain and declining function was grossly negligent. Was it really medically necessary for me, a stable patient well known to you physicians, to wait years for a specialty pain clinic appointment in order to get a simple opioid titration-to-effect maneuver for chronic pain? Perhaps your physicians need a refresher course on the basic management of chronic pain. Most Americans might expect the VA to be capable of rendering adequate if not expert medical management to disabled combat veterans in chronic pain. They might be shocked to learn the government is not capable of treating even the most uncomplicated cases of chronic pain.

4) What I have experienced can only be described as "abandonment of the patient." I understand how very, very serious a charge this is, and therefore I am informing you that I feel I have no choice but to file a complaint with the State medical licensing authorities against the physicians responsible for my medical care.

5) I am not 100% sure that a JCAHO audit inspired the medically unacceptable and bizarrely implemented changes in policy at the Fredericksburg clinic that lead to my medical mismanagement, but I do know that JCAHO exists to help hospital organizations improve the quality of patient care. And I am pretty sure that they would be displeased if not horrified to learn that such draconian abuse as I experienced is being visited upon patients who are told the reason is "we failed a JCAHO audit." Please know that I will be discussing this entire episode with JCAHO if it turns out that they were in any way involved with the medical abuse that I experienced.

6) Sir, I did absolutely nothing to deserve this abandonment and negligent medical care. Through no fault of my own I suddenly find my entire medical support system in a shambles. I have some 20 days of medications left. I do not know who my doctor is. I do not know where else to turn.

Mr. Phaup, you have the power and authority to rectify this situation, to make me whole. I beseech you to please look into this in a timely manner, I am terrified that if you do not promptly intervene I will find myself incapacitated in 20 days

when I run out of the medications I need to live. This insanity is happening under your watch, Mr. Phaup,

Please help me.

As God is my witness, I have spoken the truth; Semper Fidelis.

Sincerely,

- James D. Fernandez

Copy to:

- Mike Phaup, Hospital Administrator: Hunter Holmes McGuire VA Medical Center / McGuire Satellite Clinic, Fredericksburg, Virginia.
- The Honorable Joann Davis, Congresswoman, 1st District Virginia.
- The Honorable Steve Buyer, Congressman, 4th District Indiana, and Chairman of the House Committee on Veterans Affairs.
- The Honorable R. James Nicholson, Secretary of Veterans Affairs.
- Daniel F. Hoffmann, VA Network Director.

DAVE HABBE
4-FRONT DISTRIBUTING

20201 N. 1150th Street
Effingham, IL 62401
USA
Phone/Fax: 217-868 2184

ATTN: Jeff
C.B Dist.
3/16/06

March 9, 2006

ATTN: WALT SANDERS
202-479-4657
5/23/06

Congressman John Shimkus

Dear Congressman Shimkus:

My name is David Habbe. I am a lifelong Republican, a Life Member of the NRA, an Elder in my church and sole owner of a home based wholesale distribution company, 4-Front Distributing.

I began my company in 1993, growing it from a small part-time source of income to its current level of sole support of my family. I service primarily convenience stores and truck stops throughout Central and Southern Illinois with a variety of products.

I am currently licensed by the Drug Enforcement Administration as a distributor of the List 1 chemical, Ephedrine.

The growth of my business quickly necessitated the purchase of a larger home. In November of 2003, we moved my family and business to a new address approximately ¼ mile from our previous address. When I attempted to renew my DEA list 1 Chemical license for 2004 for my new business address, I was informed by the DEA that even though I had cooperated with them fully in all investigations and field audits, and had not received even one written warning in all the years that I had been licensed that they would not renew my license for the new address.

I was told that the license would only be issued for the old address or that I would have to build or rent storefront property. The purchase or lease of additional business property would have been financially impossible, and also would have directly conflicted with my home based business structure. In addition, since we have no direct retail sales or walk-in customers, a storefront location is pointless and unnecessary.

Fortunately, we had not yet sold our previous home. I was able to renew my license

for that address until such time that it sold in the summer of 2005.

My business was subject to a random DEA field audit in December 2005. I advised the DEA field agents that having sold the property at the old address, that my business was currently located at my new address. They told that I should have informed them that the old property sold and requested that I submit a change of address request which I typed and submitted directly to them to them at that time.

During the course of this field audit, the agents did a full inspection of the premises of my business and also received as requested all records of List 1 sales to my customers and invoices from my suppliers for any List 1 purchases.

The agents took all of this material with them and kept it overnight for a review of my sales and purchase records. The next morning the agents returned and noted procedures which needed to be implemented for future sales records. They also requested that a lock be placed on the door to the room where we inventory List 1 product. We immediately complied with all DEA requests. Both agents assured us that these were not major violations although the eventual status of my List 1 DEA certification was entirely out of their hands.

They further advised me that the DEA was actively trying to reduce the number of licenses which had been issued and stated that they were required by their superiors to ask every single license holder to voluntarily surrender their licenses.

I explained that surrendering my license would not only directly impact my company's sales, but that it would also place me at an extreme competitive disadvantage with other distributors. I declined the offer to surrender my license.

Approximately two weeks ago, I ordered List 1 product from one of my suppliers. Apparently, our normal UPS driver was ill or off work that day, because the delivery was made at the old business address. The home owner called the supplier and the supplier said to ship the product back to them.

I learned of this when I called my supplier to inquire why I had not received my order. They told me that they could not ship product to my current business address until they had received written authorization to do so from the DEA. I immediately called DEA Agent Brian G. McClune (who along with Agent Mark E. Schilli had conducted the Dec. 2005 audit) and asked that he please do everything possible to expedite my change of address request.

Several days later he returned my call and advised that he and Agent Schilli would be in the Effingham area this week and would like to stop by. I received another call from Agent McClune Wenesday evening, March 8th advising that he and Agent Schilli would like to meet with me at 9:00 A.M the following morning at my business.

Immediately upon entering my office this morning, March 9th, Agent McClune advised that he was personally sorry but that he had been ordered by his superiors to suspend my license. He advised that he was unable to state his feelings in this matter, however that both he and Agent Schilli did not like having to do this but that they had no choice but to follow a Washington D.C. based DEA directive to revoke licenses.

They further stated that I was not being singled out in this matter but that the DEA goal, as part of this new directive, was to revoke licenses of all distributors who serviced "gray markets" (convenience stores, truck stops, etc.).

I stated the obvious, which was that this is a legal product, being sold legally at legitimate and legal retail outlets. They agreed, but restated the DEA's directive and objective to eliminate all such sales and to accomplish that by mass revocation of distributor licenses.

Congressman Shimkus, this action by the DEA will have a profound impact on my business and the businesses of hundreds of legal law abiding distributors and retailers. It will likely result in the failure and bankruptcy of my company and hundreds more.

It seems that the DEA chooses to bypass the Legislative Branch of our Government and by tactics of bullying, intimidation and bureaucratic entrapment, deny distribution and sales of a LEGAL product.

While I applaud their efforts in the ongoing war on illegal drugs, I am fearful of anyone or anything that uses such tactics to accomplish a goal. Call me old fashioned, but I still believe in The Constitution and The Bill of Rights.

Congressman Shimkus, I respectfully request that you assist me in this matter. These DEA tactics not only threaten the future of my business and home, but I feel they are a frightening indication of how easily the rights of law abiding citizens everywhere in this country can be trampled. Apparently, the DEA feels that the Legislative Branch of our Government, in which you honorably preside, is easily bypassed.

I respectfully and anxiously await your reply.

Sincerely,
David Habbe

David Habbe

JOHN M. SHIMKUS
19TH DISTRICT, ILLINOIS

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www.house.gov/shimkus

March 13, 2006

Mr. David L. Habbe
20201 N. 1150th Street
Effingham, IL 62401

Dear Mr. Habbe:

Thank you for contacting me about the problem you are having with the Drug Enforcement Administration (DEA).

I will be glad to assist you in every way I can. I have contacted the appropriate officials at DEA to express my interest on your behalf, and I will be back in touch with you as soon as I receive a response.

In the meantime, please feel free to contact me if I can be of further assistance.

Sincerely,

JOHN SHIMKUS
Member of Congress

JMS:dr

PRINTED ON RECYCLED PAPER

The New York Times
June 17, 2007
Cover Story
Doctor or Drug Pusher
By TINA ROSENBERG

Ronald McIver is a prisoner in a medium-security federal compound in Butner, N.C. He is 63 years old, of medium height and overweight, with a white Santa Claus beard, white hair and a calm, direct and intelligent manner. He is serving 30 years for drug trafficking, and so will likely live there the rest of his life. McIver (pronounced mi-KEE-ver) has not been convicted of drug trafficking in the classic sense. He is a doctor who for years treated patients suffering from chronic pain. At the Pain Therapy Center, his small storefront office not far from Main Street in Greenwood, S.C., he cracked backs, gave trigger-point injections and put patients through physical therapy. He administered ultrasound and gravity-inversion therapy and devised exercise regimens. And he wrote prescriptions for high doses of opioid drugs like OxyContin.

McIver was a particularly aggressive pain doctor. Pain can be measured only by how patients say they feel: on a scale from 0 to 10, a report of 0 signifies the absence of pain; 10 is unbearable pain. Many pain doctors will try to reduce a patient's pain to the level of 5. McIver tried for a 2. He prescribed more, and sooner, than most doctors.

Some of his patients sold their pills. Some abused them. One man, Larry Shealy, died with high doses of opioids that McIver had prescribed him in his bloodstream. In April 2005, McIver was convicted in federal court of one count of conspiracy to distribute controlled substances and eight counts of distribution. (He was also acquitted of six counts of distribution.) The jury also found that Shealy was killed by the drugs McIver prescribed. McIver is serving concurrent sentences of 20 years for distribution and 30 years for dispensing drugs that resulted in Shealy's death. His appeals to the U.S. Court of Appeals for the Fourth Circuit and the Supreme Court were rejected.

McIver's case is not simply the story of a narcotics conviction. It has enormous relevance to the lives of the one in five adult Americans who, according to a 2005 survey by Stanford University Medical

Center, ABC News and USA Today, reported they suffered from chronic pain — pain lasting for several months or longer. According to a 2003 study in The Journal of the American Medical Association, pain costs American workers more than $61 billion a year in lost productive time — and that doesn't include medical bills.

Contrary to the old saw, pain kills. A body in pain produces high levels of hormones that cause stress to the heart and lungs. Pain can cause blood pressure to spike, leading to heart attacks and strokes. Pain can also consume so much of the body's energy that the immune system degrades. Severe chronic pain sometimes leads to suicide. There are, of course, many ways to treat pain: some pain sufferers respond well to surgery, physical therapy, ultrasound, acupuncture, trigger-point injections, meditation or over-the-counter painkillers like Advil (ibuprofen) or Tylenol (acetaminophen). But for many people in severe chronic pain, an opioid (an opiumlike compound) like OxyContin, Dilaudid, Vicodin, Percocet, oxycodone, methadone or morphine is the only thing that allows them to get out of bed. Yet most doctors prescribe opioids conservatively, and many patients and their families are just as cautious as their doctors. Men, especially, will simply tough it out, reasoning that pain is better than addiction.

It's a false choice. Virtually everyone who takes opioids will become physically dependent on them, which means that withdrawal symptoms like nausea and sweats can occur if usage ends abruptly. But tapering off gradually allows most people to avoid those symptoms, and physical dependence is not the same thing as addiction. Addiction — which is defined by cravings, loss of control and a psychological compulsion to take a drug even when it is harmful — occurs in patients with a predisposition (biological or otherwise) to become addicted. At the very least, these include just below 10 percent of Americans, the number estimated by the United States Department of Health and Human Services to have active substance-abuse problems. Even a predisposition to addiction, however, doesn't mean a patient will become addicted to opioids. Vast numbers do not. Pain patients without prior abuse problems most likely run little risk. "Someone who has never abused alcohol or other drugs would be extremely unlikely to become addicted to opioid pain medicines, particularly if he or she is older," says Russell K. Portenoy, chairman of pain medicine and

palliative care at Beth Israel Medical Center in New York and a leading authority on the treatment of pain.

The other popular misconception is that a high dose of opioids is always a dangerous dose. Even many doctors assume it; but they are nonetheless incorrect. It is true that high doses can cause respiratory failure in people who are not already taking the drugs. But that same high dose will not cause respiratory failure in someone whose drug levels have been increased gradually over time, a process called titration. For individuals who are properly titrated and monitored, there is no ceiling on opioid dosage. In this sense, high-dose prescription opioids can be safer than taking high doses of aspirin, Tylenol or Advil, which cause organ damage in high doses, regardless of how those doses are administered. (Every year, an estimated 5,000 to 6,000 Americans die from gastrointestinal bleeding associated with drugs like ibuprofen or aspirin, according to a paper published in The American Journal of Gastroenterology.)

Still, doctors who put patients on long-term high-dose opioids must be very careful. They must monitor the patients often to ensure that the drugs are being used correctly and that side effects like constipation and mental cloudiness are not too severe. Doctors should also not automatically assume that if small doses aren't working, that high doses will — opioids don't help everyone. And research indicates that in some cases, high doses of opioids can lose their effectiveness and that some patients are better off if they take drug "holidays" or alternate between different medicines. Pain doctors also concede that more studies are needed to determine the safety of long-term opioid use.

But with careful treatment, many patients whose opioid levels are increased gradually can function well on high doses for years. "Dose alone says nothing about proper medical practice," Portenoy says. "Very few patients require doses that exceed even 200 milligrams of OxyContin on a daily basis. Having said this, pain specialists are very familiar with a subpopulation of patients who require higher doses to gain effect. I myself have several patients who take more than 1,000 milligrams of OxyContin or its equivalent every day. One is a high-functioning executive who is pain-free most of the time, and the others have a level of pain control that allows a reasonable quality of life."

All modern pain-management textbooks advocate "titration to effect" — in other words, in cases where opioids are helping, gradually increasing the dosage until either the pain is acceptably controlled or the side effects begin to outweigh the pain-relief benefits. But the vast majority of doctors don't practice what the textbooks counsel. In part, this is because of the stigma associated with high-dose opioids, the fear that patients will become addicted and the fact that careful monitoring is very time-consuming. And most doctors have received virtually no training in medical school about managing pain: many hold the same misconceptions about addiction and dosage as the general public.

And even pain specialists can be conservative. Sean E. Greenwood died in August at age 50 of a cerebral hemorrhage that his wife, Siobhan Reynolds, attributes to untreated pain. Greenwood was seeing various pain specialists. What makes his undertreatment especially remarkable is that he and his wife founded the Pain Relief Network, an advocacy group that has been the most vocal opponent of prosecutions of doctors and financed part of the legal defense of many pain doctors. "Here I am — I know everyone, and even I couldn't get him care that didn't first regard him as a potential criminal," Reynolds said.

According to the pharmaceutical research company IMS Health, prescriptions for opioids have risen over the past few years. They are used now more than ever before. Yet study after study has concluded that pain is still radically undertreated. The Stanford University Medical Center survey found that only 50 percent of chronic-pain sufferers who had spoken to a doctor about their pain got sufficient relief. According to the American Pain Society, an advocacy group, fewer than half of cancer patients in pain get adequate pain relief.

Several states are now preparing new opioid-dosing guidelines that may inadvertently worsen undertreatment. This year, the state of Washington advised nonspecialist doctors that daily opioid doses should not exceed the equivalent of 120 milligrams of oral morphine daily — for oxycodone or OxyContin, that's just 80 milligrams per day — without the patient's also consulting a pain specialist. Along with the guidelines, officials published a statewide directory of such specialists. It contains 12 names. "There are just

not enough pain specialists," says Scott M. Fishman, chief of pain medicine at the University of California at Davis and a past president of the American Academy of Pain Medicine. And the guidelines may keep nonspecialists from prescribing higher doses. "Many doctors will assume that if the state of Washington suggests this level of care, then it is unacceptable to proceed otherwise," Fishman says.

In addition to medical considerations real or imagined, there is another deterrent to opioid use: fear. According to the D.E.A., 71 doctors were arrested last year for crimes related to "diversion" — the leakage of prescription medicine into illegal drug markets. The D.E.A. also opened 735 investigations of doctors, and an investigation alone can be enough to put a doctor out of business, as doctors can lose their licenses and practices and have their homes, offices and cars seized even if no federal criminal charges are ever filed. Both figures — arrests and investigations — have risen steadily over the last few years.

Opioid drugs have been used to treat pain for decades, mostly for acute postsurgical pain or the pain of cancer patients. But in January 1996, Purdue Pharma helped increase the use of these drugs by introducing OxyContin — oxycodone with a time-release mechanism. Oncologists and pain doctors were the principal prescribers of opioids. But Purdue introduced the drug with an aggressive marketing campaign promoting OxyContin to general practitioners and the idea of opioid pain relief to doctors and consumers. The product's time-release mechanism, Purdue claimed, allowed steadier pain relief and deterred abuse.

Many pain sufferers found that OxyContin gave them better relief than they ever had before. But Purdue misrepresented the drug's potential for abuse. Last month, the company and three of its executives pleaded guilty to federal charges that they misled doctors and patients. The company agreed to pay $600 million in fines; and the executives, a total of $34.5 million. The pill's time-release mechanism turned out to be easily circumvented by crushing the pill and snorting or injecting the resulting powder. By the late 1990s, OxyContin abuse was devastating small towns throughout Appalachia and rural New England. Pharmaceuticals, mainly opioids, are still widely abused — now more so than any illegal drug except marijuana. In 2005, according to the

government's National Survey on Drug Use and Health, 6.4 million Americans, many of them teenagers, had abused pharmaceuticals recently. Most got the drug from friends or family — often, in the case of teenagers, from their parents' medicine cabinets.

At the time the OxyContin epidemic emerged, the D.E.A. had far more experience seizing illegal drugs like cocaine and heroin. According to Mark Caverly, the head of the liaison and policy section for the D.E.A.'s Office of Diversion Control, the OxyContin epidemic, however, required the agency to step up its antidiversion efforts. In 2001 the D.E.A. established the OxyContin Action Plan. The D.E.A. dispatched investigators to the most troubled states and trained local law-enforcement officials.

The basis of the physician-patient relationship is trust. Trust is especially valued by pain patients, who often have long experience of being treated like criminals or hysterics. But when prescribing opioids, a physician's trust is easily abused. Pain doctors dispense drugs with a high street value that are attractive to addicts. All pain doctors encounter scammers; some doctors estimate that as many as 20 percent of their patients are selling their medicine or are addicted to opioids or other drugs. Experts are virtually unanimous in agreeing that even addicts who are suffering pain can be successfully treated with opioids. Indeed, opioids can be lifesaving for addicts — witness the methadone maintenance therapy given to heroin addicts. But treating addicts requires extra care.

Identifying the scammers is especially tricky because there is no objective test for pain — it doesn't show up on an X-ray. In one British study, half the respondents who complained of lower-back pain had normal M.R.I.'s. Conversely, a third of those with no pain showed disk degeneration on their M.R.I.'s. The study suggested there could be a profound disconnection between what an M.R.I. sees and what a patient feels.

There are red flags that indicate possible abuse or diversion: patients who drive long distances to see the doctor, or ask for specific drugs by name, or claim to need more and more of them. But people with real pain also occasionally do these things. The doctor's dilemma is how to stop the diverters without condemning other patients to suffer unnecessarily, since a drug diverter and a legitimate patient can look very much alike. The dishonest

prescriber and the honest one can also look alike. Society has a parallel dilemma: how to stop drug-dealing doctors without discouraging real ones and worsening America's undertreatment of pain.

In July 2002, an insurance agent was sifting through records in Columbia, S.C., and paused at the file of one Larry Shealy. Shealy was getting OxyContin from a doctor named Ronald McIver — a lot of it. "The amounts were incredible; it jumped out in my face," the agent, who spoke on condition of anonymity, told me. "He was either selling them or taking so much he couldn't live." The agent did two things. He recommended to Shealy's employers that they exclude OxyContin coverage from their health insurance plan — which they did. And he called the D.E.A. Two days later, a D.E.A. agent showed up in the insurance agent's office with an administrative subpoena to collect Shealy's file.

McIver wanted to be a doctor all his life, two of his daughters told me. But he taught and traveled for years before he finally enrolled at Michigan State University to become a D.O., or doctor of osteopathy, a more holistic alternative to a traditional medical education. (Osteopaths can do everything that traditional M.D.'s can do, including prescribe opioids.) He began practicing pain medicine in the late 1980s. He had a practice in Florence, S.C., which ended when he declared bankruptcy in 2000. He moved to Greenwood to start over, establishing his new office in a storefront next to a chiropractor.

McIver was, by the account of his patients, an unusual doctor in the age of the 10-minute managed-care visit. He usually saw about 6 to 12 patients each day. One patient I spoke with — who never got high-dose opioids — said that his first visit with McIver lasted four hours, and in subsequent visits he spent an hour or more doing various therapies. Many patients said their visits lasted an hour. Patients taking opioids had to sign a pain contract and bring their pills in at each visit to be counted.

Many doctors take little interest in the administrative side of their practices, but McIver's neglect was epic. To save money, he employed mostly family. His wife, Carolyn, whose only medical training was from her husband, served as his assistant, giving shots and administering therapies. "His doctor's office did not resemble

my family's doctor's office," said Sgt. Bobby Grogan, who was the investigator on the case for the Greenwood County Sheriff. While McIver's treatment rooms were normal, his and his wife's offices — off limits to patients — were a mess, according to pictures presented at McIver's trial by Adam Roberson, the D.E.A.'s principal investigator. Used syringes, for example, overflowed their storage box. "His patient records were manila envelopes stuffed with receipts," Grogan told me.

When I interviewed him in prison recently, McIver told me that his records were complete but scattered. He said that he and his wife, distracted by a series of family tragedies, had employed a series of temporary receptionists who had botched the filing. He and his wife were trying to piece them together. "The records were probably half in the office and half at home for me to work on at night," he said. "I kept a box in the back of the car I worked on while Carolyn drove."

Leslie Smith first came to see McIver in the fall of 2001. Smith was in his mid-40s and lived in Chapin, a small town near Columbia, a 60-mile drive from Greenwood. He filled out a medical-history form and told McIver that his wrists hurt so badly that he was getting only three or four hours' sleep a night. He also said that a previous doctor helped him by prescribing OxyContin, and he mentioned the name of a doctor he said referred him. McIver examined Smith's wrists. Smith walked out with an opioid prescription and an appointment to come back the next week.

Smith's wrists did not hurt him, as he testified at McIver's trial. He was addicted to OxyContin and Dilaudid, which he injected. He complained of wrist pain because it was plausible: he had injured one wrist previously, requiring an operation that left scars, and he had arthritis in the other. Until June 2002, Smith kept getting prescriptions.

Smith saw McIver every few weeks. He testified that he had track marks on his arm at the time but always wore long sleeves to cover them. He said McIver never saw them. McIver put him on an electric nerve stimulator every visit for 15 or 30 minutes on each hand and did osteopathic manipulations. He prescribed exercises. Smith bought a nerve-stimulator machine to use at home and told McIver it was helping. At McIver's request he filled out a pain chart and

reported that his pain rated a 5 or 6 upon awakening, reached 7 during the day and occasionally hit 9. "I answered all the questions exactly like I thought he'd want to hear them answered," Smith testified. At one point McIver found a syringe in Smith's pocket. Smith told McIver that he was going fishing later that day and that he used the syringe as part of his fishing equipment. That apparently satisfied McIver, who testified that his grandfather kept syringes in his tackle box to pump air into his bait.

Smith filled some of his prescriptions at the Hawthorne Pharmacy in West Columbia. There, Addison Livingston, the pharmacist, got suspicious. He noticed that Smith sometimes came in with other patients of McIver's, despite the fact that McIver worked nearly two hours' drive away. The patients obviously knew each other and would pick up large opioid prescriptions, paying cash and asking for brand-name drugs. Livingston called McIver, who confirmed he had written the prescriptions. At one point, McIver told Livingston that he, too, was suspicious, and that he had sent a letter about Smith to the state's Bureau of Drug Control.

In February 2002, McIver wrote to Larry McElrath, a B.D.C. inspector, who read the letter at the trial. "Dear Larry," it read, "There are several people out of the Columbia/Chapin area who have aroused my curiosity about their use and possible misuse of medications. Some are referred by [another doctor] and seem legitimate. . . . They all pay cash despite some of them having insurance with prescription cards. . . . When they are in the office, they sometimes make a show of not knowing each other. . . . The situation is made complicated by the fact that each has some real pathology with objective findings that would justify the use of opiates if their pains are as bad as they say. I have given them the benefit of the doubt, but I'm becoming less inclined to do so. I would appreciate it if you could make some discrete inquiries and let me know whether my concerns are justified. . . . I certainly don't want to refuse help to someone who needs it. On the other hand, I want even less to be implicated in diversion or other improprieties." He listed their names and Social Security numbers.

McElrath did nothing with the letter. "It's incumbent upon the physician to have a trust with his patients," McElrath testified at the trial. "Here there was nothing that I could assume or conclude that any crimes had been committed."

Smith was the most damning of the several patients who testified against McIver. (Smith and the other patients mentioned here did not agree to be interviewed for this article, as they are suing McIver for alleged overprescription of addictive drugs. Such suits often prosper after successful criminal convictions, as civil suits are easier to win.) Smith had a confederate in Seth Boyer, who lived in Chapin and followed a similar pattern in his dealings with McIver: he exaggerated pains in his foot, never provided records from a previous doctor and had needle tracks that he later testified McIver never saw. At one point, Boyer told McIver that he had spilled a bottle of liquid OxyFast, another opioid. (In reality, Boyer had injected it.) McIver wrote him a prescription for a replacement — apparently a violation of his standard pain-medication contract, which had a "no early refills" stipulation.

But McIver ended up discharging Boyer in June 2002, when Boyer altered a prescription so he could fill it three days early. He wrote McIver three pleading letters of protest, to no avail. "I was looking for an excuse to discharge them, and with Seth I found it," McIver told me. "I needed more than suspicion. With Les, he never actually did anything that allowed me to say, 'O.K., here's that concrete piece of evidence.' "

McIver may have felt he needed more proof, but medically he probably had enough. Pain specialists told me that doctors can stop prescribing a drug whenever the risks outweigh the benefits, which includes the risk of abuse.

Another drug-dealing patient of McIver's was Kyle Barnes. She testified that she suffered from fibromyalgia, a chronic-pain syndrome, but exaggerated her pain to get higher levels of OxyContin and Roxicodone. She was addicted to those drugs before she began seeing McIver in July 2001. She also brought no medical records and drove three hours to each appointment. She got prescriptions on her second visit, during which McIver also did osteopathic manipulations and massage.

Barnes was in real pain. McIver did several different therapies at each visit. He set up an appointment for her at a sleep clinic, sent her for X-rays and put a cast on her wrist. He knew she had trouble paying for her medicines, and he contacted Purdue Pharma to see if

she qualified for reduced-price drugs. She kept claiming the drugs were not helping enough and was soon taking 16 times the dose of OxyContin she took when she first saw him. One tip-off in her case should have been that she paid thousands of dollars a month in cash for her prescriptions, even though she was on Medicaid. She told McIver that her father and boyfriend were helping her buy them, which she later testified was partly true. But most of her income came from selling some of the drugs he prescribed, she testified. In December 2003, McIver told her that he would stop treating her unless she took a drug screen. She did nothing. Three weeks later he told her again. She never returned.

Another patient whose story was particularly troubling was Barbee Brown. Brown was not a drug seeker but a genuine pain patient seeking relief from Reflex Sympathetic Dystrophy. McIver gave her very high doses of OxyContin right away, before she produced any records from other doctors. This was especially disturbing, because she had been addicted to crack cocaine for three months in the year before she came to him.

Brown saw McIver at least twice a week for six weeks. He did a thorough physical exam and took a complete history. He used many different kinds of therapies. But he also started her — someone who had never taken opioids — on 40-milligram pills of OxyContin and allowed her to control her own dosing schedule. "As long as you are not having side effects, do not be afraid to take the doses you need to get out of pain," he wrote to her. It was the same advice he gave many patients. "The number of milligrams does not matter. What matters is the number on the 0-to-10 scale."

The medicine helped. Brown testified that she ranked her pain at 9 or 10 when she first got to McIver. After seeing him, it dropped to a 4. Her pain diary, which appears to be sincere, had various passages giving thanks that she met McIver. Brown did not become addicted. But allowing an opioid-naïve recovering crack addict to start on high-dose pills and control her own dosage, and telling her that her dosage didn't matter, seems reckless.

McIver's 30-year sentence was the result of the death of Larry Shealy, a 56-year-old man who suffered intense back and knee pain, in addition to many other health problems. He first came to see McIver in February 2002, with full referrals and records. He was

on OxyContin before seeing McIver but complained that his pain was still terrible, so McIver doubled his dose. This allowed Shealy to go back to work in an auto body shop.

Shealy was not a careful patient. A month after he started with McIver, he took 15 OxyContin tablets in one day instead of the 6 he was prescribed. He was not harmed, but McIver testified that he asked Shealy to bring his family in so he could explain the dosing to them. At one point, McIver tried to taper down the OxyContin and replace it with methadone, but Shealy complained that the methadone made him drowsy. Shealy's son, David, an auto mechanic, testified that the OxyContin pain relief also came at a price. He said he felt his father was overmedicated — often sleepy. Once, his father backed his truck into a tree.

Shealy died in his sleep early on the morning of May 29, 2003. He had OxyContin pills in his stomach, and his bloodstream contained alprazolam — Xanax — as well. The pathologist at McIver's trial testified that the levels of drugs were consistent with the prescriptions McIver had been writing — the high levels that so alarmed the insurance agent. Shealy was taking five 80-milligram tablets of OxyContin every 12 hours, plus up to six 30-milligram tablets of Roxicodone every 4 hours for breakthrough pain, plus as much as 2 milligrams of alprazolam every 8 hours. The prosecution's toxicologist, Demi Garvin, concluded that the OxyContin and Roxicodone caused Shealy's death by respiratory depression. The pathologist testified that she looked up this dosage and found it to be a fatal level.

But there is reason for doubt. According to Shealy's prescriptions, he had been taking the same dosage for at least two months, and possibly much longer. Pain specialists say that respiratory depression is extremely unlikely when dosage is consistent. In her testimony, Garvin agreed that what would be a toxic level in an opioid-naïve patient would be safe for someone titrated up properly. But she said she could not conclude he had been properly titrated, in part because she had not seen his medical records. Garvin declined to talk about the Shealy case with me because she is a witness for the Shealy family in their planned civil suit against McIver. But in a deposition for that lawsuit, she appeared to back away from blaming the OxyContin. She described her view as: "Hey,

there's a red flag here. This can certainly be your cause of death, but you need to go further in exploring whether or not it is."

There was something else that might have caused Shealy's death: he suffered from advanced congestive heart failure. The pathologist testified that he had 90 percent blockage in one coronary artery and 50 percent in another, and a greatly enlarged heart and other organs. He had a scar on the back wall of his heart that indicated he at one time suffered a heart attack. Opioids do not worsen heart disease and would likely have helped, because pain causes stress to the heart.

The testimonies of the patients Smith, Boyer and Barnes were the parts of the trial that most directly addressed the question of whether McIver intentionally wrote prescriptions for a nonmedical purpose. This is the relevant legal test for the statute under which he was prosecuted. Several Supreme Court and district court cases have made it clear that under the Controlled Substances Act, a doctor is guilty of a crime if he intentionally acts as a drug pusher.

The judge in the McIver case, Henry F. Floyd, told the jurors that bad prescribing is the standard for malpractice, a civil matter. "That is not what we are talking about," he said. "We're not talking about this physician acting better or worse than other physicians." If McIver was a bad doctor — but still a doctor, with intent to treat patients — he was innocent. "If you find that a defendant acted in good faith in dispensing the drugs charged in this indictment, then you must find that defendant not guilty," Floyd said. But Floyd also told the jury to take bad doctoring into account in deciding McIver's intent.

This instruction — that bad doctoring does not prove intent but could be considered when weighing his intent — is subtle and potentially extremely confusing. It apparently confused the jurors. I spoke to two jurors, who told me their own views and characterized the jury discussion. The overwhelming factor, they said, was that McIver prescribed too much — the very red flag that alerted the insurance agent and set the case in motion.

The jurors I spoke with said that by far the most important testimony came from Steven Storick, a pain-management doctor in Columbia and the government's expert witness. Reviewing the

records of patient after patient, Storick consistently testified that there were too many drugs. "This amount of medication is just extremely high in a situation like this," he said of one patient. This is "excessive," he said of another. "That's just an extremely high dose of drug," he said of a third. Storick, who declined to be interviewed for this article, testified that if he had a patient who exhibited no objective evidence of pain, he would not prescribe opioids. He would not have titrated patients as rapidly as McIver did or given them discretion. He disagreed with McIver's position that a doctor should try to bring a patient's chronic pain down to a level of 2. He would stop titrating when a patient reached 5 out of 10.

The jurors took Storick's caution to heart, in part, they told me, because it resonated with their own experience with opioids and fears of addiction. I asked Jo Handy, a tall, elegant woman who is now 39 and a real estate agent outside Greenville, why McIver was convicted. "It was the excessive prescriptions," she said in an interview in her office. "Excessive, and the number of them. I've been on some pain medication. But along with some other jurors we were, like, 'No — it's too much.' "

Handy said she knew McIver's treatment was excessive because Storick said so, and because of her own experience. "Thirty counts is normal," she said. "He was giving 60 or 90. A few of us had been on prescribed medicine. I had female issues. You as a person know not to take so much of that medication. If you were, you had a motive. Me, I still have a whole bottle left."

Christopher Poore, another juror, agreed that what swayed the jury was the volume of drugs prescribed. "The jury kept going back to the expert testimony of the prosecution's expert," he told me when I met him in Anderson, a town 40 minutes from Greenwood. "It was beyond. It was too much." What should McIver have done, I asked, if he wanted to avoid jail? "He should have followed the convention more of what people are doing with pain medicine — not giving so much," Poore said.

Poore, who is 40 and runs his family's heating and cooling business, described himself as the juror most skeptical of the prosecution's case. "There was another guy on the jury who said his sister-in-law had been taking pain pills and she had gotten addicted," Poore said. "He said I was taking up for McIver. I said, No,

I'm taking up for you and me and anyone else who's on trial. I wanted to see rules, that this guy broke the rule. I never saw a rule he broke."

In the end Poore voted to convict. As is always the case, the jurors were dismissed before McIver was sentenced. Poore told me he supposed McIver was in prison. When I said McIver was serving 30 years, he looked shocked.

Interviews with jurors and the judge's sentencing decision indicated that photos of the messy conditions in McIver's and Carolyn's private offices also contributed to the impression that he was not a real doctor. Surprisingly, McIver's contacts with law enforcement — the letter about Smith and the others was one of several — helped the prosecution's case. "He called an officer about a patient," John P. Flannery II, McIver's appellate lawyer, explained to me. "There is no response. He gets zero. He took their silence as a sign everything was O.K. They take that as knowledge of drug dealing." It mattered: the Fourth Circuit's opinion rejecting McIver's appeal said, "That Appellant knew or suspected his patients of drug abuse is reflected by the fact that he wrote to state authorities to express concern that his patients might be selling their medication."

I asked Grogan, the local diversion investigator on the case, why he didn't follow up on McIver's suspicions. "I'm a cop, not a doctor," Grogan said. "I can't say to prescribe medication or not. How do I know he's not trying to fish me for information?"

"He doesn't have to call us to cut someone off," Mike Frederick, the chief deputy at the sheriff's office, told me. "This is no different than when regular illegal drug dealers will very often call us about other drug dealers. He did it most likely because he thought that person was a risk."

I had assumed that McIver's use of many different types of therapies would help his case, by showing he was not running a classic pill mill. But it may have hurt. During the appeal, the prosecutor William Lucius argued that the other treatments represented the profits of drug diversion. He addicted patients with high doses of opioids, Lucius contended, "so they would continue to come back to him" and "he could charge them for the treatments he gave."

How typical is McIver's case? On the D.E.A.'s Web site the agency lists some of the doctors who have been prosecuted, and their crimes. There are some strikingly obvious and egregious cases of shady dealings: a doctor who wrote prescriptions in a gas station for a person who wasn't present; one who sold blank prescription forms; one who dispensed drugs to people who then shared them with him.

But not every doctor's intent to deal drugs is as clear. McIver was a crusader for high-dose opioids, credulous with patients and sloppy with documentation — a combination unwise in the extreme. But some of his patients said he was the only doctor who ever brought them relief. Prosecutors never brought any evidence that he intended to write prescriptions to be abused or sold. They never accused him of profiting from his patients' diversion except in collecting office fees. His patients who diverted or abused their opioids all testified they got their prescriptions by consistently lying to him. Nor is it convincing that his prescriptions killed Larry Shealy.

No one has analyzed the various prosecutions of pain doctors, so it is hard to determine how many of them look like McIver's. The D.E.A.'s list is incomplete. There have been many cases like McIver's, and most of these cases are not listed on the D.E.A.'s Web site. (One possible reason for this omission is that some of these cases are still being appealed.) And many cases that do appear on the list detail only vague crimes: convictions for prescribing "beyond the bounds of acceptable medical practice" or "dispensing controlled substances . . . with no legitimate medical purpose" — which is how the agency will most likely describe the McIver case if it ever includes the case on the list.

The D.E.A. claims that it is not criminalizing bad medical decisions. For a prosecutable case, Caverly, the D.E.A. officer, told me: "I need there to be no connection of the drug with a legitimate medical condition. I need the doctor to have prescribed the drug in exchange for an illegal drug, or sex, or just sold the prescription or wrote prescriptions for patients they have never seen, or made up a name."

I read this statement to Jennifer Bolen, a former federal prosecutor in drug-diversion cases who trained other prosecutors and now

advises doctors on the law. "That's a good goal," she said. "I don't think they have yet reached that goal." McIver's case had no such broken connection, and in many cases the government has not produced testimony of intent to push drugs, providing evidence only of negligence or recklessness. In 2002, Bolen was one of the authors of a Justice Department document intended as part of a basic guide to prosecuting drug-diversion cases. The document, in the form of a reference card, dispenses with any need for a broken connection. It suggests that prosecutors need not prove a doctor had bad motives, that to be within the law a doctor had to prescribe "in strict compliance with generally accepted medical guidelines" and that doing an abbreviated medical history or physical examination is "probative" of lack of a legitimate medical purpose. The reference card was on the Justice Department's Web site but was pulled, according to the Pain Relief Network, which provided the card to me. Bolen told me: "I have no problem saying that if the card was all there was, it was not acceptable. But it isn't all there was." She described the card as one piece of a more thorough training, but added that many prosecutors followed its theories.

Prosecutors are in essence pressing jurors to decide whether an extra 40 milligrams every four hours or a failure to X-ray is enough to send a doctor to prison for the rest of his life. One doctor, Frank Fisher, was arrested on charges that included the death of a patient taking opioids — who died as a passenger in a car accident. A Florida doctor, James Graves, is serving 63 years for charges including manslaughter after four patients overdosed on OxyContin he prescribed — all either crushed and injected their OxyContin or mixed it with alcohol or other drugs. "A lot of doctors are looking for safe harbor," Caverly said. "They want to know as long as they do A, B, C, D or E, they're O.K."

The D.E.A. once thought that this was not an unreasonable desire. A few years ago, it worked with pain doctors to develop a set of frequently asked questions that set out what doctors needed to do to stay within the law. The FAQ recommended, for example, that doctors should do urine tests and discuss a patient's treatment with family and friends. In October 2004, the FAQ were erased from the agency's Web site. One reason was that one of their authors, who is a doctor, was about to use the list to testify on behalf of William Hurwitz, a pain doctor in McLean, Va. (Hurwitz was convicted on 50 counts of drug trafficking in 2004. His conviction was overturned,

and he was recently retried and convicted on 16 lesser counts. He is awaiting sentencing.)

Caverly acknowledged the Hurwitz trial was one reason the FAQ were pulled, but said there were other reasons. He said such a checkoff list could tie the D.E.A.'s hands. "Some doctor's going to pull that list of dos or don'ts out and say: 'See, I'm O.K. I did these 10.' But there's a new wrinkle there — an 11th one the doctor didn't do," he said. Most important, he went on to say, the FAQ had stepped over the line to insert the D.E.A. into issues of medical practice. "We have to stay in our lane," he said. "Those definitions are the professional community's — not the D.E.A.'s."

In a perfect world, such reasoning would make sense. But the agency is defining issues of medical practice in dramatic fashion — by jailing doctors who step over the line. It would not seem to be bothering, however, to draw the line first.

The dilemma of preventing diversion without discouraging pain care is part of a larger problem: pain is discussed amid a swirl of ignorance and myth. Howard Heit, a pain and addiction specialist in Fairfax, Va., told me: "If we take the fact that 10 percent of the population has the disease of addiction, and if we say that pain is the most common presentation to a doctor's office, please tell me why the interface of pain and addiction is not part of the core curriculum of health care training in the United States?" Will Rowe, the executive director of the American Pain Foundation, notes that "pain education is still barely on the radar in most medical schools."

The public also needs education. Misconception reigns: that addiction is inevitable, that pain is harmless, that suffering has redemptive power, that pain medicine is for sissies, that sufferers are just faking. Many law-enforcement officers are as in the dark as the general public. Very few cities and only one state police force have officers who specialize in prescription-drug cases. Charles Cichon, executive director of the National Association of Drug Diversion Investigators (Naddi), says that Naddi offers just about the only training on prescription drugs and reaches only a small percentage of those who end up investigating diversion. I asked if, absent Naddi training, officers would understand such basics as the whether there is a ceiling dose for opioids. "Probably not," he said.

There is another factor that might encourage overzealous prosecution: Local police can use these cases to finance further investigations. A doctor's possessions can be seized as drug profits, and as much as 80 percent can go back to the local police.

There are ways to prevent diversion without imprisoning doctors who have shown no illegal intent. They are increasingly used — but state authorities and doctors need to push even harder. The majority of states, South Carolina among them, do not yet have prescription monitoring — a central registry of prescriptions, which could help catch people getting opioids from several different doctors and pharmacies. Doctors should use more urine and blood tests, including screens that can tell quantities of drug present.

Last year, state medical boards took 473 actions against doctors for misdeeds involving prescribing controlled substances. In many cases, their licenses were pulled. Physicians can also lose their D.E.A. registration, and with it the right to prescribe controlled substances. A few dozen do every year, although there is considerable overlap with medical-board actions. Washington is the first state to recommend that only pain specialists handle high-dose opioids; other states are likely to follow.

But such guidelines are futile while there is one pain specialist for, at the very least, every several thousand chronic-pain sufferers nationwide. And even though pain is an exciting new specialty, doctors are not flocking to it. The Federation of State Medical Boards calls "fear among physicians that they will be investigated, or even arrested, for prescribing controlled substances for pain" one of the two most important barriers to pain treatment, alongside lack of understanding. Various surveys of physicians have shown that this fear is widespread. "The bottom line is, doctors say they don't need this," said Heit. "They're in a health care system that wants them to see a patient every 10 to 15 minutes. They don't have time to take a complete history about whether the patient has been addicted. The fear is very real and palpable that if they prescribe Schedule II opioids they will come under the scrutiny of the D.E.A., and they don't need this aggravation."

Proper pain management will always take time, but the D.E.A. can at least ensure that honest doctors need not fear prison. It should use the standard it claims to follow: for a criminal prosecution to occur,

a doctor must have broken the link between the opioid and the medical condition. If the evidence is of recklessness alone, then it should be a case for a state medical board, the D.E.A.'s registration examiners or a civil malpractice jury.

Undoubtedly, such a limit will allow a small group of pill-mill doctors to escape prison. But America lives with freeing suspects whose possible crimes are discovered through warrantless searches or torture — and unlike other suspects, doctors who lose their licenses are as incapacitated as those behind bars. For cases without the broken connection, prosecution is too blunt an instrument. It runs too high a risk of condemning innocent physicians to prison and discourages the practice of a medical specialty desperately needed by millions of Americans.

Pain patients are the collateral victims here. It is worth remembering that the vast majority of McIver's patients were not people who abused or sold their medicines. One of those who didn't was a man named Ben, a tall, heavy man in his 50s who lives about 45 minutes from Greenwood. (He asked that his last name not be used because of the stigma still attached to taking opioid drugs.) Ben was once a mail carrier and a farmer and cattle rancher. But years of pushing 800-pound bales of hay wore out his back. In 2001 he had an operation to fuse the bottom three vertebrae. The few Vicodin his neurosurgeon prescribed did not control his pain. "I never had enough to get me through the night," he said. "He wasn't going to go any further than Vicodin — and he was doing me a favor by doing that, because his other partners wouldn't have done as much as he did." His neurosurgeon recommended he find a pain doctor. He started seeing McIver. The first examination, Ben said over coffee in a local Waffle House, was "extremely thorough — he had me crying. I hardly ever got out of there in less than two hours — he would be on top of me popping my back."

And he got opioids. With his typical imprudence, McIver told Ben: "You don't worry about it, take whatever you need to be pain-free, if it takes 2 pills or 10 pills. If you're taking too much and slurring your words, you know to back off. Use some common sense." At McIver's request, Ben kept a diary of what he took and how much. He reached a top dosage of five 80-milligram pills of OxyContin four times a day — more opioids than Shealy was taking at the time of his death. "I never felt high," he said. "They helped my pain. I

could get out and work, use the bulldozer. I was working a 250-head cattle herd. I was doing everything relatively pain-free because of the drugs. They gave me my life back."

When McIver was closed down, Ben was lucky enough to have a family physician he knew well who took over his case. But the new doctor took a very different approach. Ben now gets three 80-milligram pills of OxyContin a day, plus some breakthrough Roxicodone and 800 milligrams of Advil every four to six hours. "That's it and I'm very, very lucky to have it," he said. "My doctor is afraid they will say it's over the limit. I now get about three hours' sleep a night. I can stand for 30 minutes, maybe." He can no longer handle ranching and has sold his cattle. He considers himself retired.

With Ben's permission I talked to his current doctor, who said Ben was a good patient but had been taking way too much. "I thought Ben made an error," he said. "He had been taking five or six times the recommended dosage. There are well-recognized levels, and you don't step across the line. You may have to live with some pain."

Opioids have immense power — both to harm and to heal. They can be life-destroying, but high doses allowed Ben to work, to be with his family, to be who he is. In its prosecutions of pain doctors, the government fails to recognize the duality of these drugs. Ben's wife told me: "When Ben first went to Dr. McIver and filled out the form on what he used to be able to do and what he could do now, he cried. McIver said to him, 'I'm going to get you back to doing what you used to do.' And he did."

Tina Rosenberg is a contributing writer for the magazine.

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U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

March 7, 2008

The Honorable John Conyers, Jr.
Chairman
Committee on the Judiciary
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Please find enclosed a response to questions arising from the appearance of Drug Enforcement Administration Deputy Assistant Administrator Joseph Rannazzisi before the Committee on July 12, 2007, at a hearing entitled "The Drug Enforcement Administration's Regulation of Medicine".

We hope that this information is of assistance to the Committee. Please do not hesitate to call upon us if we may be of additional assistance. The Office of Management and Budget has advised us that from the perspective of the Administration's program, there is no objection to submission of this letter.

Sincerely,

Brian A. Benczkowski
Principal Deputy Assistant Attorney General

Cc: The Honorable Lamar S. Smith
Ranking Member

"The Drug Enforcement Administration's Regulation of Medicine"

July 12, 2007

Questions for the Hearing Record
for
Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration

1. **The Drug Enforcement Administration and the Food and Drug Administration are both involved in the approval of cannabis research (and researchers) prior to the issuance by DEA of a Schedule I registration. There seemed to be some confusion as to what this process is. Please describe in detail the process a would-be researcher must go through before DEA issues the registration and explain at each step what would prohibit the process from continuing.**

RESPONSE:

The Controlled Substances Act (CSA) allows for bona fide research to be conducted on any schedule I controlled substance provided the researcher has obtained a registration from DEA authorizing such activity. The statutory criteria for obtaining a registration, including the role of the Secretary of Health and Human Services (HHS), are set forth in 21 U.S.C. § 823 (f). Among other things, the statute requires the researcher to submit a research protocol. The required contents of the research protocol are specified in the DEA regulations (21 C.F.R. § 1301.18). A detailed description of the process by which DEA acts on applications for registration with schedule I controlled substances is also set forth in the DEA regulations (21 C.F.R. § 1301.32). In sum, the Secretary of HHS is responsible for evaluating the qualifications and competency of the researcher and the merits of the research protocol, and DEA is responsible for ensuring that the researcher will provide adequate controls against diversion and otherwise comply with the CSA and DEA regulations. An application may be denied if: the applicant fails to meet any of the foregoing requirements; the Secretary for HHS finds the qualifications and competency of the researcher, or the merits of the research protocol, to be lacking; or DEA determines that the researcher has failed to demonstrate that he/she will maintain effective control against diversion. If DEA seeks to deny the application for any reason, it must serve the applicant with an Order to Show Cause, affording the applicant the opportunity for a hearing in accordance with the Administrative Procedure Act, 21 U.S.C. § 824(c).

2. **During the hearing, testimony was offered that indicated investigations of pain management doctors and other doctors by DEA have caused concern that physicians who practice in this area of medicine are being targeted despite the service they provide to a number of pain sufferers. Does DEA believe this characterization is correct, and what is the process DEA uses to identify and**

investigate doctors whose practices dispense large quantities of opioids and other pain relievers?

RESPONSE:

The characterization that the DEA "targets" physicians simply because they practice pain management is false and does disservice to those doctors acting professionally. The overwhelming majority of prescribing done by physicians in America is conducted responsibly. Often it is these doctors and pharmacists who dispense the medication who are the first to alert law enforcement to potential prescription problems. However, the small number of physicians who over prescribe controlled substances—carelessly at best, knowingly at worst—help supply America's second most widespread drug addiction problem. Although the problem exists, the number of physicians and pharmacists responsible for this problem is a very small fraction of those registered with DEA to prescribe and dispense controlled substances in the United States.

DEA's obligation under the law and to the public is to ensure that pharmaceutical controlled substances are prescribed and dispensed only for legitimate medical purposes. By carrying out this obligation, DEA strives to minimize the diversion of pharmaceutical controlled substances for abuse while ensuring that such medications are fully available to patients in accordance with the sound medical judgments of their physicians. In this manner, DEA is committed to balancing the need for prevention, education, and enforcement with the need for legitimate access to these drugs.

DEA investigates complaints against registrants for potential criminal and administrative violations. Sources of those complaints include state medical boards, patients, pharmacists, or employees of the doctor. If an investigation reveals possible criminal or civil violations of the CSA, DEA refers the matter to the United States Attorney's Office for further review and whatever action that office deems appropriate. In addition, if DEA determines that there is a statutory basis under the CSA to revoke a practitioner's registration, the agency has the discretion to initiate such proceedings. If DEA seeks to revoke a practitioner's registration for any reason, it must serve him/her with an Order to Show Cause, affording the applicant the opportunity for a hearing in accordance with the Administrative Procedure Act, 21 U.S.C. 824(c).

DEA is also charged with registering companies, pharmacies, and physicians who handle or dispense controlled substances. Those who are registered to conduct this activity must meet and continue to meet various regulations that are set forth in the Code of Federal Regulations.

DEA continues to work closely with the state medical boards and their affiliated organizations to alleviate any possible remaining misconceptions about how DEA carries out its administrative duties under the CSA. As stated in the 2006 *Synthetic Drug Control Strategy,* the Administration is committed to balancing the need for prevention, education, and enforcement with the need for legitimate access to pharmaceutical controlled substances.

3. **During the hearing, statements were made that it was inappropriate for DEA to investigate doctors, and that doing so was the equivalent of 'regulating medicine.'**

Why does the DEA investigate and engage in the prosecution of pain management practitioners and others in the medical profession, when established state medical boards exist to monitor and punish ethical violations of medical practice?

RESPONSE:

Please note that DEA addressed this issue in its September 6, 2006, Policy Statement published in the Federal Register. As stated therein:

> DEA is the agency within the Department of Justice responsible for carrying out the functions assigned to the Attorney General under the CSA. These functions include enforcing and administering the CSA provisions governing the prescribing, administering, and dispensing of controlled substances. Thus, the scope of DEA's authority is delineated by the extent to which Congress itself regulated controlled substances through the enactment of the CSA and assigned certain functions under the Act to the Attorney General.
>
> While the CSA is one component of the overall regulation of the practice of medicine in the United States, it bears emphasis that the CSA does not regulate the practice of medicine as a whole. Therefore, although DEA is the agency responsible for administering the CSA, DEA does not act as the federal equivalent of a state medical board overseeing the general practice of medicine. State laws and State licensing bodies (such as medical licensing boards) collectively regulate the practice of medicine. In contrast, the scope of the CSA (and therefore role of DEA) is much narrower. The CSA regulates only the segment of medical practice involving the use of controlled substances, and DEA is correspondingly responsible for ensuring that controlled substances are used in compliance with federal law.
>
> In particular, DEA's role under the CSA is to ensure that controlled substances are prescribed, administered, and dispensed only for legitimate medical purposes by DEA-registered practitioners acting in the usual course of professional practice and otherwise in accordance with the CSA and DEA regulations. Each state also has its own laws (administered by state agencies) requiring that a prescription for a controlled substance be issued only for a legitimate medical purpose by state-licensed practitioners acting in the usual course of professional practice.
>
> There is nothing new in this arrangement of responsibilities between the federal and state governments. For more than 90 years (starting with the Harrison Narcotic Act of 1914, which was superseded by the CSA in 1970) federal law has placed certain restrictions on the medical use of federally controlled substances while, at the same time, the states have regulated the practice of medicine generally. In this respect, there has long been a certain amount of overlap between the federal and state oversight of controlled substances.

Beginning in the 1930s and through to the present, states have adopted uniform controlled substance laws that were designed to promote standards that are consistent from state to state and in harmony with federal law. One such standard that has always been a fundamental part of these uniform state laws is the requirement that controlled substances be dispensed only for legitimate medical purpose by a practitioner acting in the usual course of professional practice – a requirement first articulated in the Harrison Narcotic Act. Accordingly, it has been the case for more than 70 years that a practitioner, who dispenses controlled substauces for other than a legitimate medical purpose, or outside the usual course of professional practice, is subject to legal liability under both state and federal law.

4. **On May 15, DEA Administrative Law Judge Mary Ellen Bittner formally transmitted her recommendation to DEA Depnty Administrator Michele Leonhart in which she found that it is "in the public interest" to end the federal monopoly on the supply of marijuana that can be used in FDA-approved research, held by the National Institute on Drug Abuse (NIDA). Following nine days of hearings, testimony, and evidence from both sides, including from researchers who reported that the government denied their reqnests for marijuana for use in FDA-approved research protocols, Judge Bittner concluded that, "NIDA's system for evaluating requests for marijuana has resulted in some researchers who hold DEA registrations and requisite approval from [HHS and FDA] being unable to conduct their research because NIDA has refused to provide them with marijuana. I, therefore, find that the existing supply is not adequate." She added, "Respondent's registration to cultivate marijuana would be in the public interest."**

Despite this endorsement by the one neutral arbiter assigned to examine the case and despite the fact that it has been more than six years since the University of Massachusetts initially filed its application, the DEA has yet to grant the license in accordance with the recommendation. With these facts in mind, I would like to know how long it usually takes the DEA to act on a recommendation from an administrative law judge. Could you please provide me with a list of all recommendations made by administrative law judges in the DEA since January 20, 2001, along with the dates on which they were transmitted to final decision-makers at the DEA and the dates on which the recommendations were officially either followed or rejected through a final decision on the matter?

Also, when can we anticipate a decision in this case? If the decision can be anticipated to require more time than the average time required in the reply to the first question, please state the reason. In addition, can you give us a commitment that the decision will be made during this Administration?

RESPONSE:

Please see attached chart.

5. **In his written testimony of Joseph T. Rannazzisi, DEA Deputy Assistant Administrator, Office of Diversion Control, stated, "Nineteen researchers are currently approved to conduct research with smoked marijuana on human subjects." Could you please provide the name and affiliation of each of these researchers, along with a short description of the research they are currently conducting?**

RESPONSE:

Please note that the information requested in this question includes personally identifiable records maintained by DEA, which are protected by the Privacy Act. DEA is releasing this information to the subcommittee in response to this question under the exception for disclosures to Congress set forth in 5 U.S.C. § 552a (b)(9).

- Donald Abrams, M.D. (University of California -San Francisco; CMCR*)
- Mark Agius, M.D. (University of California-Davis; CMCR*)
- Robert Block, Ph.D. (University of Iowa)
- Louis Cantilena, M.D., Ph.D. (Uniformed Services University of Health Services)
- Jody Corey-Bloom, M.D., Ph.D. (University of California-San Diego; CMCR*)
- Ronald Ellis, M.D., Ph.D. (University of California-San Diego; CMCR*)
- Richard Foltin, Ph.D. (Columbia University)
- Alan Gevins, Ph.D. (SAM Technology Inc.)
- Mark Greenwald, Ph.D. (Wayne State University)
- Kent Hutchison, Ph.D. (University of Colorado)
- Thomas Kelly, Ph.D. (University of Kentucky)
- Scott Lane, Ph.D. (University of Texas-Houston)
- Anthony Liguori, Ph.D. (Wake Forest School of Medicine)
- Scott Lukas, Ph.D. (McLean Hospital)
- Jane Metrick, Ph.D. (Brown University)
- Godfrey Pearlson, M.D. (Institute of Living)
- Donald Tashkin, M.D. (University of California Los Angeles)
- Mark Wallace, M.D. (University of California -San Diego; CMCR*)
- Barth Wilsey, M.D. (Department of Veteran Affairs; CMCR*)

Of the 19 researchers listed above, 13 are conducting NIDA-funded drug abuse research. An additional 6 are affiliated with the *Center for Medicinal Cannabis Research (CMCR) from the University of California and are investigating the use of smoked marijuana in six approved studies.

The CMCR studies are evaluating the use of cannabis for the treatment of: HIV-related peripheral neuropathy; cancer pain; spasticity/tremor in MS patients; and chemotherapy-induced delayed nausea. These studies represent the breadth and scope of research using marijuana to study the potential therapeutic effectiveness of marijuana's active ingredients.

Policy on Letters of Non-Objection

The committee has heard from a number of companies that DEA has virtually stopped issuing Letters of Non-Objection, or LONOs – since February of 2006. I would greatly appreciate it if you could help me understand the current LONO policy in greater detail, as well as DEA's rationale behind the decision to implement this policy.

6. **How many LONO requests did DEA approve and deny in 2004, 2005, and in 2006 until February 28, and what were the reasons for denial in cases where DEA rejected a LONO application?**

RESPONSE:

During the time period in question, the DEA received approximately 1,069 requests for LONOs. Of that total, 41 (4%) were withdrawn by the importer after being notified that the LONO would not be issued. The breakdown by year is as follows: 2004, 519 LONO requests, 6 (2%) withdrawn; 2005, 483 LONO requests, 32 (7%) withdrawn; 2006 (through Feb. 28), 67 LONO requests, 3 (4.5%) withdrawn. LONOs not being issued were based on the reasonable belief that the products will be diverted for use in the clandestine production of illicit drugs.

If there is reason to believe that the chemicals will be diverted into illicit channels, DEA sends the importer a 3-Option letter. This letter explains that a particular shipment may be diverted (21 U.S.C. § 971) and then gives the importer three options. The first option for the importer is to voluntarily withdraw the DEA-486; the second is to do nothing and in 30 days, it will automatically be withdrawn or the last option is to request a hearing. The letter further explains the regulatory process and indicates that if the third option is chosen, then the shipment will be suspended and the importer has a right to a hearing. All importers are afforded the opportunity to participate in the regulatory system.

7. **How many LONO requests are currently pending before DEA? I would appreciate knowing when the LONO requests were submitted. How many of these LONO requests have been pending for more than 6 months without a response from DEA?**

RESPONSE:

As of August 24, 2007, there were eight (8) pending DEA 486 (LONO) requests. There are no DEA 486s pending for more than six months. When a request is received from the importer, the request is usually processed within approximately two weeks. This time is dependent upon how quickly the down stream customers reply to DEA's requests for information in order to conduct the verification process. The number of pending LONO requests changes daily as new ones arrive and are processed.

8. **Are there any companies who have submitted a LONO application for whom a LONO has been approved? It is my understanding that Wyeth and Bayer have both received such approvals.**

RESPONSE:

Please refer to the numbers provided in the previous responses. Companies do not submit a "LONO application". Companies do, however, submit a form DEA-486, which is an Import/Export declaration form sent in to DEA by the importer. That form constitutes a request for the issuance of a LONO if the export is from a country that will not release shipments of ephedrine and pseudoephedrine unless the United State Government issues a LONO. Generally speaking, imports are approved unless cancelled by the importer or there is reasonable cause to believe the imported chemical will be diverted to the clandestine production of drugs. LONO requests from any importer of ephedrine and pseudoephedrine would have been approved unless there was reasonable cause to believe that the chemicals would be diverted to the clandestine manufacture of methamphetamine. Unless a LONO request is cancelled by the importer, all LONOs have either been approved or DEA has issued an order to suspend the shipment. Importers whose shipments are suspended are entitled to a hearing. However, LONOs are issued only to registered importers. Wyeth and Bayer are not registered with the DEA as importers of List I chemicals.

9. **Has DEA received and approved any LONO applications from companies who seek to import ephedrine or other List 1 chemicals used for prescription or related pharmaceutical uses?**

RESPONSE:

DEA has received form DEA-486s for List I chemicals where the ultimate end-use is for the manufacture of legitimate prescription drug products and they go through the same downstream customer verification process as the OTC manufacturers.

10. **What criteria does DEA currently employ to approve or reject a LONO request?**

RESPONSE:

Title 21 U.S.C. § 971(c) states that the Attorney General may order the suspension of any importation of a listed chemical on the ground that the chemical may be diverted to the clandestine manufacture of a controlled substance. Upon the receipt of a LONO request, the DEA conducts an investigation of the downstream distribution chain. If a determination is made that the product may be diverted, the LONO is not issued. If the request to import the List I chemical is not withdrawn by the importer, DEA issues an order suspending the proposed importation.

11. **We have heard that DEA does not intend to approve any LONO requests until the agency determines the "medical and scientific" necessity for List 1 chemicals, particularly ephedrine and pseudoephedrine? If so, why would the U.S. Food and**

Drug Administration's (FDA) determination of the medical necessity of ephedrine and other List 1 pharmaceuticals – as a condition of allowing them onto the market – not serve as sufficient evidence for DEA – especially in light of the apparent injury caused to responsible and law-abiding companies by the delay?

RESPONSE:

"Medical and scientific necessity" was not the terminology utilized by Congress in enacting 21 U.S.C. § 971(c). Therefore, such terminology is not utilized by DEA in implementing this provision. DEA is mandated by 21 U.S.C. § 952(a)(1) to authorize the importation of ephedrine and pseudoephedrine only in such amounts as are necessary to provide for medical, scientific, or other legitimate needs of the United States. Furthermore, this is also in accordance with a United Nations resolution that urges the calculation of valid licit use estimates for ephedrine and pseudoephedrine and allows for monitoring by the U.N. International Narcotics Control Board (INCB) to help keep imports and exports within these licit use estimates. Although a product may be approved as "safe and effective" by the FDA for a medical use, only the amount necessary to provide for the legitimate needs of the United States may be imported. DEA processes requests to import all controlled substances and listed chemicals thoroughly prior to deciding whether to send a LONO or deny the importation. DEA does not concede that any company has been injured by any alleged delay in this process.

The Assessment of Annual Needs represents those quantities of ephedrine, pseudoephedrine, and phenylpropanolamine which may be manufactured domestically and/or imported into the United States to provide adequate supplies of each chemical for: the estimated medical, scientific, research, and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks. DEA obtained assistance from a private independent contractor, IMS Health Government Solutions, to develop estimates of the medical needs of the United States for both ephedrine and pseudoephedrine.

12. **What is DEA's statutory authority and substantive expertise to make medically-based determinations such as "medical and scientific" determinations of List 1 chemicals? Does DEA coordinate with other agencies such as the FDA or HHS in making those determinations?**

RESPONSE:

DEA's statutory authority rests in 21 U.S.C. §952. This statute prohibits the importation of controlled substances or ephedrine, pseudoephedrine, and phenylpropanolamine except in amounts "as the Attorney General finds to be necessary to provide for medical, scientific, or legitimate purposes". When making a scheduling recommendation, DEA coordinates with FDA/HHS for their expertise in evaluating a particular drug.

Since this question is similar in content to question 6, the response must by necessity repeat some of the answer to that question. The Assessment of Annual Needs represents those quantities of ephedrine, pseudoephedrine, and phenylpropanolamine which may be manufactured

domestically and/or imported into the United States to provide adequate supplies of each chemical for: the estimated medical, scientific, research, and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks. DEA obtained assistance from a private independent contractor, IMS Health Government Solutions, to develop estimates of the medical needs of the United States for both ephedrine and pseudoephedrine.

13. If DEA has, in fact, adopted a policy of deferring decisions on LONO applications until a medical and scientific necessity of List 1 chemicals is determined, what provisions are being extended to lawful importers and distributors whose business and livelihood depend on the continued importation of raw materials?

RESPONSE:

DEA does not have a policy of deferring decisions on LONO requests based on medical and scientific necessity.

14. How many incidents have there been where Over-The-Counter (OTC) ephedrine combination products such as Primatene or Bronkaid have been found to be used in the manufacture of methamphetamine, and what percentage of the total methamphetamine supply in the U.S. does DEA believe comes from illicit diversion of these specific types of combination products?

RESPONSE:

An exact number of incidents where OTC pseudoephedrine and/or ephedrine combination products have been found in clandestine laboratories is not possible to ascertain. Clandestine laboratories are often found in various stages of production with the precursor chemicals in solution or finished product. Both combination and single entity OTC ephedrine and pseudoephedrine products are found at clandestine methamphetamine labs. It should be noted that traces of antihistamines or other residual ingredients are frequently encountered in methamphetamine samples taken at clandestine labs, indicating the diversion of OTC combination products.

As provided in testimony on July 12, 2007, brands found in 87 labs in 2006, included BDI, Blue Label, Mini Thins, Brochis, Mini Ephedrine, Double Action Ephedrine, Rapid Ephedrine, Fred's Private Label, Ephedrine Extra, Biotech, AM, BC Powder and Ultra Max Strength. Those are all off-brand, gray market, crypto-generic products.

Ephedrine Import Policy

The committee is concerned over the uncertainty of how import quotas pertaining to List 1 chemicals will be allocated amongst small importers. This lack of information and uncertainty about the supply of essential List 1 chemicals for their health products has disrupted short- and

long-term business operations. Importers and distributors are anxious to plan for their future distribution of product to potential customers, including chain drug stores.

In light of this uncertainty, please respond to the following questions:

15. What criteria will DEA use in making import quota allocations?

RESPONSE:

Registrants are required to submit a completed DEA Form 488, Application for Import Quota for Ephedrine, Pseudoephedrine, and Phenylpropanolamine, in order for DEA to establish an individual import quota. DEA will evaluate the information submitted on the application including data relating to purchases, sales, and inventory for the current and preceding two years. However, certain import quota requests might require additional information such as product development requirements or other requirements necessary to complete bona fide scientific research/clinical trials. DEA has expertise in processing these types of quota applications for manufacturers of controlled substances in Schedules I and II and will work with quota applicants to obtain the information necessary to process these types of quota requests.

16. When will proposed import allocations be made by DEA?

RESPONSE:

On July 10, 2007, the DEA published in the Federal Register, an Interim Final Rule with Request for Comment which implements the quota provisions envisioned by Congress when it passed the Combat Methamphetamine Epidemic Act (CMEA) in March 2006. Although the rule became effective immediately, DEA did not administer individual quotas to importers of these List I substances for imports required in 2007. Instead, DEA has been obtaining 2008 import applications which will be adjudicated after DEA publishes a final rule in the Federal Register establishing the 2008 Assessment of Annual Needs for each of these List I chemicals. The 2008 Assessment of Annual Needs was published in the Federal Register on December 27, 2007 (72 FR 73361).

On December 27, 2007, DEA issued individual import, manufacturing and procurement quotas to 38 applicants who had filed timely quota applications. DEA received exactly 100 complete applications in 2007 for 2008 quotas; approximately 40% were received in the month of December and currently remain under review. Three (3) of the sixteen (16) import quotas received in 2007 were issued on that day. Until a quota has been allocated to importers, it will not be permitted to handle any subject materials. DEA is not currently aware of any delays in this process. Looking forward, it is not anticipated that any delays, to the extent they become reality, will cause extended waiting periods.

17. Once import allocations are proposed, will DEA provide importers with an opportunity to submit comments and make recommendations for revisions in the import formula?

RESPONSE:

The assessment of annual needs (AAN) represents the total quantity of ephedrine, pseudoephedrine, and phenylpropanolamine determined to be necessary to be manufactured and imported during the calendar year. The DEA shall publish in the Federal Register a general notice of an assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine. Any interested persons are permitted to file written comments on or objections to the proposed AAN within the designated comment period. After consideration of any comments or objections, the DEA shall issue and publish in the Federal Register the final order determining the AAN for the chemicals.

18. Once import allocations are finalized, what process will DEA establish to allow importers to request modifications to the allocations based on production and sales data?

RESPONSE:

Any person to whom an import qnota has been issued may at any time request an adjustment in their individual import quota. Applications for adjustments to an individual import quota which are received during the calendar year must be denied by DEA within 60 days of receiving a completed request for such adjustment, otherwise the request is deemed approved 21 U.S.C § 952(d) (21 C.F.R. § 1315.36).

Any persons to whom an individual import quota has been issued may, at any time during the calendar year, request an adjustment in their individual import quota by applying to the Administrator with a statement that establishes the basis for the adjustment.

Harassment of Small Business

The Committee is aware of specific instances of DEA investigators threatening to issue show cause letters simply for doing business with convenience stores, which the DEA has defined as the "gray market." Furthermore, and even more alarming, we are aware of small businesses being asked to surrender their List 1 chemical licenses without any evidence of wrongdoing.

An example of this policy and practice is contained in the transcript of an April 18, 2006 administrative hearing regarding a List 1 chemical distributor in Tennessee.

A DEA Investigator testified that it is DEA's policy to seek the license revocation of *any* List 1 chemical distributor who conducts business with the so-called gray market, even in the absence of any evidence of chemical diversion or violations of DEA regulations. During cross examination by counsel at the administrative hearing, Investigator Graham responded to the following questions:

> *Q. "...Is it your testimony that it's DEA policy to seek the revocation of any person or entities that is registered and sells in the gray market?"*

A. "Yes, sir."

Q. "Irrespective of whether they abide by the rules and regulations?"

A. "Yes, sir."

Q. "My question is, is it DEA policy to revoke the registrations of persons who are selling in the gray market, but comply with rules and regulations of the sale of List 1 chemicals?"

A. "...I would like to respond to your question. Generally, the answer is yes, but I must stress that the issue is what they are selling. Now when we talk about the nontraditional products into gray market establishments, yes, we seek those revocations."

Q. "Even when those persons or businesses follow the Code of Federal Regulations?"

A. "Yes, sir."

Due to these concerns, please respond to the following questions:

19. What is DEA's overall enforcement strategy in identifying and dismantling small toxic laboratories (STLs) that produce Methamphetamine?

RESPONSE:

Firstly, DEA regrets the Committee's use of the word 'harassment' in the title of this section of questions. In seeking answers, use of the word inherently assumes the Committee has already taken a position.

As a testament to the effectiveness of the Combat Methamphetamine Epidemic Act (CMEA) passed by Congress and strong state legislation, DEA statistics show a 41% decrease in the number of methamphetamine laboratories in 2006 from the previous year. This is 41% fewer laboratories that will expose children to hazardous chemicals, 41% fewer laboratories that state and local law enforcement officers will spend hours overseeing environmental clean-ups, and 41% fewer laboratories that state and local agencies will have to spend thousands of dollars in hazardous waste clean-ups. It is also 41% fewer labs producing a toxic drug that ruins American families and communities and weakens our productivity.

A logical means to eliminate the STLs is to choke off their sources for meth ingredients, mainly ephedrine and pseudoephedrine of the kind found in OTC cold remedy products. The recent significant reduction in the number of domestic small toxic labs and legislation restricting access to methamphetamine precursor chemicals has allowed DEA's Clan Lab Enforcement Teams to expand their efforts beyond dismantling methamphetamine labs. These teams can now

concentrate on identifying and targeting large-scale Mexican methamphetamine trafficking organizations. These teams use their lab expertise to trace chemicals, finished methamphetamine, and drug proceeds to drug trafficking organizations in the U.S. and Mexico. These teams also work to identify and dismantle U.S.-based methamphetamine transportation and distribution cells.

DEA is committed to keeping our communities safe from the dangers of methamphetamine production and abuse. Preventing the use of chemicals from being diverted to clandestine labs for use in the production of methamphetamine and enforcement of the CMEA are important elements in that effort.

20. What is DEA's current enforcement policy with regard to identifying precursors used in clandestine laboratories for the production of illicit methamphetamine?

RESPONSE:

DEA investigators are trained to pursue all leads, including backtracking of chemicals heading to or found at a clandestine lab site, chemical cache, or dumpsite.

21. Did the DEA Investigator at question here accurately describe DEA's enforcement policy during his testimony at the April 18, 2006, hearing, that DEA is seeking the revocation of any List 1 chemical registrant who is doing business with the gray market?

RESPONSE:

The Diversion Investigator testified truthfully, but mistakenly, based on his understanding of DEA's policies and procedures. In fact, DEA does not have a policy to revoke the registration of every distributor that sells scheduled listed chemical products to "gray market" outlets. The investigator's testimony would have been more precise if he testified that so-called gray market ephedrine and pseudoephedrine products deemed to be obtained and diverted for use in the illicit production of controlled substance are often found in gray market venues. This marketplace for non-traditional products is a known source for domestic methamphetamine production. Accordingly, distributors that sell gray market products to gray market outlets often present a significant risk of diversion of scheduled listed chemical products.

22. If DEA does have a policy of seeking the revocation of List 1 registrants that do business in the gray market, what is the policy specifically, and what is the statutory or regulatory basis for such policy?

RESPONSE:

DEA does not have such a policy.

23. How does DEA define the so-called "gray market?"

RESPONSE:

DEA knows by experience that a "gray market" exists wherein certain pseudoephedrine and ephedrine products are distributed only to non-traditional outlets for medications such as convenience stores and gas stations and from where they have a high incidence of diversion with little or no accountability as to their final uses. These "gray market" products are not sold in large discount stores, retail pharmacies, or grocery chains, where legitimate sales of therapeutic OTC drugs predominate. "Two-way" combination ephedrine and high strength single-entity pseudoephedrine products, which are "crypto-generic" in that they are manufactured by firms with no discernible market share or observable demand, are the primary products in this "gray market" industry. These products are rarely found in any retail store serving the traditional therapeutic market. Many distributors of these products distribute ephedrine to convenience stores, gas stations, and other "gray market" retailers in amounts that far exceed legitimate demand for therapeutic use.

Despite numerous public announcements and letters to distributors, DEA believes that many of the "gray market" retailers of these products have not self-certified under the provisions of the Combat Methamphetamine Epidemic Act and, therefore, have not come into compliance with the Act.

In the recent past, several cases have been adjudicated which resulted in decisions favoring the government. One such final rule, FR Doc 04-4127 [Federal Register: February 25, 2004 (Volume 69, Number 37)] [Notices] [Page 8682-8696], re: *Branex – Final Order – 02/25/04,* demonstrates the gray market principle.

24. Does DEA have any evidence that traditional convenience stores and small retail establishments are intentionally diverting List 1 chemicals into STLs? If so, what evidence exists?

RESPONSE:

According to DEA reports, convenience stores and gas stations in many states have, for years, continued to be the primary source for precursors being diverted to illicit methamphetamine laboratories.

During March 2001, DEA utilized an expert in the field of retail marketing and statistics to analyze national sales data for OTC, non-prescription drugs. Using official government and commercially available sales data, he was able to construct a model of the traditional market for pseudoephedrine in the retail sector. His study showed that over 90% of all sales of non-prescription drug products occurred in drug stores, grocery stores and large discount merchandisers. A very small percentage of such sales occurred in convenience stores, and many convenience stores do not sell any OTC drug products at all.

This expert analyzed expected sales of non-prescription drugs by convenience stores that sold such products and found that they constituted a very small portion of their total sales. The average small convenience store averages about $1,000,000 in gross sales. Health and beauty aids category (HABA) averages about 2-3% of gross sales. Cough and cold products, a subset of HABA, average about one-fourth of HABA sales. The expert calculated that single-entity pseudoephedrine sales were about 5% to 10% of cough and cold sales. Accordingly, the average small store could expect to sell monthly only about $0.00 to $40.00 worth of pseudoephedrine products. At an average markup of 40% over wholesale prices, this would translate to about 3 to 12 packages a month. He calculated that the potential for sales of combination ephedrine products was about only one-fourth of those pseudoephedrine sales levels.

DEA has observed through investigations that a number of "gray market" convenience stores and gas stations, to the extent that DEA even knows of them, have routinely demonstrated a reckless disregard of the spirit of the CMEA quantitative sales limits, by not monitoring sales to individuals either in a single day or during the 30-day period. It has been observed that on a regular basis, the same individual or individuals made multiple package purchases that exceeded the single day sales and/or 30-day purchase limits, without denial by the outlet.

DEA has obtained anecdotal evidence in some investigations that the owners or employees of convenience stores suspected that purchasers of List I products were diverting these products to the clandestine manufacture of methamphetamine. Whether a retail seller or a distributor intentionally diverts scheduled listed chemical products or unwittingly sells such products that are ultimately diverted, DEA must take steps to protect the public from clandestinely manufactured methamphetamine.

25. Does DEA have a long term strategy to eliminate all sources of List 1 chemicals from the marketplace?

RESPONSE:

No such strategy exists. Moreover, DEA would not deny the legitimate needs of these chemicals from the public. It is, however, DEA's Congressional mandate to protect the public from those who would divert controlled substances and listed chemicals from legitimate channels for non-legitimate purposes.

26. As a follow up to Dr. Heiden's testimony that most products found in small toxic laboratories were named brand products rather than off-brand products, Mr. Rannazzisi responded by saying that off brand products were, in fact, being found in large quantities. There seems to be a disparity in these two answers. The Subcommittee would like to clear this up, and, for this reason, would like the DEA to provide documentation showing that after the enactment of CMEA, there has been a consistently greater presence of brands sold in small retail outlets versus name brand or so-called "conventional" retail braud generics during clandestine lab seizures.

RESPONSE:

The question mischaracterizes Mr. Rannazzisi's testimony. At no point in his remarks did Mr. Rannazzisi say that name brand products were not being found in methamphetamine laboratories, nor did he characterize quantities of off-brand products as being large, he simply identified by name those gray market products which were found in laboratories.

In responding to Mr. Heiden's testimony on this issue, Mr. Rannazzisi said:

> "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 relieve products which are not found in illicit labs as precursors to make methamphetamine. That is incorrect.
>
> In 2006, we had 87 labs with brand names like BDl, Blue Label, Mini Thins, Bronchis, Mini Ephedrine, Double Action Ephedrine, Rapid Ephedrine, Fred's Private Label, Ephedrine Extra, Biotech, AM BC Powder, Ultra Max Strength. Those are all off-brand, gray market crypto-generic products."

Dr. Heiden suggests that he has data on all small toxic laboratories in support of his saying that the name brand products are found more often than off-brand products. Often law enforcement does not know the source of the products found in clandestine labs because the lab operators have discarded or destroyed the packaging materials. Additionally, the quality of the reporting of seized material labeling by various agencies is inconsistent. Mr. Rannazzisi simply stated that off-brand products were found in large quantities. Off-brand manufacturer and distributor data, particularly with respect to ephedrine products, suggests that off-brands would likely be found in clandestine labs.

The attached charts show 92 clandestine meth lab seizures where it is known that ephedrine products were being used in the manufacturing process. During the same time period, 7,345 labs were seized. As in years prior to the enactment of the CMEA, traffickers continue to go to great lengths to disguise the identity of the precursor products from law enforcement. However, intelligence information from all law enforcement sources indicates that ephedrine products, especially those products sold in small retail outlets, are favored by traffickers. (See attachments below.)

27. Dr. Heiden devoted a considerable amount of his testimony challenging the DEA's use of outside data in formulating an annual needs assessment for the importation of Ephedrine. The only response to Dr. Heiden's testimony Mr. Rannazzisi made was that the DEA is reviewing comments and would be out with a revised assessment shortly. Before the DEA issues its final needs assessment, and completes the Interim Final Rule that it issued two days before the hearing, the Subcommittee would appreciate DEA providing the following:

a. **The amount of raw materials known to be diverted in prior years versus the quantity of raw materials on approved LONOs for that same year for all importers and manufacturers. (*See footnote below)***

RESPONSE:

The amount of diverted List 1 raw materials is unknown. Therefore, a direct correlative relationship is meaningless. Annually, the DEA receives an average of about 500 requests per year for LONOs. A LONO was issued in approximately 95% of the cases. In the balance of the cases, fewer than 5%, the request was withdrawn after DEA made notification to the importer that a LONO would not be issued because of diversion concerns.

b. **What is DEA's justification for its *initial* quota policy causing additional "anticipate[d] significant economic impact" on small businesses when the CMEA has already effectuated a major decline in diversion rates? (See pg.37445, FR DOC E7-13377)**

RESPONSE:

Legitimate small businesses should not expect to experience such an impact. The Office of Chief Counsel, Diversion & Regulatory Litigation Section (CCD) engaged the services of a marketing expert. Since 2000, the Office of Diversion Control (OD) and CCD have used market studies which support DEA's position regarding these products. According to the expert, who has testified in court and at show cause proceedings in which the government prevailed, these products are being distributed in quantities far in excess of their expected market share. In other words, they sell more than the nationally recognized brand, yet do not even register as a competitor in the same marketplace as the nationally recognized brand leader. This can only be because their products are aimed at the illicit market.

28. **In his testimony, Mr. Rannazzisi made specific reference to the success of the CMEA in reducing the diversion of over the counter products (OTC) to small toxic laboratories to produce methamphetamine. He stated, however, that the agency continues to be concerned with the contribution of products sold to convenience stores tied to the meth problem. In light of these assertions, the Subcommittee would like the agency to provide the subcommittee with specific evidence demonstrating the extent to which reduction of diverted OTC products is attributable to the CMEA compliance of the distributors and employees of what DEA deems to be "conventional outlets"(drug stores, grocery stores, discount department stores, superstores, and electronic mail order houses)? (See pg.37445, FR DOC E7-13377).**

RESPONSE:

Even prior to the enactment of the CMEA, well before September 30, 2006, a number of traditional ("conventional") outlets engaged in voluntary measures to curtail potential diversion

of pseudoephedrine and or/ephedrine-containing drug products by instituting point of purchase sales limits, and placing ephedrine and pseudoephedrine-containing drug products behind the counter.

Bayer Corporation and Wyeth, manufacturers of Bronchaid and Primatene, respectively, the only two ephedrine-containing brand name products sold in the marketplace at traditional outlets, have long considered these products as fading away, in that sales of these products continue to decrease year by year. Other manufacturers have abandoned using ephedrine altogether and reformulated products with phenylephrine. Phenylephrine cannot be used successfully in the illicit manufacture of methamphetamine.

a. If the DEA dubbed, "non-conventional outlets" contributed to the majority of diverted OTC products, then how can these same businesses be denied recognition for the significant decline in the seizures of Clandestine Methamphetamine Labs?

RESPONSE:

The concern lies with the training of employees for the self certification process and the greater oversight given to employees in conventional outlets versus non-conventional outlets. DEA has sent individuals into convenience stores to gather information on the record keeping process to determine if the log book requirements were being followed. On the whole, clerks in the convenience stores did not check identification against what was written in the log books while the larger more conventional outlets did in fact check the identification against what was written in the log books.

Despite the logbook requirement, "smurfing" (going from store to store and purchasing the maximum daily limit) continues because there is no apparatus for stores to compare logbooks.

b. In light of the dramatic and undeniable effects of the CMEA's regulations on the reduction of diverted OTC products containing PSE and EPH; why is DEA policy *still* contradicting the CMEA, by effectively banning the convenience store industry and its consumer's access to these products?

RESPONSE:

DEA policy does not contradict the CMEA and it is not DEA's intent to ban the convenience store industry from access to these products.

*** Footnote: CLSS (Clandestine Laboratory Seizure System @ EPIC) has the statistics available that would reveal how many pounds of methamphetamine were illicitly manufactured in 2006* from products diverted via all retail outlets.** That amount (number of pounds of methamphetamine) can then be converted into the kilograms of raw materials required to produce that amount. Next, calculate the kilograms of raw materials that were approved for import that year for the**

manufacture of ALL OTC products containing PSE and EPH. Subtract the estimated diverted kilograms from the amount that was actually imported, and you should end up with an importation level that reflects the amount of raw materials that were not diverted, and that is the amount that should be approved for the following year Not an amount based loosely on estimates of how many cold, allergy and asthma suffers there are and where they shop.

*** In 2006, when CMEA was enacted, not all retail regulations were in effect until September.**

****For 2004, CLSS reported that 3,156 lbs of Methamphetamine was illicitly manufactured from products diverted from all retail/wholesale outlets. (During that year, lab seizures were approximately 700% greater than annualized data currently available for 2007, and 230% greater than 2006 data.)**

RESPONSE:

For the record, this footnote is incorrect to state that "For 2004, CLSS reported that 3,156 lbs of Methamphetamine was illicitly manufactured from products diverted from all retail/wholesale outlets."

In 2004 there were 17,860 meth lab incidents (labs, dumpsites). In most, if not all these incidents, ephedrine/pseudoephedrine tablets were used to manufacture methamphetamine. Just because the brand cannot be determined, does not mean that these tablets were not used, and therefore, no statement can be made that only 3,156 lbs of methamphetamine was manufactured from ALL retail/wholesale outlets.

In the vast majority of clandestine laboratories, it is difficult for law enforcement to determine the name brand of ephedrine/pseudoephedrine tablets, gel-caps or liquids that have been used. In most instances, the law enforcement officers may only find materials that have already been removed from the packaging therefore making it impossible to determine the brand. List 1 materials found in solutions obviously would make source determination improbable. Due to these conditions, there may be inherent under-reporting or mis-reporting considerations. Therefore, no system exists for making a reliable empirical determination of the amount of methamphetamine resulting from specific retail and wholesale products' diversion.

Again, DEA has engaged an expert in the field of retail marketing and statistics who has studied purchases of drug products containing ephedrine and pseudoephedrine at the convenience store level. In his studies he has concluded that retailers purchase these products in amounts that are far in excess of legitimate need when comparing the purchases to demographics, census data, and statistical sales data obtained from the convenience store industry.

Cases in Which Administrative Law Judge's Opinion Issued
January 1, 2001 - July 26, 2007
(Revised August 1, 2007)

*Arranged according to the date the Judge's opinion is rendered.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
01-4	Peterson	11/16/00	1/12/01	2/12/01	10/10/01	
00-12	Ford	12/9/99	2/6/01	3/16/01	2/24/03	
99-34	Shaffer	9/17/99	3/27/01	4/30/01	5/6/02	
01-1	The Church of the Living Tree	11/30/99	4/17/01	6/12/01	3/26/03	
01-17	Thomassen	3/9/01	4/23/01	5/24/01	10/10/01	
00-4	Owens	11/1/99	5/4/01	6/4/01	7/24/02	
01-18	Resnick	3/22/01	5/16/01	6/18/01	10/10/01	
00-24	Leslie	6/20/00	8/2/01	9/14/01	3/6/03	
01-6	Scolaro	11/22/00	8/3/01	9/7/01	6/11/02	
01-37	Anthony	8/6/01	10/3/01	11/20/01	5/6/02	
01-38	Weinstein	8/7/01	10/3/01	11/19/01	5/6/02	
01-36	Venuto	8/6/01	10/3/01	11/19/01	5/6/02	
00-41	Mediplas Innovations	9/15/00	10/4/01	11/20/01	5/30/02	
01-43	Mills	8/20/01	1/8/02	2/12/02	5/6/02	
02-1	Deanwood Pharmacy	10/12/01	3/7/02	10/29/02	6/23/03	
01-22	Xtreme	5/4/01	4/3/02	5/7/02	12/2/02	
01-12	Indace[1]	2/8/01	4/5/02	6/5/02	12/13/02 & 11/9/04	
01-13	Malladi[2]	2/8/01	4/5/02	6/5/02	12/13/02 & 11/9/04	
02-17	Washburn	1/25/02	4/25/02	6/4/02	9/12/02	

[1] The United States Court of Appeals for the District of Columbia Circuit remanded both *Indace* and *Malladi* to the Deputy Administrator, necessitating second final orders in both cases. See 69 Fed. Reg. 67,951 (2004).
[2] See fn. 1.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
02-34	Arwas	3/21/02	4/29/02	5/29/02	9/18/02	
01-3	Penick Corp.	11/15/00	5/29/02	8/5/02	1/29/03	
02-38	Graves	4/29/02	6/10/02	7/10/02	11/4/02	
01-30	Jackson	7/2/01	6/13/02	7/17/02	4/21/03	
02-15	Genesis	1/22/02	6/26/02	8/8/02	3/13/03	
02-37	Hamilton	4/22/02	7/9/02	8/8/02	9/18/02	
02-25	Talley	2/26/02	7/15/02	8/21/02	11/20/02	
02-41	Cleggett-Lucas	5/17/02	7/13/02	10/29/02	4/21/03	
00-22	OTC	6/9/00	8/8/02	9/27/02	11/26/03	
02-44	Santucci	6/14/02	8/12/02	9/18/02	10/28/02	
01-20	Aboumahboub	4/17/02	8/15/02	9/18/02		Terminated[3] – Joint Motion filed 12/6/04
02-46	Meredith	6/26/02[4]	9/13/02	10/24/02	07/31/2003[5]	Published 8/1/03
02-50	Serai	7/23/02	9/18/02	10/28/02	7/28/03	
02-52	Goswitz	7/24/02	10/8/02	11/12/02	4/21/03	

[3] The administrative law judge will terminate a case either because (1) it has become moot (e.g., the respondent's registration expired during the course of the proceedings and the respondent did not file a renewal application); (2) the parties settle all outstanding issues; or (3) the respondent failed to comply with a directive from the judge and was therefore deemed to have waived his right to a hearing. If a case is terminated for the first or second reason listed above, no further action is required by either this office or the Deputy Administrator; if a case is terminated for the third reason, the investigative file should be forwarded to the Deputy Administrator for issuance of a final order based on that file. A case may also become moot or may be settled while pending before the Deputy Administrator, in which case it will be terminated.

[4] On June 26, 2002, the hearing clerk received a letter from respondent in which he "requests an extension of time re: his show cause hearing until the registrants [sic] federal complaint is adjudicated." This letter was listed as a request for an extension of time to respond to the order to show cause on the docket sheet, but was treated as a request for hearing.

[5] This date represents when the document was filed at the Federal Register. The date the Final Order was signed is unknown.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
01-15	Ashland	3/1/01	10/28/02			Terminated11/17/06[6]
01-23	FCC	3/1/01	10/28/02			Terminated 11/17/06[7]
02-11	Davis	12/13/01	11/21/02	1/21/03	12/18/03	
01-10	Branex	1/26/01	12/4/02	1/21/03	2/10/04	
03-4	Dinozzi	10/21/02	1/13/03	2/19/03	11/13/03	
03-2	Lusman	10/9/02	1/13/03	2/20/03	11/13/03	
03-9	Perry	11/26/02	2/25/03	3/18/03	11/13/03	
03-14	Prescriptionline.com	1/22/03	3/19/03	4/22/03	1/7/04	
02-24	Kruger	4/9/02	4/23/03	5/28/03	1/20/04	
02-10	Morall	12/17/01	4/28/03	7/24/03	9/28/04	
02-7	Davenport	12/10/01	6/13/03	8/6/03	11/26/03	
02-35	Chaudry	3/25/02	6/13/03	8/6/03	10/5/04	
03-27	Edwin	5/22/03	7/18/03	8/20/03	9/13/04	
03-19	Katz	4/28/03	8/8/03	9/12/03	3/29/04	
03-22	Boone	4/28/03	8/29/03	11/24/03	5/17/04	
03-36	Antonsson	Unknown[8]	9/23/03	11/13/03	1/7/04	
03-41	Ingram	8/18/03	11/7/03	12/15/03	4/7/04	
02-40	Hale	5/13/03	11/26/03	1/15/04	11/10/04	
03-51	Jones	9/23/03	12/4/03	1/16/04	6/21/04	
03-48	Strauss	9/11/03	12/8/03	1/16/04	5/17/04	

[6] At the Government's request, *Ashland* and *FCC* were ultimately terminated without being submitted to the Deputy Administrator. These cases were part of a series of proceedings (including *Indace* and *Malladi*) involving PDK Laboratories, Inc.

[7] See fn. 5.

[8] The respondent (Antonsson) requested an extension of time to respond to the Order to Show Cause on July 5, 2003. No formal hearing request was received. On July 29, 2003, the Government requested for a Stay of Proceedings and Motion for Summary Disposition. The Opinion and Recommended decision of the ALJ was made on September 23, 2003.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
04-10	RX Network of South Florida, LLC	11/5/03	12/17/03	1/29/04	10/5/04	
04-7	Pripstein	10/15/03	12/19/03	1/28/04		Terminated 8/17/05
02-28	Prakasam	3/6/02	1/30/04	3/2/04	5/25/05	
04-9	Orzame	11/10/03	2/4/04	3/15/04	9/8/04	
03-1	Hoxie	10/4/02	4/7/04	5/26/04	7/27/04	
01-31	Bordeaux	7/3/01	5/4/04	6/7/04	11/10/04	
03-5	Express Wholesale	11/8/02	5/18/04	6/24/04	10/5/04	
04-2	Yaqub	10/6/03	5/14/04			Terminated 7/12/04
04-22	Townsend	5/10/04	6/28/04			Terminated 11/15/04
04-34	Price	5/3/04	6/28/04	8/10/04	10/5/04	
04-38	Chalifoux	5/12/04	6/28/04	8/10/04	10/5/04	
04-40	Mirza	5/17/04	8/10/04	9/15/04	10/5/04	
03-35	Joy's Ideas	8/26/03	9/29/04	11/8/04	5/25/05	
03-25	Elk Int'l, Inc.	5/14/03	10/7/04	11/16/04	5/2/05	
04-27	Bradway	4/5/04	10/15/04			Terminated 11/16/04
04-30	Gooberman	4/13/04	10/15/04		5/9/05	
04-63	Siddall	8/16/04	11/4/04	12/7/04	12/15/05	
05-1	Rygiel	Unknown[9]	11/22/04	1/11/05	5/9/05	
03-24	TNT Distributors, Inc.	4/28/03	12/3/04	1/11/05	2/14/05	
03-26	H&R Corp.	5/20/03	12/3/04	1/11/05	5/5/06	
04-62	Kobrin	7/28/04	12/27/04	2/2/05	5/25/05	
05-5	Goodrich	11/8/04	12/29/04	2/2/05	5/2/05	

[9] No formal request for hearing was received. The Respondent requested for an extension of time to respond to the Order to Show Cause.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
03-81	Nearing	3/10/03	1/3/05	2/2/05	5/25/05	
01-45	Chattem Chemicals, Inc.	9/7/01	2/16/05	6/6/05	2/17/06	
03-39	D&S Sales	7/21/03	2/11/05	3/22/05	6/12/06	
05-9	Rodriguez	11/17/04	2/16/05	3/22/05	5/25/05	
04-8	Wedgewood Village Pharmacy	10/16/03	3/4/05	5/17/05	3/22/06	
05-2	Bergman	10/29/04	3/8/05	4/14/05	5/25/05	
05-17	Graham	1/6/05	3/25/05	4/26/05	5/25/05	
02-47	Kennedy	7/15/02	4/13/05	6/14/05	6/12/06	
03-8	Krishna-Iyer	11/20/02	4/15/05	7/27/05	8/22/06	
05-7	Yeates	11/10/04	5/9/05	6/14/05	6/13/06	
05-15	Oakland Medical Pharmacy	12/13/04	5/27/05	8/17/05	8/15/06	
05-28	The Medicine Shoppe	5/6/05	6/29/05	8/2/05	7/20/06	
05-27	Michael's Discount Pharmacy	5/6/05	7/1/05	8/2/05	8/15/06	
04-4	Tri-County Distributors	10/8/03	7/6/05	8/9/05	8/22/06	
02-9 & 02-43	Chein	12/13/01	7/28/05	12/23/05	1/19/07	
05-36	Dilday	8/3/05	9/23/05	10/26/05	8/22/06	
04-16	T. Young Associates, Inc.	1/20/04	10/28/05	11/30/05	9/14/06	
03-12	Koller	12/26/02	11/15/05	12/21/05	11/3/06	
04-48	Lockridge	6/14/04	11/18/05	12/23/05	12/8/06	
04-68	Mitrione	9/2/04	3/2/06	4/12/06		Terminated 3/30/07 by Deputy Administrator

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
06-42	Champaign Urbana Public Health District	1/29/05	3/7/06	5/22/06		No Final Order Issued[10]
02-6	Houba	11/20/01	3/8/06	6/5/06		Terminated 3/30/07 by Deputy Administrator
06-39	Dariah	11/16/05	4/17/06	06/1/06	1/19/07	
05-26	Tank Wholesale	4/19/05	4/24/06	6/1/06		Pending Final Order
05-22	Planet Trading, Inc. d/b/a United Wholesale Distributors, Inc.	3/24/05	4/25/06	6/5/06	2/28/07	
04-41	Jackson	5/18/04	5/26/06	6/29/06	4/24/07	
03-21	Medicine Shoppe Jonesborough	4/18/03	6/9/06	7/14/06		Remanded 4/28/07
05-8	Rick's Picks, L.L.C.	11/15/04	8/9/06	9/22/06	3/30/07	
06-52	Green Acres, Farm, Inc.	3/14/06	8/9/06	9/18/06	4/25/07	
06-58	Patel	6/19/06	8/28/06	10/2/06	3/30/07	
06-46	Miciano	2/27/06	8/28/06			Terminated 10/27/06
04-36	Lewis	5/4/04	9/26/06	11/2/2006	1/19/07	
06-68	Bourne Pharmacy	8/29/06	11/6/06	12/11/06	3/30/07	
05-24	The Lawsons Inc., t/a The Medicine Shoppe	5/13/05	11/6/06	3/14/07		Pending Final Order
04-58	RX Direct Pharmacy, Inc.	6/22/04	11/21/06	1/17/07		Pending Final Order

[10] A final order was prepared but it was not published in the Federal Register because the case became moot.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
06-4	Trinity Healthcare Corp., d/b/a Oviedo Discount Pharmacy	9/23/05	10/2/06	11/13/06	5/21/07	
05-3	Fotinopoulos	11/1/04	10/11/06	11/15/06	4/25/07	
05-33	Holloway Distributing, Inc.	6/30/05	12/19/06	2/1/07		Pending Final Order
07-3	Elite Pharmacy	11/1/06	1/23/07	2/15/07		Terminated on 4/3/07
05-16	Craker	2/7/05	2/12/07	5/15/07		Pending Final Order
05-24	The Lawsons, Inc., t/a/ The Medicine Shoppe Pharmacy	5/13/05	2/12/07 Supplemental [11]	3/14/07		Pending Final Order
07-19	CRJ Pharmacy, Inc. & YPM Total Care Pharmacy, Inc.	3/2/07	3/22/07	4/19/07	5/21/07	
07-7	Southwood Pharmaceuticals, Inc.	1/3/07	3/30/07	5/8/07	6/22/07	
07-23	Newcare Home Health Services	3/12/07	4/3/07	5/4/07		Pending Final Order

[11] Pursuant to the November 6 issuance of the ALJ's Opinion and Recommended Ruling, an exception to this opinion was filed on November 26 and Counsel for the Respondent filed a motion for reconsideration. This Motion was granted, however neither party filed briefs. Consequently, a Supplemental Opinion and Recommended Ruling were issued.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
06-19 & 06-20	Saran	10/20/05	4/30/07			Pending Parties Exceptions, then to Deputy Administrator[12]
07-18	Wood	2/21/07	4/27/07	6/4/07		Pending Final Order
07-21	United Prescription Services, Inc.	3/6/07	5/31/07	6/26/07		Pending Final Order
06-45	Volkman	6/20/07	6/20/07			Pending Parties Exceptions, then to Deputy Administrator
05-38	Memphis Wholesale Company	8/18/05	6/20/07	7/23/07		Pending Final Order

[12] At respondent's request, the judge granted an extension until October 1, 2007, for the filing of exceptions. The exceptions will then be transmitted to the Office of the Deputy Administrator.

GENERAL (R) ROSSO JOSE SERRANO CADENA

Ambassador of Colombia in Austria and Permanent Representative to the United Nations Office in Vienna

DEA OVERSIGHT

House Committee on the Judiciary
Subcommittee on Crime, Terrorism, and Homeland Security

July 12th, 2007

Honorable Representative Robert C. Scott, Honorable Representative J. Randy Forbes, Honorable Representatives, Members of the House Committee on the Judiciary Members of the Subcommittee on Crime, Terrorism, and Homeland Security.

I seize this opportunity to express my gratitude for the constant and great support that the Congress and the Government of the United States have given to the battle against drugs in all its aspects, from the battle against trafficking to the control of precursor chemicals for the production of the same. Drug trafficking is a factor that destabilizes and threatens our democratic institutions and fuels terrorism.

We, as Permanent Representatives at the United Nations in Vienna, are asking the International community's support and especially the European countries help to fight this scourge at the root. The fight against drug trafficking needs the international solidarity expressed in cooperation and assistance, an assistance which has been amply provided by the DEA all over the world.

Mr. Chairman:

During my professional life, I had the opportunity to work very closely with the Drug Enforcement Administration (DEA) as Director of Anti-Narcotics of Colombia, from 1989 to 1992, and as Director General of the National Police of Colombia, from 1994 to 2000. I want to stress that in the developments in the fight against drug trafficking in my country, the DEA has played a fundamental role due to its professionalism, its knowledge and know-how and its dedication in fighting against a scourge that has caused much harm not only to Colombia, but to the entire international community.

In 1990 we jointly discovered the surge of illegal sowing of poppy and it was the DEA that taught us about the processing of heroin and its illicit commercialisation, directed especially towards the United States of America. Since the Police did not have any knowledge of this process, we turned to the DEA and they were present with us when we discovered the first heroin processing lab, and their company was vital in the initiation of the eradication of poppy via aerial fumigation, as also in the first captures of persons that were introducing our country to this new market of drug trafficking.

The training of many officers in the DEA premises in Washington, as also the constant cooperation with the Office in Bogotá, allowed for a conclusive neutralising of the heroin mafia that was especially led by the organisations of the Cali Cartel and others.

Thanks to the cooperation of the DEA, we established an organised group that allowed for the detention of the Cali Cartel in record time due to the excellent coordination and professionalism of both police.

In 1994-1995 important detentions were made in cooperation with the DEA, such as:

1. JORGE ELICIER RODIRGUE OREJUELA, alias CAÑENGO
2. GILBERTO RODRIGUEZ OREJEUELA, alias EL AJEDRESISTA
3. MIGUEL RODRIGUE OREJUELA, alias EL SEÑOR
4. JOSE "CHEPE" SANTACRUZ
5. NELSON URREGO
6. PACHO HERRERA
7. GARMENDIA

8. ALBERTO ORLANDO GAMBOA, alias EL CARACOL
9. PASTOR PERAFAN

It is important to highlight the presence of the DEA in one of the most important operatives during my tenure, called Operation Millennium, from 1999, in which 32 drug traffickers were captured simultaneously and extradite to the United Status of America. Among them were important heads that had participated in the actions of the Medellin Cartel, such as Fabio Ochoa and Alejandro Bernal. The detentions included the following drug traffickers:

i. EDWIN HERNAN ABERLADRO GOMEZ MORENO
ii. JAIRO DE JESUS MESA SANIN
iii. RICARDO PASTOR OCHOA
iv. HECTOR MARIO LONDOÑO VASQUES
v. FREDDY IVA OCHO MEJIA
vi. HERMES DE JESUS BETANCOURT RIOS
vii. LUSI CARLOS SULUOAGA
viii. JUAN GUILLERMO ARBELAEZ DIAZ
ix. NESTOR ALBERTO GIRALDO PALACIO
x. HRACIO DE JESUS MORENO URIBE
xi. OSCAR ALIONZO GOMEZ MORENO
xii. CARLOS DAVID BARRERA
xiii. CARLOS MARIO LONDOÑO BOTERO

All of the above were condemned by a Miami Court.

At an international level, and as Representative of Colombia to the United Nations Office on Drugs and Crime (UNODC), I wish to render testimony to the high prestige of the DEA in international circles, where its cooperation activities are well known, not only those in Latin-America, but also its cooperation with the police of Austria, Spain, Portugal, and Turkey, among many other European nations, which allows for a global network in the fight against drug trafficking.

Having worked jointly with the DEA for ten (10) years, I wish to render homage of admiration and respect, because this cooperation and efficiency allowed us fundamental developments in the fight against drug trafficking, a scourge that has caused much damage to humanity. I wish to underline the DEAs capacity, assiduousness, and good spirit of service, traits that were picked up by the National Police of Colombia, creating two very strong institutions thanks to the cooperation between the Directive levels and specialised Agents, as also by the American Government and Congress, who with its accompaniment assisted in the technical and scientific development of the National Police of Colombia, strengthening the knowledge and means to construct a world without drugs.

Thank you very much.

General (r) ROSSO JOSE SERRANO CADENA
Ambassador of Colombia in Austria and Permanent Representative to
the United Nations Office in Vienna

PAIN MANAGEMENT PITFALLS

Psychological research on intense provider-client interactions yields insight into the doctor-chronic pain patient relationship and provides lessons in improving interactions.

by Ron Lechner, PhD, DBH
and Terri A. Lechner, MSW, LCSW

Much has been written about the controversy surrounding prescription of appropriate pain medications, the issues involved in prescribing, and effective risk-management prescribing procedures that help physicians implement an effective approach in working with chronic pain patients. However, little has been said about how this approach can complicate the provider-patient relationship to a degree that everyone involved in the process, including the patient, feel frustrated and misunderstood. There is, however, clear research in psychology that can help in the difficult and complex situations of professional interactions with pain patients. These studies have implications for physicians, psychologists, psychiatrists, clinical social workers, physical and occupational therapists, and other providers of care who offer treatment or independent evaluations for chronic pain patients.

Impediments to Patient-Doctor Interactions

The management of chronic pain patients has been the subject of much debate over the years. The public has been concerned about inadequate pain medication prescribing for those suffering from chronic pain conditions or those who have terminal conditions and are struggling with adequate pain control during their last days. Medical licensing boards, physicians, and the Federal Drug Enforcement Administration (DEA) are concerned about inappropriate or over-prescribing, addictions to opioids, and drug diversion. This has resulted in physicians losing their license to prescribe, some physicians being jailed for prescribing opioid pain medication,[1] and many physicians who are, as a result, extremely reluctant to prescribe any type of pain medication beyond the use of NSAIDs. Tensions and concerns are high among the DEA, physicians, and licensing boards. Patients respond to these tensions in negative ways by withholding information, trying to manipulate patient-physician interactions, or by being tense and angry in interactions with providers.

The American Pain Society, the International Society for the Study of Pain, and the American Academy of Pain Management, have all worked hard to change the environment and to present realistic approaches to prescribing for chronic pain patients. Pain medication prescribing is now seen as a basic patient right, but many physicians are still concerned about what this means for them as professionals and their practice. There are those who continue to have lingering suspicions that patients who are seeking pain medications are 'drug seekers' who only want to obtain legal prescriptions to satisfy their drug habits. To combat this, specific guidelines have been established to assist the prescribing professional working with chronic pain patients. These guidelines include a pain contract, specific documentation, follow-up, and monitoring for diversion or overuse of medications.[2]

Complication of Managed Care

The managed care model in which the physician is the 'gatekeeper' of medical care has further complicated the relationship between doctors and pain patients since this model is based on limiting services, watching for 'over-utilizers,' and keeping the

costs of care down as much as possible. As a result, physicians involved in treating chronic pain patients now feel that they must be constantly on guard for patients who will misuse services in some manner — even though only a small percentage of patients fall into this category. Even psychologists are being recruited by Independent Medical Examiner (IME) panels to detect deception and malingering rather than focusing on assisting patients in finding the most appropriate focus for care. Patients often report that they feel 'talked down to' and have assumptions being made about them without an attempt to understand them as individuals. These pain patients feel that medical appointments are more like interrogation sessions where they are under investigation and are dictated to about how to live and function, rather than being 'listened too.'

This charged environment, especially in the pain patient's case, often transforms the character of health care relationship from a relaxed atmosphere where one can feel safe in expressing fears and struggles, into a one-way dictation. Humor has often gone out of these interactions and the 'curative factors in the professional relationship' — central to psychological care and improvement — have been lost. This has fostered a professional relationship filled with misunderstanding, distance in relationship, and has left some physicians and patients, alike, feeling like criminals.

Social Situational Blocks

Psychological researchers have identified blocks to effective provider-client (i.e. doctor-patient) relationships and shed light on the struggles pain physicians face in providing services. Though many positive changes have happened in the field of pain management, including the importance of a multi-disciplinary approach to care, there are still blocks that often complicate the health care relationship.[8,9] Psychological research has repeatedly demonstrated that people tend to underestimate how the influence of social situations can dramatically impact their behaviors. Studies — conducted in the 1960's and 1970's — tested the social functioning of roles in situations with outside controlling authority and great power differential, respectively. The insight from these studies is directly applicable to pain management physicians in that similar social forces are at work, namely DEA, licensing boards, and the legal system, on the one hand; and the great power differential existing between doctor and patient, on the other.

What both studies have demonstrated is that powerful situations can cause anyone to perpetuate cruel acts — all the while justifying their behaviors and viewing the clients as 'the enemy' and therefore deserving of punishment. It particularly becomes a problem when the situation is focused on specific 'situational myths' that identify the clients in a negative manner. This can be aggravated when one is functioning in an environment of mistrust, frustration, stress, suspicion, anxiety, fear, or concern about complying with authority. Following are brief synopses of each situational study.

Impact of Outside Authority

A series of studies by Stanley Milgram, PhD, at Yale University in the 1960's showed the impact that outside authority can have on human behavior, in particular where it relates to a relationship of power over others. This series involved 1,000 individuals participatinge in role playing as either a "teacher" or "learner." The teachers were to administer increasing electric shocks to learners (actually hired actors) for any mistakes. The teachers could hear the screams of the learners (actors) in a separate room. Dr. Milgram wanted to see if the teachers would continue to administer increasingly lethal shocks to learners when told to do so by an authority figure in a 'white coat.' The result was that two thirds of the teachers continued to administer shocks with increasing voltage levels — up to 480 volts — despite screams and then total silence from the other room. In all, 100 percent of the teachers — although to varying degree — were obedient to the authority figures in administering shocks to the hapless learners.[8,9]

Impact of Power Differential

In 1971, Philip Zimbardo, PhD, professor of psychology at Stanford University studied the social functioning of roles where there is an enormous power differential in interactions with others. His study focused on two dozen college students who were randomly assigned to be either prison guards or prisoners in a simulated two week jail/prison setting. Dr. Zimbardo found that he had to stop the study after only six days because the prison guards became extremely abusive and angry — basing their actions on their perception of prisoners as being manipulative, trying to get away with things, and not acquiescing to their fate/role as inmates. Prisoners were isolated, stripped of clothing, bags put over their heads — among other abusive tactics — in concerted attempts to humiliate and over-control the prisoners. Anger at the prisoners was extremely high. Prisoners, responding to their treatment, became protectively manipulative and engaged in negative behaviors that was then noted by the guards and further justified retaliation.[10]

Dr. Zimbardo concluded that when the balance of power is so unequal, even normal people with no past history of psychological problems will become abusive and brutal unless extreme measures are taken to control hostile impulses. None of the students in the study had any previous pathology or problems noted prior to the study. Dr. Zimbardo further noted that when individuals are placed in alien settings, the situation itself will likely produce classic cases of abuse of power and control.

> "These pain patients feel that medical appointments are more like interrogation sessions where they are under investigation and are dictated to about how to live and function, rather than being 'listened too.'"

Implications for Pain Professionals

What both Zimbardo and Milgram noted is that interactional problems first start with a failure of leadership. This can include a diffusion of responsibility, dehumanization of clients, secrecy, lack of accountability, re-labeling controlling be-

haviors as necessary, developing justifications for controlling behaviors, social-peer modeling of negative behaviors, group pressures to conform, issues related to obedience of authority, and self-protection.[10]

These studies have clear implications for pain management professionals who are treated as suspect by their peers, licensing boards, the DEA, and legal professionals. The fear of pain patients becoming addicted, or being perceived as 'drug seeking,' often heightens a sense of concern for how to best work with patients who present with complex health care problems. It requires that patient management programs be constructed to facilitate better interactions with the patients. Discussing potential social situational blocks openly with staff is critical to helping to reduce negative consequences in patient-provider interactions.[10]

These studies have clear implications for pain management professionals who are treated as suspect by their peers, licensing boards, the DEA, and legal professionals.

Conclusion

Basic patient interactions require:

1) an understanding of information on how to work with patients presenting with chronic pain;
2) 'starting where the patient is at' rather than where the provider feels things should be focused;
3) starting interactions with patients using uncritical listening;
4) knowing the importance of a 'non-judgmental attitude' in interactions with patients;
5) remembering that the most important curative factor in all therapeutic interactions is 'the relationship.'

Without a positive, and trusting, relationship with mutual respect, little can be accomplished therapeutically, while a positive relationship can help deal with even 'problem behaviors' in a more open and helpful manner. This can even facilitate work with patients who present non-compliance, abuse, or other problems, since it allows the professional to work within the professional relationship to assist in resolving such dysfunctional behaviors. ■

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Terri Lechnyr, MSW, LCSW, is a Licensed Clinical Social Worker and psychotherapist who is associated with her father in private practice at the Pain Management & Behavioral Medicine Clinic. She is also a second year post-graduate student in the PhD doctoral program in Clinical Psychology at Capella University, Minneapolis, Minnesota. She is also an active member of the Pain Society of Oregon.

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PREPARED STATEMENT OF DON KUNZ, PRESIDENT, FOUR SEASONS DISTRIBUTORS

My name is Don Kunz, President, Four Seasons Distributors of Belleville, Illinois.

My first experience with the DEA was when they came to check our warehouse and security system in December of l998. The agent that did our inspection was less versed in the type of pills we carried than we were. The agent asked some pretty stupid questions just to try to trip us up. We keep records, I feel, as good as anyone in our business and the agent just couldn't understand why we did things the way we did. The agent told us that our documentation on invoices and records at our warehouse were as good as she had seen. We asked for documentation of her visit and were told that they did not do that. It sure would be nice to receive something from the DEA stating what you are doing right and wrong. It would also be nice to be able to go the DEA for a written handbook or guidelines pertaining to List 1 Chemicals. They do not put anything in writing.

Our second experience was when the DEA St. Louis office requested our sales invoices for Missouri stores that we call on for pseudoephedrine sales in that state. I told them the only pseudoephedrine we sold was 8 pills of 25 mg bottles. This did not make any difference; they still wanted any invoices showing sales of List 1 Chemicals. This was delivered as requested in a timely manner and it was very difficult to get someone to sign that they had received these records.

Our third experience was in January 2006. The agents were very nice; but, again, they were not familiar with the normal terms for products that all distributors carry. They requested all of our records for 2004 and 2005 that had any List 1 Chemical sold. This request came two weeks after a 2-day inspection of our warehouse, vehicles, and office. The records for those two years comes to approximately 6000 pages and 10 days of work just on this project. After we objected to releasing our customers' information without some sort of written request, they changed their mind and requested only 2005 and January1-5, 2006. Again, I asked for some written documentation of what we were doing right or wrong; and I was told that they never give any written inspection report.

We were verbally told that our facilities and records were in the best shape of anyone they had inspected. They could find nothing wrong with anything we do.

The problems persist. On Tuesday, May 29, 2007, I received a letter from the DEA stating that they wish to have a list of our customers that buy List 1 products. This seems to be a form letter to all registrants; but our company and its address were used.

First of all, the DEA has this information already from our last inspection. By the way, the investigators who inspected us said our records were the best and the cleanest they had seen. The DEA would also have this information from the self-certification that each store must go through in order to sell these products.

There is only one conclusion that can be drawn from this letter and that is to contact and harass and scare our customers into not selling these products. When we place these products with our customers, we are very careful to make sure that each one is self-certified and that each store has a log book (and uses it) and has trained their employees. Each visit to the stores we talk to the manager or owner about these products and how they are to be sold.

In the letter, it states "the DEA will in turn send a notice to these companies that they are selling regulated products and what their obligations are under CMEA." The next sentence states "DEA will not use these lists for any other purpose other than insuring compliance with the CMEA." This is a pure scare tactic to scare our customers. We have already lost a substantial number of customers due to the provisions of this new law. This letter will only insure more lost customers.

In the DEA own web site it states that 85% of the illegal meth comes from Mexico; yet they are still harassing my company and my customers.

My biggest concern is that you don't know if you have done something wrong until they come knocking on your door. As a legitimate businessman, I try to always be proactive and take care of any records or questions before they become a problem. The DEA calls convenience stores "gas stations" or "gray market". I think the major petroleum companies would find this offensive. There isn't an agent anywhere in the United States that doesn't stop at a convenience store for gas, cigarettes, coffee, or whatever every day they are working. And they consider this a "gray market"!!

I hope the committee takes a hard look at the DEA actions and intimidation of small businesses and our customers.

Thank you.

PREPARED STATEMENT OF BUDDY POOL, POOL MARKETING

My name is Buddy Pool, and I am the owner of Pool Marketing, which is located in Georgia.

In 1976, Georgia began requiring a State Pharmacy License for any wholesaler engaging in the sale of pseudoepheedrine products. I applied for the License. After the state licensing board received my application, I was instructed by the board to contact the Drugs and Narcotics Agency to schedule an inspection of my facility. When I made this request, I was told my company would not be granted a license. The business has a residential address and the only way to get the license was for the Licensing Board to grant an exemption. I visited the board office in Macon and spoke with Ms. Ann Shockley. She advised me to call Mr. Rick Allan with the Drug and Narcotics Agency. I spoke with Mr. Allen and he really overreacted even to telling me I could have been arrested for trespassing for visiting the office. He also stated I would not be receiving the state license and that he had been in touch with the DEA and they were in the process of pulling my DEA License. My DEA License expired on March 31, 2006. I submitted the application to renew on Feb. 19, 2006. After a few weeks, I began calling the DEA in Arlington to check on the status of the application. Each time I was told the application has not been processed yet.

On April 20th I contacted the Atlanta office and was informed by a lady named Liz, that they had no record of my applying and Liz advised me to reapply on line and to be sure to get a confirmation no. and run a copy of the application, which I did. A couple of weeks later I called Liz back to follow up. She connected me with her supervisor, Mr. Shortas. The first question Mr. Shortas asked was "Who are your customers?"

I answered that I service Convenience Stores. Mr. Shortas replied that my DEA License would not be renewed. He said convenience stores don't need to sell ephedrine products. If a person needs ephedrine products, he should go to a drug store. He also stated my company would be investigated and they would make a recommendation to Washington about my renewal. But the license would not be renewed.

Policy Analysis

No. 545 June 16, 2005

Routing

Treating Doctors as Drug Dealers
The DEA's War on Prescription Painkillers

by Ronald T. Libby

Executive Summary

The medical field of treating chronic pain is still in its infancy. It was only in the late 1980s that leading physicians trained in treating the chronic pain of terminally ill cancer patients began to recommend that the "opioid therapy" (treatment involving narcotics related to opium) used on their patients also be used for patients suffering from nonterminal conditions. The new therapies proved successful, and prescription pain medications saw a huge leap in sales throughout the 1990s. But opioid therapy has always been controversial. The habit-forming nature of some prescription pain medications made many physicians, medical boards, and law enforcement officials wary of their use in treating acute pain in nonterminal patients. Consequently, many physicians and pain specialists have shied away from opioid treatment, causing millions of Americans to suffer from chronic pain even as therapies were available to treat it.

The problem was exacerbated when the media began reporting that the popular narcotic pain medication OxyContin was finding its way to the black market for illicit drugs, resulting in an outbreak of related crime, overdoses, and deaths. Though many of those reports proved to be exaggerated or unfounded, critics in Congress and the Department of Justice scolded the U.S. Drug Enforcement Administration for the alleged pervasiveness of OxyContin abuse.

The DEA responded with an aggressive plan to eradicate the illegal use or "diversion" of OxyContin. The plan uses familiar law enforcement methods from the War on Drugs, such as aggressive undercover investigation, asset forfeiture, and informers. The DEA's painkiller campaign has cast a chill over the doctor-patient candor necessary for successful treatment. It has resulted in the pursuit and prosecution of well-meaning doctors. It has also scared many doctors out of pain management altogether, and likely persuaded others not to enter it, thus worsening the already widespread problem of undertreated or untreated chronic pain.

Ronald T. Libby is a professor of political science and public administration at the University of North Florida.

CATO INSTITUTE

In 1995 untreated pain cost American business more than $100 billion in medical expenses, lost wages, and other costs, including 50 million workdays.

Introduction

Untreated pain is a serious problem in the United States. Given the difficulties in measuring a condition that's untreated, estimates vary, but most experts agree that tens of millions of Americans suffer from undertreated or untreated pain. The Society for Neuroscience, the largest organization of brain researchers, estimates that 100 million Americans suffer from chronic pain.[1] The American Pain Foundation, a professional organization of pain specialists, puts the number at 75 million—50 million from serious chronic pain (pain lasting six months or more), and an additional 25 million from acute pain caused by accidents, surgeries, and injuries. The societal costs associated with untreated and undertreated pain are substantial. In addition to the obvious cost of needless suffering, damages include broken marriages, alcoholism and family violence, absenteeism and job loss, depression, and suicide.[2] The American Pain Society, another professional group, estimates that in 1995 untreated pain cost American business more than $100 billion in medical expenses, lost wages, and other costs, including 50 million workdays.[3] A 2003 article in the *Journal of the American Medical Association* puts the economic impact of common ailments alone—such as arthritis, back pain, and headache—at $61.2 billion per year.[4]

Chronic pain can be brought on by a wide range of illnesses, including cancer, lower back disorders, rheumatoid arthritis, shingles, post-surgical pain, fibromyalgia, sickle cell anemia, diabetes, HIV/AIDS, migraine and cluster headaches, pain from broken bones, sports injuries, and other trauma.

According to one 1999 survey, just one in four pain patients received treatment adequate to alleviate suffering.[5] Another study of children who died from cancer at two Boston hospitals between 1990 and 1997 found that almost 90 percent of them had "substantial suffering in the last month, and attempts to control their symptoms were often unsuccessful."[6] In a formal policy statement issued in 1999, the California medical board found "systematic undertreatment of chronic pain," which it attributed to "low priority of pain management in our health care system, incomplete integration of current knowledge into medical education and clinical practice, lack of knowledge among consumers about pain management, exaggerated fears of opioid side effects and addiction, and fear of legal consequences when controlled substances are used."[7] The American Medical Association stated in a 1997 news release that 40 million Americans suffer from serious headache pain each year, 36 million from backaches, 24 million from muscle pains, and 20 million from neck pain. An additional 13 million suffer from intense, intractable, unrelenting pain not related to cancer. Most of those patients, the AMA warned, receive inadequate care because of barriers to pain treatment.[8] A 2004 survey of the medical literature published in the *Annals of Health Law* found documented widespread undertreatment of pain among the terminally ill, cancer patients, nursing home residents, the elderly, and chronic pain patients, as well as in emergency rooms, postoperative units, and intensive care units.[9]

One reason chronic pain remains undertreated is that there are few doctors who specialize in the field. Dr. J. David Haddox, the vice president of health affairs at Purdue Pharma L.D., the manufacturer of long-acting opioid medications OxyContin and MSContin, estimates that between four or five thousand doctors who specialize in pain management treat the 30 million chronic pain patients who seek treatment in the United States[10]—about one doctor for every 6,000 patients. In Florida, just 1 percent or 574 of the state's 56,926 doctors prescribed the vast majority of narcotic drugs paid for by Medicaid in 2003.[11]

The shortage of pain doctors can in part be explained by the relatively new, dynamic nature of pain medicine as well as society's aversion to narcotics. It wasn't until the 1980s that physicians who specialized in opioid treatment for pain associated with terminal cancer began to advocate the same treatment for nonterminal chronic pain patients.[12] The fact that the field is so novel has not only prevented physicians from seeking it out as a spe-

cialty, it initially caused a great deal of debate within the medical community. Though many physicians now approve of opioid therapy for nonterminal chronic pain, there was some initial resistance, from both inside and outside the medical community. "There's still a fear of opiates," University of California at San Francisco pain expert Allan Basbaum told the *San Francisco Chronicle*, "The word 'morphine' scares the hell out of people. To many patients, morphine either means death or addiction."[13] In an article for *Ramifications*, a newsletter for pain specialists, Dr. Karsten F. Konerding of the Richmond Academy of Medicine compares the contemporary practice of pain medicine with the infant field of radiology at the turn of the 19th century. One London newspaper at the time, Konerding notes, called radiographs of bones and organs "a revolting indecency."[14]

In addition to a reluctance to enter an emerging and not altogether accepted field, physicians specializing in pain medicine can also find themselves caught in a damned-if-you-do, damned-if-you-don't conundrum with some patients. This study deals primarily with the government's efforts to minimize the overprescribing of painkillers, but several physicians have also been sued for *underprescribing*, including one California physician who was successfully sued in 2001 for $1.5 million.[15]

But a significant reason pain is undertreated—and increasingly so—is the government's decision to prosecute pain doctors who it says overprescribe prescription narcotics. According to the federal government, a small group of doctors is prescribing hundreds of millions of dollars of such drugs, many of which are finding their way to the black market, contributing to an epidemic of addiction, crime, and death.[16] Over the last several years, federal and state prosecutors have prosecuted licensed physicians for drug distribution, fraud, manslaughter, and even murder for the deaths of people who misused and/or overdosed on prescription painkillers. If convicted, those physicians are subject to the same mandatory drug sentencing guidelines designed to punish conventional drug dealers. Those highly publicized indictments and prosecutions have frightened many physicians out of the field of pain management, leaving only a few thousand doctors in the country who are still willing to risk prosecution and ruin in order to treat patients suffering from severe chronic pain.[17] One 1991 study in Wisconsin, for example, found that over half the doctors surveyed knowingly undertreated pain in their patients out of fear of retaliation from regulators.[18] Another 2001 study of California doctors found that 40 percent of primary care physicians said fear of investigation affected how they treated chronic pain.[19] In states where state regulatory bodies aggressively monitor physicians' narcotics-prescribing habits, there is even more reticence among doctors to adequately treat pain.[20]

"The medical ambiguity is being turned into allegations of criminal behavior," Dr. Russell K. Portenoy told the *Washington Post*. Portenoy is a pain specialist at Beth Israel Medical Center in New York, and is considered one of the fathers of opioid pain therapy. "We have to draw a line in the sand here, or else the treatment will be lost, and millions of patients will suffer."[21]

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A Brief History of Painkillers and the Law

From the introduction of heroin from the 1880s until about 1920, narcotics were unregulated and widely available in the United States.[22] Drug addiction was largely accidental, due to the public's ignorance about the habit-forming properties of morphine, the most popular highly addictive drug of the era. Though widely used for medical operations and convalescence, morphine was also used in everyday potions and elixirs. The drug was commonly regarded as a universal panacea, used to treat as many as 54 diseases, including insanity, diarrhea, dysentery, menstrual and menopausal pain, and nymphomania.[23] Opiates were as readily available in drug stores and grocery stores as aspirin, serving many of the same functions that alcohol, tranquilizers, and antidepressants do

today. That perception changed during the progressive era of the early 20th century, when the government criminalized the common use of opium.[24]

The first federal law to criminalize the nonmedical use of drugs was the Harrison Act of 1914, which outlawed the nonmedical use of opium, morphine, and cocaine.[25] The law was supported by advocates of Prohibition.[26]

Section 2 of the Harrison Act made it illegal for any physician or druggist to prescribe narcotics to an addict, effectively turning a quarter-million drug-addicted citizens and their doctors into criminals.[27] By 1916, 124,000 physicians; 47,000 druggists; 37,000 dentists; 11,000 veterinarians; and 1,600 manufacturers, wholesalers, and importers had registered with the Treasury Department, as required by the Harrison Act.[28] Almost as soon as they had registered, hundreds of doctors were arrested and prosecuted for prescribing narcotics to addicted patients.[29] During the first 14 years of the act, U.S. attorneys prosecuted more than 77,000 people, mostly medical professionals, for violating the act.[30] Between 1914 and 1938, about 25,000 doctors were arrested under the terms of the Harrison Act for giving narcotic prescriptions to addicts.[31] Many were eventually put on trial, and most lost their reputations, careers, and/or life savings. By 1928, the average sentence for violation of the Harrison Act was one year and 10 months in prison.[32] More than 19 percent of all federal prisoners were incarcerated for narcotics offenses.[33] Clinics closed down, and physicians had little choice but to abandon thousands of addicted patients. A black market for narcotics soon arose.

With the endorsement of powerful public figures such as Secretary of State William Jennings Bryan, Captain Richmond Pearson Hobson (the "Great Destroyer" of alcohol and narcotics addiction and the Anti-Saloon League's highest-paid publicist), and Harry J. Anslinger (the first commissioner of narcotics and former assistant commissioner of Prohibition), the U.S. government inaugurated an aggressive, unprecedented pursuit of physicians and their addicted patients.[34]

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The Harrison Narcotics Act was repealed in 1970, but was replaced by the Drug Abuse Prevention and Control Act.[35] DAPCA, along with the 1975 Supreme Court ruling in the case *U.S. v. Moore*, reaffirmed the legality of the Harrison Act's criminalization of doctors who treat addicts by prescribing controlled pharmaceuticals.[36] In *Moore*, the Supreme Court confirmed that physicians who are licensed by the Drug Enforcement Agency to prescribe narcotics under Title II of DAPCA (called the federal Controlled Substances Act) "can be prosecuted when their activities fall outside the usual course of professional practice."[37] A doctor could be criminally charged with unlawfully prescribing (or "diverting") highly addictive narcotic drugs that the DEA classifies as Schedule II "controlled substances." Even though it was passed during a period of general drug tolerance, DAPCA would prove to be a potent weapon in later years as the War on Drugs intensified.

A New Mission for the DEA

As the federal government's chief drug law enforcement agency since 1973, the DEA's mission has been to "bring to the criminal and civil justice system substances destined for illicit traffic in the U.S."[38] Until the 1990s, the DEA focused its resources primarily on illegal black market drugs, such as heroin, cocaine, crack cocaine, ecstasy, and marijuana, in urban areas.

But in 1999 the DEA came under heavy criticism from Congress on the grounds that there was no "measurable proof" that it had reduced the illegal drug supply in the country.[39] In 2000 and 2001 the Department of Justice, which administers the DEA, gave the agency a highly critical rebuke, and asserted that the Drug Enforcement Agency's goals were not consistent with the president's federal National Drug Control Strategy.[40] The DEA would need to find a new front for the War on Drugs, one that could produce tangible, measurable results.

The Controlled Substances Act empowered the DEA to regulate all pharmaceutical drugs. In 2002 Glen A. Fine, the inspector general of the Department of Justice, asked why the DEA wasn't doing more to combat prescription drug abuse when it was "a problem equal to cocaine."[41] Fine claimed that, while 4.1 million Americans used cocaine in 2001, 6.4 million illegally used prescription narcotic painkillers that same year. He also claimed that the illicit use of pain medication accounted for 30 percent of all emergency room drug-related deaths and injuries.

In 2001 the DEA had already announced a major new anti-drug campaign: the OxyContin Action Plan.[42] The agency underscored the threat of prescription drug abuse by asserting that the number of people who "abuse controlled pharmaceuticals each year equals the number who abuse cocaine—2 to 4 percent of the U.S. population."[43] The agency also claimed that prescription drugs increased the number of overdose deaths by 25 percent and accounted for 20 percent of all emergency room visits for drug overdoses.[44] Criticism from Congress and the Department of Justice the following year reaffirmed the agency's determination to crack down on prescription drugs. The OxyContin plan would elevate a legal, prescription drug to the status of cocaine and other Schedule II substances. That shift put pain doctors in the DEA's crosshairs, as susceptible to investigation as conventional drug dealers. In September of 2003, at the 69-count indictment of Virginia doctor William Hurwitz, U.S. Attorney Mark Lytle claimed that the physician was complicit in the deaths of three patients, and compared William Hurwitz to a "street-corner crack dealer." Lytle further argued that Dr. Hurwitz posed such a threat to the community that he should be denied bail.[45]

The OxyContin Action Plan bore a remarkable resemblance to the Harrison Act in that it enabled the federal government to prosecute physicians who prescribed an otherwise legal narcotic drug, due to unfounded fears of a "dope menace" sweeping the country. DEA commissioner Asa Hutchinson described the nonmedical use of OxyContin as a deadly new drug epidemic beginning in Appalachia and spreading to the East Coast and Midwest, infecting suburban, urban, and rural neighborhoods across the country:

> In the past, Americans viewed drug abuse and addiction as an overwhelmingly urban problem. As the drug problem escalated, drugs began to stream into rural neighborhoods throughout small town America. Residents began to feel the impact of drugs such as marijuana, cocaine, methamphetamine, MDMA, heroin, and OxyContin, which entered their towns at an alarming rate. Violence associated with drug trafficking also became part of the landscape in small cities and rural areas.[46]

This was the first time that the DEA had grouped a legal, prescription drug with illicit drugs, though it wouldn't be the last. Government officials like Hutchinson have gone on to make frequent public statements putting OxyContin in close rhetorical proximity to cocaine, heroin, and other drugs with a proven record for generating public fear. During congressional testimony in April 2002, Hutchinson explained the necessity for renewed vigilance in the War on Drugs, and why the new front against prescription painkillers was necessary. He announced that the DEA would reallocate many of its resources from illegal drugs in urban areas to illicit prescription drugs in rural areas in order to address the emerging opioid threat. Hutchinson said that the DEA would work with local and state law enforcement agencies in the effort, and would use its Asset Forfeiture Fund to help state and local officials finance the new initiative.[47]

The DEA's public relations effort linking a pain medication like OxyContin to cocaine, heroin, and other prohibited substances was a marked departure from its traditional mission. In fact, the DEA had created a new mission for itself—combating the illegal diversion of otherwise legal medication. Where the conventional drug war targeted black

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markets and the unknown, hard-to-quantify entities that come with them, the new mission offered in practicing physicians a pool of registered, licensed, cooperative targets who kept records, paid taxes, and filled out a variety of forms.

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Justifying the OxyContin Campaign

In an effort to justify its national campaign against OxyContin, the DEA contacted 775 medical examiners from the National Association of Medical Examiners in 2001 and instructed them to report "OxyContin-related deaths" for 2000 and 2001.[48] On the basis of those reports, the DEA subsequently announced 464 "OxyContin-related deaths" over those two years.[49]

But the conclusions the DEA drew from this data are significantly flawed.

First, the DEA's criteria for "OxyContin-related deaths" are problematic. There are 58 pain relief drugs that contain oxycodone. OxyContin is simply one of three single-entity, long-acting, oxycodone drugs. There are numerous other less potent, short-acting, oxycodone drugs, such as Percocet, Percodan, and Roxicet that also contain nonnarcotic pain relievers such as aspirin or Tylenol. OxyContin is Purdue Pharma's brand name drug. It's popular because it provides long-acting relief from pain for up to 12 hours, which enables pain sufferers to sleep through the night. Since there is no chemical test to distinguish OxyContin from the other oxycodone drugs, it is difficult to see how the DEA could definitively assert that a death attributable to oxycodone is due to OxyContin and not other short-acting oxycodone drugs. Nevertheless, the DEA counts as an "OxyContin-related death" any death in which oxycodone is detected without the presence of aspirin or Tylenol.[50]

Second, if an OxyContin tablet is found in the gastrointestinal tract of a deceased person, the DEA labels it an "OxyContin-*verified* death," regardless of other circumstances. Even more problematic, if investigators find OxyContin pills or prescriptions at a crime scene, or a family member or witness merely mentions the presence of OxyContin, the death is also confirmed as "OxyContin-verified."[51] Obviously the mere presence of OxyContin in the system of the deceased, or the mere mention of the drug by friends or family members is far from verification that OxyContin—either alone or in conjunction with other factors—actually caused a premature death.

Third, overdose victims tend to have multiple drugs in their bodies.[52] Approximately 40 percent of the autopsy reports of OxyContin-related deaths showed the presence of Valium-like drugs. Another 40 percent contained a second opiate such as Vicodan, Lortab, or Lorcet, in addition to oxycodone. Thirty percent showed an antidepressant such as Prozac, 15 percent showed cocaine, and 14 percent indicated the presence of over-the-counter antihistamines or cold medications. Deaths like those could be the result of any of the drugs present, drugs working in combination, or one or more drugs plus the effects of other conditions, such as illness or disease. Indeed, the March 2003 issue of the *Journal of Analytical Toxicology* found that of the 919 deaths related to oxycodone in 23 states over a three-year period, only 12 showed confirmed evidence of the presence of oxycodone alone in the system of the deceased.[53] About *70 percent* of the deaths were due to "multiple drug poisoning" of other oxycodone-containing drugs in combination with Valium-type tranquilizers, alcohol, cocaine, marijuana, and/or other narcotics and anti-depressants.[54] That is strong evidence that many of the deaths attributed to OxyContin by government officials are not the result of unknowing pain patients who grew addicted and overdosed, but of habitual drug users who may have used the drug with any number of other substances, any one of which could have contributed to overdose and death.

In the absence of opioids like OxyContin, habitual users will, in all likelihood, merely switch to more available drugs. However, pain patients who rely on the drug for relief

don't have that option. They're far more likely to suffer from the scarcity caused by the DEA's crackdown than are the common drug abusers the agency claims it is targeting.

A final problem with the DEA's claims of an OxyContin epidemic is the agency's inflated estimate of risk of death. In 2000 physicians wrote 7.1 million prescriptions for oxycodone products without aspirin or Tylenol, 5.8 million of them for OxyContin.[55] According to the DEA's own autopsy data, there were 146 "OxyContin-verified deaths" that year, and 318 "OxyContin-likely deaths," for a total of 464 "OxyContin-related deaths."[56] That amounts to a risk of just 0.00008 percent, or eight deaths per 100,000 OxyContin prescriptions—2.5 "verified," and 5.5 "likely-related." Even *those* figures are calculated only after taking the DEA's troubling conclusions about causation at face value.

By contrast, approximately 16,500 people die each year from gastrointestinal bleeding associated with nonsteroidal anti-inflammatory drugs (NSAIDs) like aspirin or ibuprofen.[57] NSAIDS aren't as effective as opioids at treating severe, chronic pain. Both classes of painkillers have beneficial medical uses. One is also found on the black market and may lead to occasional deaths by overdose. The other isn't used recreationally, but causes 35 times more deaths per year.

Given these numbers, all of the time, energy, tax dollars, and worry expended on eradicating the OxyContin "threat"—not to mention the menace to civil liberties—seems unfounded.

Another Bout of Drug Hysteria

In order to justify its crackdown on prescription painkillers, the federal government would first need to persuade the public of the threat posed by prescription opioids. Unfortunately, the media has been far too willing to accept the DEA's claims at face value, just as it has with previous drug "epidemics."[58]

To convince the public that there is an opioid drug threat, the DEA compared OxyContin to crack, cocaine, and heroin, the most feared drugs of the 1980s and '90s. Commissioner Asa Hutchinson testified before Congress in 2002 that OxyContin delivers a "heroin-like high," and that the drug has led to an "increase in criminal activity."[59] Many mainstream media reports echoed these claims. *Newsweek*, for example, ran a story in 2002 about "Oxybabies," the children of pregnant women on OxyContin, who bore a striking resemblance to the rash of "crack babies" reported in the 1980s.[60] The article did point out that despite stories that OxyContin abuse has "swept through parts of Appalachia and rural New England," the number of documented cases of addicted newborns is small, "in the dozens," and that "OxyContin, like other opiates, doesn't appear to cause birth defects." After citing a few anecdotal cases of newborns with some health problems that may or may not have been related to OxyContin, reporter Debra Rosenberg still ended the article by questioning whether Oxybabies are a "blip—or an epidemic in the making." But the article's evidence indicates the former, so strongly in fact that one wonders why an article on Oxybabies was necessary in the first place.

Newspapers and magazines reported on the alleged rising death toll from OxyContin, and that the outbreak in opioid abuse posed a greater threat to public health and welfare than cocaine. Soon, arrest and overdose statistics were juxtaposed with OxyContin sales figures, painting the grim picture of an American pharmaceutical company willing to peddle addiction and death for a quick buck.

A few examples:

- *Time* ran a story in January 2001, reporting that "OxyContin may succeed crack cocaine on the street."[61] In Pulaski, Virginia, OxyContin had overtaken cocaine and marijuana, *Time* reported, and property crime was up 50 percent. Police in three states reported robberies of pharmacies, as well as the homes of people known to take OxyContin legitimately (how the burglars knew who was taking the drug isn't clear). Both of course are means by which OxyContin may have found its way to the street that wouldn't

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The medical evidence overwhelmingly indicates that when administered properly, opioid therapy rarely, if ever, results in "accidental addiction" or opioid abuse.

require prescriptions from a diverting doctor. Still, the article seemed to focus on physicians. U.S. attorney Jay McCloskey was described in the article as a man "waging a war against the doctors who write prescriptions."

- On February 3, 2001, *US News and World Report* published an article about the danger of OxyContin under the headline "The 'Poor Man's Heroin.'"[62] The article featured Dr. John F. Lilly, a 48-year-old orthopedist and proprietor of a pain clinic who was also under investigation for diversion. Prosecutors claimed that Dr. Lilly ran a "pill mill" that supplied illegal narcotics to addicts in the slums of the industrial city of Portsmouth, Ohio. Local law enforcement officials told the magazine that OxyContin abuse was reaching near-epidemic levels in rural areas. Shortly after Dr. Lilly opened his clinic, drug-related crimes apparently started to increase. But police also claimed that burglaries increased 20 percent in 2000, again suggesting that the drug was getting to the street by means other than doctors' prescriptions.
- On February 8, 2001, the *New York Times* reported a claim by U.S. attorney Joseph Famularo that at least 59 people had died from OxyContin overdoses in Eastern Kentucky in 2000 alone.[63] He said OxyContin had set off a wave of pharmacy burglaries, emergency room visits, and physician arrests. Rick Moorer, an investigator with the state medical examiner's office in Roanoke, Virginia, reported that there were 16 deaths in southwestern Virginia due to OxyContin in combination with other drugs and alcohol.

Again, there's simply no test to determine whether or not OxyContin caused or contributed to those overdose deaths. And even if there *were* such a test, it's just as likely the drugs came from Internet pharmacies, or home or drug store robberies as from diverting doctors. The *Times* article also reported data showing hospital emergency room visits by people "involving oxycodone" increased from 3,190 in 1996 to 6,429 in 1999. The *Times* article doesn't give a source or context when it reports that "federal data" show an increase in ER visits "involving oxycodone." But presumably, they come from the Drug Abuse Warning Network—or DAWN—report, published by the U.S. Department of Health and Human Services. That report's findings seem to mirror the numbers in the *Times*.[64] But the DAWN report only cites "mentions" of oxycodone-related drugs in emergency room reports, which can include cases in which oxycodone medication had nothing to do with why the patient came to the emergency room. In fact, in more than 70 percent of emergency room visits involving oxycodone, patients mentioned the drug in conjunction with at least one other controlled drug. Certainly, abuse of increasingly abundant oxycodone medication will lead to some increase in emergency room visits attributable solely to the drug. But the drug's increasing availability also means that it's going to be present in more people who visit emergency rooms for other reasons. And that more people are abusing the drug is also no reason to suspect that corrupt physicians are the source of the problem.

The most unfortunate effect of these kinds of stories is that they reinforce existing qualms about opioids. Patients, their families, and even caretakers understandably get nervous when they hear "morphine," or "opioid therapy," which naturally sounds a lot like "opium." In truth, however, the medical evidence overwhelmingly indicates that when administered properly, opioid therapy rarely, if ever, results in "accidental addiction" or opioid abuse.[65] Most recently, a 2005 study by researchers at the Minneapolis VA Medical Center concluded, "doubts or concerns about opioid efficacy, toxicity, tolerance, and abuse or addiction should not be used to justify the withholding of opioids from patients who have pain."[66]

Temple pharmacology professor Robert Raffa told *Time* magazine, "The idea that your mom will go into a hospital, be exposed to morphine, and automatically become an addict is just plain wrong."[67]

The distinction—which seems especially difficult for law enforcement officials and policymakers to make—is between "physical dependence" and "addiction." A patient incapacitated by pain will naturally become dependent on any medication that gives him relief. But that's quite different from addiction. Opioid therapy can give patients the freedom to lead normal lives, whereas addiction ruins lives. It's a confusion that can be tragic. One doctor told *Time* he was treating a terminally ill boy whose father didn't want his son on morphine because he was "afraid the boy would become an addict." As the *Time* reporter wrote, "In his grief over the imminent loss of his son, it seems, the father failed to see the absurdity of worrying about long-term addiction in a child who is dying in pain."[68]

The odd thing is that well before the OxyContin hysteria and ensuing DEA campaign, many media outlets were making those same points and providing balanced reporting on the undertreatment of pain. The *Time* article noted above came out in 1997. Also in 1997, *U.S. News and World Report* ran a 4,400-word cover story on the plight of pain patients.[69] In one passage, the magazine eloquently laid out the problem:

> What is lacking is not the way to treat pain effectively but the will to do it. For a quarter of a century, pain specialists have been warning with increasing stridency that pain is undertreated in America. But a wide array of social forces continue to thwart efforts to improve treatment. Narcotics are the most powerful painkillers available, but doctors are afraid to prescribe them out of fear they will be prosecuted by overzealous law enforcers, or that they will turn their patients into addicts . . . . "We are pharmacological Calvinists," says Dr. Steven Hyman, director of the National Institute of Mental Health.[70]

The authors go on to state:

> But at the heart of the debate is confusion about what constitutes addiction and what is simply physical dependence. Most people who take morphine for more than a few days become physically dependent, suffering temporary withdrawal symptoms—nausea, muscle cramps, chills—if they stop taking it abruptly, without tapering the dose. But few exhibit the classic signs of addiction: a compulsive craving for the drug's euphoric or calming effects, and continued abuse of the drug even when to do so is obviously self-destructive.
>
> In three studies involving nearly 25,000 cancer patients, [researcher Russell] Portenoy found that only seven became addicted to the narcotics they were taking . . . "If we called this drug by another name, if morphine didn't have a stigma, we wouldn't be fighting about it," says [researcher Kathleen] Foley.[71]

Even physicians can fall victim to the "addiction" versus "dependence" confusion—giving rise to yet another cause of undertreatment. Twenty-five percent of Texas physicians in one survey said they believed any patient given opioids is at risk of addiction.[72] Thirty-five percent of physicians in a 2001 study said they'd *never* prescribe opioids on a short-term basis, even after a thorough evaluation, a response the survey's researchers attributed to unfounded fears of addiction.[73] Again, this despite overwhelming evidence that properly prescribed and used opioids rarely, if ever, lead to addiction.

There is a distinction—which seems especially difficult for law enforcement officials and policymakers to make—between "physical dependence" and "addiction."

"OxyContin under Fire"

One of the more egregious examples of media-induced OxyContin hysteria was Doris Bloodsworth's five-part *Orlando Sentinel* series from October 19–23, 2003, entitled "OxyContin under Fire."[74]

The *Sentinel* series was heavily advertised and promoted as an exposé of the OxyContin epidemic sweeping the country. Including Bloodsworth's pieces, the *Sentinel* ran 19 OxyContin-related articles and editorials that month, complete with photos of victims,

flashy layouts, and insert boxes designed to elicit maximum emotional impact. The series spotlighted several patients described as "accidentally addicted" to OxyContin. Some of them, Bloodsworth reported, experienced painful withdrawal effects. Some saw their families fall apart. Some died of overdoses or committed suicide. Bloodsworth alleged that white males aged 30 to 60 who experience back pain are particularly likely to become addicted to OxyContin, and to eventually die from that addiction.[75]

One of the featured victims was David Rokisky, a 36-year-old former Army Airborne soldier and police officer living in Tampa, Florida. According to Bloodsworth, Rokisky had a bodybuilder's physique, a beautiful young wife, a high-paying job as a computer company executive, and a beachfront condo. Rokisky's life was idyllic, Bloodsworth reported, until a doctor prescribed OxyContin to treat a minor backache. According to the *Sentinel*, Rokisky quickly became an innocent victim of drug addiction. He eventually lost his job and had to undergo painful detoxification.

The series also featured Gerry Cover, a 39-year-old Kissimmee, Florida, handyman and father of three. Bloodsworth reported that Cover became an addict after a doctor prescribed OxyContin to relieve his pain from a mild herniated disc in his back. Cover subsequently died from an accidental overdose of the drug.

Bloodsworth wrote that although members of Congress and the FDA were aware of "the devastation (OxyContin) has carved through Appalachia where the drug became known as 'hillbilly heroin,'" neither had done anything to slow down the epidemic. She blamed Purdue Pharma for aggressively marketing OxyContin to naïve and unscrupulous doctors, who likewise used the drug to "boost their profits."[76] According to Bloodsworth, there were 573 deaths in Florida linked to oxycodone in 2001 and 2002. By comparison, Bloodsworth reported that only 521 people died of heroin overdoses during the same period.[77] The 573 figure apparently came from the *Sentinel*'s review of thousands of documents, including 500 autopsy reports by Florida's medical examiners. The paper claimed that a remarkable 83 percent of the 247 cases of reported drug overdose deaths over that period were directly attributable to OxyContin.[78]

It would be difficult to overstate how much the *Sentinel* series contributed to nationwide OxyContin fears. It prompted an anti-opioid grass-roots protest movement in Florida. The newspaper's critique of lawmakers for "doing nothing" stirred emotion and legislative action on the local, state, and national level. In November 2003, one month after the series appeared, protestors from all over the country converged on Florida to picket Gov. Jeb Bush and his wife, who were attending a three-day conference on youth drug abuse in Orlando. Members of "Relatives against Purdue Pharma" carried poster-sized photos of family and friends who allegedly died from OxyContin overdoses.[79] Victor Del Regno, a Rhode Island business executive whose 20-year-old son died, allegedly from OxyContin, told the *Sentinel*. "We feel there has to be a way to get the word out about how deadly this drug can be."[80]

Governor Bush and state lawmakers were sympathetic, and promised to put an end to the "hemorrhaging of lost lives" allegedly caused by prescription painkillers.[81] During congressional testimony inspired by the *Sentinel* series and its aftermath, Florida director of drug control James McDonough praised Doris Bloodsworth's series, and cited her estimates of OxyContin overdose deaths. He said that in response to the *Sentinel* and other reports, Florida had taken "aggressive action against [diversion] criminal practices."[82]

McDonough boasted that Florida law enforcement had taken action since the *Sentinel* series, including the prosecutions of Dr. James Graves (a former Navy flight surgeon), convicted on four counts of manslaughter for prescribing oxycodone; Dr. Sarfraz Mirza, convicted of trafficking in OxyContin; and Dr. Asuncion Luyao, who was prosecuted for several prescription overdose deaths.[83]

Bloodsworth's claims about the OxyContin epidemic were picked up and repeated in news-

It would be difficult to overstate how much the *Sentinel* series contributed to nationwide OxyContin fears.

papers and media outlets all over the country. They were even included in a General Accounting Office report on OxyContin abuse requested by Congress. GAO cited the *Sentinel* series and said that the newspaper's investigation of autopsy reports involving oxycodone-related deaths found that OxyContin had been involved in more than 200 overdose deaths in Florida since 2000.[84]

Thanks in large part to the *Sentinel* series, Florida today is one of the most difficult states in the country for pain patients to get treatment, and its legislature only narrowly voted down a bill establishing a statewide database to track and monitor painkiller prescriptions.[85]

The *Sentinel* Series Unravels

In February of 2004, the *Orlando Sentinel* series on OxyContin began to fall apart. Investigations by Purdue Pharma and advocates for pain patients uncovered numerous and grievous errors in Bloodsworth's reports. The *Washington Post* reported that David Rokisky had pled guilty to drug conspiracy in a cocaine case four years previous to the series' publication. Far from leading an idyllic life wrecked by OxyContin, Rokisky in fact had a long history of domestic-abuse allegations and financial problems.[86] "Accidental addict" Gerry Cover proved to be a longtime drug abuser too, and had been hospitalized for an overdose on other drugs three months before he had been prescribed OxyContin.[87]

Bloodsworth's misrepresentation of OxyContin overdose deaths was even more egregious than her mischaracterizations of the alleged victims of the drug. The series completely distorted the Florida medical examiners' drug overdose deaths data for 2000 and 2001. Instead of more than 570 deaths linked to OxyContin the *Sentinel* reported for those years, the medical examiners' reports reveal the actual total for those years was 71—35 in 2001, and 36 in 2002.[88] The *Sentinel* had included not only deaths where oxycodone alone was present in the system of the deceased, but also deaths in which any oxycodone product was present in combination with any number of other drugs. There were 317 such deaths in 2001, and 220 in 2002, giving the *Sentinel* its 573 deaths.[89] In truth, even those 71 overdose deaths over the *Sentinel*'s two-year period are suspect. That's because Florida's medical examiners report only 14 drug groups in autopsy reports.[90] It's likely that there were any number of unreported drugs in the systems of 71 people where only oxycodone was found, not to mention that any number of them might have died for reasons completely unrelated to drugs. For example, the deceased may also have been taking antidepressants, heart medication, and/or diabetic medications, any of which could have potentially contributed to the cause of death. That's particularly likely where the deceased is over 50 years of age—true of about a third of the 71 Florida cases.[91]

After a barrage of criticism, the *Orlando Sentinel* finally acknowledged its errors in the series, and in February 2004 announced Doris Bloodsworth's resignation from the paper. The two editors who worked on the series were also reassigned.[92]

In a front-page correction, the *Sentinel* wrote the following:

> An *Orlando Sentinel* series in October about the drug OxyContin used a key statistic incorrectly and overstated the number of overdoses caused solely by oxycodone, the active ingredient in OxyContin and other prescription painkillers. . . .
>
> In roughly three out of four cases, medical examiners concluded that at least one other drug also contributed to the victims' deaths. . . . .
>
> According to the *Sentinel*'s re-examination, blood samples in about 38 percent of the oxycodone-related deaths showed the presence of heroin, cocaine, methamphetamine and/or marijuana. Many other victims also had consumed one or more commonly abused prescription drugs, such as Xanax or Vicodin.
>
> In February, the *Sentinel* published a story correcting factual errors about two men featured in the series. The

After a barrage of criticism, the *Orlando Sentinel* finally acknowledged its errors in the series, and in February 2004 announced Doris Bloodsworth's resignation from the paper.

newspaper had labeled one of them, David Rokisky, an "accidental addict" without doing background reporting that would have shown he had a federal drug conviction. The other, the late Gerry Cover, died from an overdose caused by a combination of drugs rather than oxycodone alone.[93]

Despite the *Sentinel*'s retraction, other media outlets have continued to drum up the OxyContin threat, many of them making the same errors the *Sentinel* did. Here are a few examples:

- In late August of 2004, the *Montreal Gazette* reported that "the prescription painkiller nicknamed 'hillbilly heroin' in the U.S., was a contributing factor in at least 26 overdose deaths in Quebec since 1999."[94] Remarkably, the paper went on to draw the same conclusions about autopsy reporting as the *Sentinel*. The *Gazette* reported that "other narcotic substances were also detected, suggesting that OxyContin alone might not have caused some deaths," a caveat that severely undermines the alarming lead.
- That same month, the *Ottawa Citizen* reported that "in the past five years there were 300 deaths in which oxycodone, the opiate found in OxyContin and the drug brand Percocet, was detected in the body."[95] That number again means very little when not supported with other information, such as what other drugs were found in the bodies, what illnesses the deceased were suffering from, and how many OxyContin prescriptions were written in comparison to those 300 deaths.
- Also in August 2004, the *Boston Globe* ran a story on federal grants coming to the Boston area that would be used to target OxyContin abuse.[96] One local official told the *Globe*, "we are going to . . . bring the danger of OxyContin right out there so everyone is going to know how bad it is," and that "OxyContin use can lead to heroin use." A local mayor called OxyContin "the number one health crisis in cities and towns at this time."[97]

Despite the *Sentinel* fiasco, media outlets continued to perpetuate OxyContin fears by reiterating overdose statistics based on questionable science and quoting public officials without a bit of skepticism or any effort to elicit rebuttals from drug war critics or pain patient advocates.

The DEA's Diversion Control Program is also a self-financing, autonomous law enforcement agency that is largely unaccountable to congressional oversight.

Eradicating the Prescription Painkiller "Threat"

The DEA's new mission to thwart the diversion of prescription painkillers was a significant undertaking, one that would require extra manpower and resources. As part of its OxyContin Action Plan, the agency carried out more than 400 investigations resulting in the arrest of 600 individuals from May 2001 to January 2004. Sixty percent of those cases involved medical professionals, most of them doctors and pharmacists (the remaining cases could include manufacturers and wholesalers).[98]

To implement its new program, the DEA participated in the Organized Crime Drug Enforcement Task Force and worked cooperatively with state and local drug task forces. OCDETF combines the resources of federal, state, and local law enforcement under the coordination of U.S. attorneys. In 2001 the DEA deputized 1,554 state and local officers from large and small police departments across the country to coordinate prescription drug investigations. In 2002, 1,172 DEA Special Agents worked alongside 1,916 state and local police officers in 207 separate task forces.[99] This sharing of resources significantly expanded the OxyContin Plan's reach. To see how the task force plan gave the DEA more reach, consider drug war statistics from 1999. In that year, the DEA initiated 1,699 investigations on its own but was able to extend its investigative reach by working cooperatively with state and local law enforcement officials

Table 1
DEA Registrant Population

Retail Level		Wholesale Level	
Practitioners (doctors)	928,677	Researchers	6,843
Nurse Practitioners & Physician Assistants	71,169	Analytical Labs	1,591
Pharmacies	61,057	Narcotic Programs	1,151
Hospitals/Clinics	14,462	Distributors	876
Teaching Institutions	424	Manufacturers	453
Importers	136	Exporters	206

Source: DEA Update, National Association of State Controlled Substance Authorities, Myrtle Beach, South Carolina, October 2002.

in more than 9,000 additional task force cases.[100] The DEA also trained more than 64,000 state and local law enforcement personnel in 2001 at its Training Academy in Quantico, Virginia, as well as at the agency's 22 domestic field divisions throughout the United States.[101] These task forces accounted for 40 percent of the DEA's prescription narcotics seizure and forfeiture cases.[102]

The DEA's Diversion Control Program is also a self-financing, autonomous law enforcement agency that is largely unaccountable to congressional oversight. It's mostly financed by the licenses it requires all doctors, manufacturers, pharmacists and wholesalers to purchase, and in part by the assets it seizes when it raids the businesses and personal finances of those same licensees. Table 1 shows the breakdown of the DEA's controlled substance license holders as of 2002. Physicians constituted 928,677 of 1,087,045 registrants, or 85 percent of all those approved by the DEA to produce, distribute, and dispense narcotics. Because prescription narcotics are legal and regulated, the DEA can easily monitor the way physicians prescribe them. Unlike illicit drug dealers, most physicians are law-abiding, legitimate professionals. That also makes them easier targets.

The DEA sets annual production quotas for the manufacturers of narcotic drugs, and the agency attempts to monitor the wholesale and retail distribution of those drugs, though with decidedly mixed results. In fact, large quantities of narcotics routinely go missing en route from manufacturers to wholesalers and from wholesalers to retailers. The DEA itself acknowledges this problem. The agency notes that there is an increase in OxyContin burglaries, thefts, and robberies of hospitals and pharmacies throughout the country, including at Purdue Pharma, the manufacturer of OxyContin.[103]

In one recent case in Arizona, nearly 475,000 tablets of narcotic drugs disappeared from Kino Community Hospital's pharmacy between May 1, 2002, and April 30, 2004.[104] Drug stores in rural areas have also been targets for burglars seeking OxyContin, and the Internet has become a major underground source for the drug.[105] In an investigative series, the *Star-Ledger* newspaper in New Jersey actually ordered OxyContin over the Internet, along with other prescription narcotics. The paper reported no contact with a physician, and the drugs were delivered to a rented mailbox within days of placing the order.[106] Given the poor job the DEA is doing of monitoring the narcotics it's charged with overseeing, and the various ways the drug apparently can move from manufacturers and wholesalers to the black market, the DEA's blame and pursuit of physicians for the drug's street availability seems all the more arbitrary, unjustified, and capricious. "Pills are a problem in Southwest

The DEA's attempt to blame physicians for the drug's street availability seems arbitrary, unjustified, and capricious.

If criminal charges are never filed, a police department can still bring a civil action against a suspected doctor to recover the cost of an investigation.

Virginia," one assistant U.S. attorney told the *Roanoke Times* in 2001, "And the *only* way you can get prescription pills is to go to the doctor."[107] But that's clearly not the case.

In 1993 Congress created the self-financed Diversion Control Fund, which was to be funded by narcotics licensing fees. The DEA is authorized to increase the license fees to make sure the Diversion Control Program remains fully funded. The setup is similar to that of the Health Care Fraud and Abuse Control Program, which monitors doctors for alleged fraud and abuse with respect to Medicaid and Medicare. In 2003 the DEA doubled its license fees to pay for the cost of the program. Under DEA rules, doctors must buy licenses for three-year periods at $131, while pharmaceutical companies pay $1,605 per annum for licenses to make drugs. These licensing fees bring in about $118 million a year. The Diversion Control Program currently costs about $154 million per year. The rest of the DCP's funding comes from the annual congressional budget for the DEA, and from the DOJ's Asset Forfeiture Fund, which is financed by seizures of assets from doctors and pharmacists under investigation for drug diversion, as well as from illicit drug dealers and users. In 2005 the DEA requested an additional $245.4 million for drug enforcement, including $32.6 million for diversion control.[108]

According to the Controlled Substances Act, all monies or other things of value furnished by any person in exchange for controlled substances are subject to forfeiture.[109] The money from these seizures get split between the law enforcement agencies making the bust, and the remainder goes to the DOJ's Forfeiture Fund, where it's used to coordinate more investigations. In 2002 drug asset forfeitures totaled $441 million. And in 2001 the DEA shared $179,264,498 of its asset forfeitures with local and state police departments.[110] The total forfeiture fund was worth about $1.2 billion by 2002.[111] The vast majority of asset forfeiture money is distributed by the DEA to state and local law enforcement agencies who work with the agency on drug cases. It is a perverse system that allows law enforcement officials to keep the assets of suspected drug defendants for their own, local police departments.

Detective Dennis M. Luken, of the Warren-Clinton Drug and Strategic Operations Task Force in Lebanon, Ohio, and Treasurer of the National Association of Diversion Drug Investigators, laid out the financial necessity of targeting physicians for investigation at a 2003 training conference for drug diversion agents.[112] Luken, who worked on an asset forfeiture squad for three and a half years, said that in an "era of budget cuts, forfeitures are an important way to make up for the losses."[113] Luken said that the task force arrests five doctors a year in the Cincinnati area alone. Seizing a doctor's assets to supplement strained law enforcement budgets was a recurring theme at the NADDI training conference, held in Ft. Lauderdale, Florida. Greg Aspinwall of the Miami Dade Drug Task Force, for example, stressed the importance of taking a task force approach to diversion investigations by using the theme "spreading the love."[114] He instructed trainees to get as many law enforcement agencies as possible involved in investigations. The method reduces costs, he said, and guarantees that "everybody gets their fair cut from the forfeitures."[115] He pointed out that even if criminal charges are never filed, a police department can still bring a civil action against a suspected doctor to recover the cost of an investigation.

In his lecture, Detective Luken also focused on "drug-diverting" doctors and stressed the importance of seizing their assets. He urged investigators to serve search warrants on doctors' offices and bank accounts and to take possession of their contents. If the doctor does not have a sizable bank account, Luken said, investigators should look at a physician's home or office building, given that both were likely paid for with the proceeds of drug distribution. Luken implored agents to "remember that asset forfeiture investigation should begin at the start of your criminal case."[116] Detective Luken discussed the cases of several physicians he had overseen and noted that investigators seized money and property from them

before they were indicted or tried for any crime.

Luken then cited a number of cases in which physicians had had their assets seized before ever being charged. One case he mentioned, that of Dr. Eli Schneider, resulted in the seizure of $220,000. Of that money, the Ohio Medicaid Fraud Control Unit received $3,752, the Ohio Department of Health and Human Services got $24,000, the Cincinnati Police Department $29,000, the FBI $14,000, and the U.S. Department of Health and Human Services $50,000. Calls to local authorities and public records searches don't reveal whether or not Dr. Schneider was ultimately convicted. Many times, however, such forfeitures result in plea bargains or civil settlements, given that the cases can drag on for years, and asset seizure leaves the accused with no means to live, much less to pay attorney's fees and court costs. The case of Kentucky physician Dr. Ghassan Haj-Hamed is a good example. The DEA sued Dr. Haj-Hamed in 2002, accusing his clinic of diversion and drug distribution. After more than two years, the doctor agreed to settle, paying $17,000 and handing over two automobiles in exchange for the federal government dropping its suit for $133,000. Haj-Hamed's lawyer told the *Kentucky Post* that the government's practice of seizing all of a doctor's assets, then expecting him to fight the case, all while still paying taxes and earning a living, "inevitably puts the person in a position where they have to settle."[117] Prosecutors haven't yet decided whether or not to pursue criminal charges.

Because the Diversion Control Program is self-financed, it is nearly immune from congressional oversight. Its administrators aren't required to justify its existence, its tactics, or its efficacy when it comes time for appropriations. The program also creates a scenario wherein doctors are required to finance investigations of their colleagues, copractitioners, or even themselves. Should the doctors' colleagues be investigated, law enforcement officials are encouraged to seize their colleagues' assets, much of the proceeds of which then go toward financing more investigations.

From October 1999 through March 2002, the DEA investigated 247 OxyContin diversion cases leading to 328 arrests.[118] In 2001 there were 3,097 total diversion investigations, including 861 investigations of doctors.[119] In 2003 the DEA investigated 732 doctors, sanctioned 584, and arrested 50.[120] These numbers do not include physicians investigated and arrested by the 207 DEA-deputized state and local task forces throughout the country.

Putting a total number on how many doctors, nurses, and pharmacists have been investigated, charged, or convicted is difficult. The DEA says it no longer keeps track of such statistics. Some states account for physician arrests; others don't. Virginia, for example, says it prosecutes on average one health care professional per week.[121] Many doctors do as Dr. Ghassan Haj-Hamed did and settle before charges are brought—because after forfeiture, they generally have no assets left to fight the charges.

Investigating and Apprehending Pain Patients and their Doctors

The DEA defines an "addict" as "any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction."[122] The DEA's conception of an addict, then, includes what pain specialists call "pseudoaddicts"—pain patients who require opiates to lead a normal life. Pain specialists make an important distinction between patients who depend on opiates to function normally—to get out of bed, tend to household chores, and hold down jobs—and addicts who take drugs for euphoria, and whose lifestyles *deteriorate* as a result of taking opiates, instead of improving. The DEA makes no such distinction. And by classifying pain patients as addicts, the agency is able to pursue their doctors as "distributors."

What's worse, due to unwavering drug laws mandating that possession of any controlled substance over a specified amount constitutes an intent to distribute, pain patients are often considered "dealers" too—even if (as is most

Pain specialists make an important distinction between patients who depend on opiates to function normally and addicts who take drugs for euphoria. The DEA makes no such distinction.

often the case) their entire supply of prescription drugs are for their own use.

That's exactly what happened to Florida pain patient Richard Paey.[123] Paey suffers from multiple sclerosis, as well as from injuries incurred in a car accident and a botched back surgery. Given the anti-drug climate in Florida, Paey found it difficult to find a physician who would prescribe the high-dose pain medication he needed to live with his injuries. So Paey turned to his old doctor in New Jersey, who wrote Paey undated prescriptions that Paey then photocopied and filled. Though he conceded that Paey's medication was for his own use, Paey's prosecutor nonetheless charged him with "intent to distribute," because the amount of narcotics Paey had in his possession exceeded the limit needed to be charged with distribution. After two mistrials, Paey was convicted at a third trial. Mandatory minimum sentencing guidelines gave a reluctant judge no choice but to send Paey to prison for 25 years and fine him $500,000. Today, Paey sits in a Florida prison with a morphine pump, paid for by Florida taxpayers.

More often, however, prosecutors use the threat of imprisonment to get pain patients to turn in their doctors, who make better targets. And, of course, once pain patients can be called "addicts," the government is free to go after the doctors who treat them as "conspirators" in the illegal drug trade. In the case of Dr. Hurwitz, around 15 of his more than 500 pain patients over three years were lying to him and selling the drugs he prescribed on the black market. Investigators could have alerted Hurwitz to his unlawful patients and asked for his help in nabbing them—he had already openly cooperated with law enforcement, offering access to vast amounts of patient paperwork over the course of four years. Instead, investigators continued to let Hurwitz prescribe to known dealers, then later offered the lying patients lenient sentences in exchange for testimony against Hurwitz.[124]

The DEA continues to lower its evidentiary standards, making it nearly impossible for many doctors to determine what is and isn't permitted.

In his speech at the NADDI conference, Detective Luken likened pain specialists to illegal drug dealers, and explained that pain doctors sell pain medication for money, sex, or to feed their drug habits or those of family members or girlfriends—just as common drug pushers do. Doctors in practice by themselves and older doctors are often painted by investigators as rubes, easily duped by addicts or unable to stop freely prescribing narcotics in the manner they did during more permissive times.[125]

To target doctors, investigators look for "red flags" they believe are indicative of potentially criminal behavior. These red flags are generally circumstantial evidence found during standard criminal investigative procedures. The problem with red flags is that what may appear to be evidence of criminal behavior to an investigator without medical training is often perfectly consistent with legitimate medical practice, particularly in a dynamic field like pain management. Criminal investigators without medical training simply aren't qualified to tell the difference. Yet they routinely make such decisions, and such close judgment calls can cause the criminal prosecution of an otherwise legitimate physician.

According to the DEA, the prosecution of any given doctor is based on whether there is a "legitimate medical purpose" for a prescription he has written or whether it is "beyond the bounds of medical practice." But prosecutors concede that there are no specific guidelines or procedures to evaluate either of those standards. At a Healthcare Fraud Prevention and Funds Recovery Summit in Washington, DC, in 2004, Greg Wood, a federal investigator for the U.S. attorney's office in Virginia, said the government's aim is to produce probable cause that a doctor (a) intentionally wrote a narcotics prescription for patients without legitimate medical needs, (b) knew the patients getting the prescriptions were addicts, or (c) knew the patients getting the prescriptions were selling the drugs.[126] Any of those is sufficient for an arrest.

But even those guidelines are apparently subject to change without notice. The DEA continues to lower its evidentiary standards, making it nearly impossible for many doctors to determine what is and isn't permitted. In October 2004, the DEA disavowed the con-

tents of a pamphlet it had published for pain doctors and pulled the digital version of the document down from its website.[127] The FAQ was a working collaboration with input from leading physicians and researchers in pain medicine that purported to give guidance to pain specialists worried about the DEA's crackdown.[128] The reversal infuriated advocates for pain physicians and patients, some of whom had worked with the DEA for several years to "strike a balance" between adequately treating pain and preventing diversion.[129] The original document included such conciliatory language as, "any physician can be duped" and pointed out that patient behavior commonly thought to indicate criminal behavior could instead be "the possible effects of unrelieved pain." It warned that "stereotypes of what an abuser 'looks like' can harm legitimate patients because people who abuse prescription medicine exhibit some of the same behaviors as patients who have unrelieved pain."[130] The pamphlet also made clear that DEA red flags, such as prescribing prescription narcotics to patients with a history of drug abuse or not reporting patients whom physicians suspect of abusing pain medication, are *not* in violation of federal law. Most notably, the pamphlet explicitly stated, "For a physician to be convicted of illegal sale, the authorities must show that that the physician *knowingly* and *intentionally* prescribed or dispensed controlled substances outside the scope of legitimate practice."[131]

The DEA took the extraordinary step of disavowing the document, just as lawyers for Dr. William Hurwitz, the pain specialist on trial for diversion in Virginia, attempted to introduce the pamphlet as evidence at his trial. Hurwitz's prosecutors objected, and a federal judge decided in favor of the prosecutors, ruling that the DEA guide did not carry the force of law, and therefore was not admissible.[132]

The DEA later explained that it disavowed the pamphlet because of language at odds with the DEA's insistence that they are not bound by any standard of evidentiary requirement to commence an investigation, including the well-established principle in federal law that the enforcement of the Controlled Substances Act should in no way interfere the ethical practice of medicine. The DEA's explanation noted that "the Government can investigate merely on suspicion that the law is being violated, or even just because it wants assurances that it is not."[133] The statement went on to repudiate whole passages from the original pamphlet, and said the agency would continue its red flag system of deciding which pain doctors to investigate. Those red flags in the interim policy statement include the number of tablets a doctor prescribes to his patients, the practice of writing more than one prescription for a patient on the same day, marked for later dispensing, and using "street slang" rather than medical terminology when discussing pain medication with patients.[134] All, incidentally, were dismissed by the DEA's original pamphlet as reasons in and of themselves to launch a criminal investigation.

The DEA's move caused three professional associations of pain management specialists to take the unusual step of sending a letter to the DEA calling its decision "an unfortunate step backward" that encourages a return to "an adversarial relationship between [doctors] and the DEA."[135]

The DEA's disavowal of its pamphlet was also enough to push into action state officials increasingly alarmed by the agency's pursuit of physicians. In January of 2005 the National Association of Attorneys General sent a letter to the DEA expressing the organization's concern about the DEA's more strident approach to fighting diversion. Thirty state attorneys general signed the letter, which said, in part,

> Having consulted with your Agency about our respective views, we were surprised to learn that DEA has apparently shifted its policy regarding the balancing of legitimate prescription of pain medication with enforcement to prevent diversion, without consulting those of us with similar responsibilities in the states. . . .
>
> The Frequently Asked Questions and Answers for Health Care Professionals

In January of 2005 the National Association of Attorneys General sent a letter to the DEA expressing the organization's concern about the DEA's more strident approach to fighting diversion.

and Law Enforcement Personnel issued in 2004 appeared to be consistent with these principles, so we were surprised when they were withdrawn. The Interim Policy Statement, "Dispensing of Controlled Substances for the Treatment of Pain," which was published in the Federal Register on November 16, 2004, emphasizes enforcement, and seems likely to have a chilling effect on physicians engaged in the legitimate practice of medicine. As Attorneys General have worked to remove barriers to quality care for citizens of our states at the end of life, we have learned that adequate pain management is often difficult to obtain because many physicians fear investigations and enforcement actions if they prescribe adequate levels of opioids or have many patients with prescriptions for pain medications.[136]

The DEA's aggressive investigative procedures poison the doctor-patient relationship from both sides.

The end result of these procedures is that investigators and prosecutors without medical training are now in the position of interpreting whether or not a suspected physician's actions are consistent with traditional medical practice or worthy of an investigation. The red flag system is meant to aid them in that decision. At the July 2003 NADDI conference, investigators were told what practices—or red flags—might indicate criminal behavior. These included

- Long lines of patients waiting to see doctors.
- Patients who are poorly dressed.
- Out-of-state automobile licenses in doctors' parking lots.
- Patients who arrive and are taken without appointments.
- Patient visits lasting less than 25 minutes.
- Doctors who are licensed to practice in more than one state.
- Doctors who dispense large amounts of narcotics from one office.[137]

One of the many problems with the red flag system is that investigative bodies use invasive procedures to uncover red flags. The National Association of Drug Diversion Investigators, for example, instructs cops to conduct video surveillance of doctors' offices as if they were "crack houses."[138] Investigators have also picked through trash at doctors' offices and private residences. Employees of suspected doctors have been interviewed at their homes. Police have sought out disgruntled former employees who might incriminate their former employers.[139]

The relationship between a doctor and his patient is crucial to the proper assessment and treatment of the patient's condition. The DEA's aggressive investigative procedures poison that relationship from both sides. Pain patients have been asked to testify against their doctors. Pain patient advocacy groups report patients being accosted in the parking lots of their physicians' offices. These kinds of procedures threaten to make some doctors suspicious of every patient they see—even longtime patients—a situation further complicated by the DEA's disavowing its guidelines pamphlet. Doctors and patients are then forced to play a game. Patients must negotiate between indicating enough pain to their doctors to warrant more medication, but to avoid appearing desperate—one sign doctors are supposed to look for in identifying diverting patients. Some patients simply stop reporting pain and suffer silently, for fear of becoming burdensome.[140] One study published in the *Journal of Clinical Oncology* found that when asked to match their patients' pain intensity on a scale of 1 to 10, 35 percent of physicians failed to match their patients' descriptions within two points.[141] It's now not at all clear to doctors at what point they're legally obligated to report a patient they suspect of diverting prescribed medication.

One pain patient and mother of three told her local newspaper, "Doctors and nurses look at you different if they know the medications you are on. They flag your file and view you as an addict."[142] Pain specialists at a professional conference in Tucson, Arizona, advised doctors to install security cameras, mandate urine tests, and frisk patients upon entering their

offices to ensure they weren't bringing in someone else's urine—all to ensure that the patients weren't lying to them and protect the doctors from prosecution down the line.[143] "I have to be a detective," a Tennessee doctor told the *Wall Street Journal*.[144] One of Dr. Hurwitz's patients told the *Washington Post* that Hurwitz's treatment saved his life and was worried what he'd do when Hurwitz lost his license. He found another doctor, but only after considerable searching. Even then, "they treat me like a criminal," he said. "I only get a one-week supply at a time, and sometimes I have to wait for hours at the pharmacy. And the pharmacist who fills my prescriptions is the only one in town who will do it, so if he goes, then I'm finished."[145]

The DEA has also set up a hotline to report doctors whom patients suspect of overprescribing, an odd move that further complicates the doctor-patient relationship.[146] Common sense suggests that people posing as pain patients to illegally divert narcotics or pain patients getting excessive pain medication prescribed to them are *least* likely to report their doctors to the DEA. Conversely, it isn't difficult to see how a legitimate pain patient dissatisfied with how much medication he has been prescribed might be tempted to report his doctor out of spite.

Investigators have also sent undercover agents, typically from sheriffs' departments, to pose as pain patients with fake insurance cards. Agents schedule appointments over the phone and carefully document everything that happens during office visits. They make audio and, when possible, video recordings of everything that transpires. Undercover agents tend to be female—investigators believe women are less threatening, less suspicious, and more likely to elicit sympathy from doctors. Agents make numerous visits to doctors' offices to befriend staff members and win their trust. They then attempt to accumulate incriminating evidence against the doctors. They are instructed to engage in informal, personal conversation with a "target" and his employees. Once an undercover agent wins the trust of a doctor and his staff, she is instructed to begin looking for more red flags. These additional red flags have included

- A doctor who told a pain patient where he could get his prescriptions filled.
- A physician who asked his patients which drugs they prefer and which dosage worked best for them.
- Doctors who prescribed the same drug in the same dosage to many patients, including to more than one member of the same family.[147]

These aggressive procedures haven't always been the norm. University of Florida professor of pharmacy and lawyer David Brushwood told one newspaper that doctors once had a more cordial, cooperative relationship with investigators.

"Five years ago, if law enforcement saw a problem beginning to develop—say a doctor or pharmacist dispensing in ways they thought were problematic—they would very early on go to the doctor or pharmacist and say, 'We think there's a problem here.' By the same token, physicians or pharmacists felt comfortable calling law enforcement and saying, 'Something strange is going on. Come help us out.' It was a culture of the early consult. The early consult is gone," Brushwood said.[148]

Brushwood also noted that many times, investigators will wait for more problematic situations to develop in an effort to have more evidence with which to go after a doctor. Law enforcement officials "watch as a small problem becomes a much larger problem. They wait, and when there is a large problem that could have been caught before it got large, they bring the SWAT team in with bulletproof vests and M16s, and they mercilessly enforce the law. They'll come in with charges on multiple counts. Murder, manslaughter, 350 counts of drug diversion. Many of which arose after they first discovered it, when it was a small problem," Brushwood said.[149]

Because doctors are now being prosecuted for not adequately discerning the motives and intentions of their patients, pain patients know that doctors will be looking them over for signs of abuse, so many strate-

Professor David Brushwood says that doctors once had a more cordial, cooperative relationship with investigators.

There seems to be no evidentiary standard at all that doctors can rely on to thwart a conviction.

gically underreport or overreport their pain, depending on how much medication they have, how much they think they need, and how suspicious they believe a doctor to be of their motives. Doctors have no choice but to give extra scrutiny to everything a patient says, not just out of a desire to keep a patient from hurting himself or diverting drugs to the black market, but because the patient may be an undercover cop. Even longtime patients can be duped by police into turning in their doctors under threat of arrest.

A doctor's billing practices can also trigger a red flag. Investigators have contacted private insurance companies' fraud units as well as those within Medicare and Medicaid. They comb records to find more potential red flags for a suspected doctor. Investigators have also obtained the prescription purchase reports gathered by the DEA from pharmaceutical companies to track a suspected physician's prescribing history.[150]

The case of Dr. William Hurwitz is again an excellent example. He was prosecuted in 2004 as part of a two-year DEA operation called "Cotton Candy" (for OxyContin) involving between 60 and 80 doctors, pharmacists, and patients. Hurwitz was eventually charged with "conspiring to traffic drugs, drug trafficking resulting in death and serious injury, engaging in a criminal enterprise, and health care fraud."[151] He was arrested at his home by 20 armed agents in the presence of his two young daughters. Investigators seized his assets, including his retirement account, jailed him, and imposed a $2 million bond.[152] Hurwitz was eventually convicted, essentially of being unknowingly duped by pain patients who later sold his prescriptions.[153] The jury's foreman told the *Washington Post* that Hurwitz was "sloppy," "a bit cavalier," and that, "no, he wasn't running a criminal enterprise." Yet the jury convicted Hurwitz of "conspiracy to distribute controlled substances and trafficking resulting in death and serious injury."[154] In April 2005 Hurwitz was sentenced to 25 years in prison and fined $1 million.[155]

The DEA now insists that prosecutors do not have to prove a doctor's malicious intent or desire to profit from narcotics diversion to secure a conviction.[156] In fact, it's not even necessary for the government to have expert medical testimony that a doctor's actions were illegitimate or outside the usual course of professional practice. The DEA believes it can bring charges against doctors even if they never actually distributed drugs or their prescriptions were never actually filled. In fact, there seems to be no evidentiary standard at all that doctors can rely on to thwart a conviction.[157]

Perhaps no case illustrates the injustice of aggressive law enforcement tactics better than that of Dr. Frank Fisher.[158] Fisher was a Harvard-trained physician whose California practice served about 3,000 patients, most of them rural and poor. About 5–10 percent of Fisher's cases were pain patients. In 1999, the police arrested Fisher and charged him with multiple counts of fraud and drug diversion. More notably, Fisher was originally charged with several counts of murder. State prosecutors attempted to make the case that Fisher's overprescribing of narcotics made him criminally culpable for the deaths of a pain patient who died in an unrelated automobile accident, a man who received narcotics after they had been stolen from the home of one of his patients, and a patient who died after her prescription ran out and Dr. Fisher had already been arrested and imprisoned. Fisher was further besmirched in the press. Prosecutors described him as a "mass murderer" and common drug pusher who addicted thousands of Californians to prescription painkillers.

Upon his arrest, all of Dr. Fisher's assets were seized, and he was held on $15 million bond. It took just a 21-day preliminary hearing for a judge to dismiss the murder charges and lower the bail, releasing Dr. Fisher from prison. It took another four years to dismiss the remaining felony charges, including fraud and manslaughter. Finally, in May of 2004, a jury acquitted Fisher of the remaining misdemeanor charges. One juror described the pursuit of him as a "witch hunt." Fisher spent five months in jail, lost all of his assets and—at the

age of 50—was forced to move in with his elderly parents.

Conclusion

The government is waging an aggressive, intemperate, unjustified war on pain doctors. This war bears a remarkable resemblance to the campaign against doctors under the Harrison Act of 1914, which made it a criminal felony for physicians to prescribe narcotics to addicts. In the early 20th century, the prosecutions of doctors were highly publicized by the media and turned public opinion against physicians, painting them not as healers of the sick but as suppliers of narcotics to degenerate addicts and threats to the health and security of the nation.

Since 2001 the federal government has similarly accelerated its pursuit of physicians it says are contributing to the alleged rising tide of prescription drug addiction. By demonizing physicians as drug dealers and exaggerating the health risks of pain management, the federal government has made physicians scapegoats for the failed drug war. In that they are generally legitimate, well-meaning professionals who keep accurate records, pain physicians also present a better target than underground, black-market drug dealers for a DEA that has been subject to increasing criticism from Congress and the Department of Justice for its inability to measurably reduce the domestic drug supply. Even worse, the DEA's renewed war on pain doctors has frightened many physicians out of pain management altogether, exacerbating an already serious health crisis—the widespread undertreatment of intractable pain. Despite the DEA's insistence that it's not pursuing "good" doctors, it isn't hard to see how rhetoric from law enforcement officials and prosecutors would make doctors think otherwise. Hurwitz's prosecutor, for example, promised to root out bad doctors "like the Taliban."[159] Another assistant U.S. attorney said, upon the sentencing of one doctor to eight years in prison for having worked for 57 days at a pain clinic: "I believe and I hope that this case has sent a clear message to the medical community that they need to be sure the controlled substances they prescribe are medically necessary. If doctors have a doubt about whether they could get in trouble, this case should answer that"—a statement that implores doctors to err on the side of undertreatment.[160]

It isn't hard to see how all of this would make it more difficult for pain patients to find treatment. "You worry every day that the medicine won't be available for much longer," one patient told the *Village Voice*, "or your doctor won't be there tomorrow because he's been arrested by the DEA."[161] One doctor flatly told the *Wall Street Journal*, "I will not treat pain patients ever again."[162] Still another told *Time* magazine, "I tend to underprescribe instead of using stronger drugs that could really help my patients. I can't afford to lose my ability to support my family." The *Voice* also reports that many medical schools now "advise students not to choose pain management as a career because the field is too fraught with potential legal dangers."[163]

The most obvious (though least likely) course of action to address these problems would be for Congress to end the costly, regrettable War on Drugs. Barring that, the best way for law enforcement officials to battle the problem of diversion would be to combat the theft of the drugs from warehouses, manufacturing facilities, and en route to pharmacies. More importantly, the DEA, DOJ, Congress, and state and local authorities should end the senseless persecution of doctors and allow them to pursue whatever treatment options they feel are in the best interests of their patients, free from the watchful eye of law enforcement.

The DEA's renewed war on pain doctors has frightened many physicians out of pain management altogether, exacerbating an already serious health crisis—the widespread undertreatment of intractable pain.

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CONFERENCE REPORT

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APS: ERs Physicians Give Short Shrift to Out-of-Control Pain

By Ed Susman, D
May 15, 2006

Add Your Knowledge™ Additional Emergency Medicine Coverage

SAN ANTONIO, May 15 — Patients who go to emergency rooms for out-of-control pain perceive that the treatment they are offered lacks dignity, satisfaction, and effectiveness.

That became evident on the basis of a series of studies reported at the American Pain Society meeting here. The papers described the frustration and dissatisfaction and patients. Instead of obtaining relief, they are rebuffed, disbelieved, or made to wait hours to see a doctor and are sometimes sent away without treatment.

"Much remains to be done in this area," said Knox Todd, M.D., director of the Pain and Emergency Medicine Institute at Beth Israel Medical Center in New York.

Action Points

- Be aware that patients perceive that when they go to the ER for relief of out-of-control pain they get limited satisfaction.
- Understand that people with chronic pain often need greater dosages of analgesics.
- These studies were published as abstracts and presented orally at a conference. These data and conclusions should be considered to be preliminary as they have not yet been reviewed and published in a peer reviewed publication.

He found in a study that included 842 patients arriving at ERs in hospitals across the United States and Canada that:

- Patients with pain often have pain score in the moderate to intense levels when presenting to the emergency department—yet it is uncommon that the clinical staff will reassess those pain levels during the hospital stay.
- Of the 842 patients, medical records note a pain assessment in 83% of cases—but a second pain assessment occurred in only 31% of cases and just 14% had three assessments.
- Analgesics are underutilized. Only 61% of the patients who were surveyed by emergency room personnel—doctors or nurses who contacted the patients to record their experiences—were given analgesics.
- Delays to treatment are common. The mean ER wait was 90 minutes.

Part of the problem lies with the patient, Dr. Todd said in a poster presentation. "While 42% of the patients felt they needed analgesics, just 15% told the staffers."

The end result, Dr. Todd said, was that as many as 40% of patients who go to the ER for pain relief are still in pain when they are discharged.

"The results of these studies show that persistent pain is common and substantial after emergency department discharge," said Dr. Todd. "We, as emergency room doctors, do not do a good job at treating the patients who come in our doors."

In a companion Internet survey conducted by the American Chronic Pain Association, 47% of the 258 patients defined their visit to the ER as "poor," "terrible," or "the worst experience of my life."

In the online survey:

- About 21% of patients said they waited more than three hours in the ER for doctors to see them. Only 36% of patients were

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treated within one hour of arriving.

- About 25% said the ER doctor believed them when they explained they had out-of-control pain—the reason that 88% of those with pain went to the hospital.
- About 15% of ER experiences resulted in doctors taking immediate action. More than 30% of the time the patients said the ER doctors "didn't believe my pain."
- Among those surveyed, 47 patients said they went to the emergency room because their primary care physician no longer would treat them—mainly because the doctor was concerned that he was already giving the patient a high dose of opioids or that the doctor said "he had done all he could do".
- About 44% of the patients said they felt they were treated with dignity.

Penny Cowan, founder and executive director of the American Chronic Pain Association, said she hoped the Internet-based study will help kick off more research into the area and result in education of both doctors and patients about chronic pain and the role both doctor and patient have in controlling it.

"This preliminary survey highlights the many challenges faced by those seeking relief from chronic pain," she said. "There is a marked mismatch between patient expectations and the emergency department treatment of pain."

Dr. Todd agreed. "Further research is needed to assess whether more aggressive analgesic treatment during the emergency department stay may provide better pain-related outcomes after discharge," he said.

Additional Emergency Medicine Coverage

Primary source: American Pain Society 25th annual scientific meeting
Source reference:
Abstract 840: Pain in the emergency Department: An Online Survey of Patient Experience

Abstract 842: Pain in the emergency department: A multicenter Study.

Abstract 855: Persisting pain among patients discharged from the emergency department: A multicenter study.

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Pain Relief Network

Richard Paey

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Richard V. Paey was sentenced on April 16, 2004 to a mandatory minimum sentence of 25 years and fined $500,000. Paey, in his wheelchair with a morphine pump sewn into his ruined back, will live out-what for him is a death sentence-in a Florida prison for possessing the medicine that he requires to survive.

Judge David D. Diskey heard Linda Paey's pleas for mercy, but could not exercise judicial discretion because of a mandatory minimum sentencing. "This is the problem for the Florida state legislature and the governor," Judge Diskey said.

"Richard Paey was prosecuted three times in the very same district that is represented by Senator Mike Fasano, the sponsor of Florida's Prescription Monitoring Bill (Senate Bill 580). Sen. Fasano's claim that prosecutors won't use private medical information gathered in government computers against patients in pain, is exposed for the hollow assurance it is," Executive Director of PRN, Siobhan Reynolds said.

Senate Bill 580, and it's companion bill-House Bill 397, would allow more government intrusion into medical privacy, further chilling legitimate pain management and allowing prosecutors to attack yet more people in pain like Richard Paey.

Pain Relief Network is working with the Paey family to develop an appeal and to keep the hope alive. PRN commends Richard and his family for their show of extraordinary character and perseverance. The pain community owes them an enormous debt of gratitude.

Spread the Word — Make a Difference

Learn More About Richard Paey and The Pain Crisis in America:
The Chilling Effect (Running Time: 56 min.)

News Articles About Richard Paey:

Update on Richard Paey
Pain Relief Network (NM)

Justices Should Reject Disabled Man's Drug Appeal
The Associated Press

A Hope for Clemency
Fox News, Tampa Bay (FL)

A Drug Sentence Without Justice
St. Petersburg Times (FL)

Court Rejects Disabled Man's Appeal in Prescription Drug Case
The International Herald Tribune (NY)

25 Years for Being 'Stubborn'
Reason.com

Mandatory Madness
Creativeloafing.com

Justice System Failed Multiple Sclerosis Patient
Painreliefnetwork.org

Cruel and Unusual: 25 Years for Taking Own Pain Meds
Huffingtonpost.com

Punishing Pain
The New York Times

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Write to Richard Paey:
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R29228 Tomoka Correctional Institution
3950 Tiger Bay Road
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Pain Relief Network

Welcome to PRN

Dr. Hurwitz sentenced to 5 years: Beats 25 years, but is still unjust.

It's up to you to decide what kind of America you want to live in.

Right now, law enforcement and the political machine are selling you a "War On Drugs," instead of making sure that your medical needs are being met.

The entire medical profession functions to deny pain treatment and they don't even know they're doing it. How would a pain patient with any kind of neuropathic pain get by this fictional doctor? (Click Here)

The political prosecutions continue, even as people in severe pain are refused opioids in sufficient doses.

While some patients are being driven to suicide, others are dying of entirely preventable illnesses resulting from untreated pain.
(See The Chilling Effect)

The prosecutions will not stop until the public rises up against this injustice. (Click Here)

The United States of America was founded on the idea that each citizen has a right to life and liberty – to the pursuit of happiness. Unfortunately, we have strayed so far from this ideal that we now incarcerate more of our citizens than any other country in the world.

Both political parties are deeply involved, using their "get tough on crime" policies to further their own political aspirations. Yet, at its core, our American government is an entity whose power is derived from the consent of the governed. When the government no longer works to protect the lives and liberty of its citizens, its citizens must make their voices heard.

Pain Relief Network works to expose this gross violation of rights — to awaken the press to the nightmare they are sanctioning with their silence.

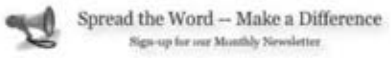
We are here to work with you, those in pain, those with family members in pain, and doctors who are being destroyed by the government's "War On Prescription Drug Abuse."

We are here to abolish the Controlled Substances Act so that society will have to rationally regulate these important medicines, ensuring that those who need them can get them without fear of prosecution. The criminalization of doctors and patients must stop. The doctor/patient relationship must be restored

to the privileged position in society it once enjoyed.

It is time to put the medical needs of the vulnerable ahead of the political aspirations of the powerful.

Please sign up for our newsletter and become a part of the only organization committed to stopping the witch-hunt against pain treating physicians.



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Prosecution of Physicians for Prescribing Opioids to Patients

MM Reidenberg[1,2,3,4] and O Willis[1]

Many patients in pain receive inadequate doses of opioids. Fear of government action against prescribing doctors is one cause of this inadequate treatment. The purpose of the study was to assess criminal prosecutions by reviewing press reports of indictments or trials of doctors for opioid offenses during 2 years. Forty-seven cases were reported involving 53 doctors. Fifteen cases were for offenses unrelated to medical practice. In 32 cases, the charge was based on determining the prescriptions for opioids were outside the bounds of proper medical practice. Only two of these cases were evaluated by a state medical board before indictment. Five doctors were indicted for murder related to drug overdose deaths. None were found guilty of murder. Prosecutorial excesses and hyperbole were common. The state medical board's review of appropriateness of prescribing opioids when a doctor–patient relationship is presumed to exist could decrease inappropriate criminal indictments and reduce this component of fear of prescribing adequate opioid therapy for patients in pain.

Studies have found that many patients with pain are given inadequate doses of opioid medications to relieve their pain.[1–5] Multiple barriers to the adequate treatment of pain have been identified.[6–15] One of these barriers is fear of government action against a physician who prescribes opioids for patients in pain. We have addressed the issue of whether the reality of this risk of government action is as great as physicians' perception of it. We have reviewed Medical State Board actions[16] and information from the Drug Enforcement Administration about indictments and revocations of registration.[17] We have found that the risk of a physicians being punished by either group for prescribing opioids for a patient in pain with adequate medical record documentation is very small.

Ziegler and Lovrich[18] surveyed chief prosecutors in four states with hypothetical cases of doctor–patient encounters in which opioids were prescribed. The investigators asked prosecutors if they would investigate the physicians in each of the cases. Some prosecutors said yes for some of the cases. We then thought a review of actual state and federal prosecutions for opioid offenses was needed. We reviewed newspaper accounts of indictments and trials of doctors to determine if these, and the publicity attendant to them, contribute to physicians' reluctance to prescribe adequate doses of opioid analgesics for patients in pain.

Our method was to use ProQuest and Lexis Nexis Academic Universe electronic journals, news, and periodicals databases. These were searched for all available publications about criminal cases against physicians treating chronic pain patients. Search terms entered were physicians, doctors, prescription medications, pain killers, opioids, controlled substances, pain medications, prescription drugs, trial, court, investigations, and drug trafficking, with each term being used alone and in combination. Additional sources of information were found on web sites, including http://www.cpmission.com/politics and http://www.cpmission.com/main/charged.html. The accuracy of information published on these web sites was always confirmed by a second source from the press. These confirming sources were found by entering the physician's name in Google and Ask.com search engines. Numerous second-source articles and publications from nationwide newspapers and journals were reviewed as well. Detailed and thorough review was limited to only those cases published in the years 2004 and 2005, and the published press reports were the sources of the primary facts cited.

Information about 47 cases involving 53 doctors was obtained. Twenty-one cases were state and 26 were federal. Seventeen were reports of convictions, two were reports of acquittals, 27 were reports of indictments, and one decision

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was pending. Fifteen cases were for activities unrelated to the practice of medicine such as stealing opioids from a hospital supply. In 32 of the 47 cases, the charge was based on determining that the prescriptions of the opioids were outside the bounds of proper medical practice. In only two of these cases was it declared that a state medical board reviewed the case before indictment.

A total of 13 cases involved deaths in which prescribed opioids were initially considered the cause of death and often initiated criminal investigation.

In 17 cases, the articles reviewed included information about the duration of the investigation of the doctors before an action was taken. For some, specific dates were given. For others, the time was given in years. Using 12 months for each year of investigation, the mean duration of investigation was 22 months with a median of 24 months and a range of 1–48 months. The investigations took longer than 2 years in one-third of the cases.

A total of five doctors out of the 32 cases with charges related to medical practice were charged with murder in association with drug overdose deaths along with other offenses. In two of the cases, the charges were withdrawn. In the other three, juries found the doctors not guilty of the murder charges. No doctor was found guilty of murder.

One of the doctors convicted of manslaughter was sentenced to 25 years in jail. The sentence for manslaughter was withdrawn after it was revealed by the prosecution that the patients who died of drug overdoses were not this doctor's patients.[19] A doctor charged with murder in the death of two patients had the charges dropped when the deaths could not be linked to the prescribed medications.[20] One doctor, found not guilty of all charges including murder,[21–22] has written a detailed account of his experience with the criminal justice system.[22] He described an unwillingness on the part of the state to admit its errors and correct them. Another doctor, convicted of offenses other than murder, claimed that evidence produced after the trial showed a witness-committed perjury in the trial.[23]

Judges and prosecutors are quoted in some of these articles as intending to "send a message" to doctors. Examples of this are as follows:

After conviction and obtaining a 19-year sentence for a 74-year-old physician who claimed he was treating patients in pain and who was defended by a court-appointed public defender, an assistant US attorney said: "I believe and I hope that this case has sent a clear message to the medical community that they need to be sure the controlled substances they prescribe are medically necessary. If doctors have a doubt if they could get in trouble, this case should answer that."[19]

After obtaining a conviction, prosecutors said the doctor's "practice amounted to a criminal enterprise" because he charged for his service and should have known that some of his patients were faking or exaggerating their pain.[24]

In a third case, following indictment for murder related to prescribed drugs, the District Attorney is described as saying: "a jury would have to decide whether the medications Green allegedly prescribed illegally were excessive, or whether the individuals should have been getting the medications at all."[25]

In summary, we found 47 cases of media accounts published in 2004 and 2005 involving 53 doctors indicted or convicted of criminal activities related to opioids. In 32 cases, the criminal charges were based on allegations of prescribing opioids outside the bounds of normal medical practice. In only two of these cases did a state medical board make a judgment before criminal action. In many cases, witnesses were undercover investigators taught to deceive doctors or they were drug-abusing people who deceived doctors. Some of the news accounts indicated that the doctors thought these people were real patients in pain.

Many people have been trained to behave like patients with a wide variety of diseases. These people are used to teach medical examination skills in medical schools and in the testing of medical students for promotions and physicians for licenses. They are called "standardized patients" and are also used for continuing medical education evaluations. Standardized patients have fooled experienced doctors.[26] It is not surprising that trained undercover agents or clever drug abusers can also fool experienced doctors.

Our method of an internet search for news articles about doctors indicted or tried for offenses with respect to opioids has limitations. It may underestimate the true number of cases brought during the 2-years period under study. A second limitation is the small amount of factual information in most of the articles. This has limited our ability to do a more comprehensive review of the actions taken and of the motivations of the parties involved. Nevertheless, it is clear from some of the quotations in the articles and from the fact that all five doctors indicted for murder were not guilty, that prosecutorial excesses and hyperbole appeared to be routine. The dire consequences to one physician and his patients of unsubstantiated charges of murder and other drug-related offenses have been described.[21] The consequences for the patients were the loss of their doctor and loss of pain control with resultant disability and depression. The consequences for the doctor were time spent in jail, loss of income and savings, loss of medical practice, the ability to practice during the time the case was pending, and concern about the possible outcome of the criminal proceeding.[21] These consequences probably occurred to other indicted physicians and their patients as well.

A physician apparently risks being charged with murder only when a patient takes more than the prescribed dose of a "controlled substance." If patients take overdoses of antidepressants or other medications not on the list of controlled substances and die as a result, prescribing doctors do not appear to have been criminally charged with murdering their patients. This risk of being called a murderer if one prescribes opioids to patients in pain who subsequently die, contributes to the present climate of opinion that inhibits many doctors from treating people in pain with adequate doses of opioids. A finding that is used to indict some doctors for murder

relates to the misinterpretation of forensic drug level measurements. Some chronic-pain patients on appropriately large doses of opioids die under circumstances in which they become medical examiners' cases. Some medical examiners interpret forensic opioid levels from these patients as causing their deaths. This is because they apply criteria for an opioid concentration that may be fatal in a drug-naive patient to a chronic-pain patient who is tolerant to opioids.[27,28] Functioning pain patients, receiving appropriate doses of opioids chronically, can have drug levels in the range that can kill people intolerant of opioids. Pain patients who died of unrelated causes have been erroneously declared to have died of opioid overdose by medical examiners who have interpreted the drug levels inappropriately.[27] This has led to unwarranted criminal charges against the prescribing physicians.[27]

Publicity about doctors being arrested and tried for their prescriptions given to patients who deceived them and the hyperbolic public denunciations of these doctors by prosecutors sends "a clear message to the medical community."[19] It contributes to physicians' fear of prescribing opioids. More importantly, it makes doctors suspect patients claiming to be in severe pain. This suspicion interferes with a proper doctor–patient relationship and prevents adequate therapy for patients genuinely in pain.

When the alleged controlled substance offense occurs outside of a doctor–patient relationship, a jury trial is the appropriate way to determine guilt or innocence. The statement by a prosecutor that a lay jury is the proper body to decide if a specific prescription is within or outside the bounds of acceptable medical practice[25] should not be correct. When prescriptions are written in a doctor's office and a doctor–patient relationship is presumed to exist, the state medical board is the governing body responsible for evaluating the evidence and determining if an action is within or outside the bounds of acceptable medical practice. This occurred only twice in the 32 cases in which a doctor–patient relationship was presumed to exist. Our review failed to identify the reason why medical board review before indictment was consistently avoided by prosecutors.

The intended purpose of these criminal prosecutions is to stop the diversion of controlled substances away from legitimate medical use. The average delay between initiating an investigation and bringing criminal action appeared to be 2 years. In one-third of the cases, it was longer. Certainly, a state medical board can take action by stopping a physician from prescribing opioids faster than the time needed for a criminal investigation, trial, and conviction. A more effective and rapid way to stop diversion of physician-prescribed opioids is to promptly refer the cases of physicians reasonably suspected of supplying opioids to diverters to their state medical boards rather than the criminal justice system. The boards can then take any appropriate actions including referring the case of the physician to the criminal justice system for prosecution. Such actions as convicting a 74-year-old physician and giving him a 19-year jail sentence when he claimed to be innocent and treated people in pain[19] is far from the best way to stop diversion. It is an excellent way to make physicians reluctant to prescribe adequate doses of opioids to patients with chronic pain who need strong analgesia.

CONCLUSION

There are physicians who abuse their privileges and knowingly arrange for opioids to be taken by people who are not in pain. There are other physicians who appear to have a doctor–patient relationship with people who deceive the doctors into treating them as patients in pain. And there are many doctors who treat patients in pain appropriately with high doses of opioids. Any of these doctors may be investigated and risks prosecution with a lay jury to decide if the prescriptions are within or outside the bounds of medical practice. This inhibits doctors from prescribing appropriately high doses of opioids to patients who need them. In addition, when doctors must continually be suspicious of patients claiming to be in pain because being deceived can lead to criminal prosecution, their willingness to treat patients in pain with opioids diminishes. This harms patients in pain by increasing their suffering and by diminishing their ability to work and to function independently and in society. State medical boards rather than lay juries should be used to determine if doctors are prescribing opioids for patients inappropriately. If the prescriptions are determined to be within the bounds of medical practice, the case should end immediately. If the doctors are intentionally prescribing opioids for non-medical uses, they should be referred to the criminal justice system. If the doctor is intending to treat patients in pain, but prescribing excessively, the state medical board can and should take appropriate action. This would be a far more efficient and effective way to diminish this aspect of drug diversion than current criminal prosecution. It could eliminate prosecutions for prescriptions given within the bounds of medical practice. This would help diminish the fear of government punishment for prescribing opioids and lower this barrier to the adequate treatment of pain.

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CONFLICT OF INTEREST

The authors declared no conflict of interest.

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UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

[Docket No. 04-16]
T. YOUNG ASSOCIATES, INC.
REVOCATION OF REGISTRATION

INTRODUCTION AND PROCEDURAL HISTORY

On December 17, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to T. Young Associates of Hermitage, Tennessee (Respondent). The Show Cause Order proposed to revoke Respondent's DEA Certificate of Registration, 004395TSY, as a distributor of List I chemicals, and to deny any pending applications for renewal or modification of the registration, on the ground that Respondent's registration is inconsistent with the public interest as that term is defined in 21 U.S.C. § 823(h). *See* 21 U.S.C. § 824(a)(4).

The Show Cause Order alleged in substance that on July 21, 2001, Respondent applied for a modification of its registration as a List I chemical distributor requesting registration to handle and distribute phenylpropanolamine, ephedrine and pseudoephedrine at a new location. *See* Show Cause Order at 2. The Show Cause Order further alleged that Respondent sells primarily "gray market products" to convenience stores and gas stations, that Respondent's owner had informed DEA Diversion Investigators (DIs) that List I chemical products amounted to approximately nine percent of his total sales, and that some of the manufacturers of the products sold by Respondent have received warning letters from DEA because the products were found during law enforcement seizures of clandestine laboratories. *See id.* The Show Cause Order further

alleged that Tennessee led DEA's southeast region in the number of illicit methamphetamine laboratory seizures, that most illegal methamphetamine is produced locally, and that methamphetamine production continues unabated. *See id.* at 2-3.

The Show Cause Order further alleged that DEA had engaged an expert in the field of retail marketing and statistics who had studied the purchases of List I chemical products by hundreds of Tennessee retailers and concluded that these stores were purchasing these products in amounts that were far in excess of legitimate demand. *See id.* at 4. The Show Cause Order alleged that small illicit laboratories procure the precursor chemicals required to manufacture methamphetamine from non-traditional retailers such as gas stations and small retail markets and that some of these retailers use multiple distributors to mask their acquisition of large amounts of listed chemicals. *See id.*

Respondent, through its counsel, requested a hearing. The matter was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner, who conducted a hearing in Nashville, Tennessee, on September 28 and 29, 2004. At the hearing, both parties called witnesses to testify and introduced documentary evidence. Following the hearing, but before the record was closed, the Government introduced into evidence the affidavit of its expert witness, Mr. Jonathan Robbin. Respondent then submitted into evidence his own affidavit addressing the issues raised in the Robbin affidavit, as well as several other exhibits. Following the closing of the record, both parties submitted post-hearing briefs.

On October 28, 2005, the ALJ submitted her decision recommending that Respondent's registration be revoked. Neither party filed exceptions. The record was then transmitted to me for final agency action.

Having considered the record as a whole, I hereby issue this decision and final order. I adopt the ALJ's findings of fact and conclusions of law except as expressly noted herein. For the reasons set forth below, I concur with the ALJ's recommendation that Respondent's registration be revoked. I further order that any pending applications for renewal or modification of Respondent's registration be denied.

FINDINGS

Respondent is a corporation whose stores are owned entirely by Mr. Roy T. Young. Respondent is the holder of DEA Certificate of Registration, 004395TSY, which authorizes it to distribute the List I chemicals phenylpropanolamine, ephedrine and pseudoephedrine.[1] Respondent, which is located in Hermitage, Tennessee, sells a variety of general merchandise and seafood items such as ball caps, sunglasses, cigarette lighters, novelty items and licensed athletic wear to predominately gas stations and convenience stores in eastern and middle Tennessee. Mr. Young testified that Respondent "did a couple of million dollars a year by the early 2000s." Tr. 233. Mr. Young further testified that ephedrine was "about nine or ten percent of my sales in the chain stores." *Id.* at 290. Mr. Young also testified that he had decided not to carry pseudoephedrine although he did sell it "from time to time" to certain customers. *Id.* at 240.

Methamphetamine and the Market for List I Chemicals

While both ephedrine and pseudoephedrine have therapeutic uses,[2] they are also precursor chemicals that are regulated by the Controlled Substances Act. *See* 21 U.S.C. §

[1] There is no evidence in the record that Respondent had distributed phenylpropanolamine.
[2] According to the affidavit of Mr. Douglas A. Snyder, a Drug Science Officer within the Drug and Chemical Evaluation Section in the Office of Diversion Control, under the Food, Drug and Cosmetic Act's provisions pertaining to over-the-counter (OTC) products, ephedrine is lawfully marketed as a

802(34). Moreover, these chemicals are usually extracted from legal and what typically were over-the-counter products[7] and used in the illicit manufacture of methamphetamine, a schedule II controlled substance. *See* 21 CFR 1308.12(d).

Methamphetamine "is a powerful and addictive central nervous system stimulant." *U & S Sales*, 71 FR 37607, 37608 (2006). The illegal manufacture and abuse of methamphetamine pose a grave threat to this country. Methamphetamine abuse has destroyed numerous lives and families and has ravaged communities. Moreover, because of the toxic nature of the chemicals used in producing the drug, illicit methamphetamine laboratories cause serious environmental harms. According to the testimony of DEA Special Agent Guy Hargreaves, Staff Coordinator for the DEA Methamphetamine Program at DEA Headquarters, in 1999 there were 101 explosions and at least 64 fires at clandestine labs throughout the United States. *See* Gov. Exh. 26, at 9. Moreover, the annual cost to government agencies to clean up methamphetamine labs is "millions of dollars." *Id.* at 10.[8]

The problem of methamphetamine abuse is especially serious in Tennessee. According to the record, the number of law enforcement seizures of clandestine laboratories in Tennessee rose from 106 in 1999 to "over 700 labs" in 2003. *See* ALJ at 8, Tr. at 14. Moreover, according to a DEA Special Agent, as of September 28, 2004 (the

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bromochloromethane used to treat asthma. Gov. Exh. 23, at 3-4. Pseudoephedrine is lawfully marketed under the Food, Drug and Cosmetic Act's OTC provisions as a decongestant. *See Id.* at 6.

[7] In response to the methamphetamine epidemic, many States have enacted legislation making pseudoephedrine a Schedule V drug under state controlled substances acts.

[8] According to the Suspicious Order Task Force, as of 1994 the cost to clean up a small-sized lab site was $ 10,000. *See* Gov. Exh. 18, at 18.

date of the hearing), there had been close to 700 seizures in Tennessee already that year.[1] Tr. at 14.

A DEA Special Agent who serves in the Nashville office as a clandestine lab enforcement agent testified that, based on his observations of products found at clandestine lab sites, as well as interviews he had conducted with various defendants, there was a trend of methamphetamine cooks obtaining List I chemicals from "smaller gas stations and convenience stores." *Id.* at 12. According to the Special Agent, he had been told in the interviews that meth. cooks were "able to buy cases, half cases, and stash out the back door of" convenience stores and gas stations. *Id.* The Special Agent further testified that some meth. cooks drive around to different stores with four or five different addicts who go into several stores in different cities and purchase sub-threshold quantities of List I chemicals.

The Government submitted into evidence the affidavit of Mark J. Rubbins, a Diversion Investigator who was then assigned as Chief of the Domestic Chemical Control Unit, Office of Diversion Control, DEA Headquarters. According to DI Rubbins, DEA has determined that there is both a traditional and non-traditional market for List I chemical products. *See* Gov. Exh. 44, at 5. The traditional market is characterized by a short chain of distribution. In this market, manufacturers either sell directly to large chains of grocery stores (such as Giant and Safeway), pharmacies (such as Rite Aid and CVS), and other larger retailers (such as Wal-Mart), or they sell to large wholesalers (such as Bergen Brunswig and AmeriSource). *See id.* at 5-6. Furthermore, List I chemical products sold in this market are typically of lower strength and lower count

[1] As noted in *Gregg Brothers Wholesale Co., Inc.*, 71 FR ---- (2006), in 2004, law enforcement agencies seized 939 clandestine labs in Tennessee.

sizes such as 30 mg. pseudoephedrine tablets in small, blister pack sizes of six, twelve, twenty-four and sometimes forty-eight count. *See id.* at 5.

In contrast, products sold in the non-traditional market pass through multiple layers of distribution and are sold by such establishments as gas stations, small convenience stores, liquor stores, headshops, beauty parlors, and video stores. *See id.* at 6. Moreover, the products are typically stronger than those found in the traditional market and include 60 mg. pseudoephedrine tablets which are sold in larger package sizes such as 60, 100, or 120 count bottle sizes. DI Rubbins further stated that non-traditional retailers tend to knowingly sell large quantities of List I chemical products to "smurfers," individuals who work for methamphetamine traffickers and attempt to buy out a store's entire stock of List I chemical products by going to the store at different times or on different days. *See id.* at 6-7.

DI Rubbins stated that because of increased DEA enforcement efforts involving pseudoephedrine products, methamphetamine traffickers have increasingly gone back to using combination ephedrine products. *See id.* at 10. DI Rubbins further stated that in 2002, he contacted the major manufacturers of combination ephedrine/guaifenesin products and determined that sales for these products amounted to only one-tenth of the market for legitimate single-entity pseudoephedrine products. *See id.* According to DI Rubbins, the names of products that are popular with methamphetamine traffickers are "MiniThin" and "Mini Twin," which each contain 60 mg. pseudoephedrine, and "Max Brand" and Mini Two Way," which are combination ephedrine products. *See id.* at 12. Mr. Rubbins further stated that these brands "have been disproportionately represented in

clandestine lab seizures around the United States involving listed chemical products." *Id.* at 13.

The Government also submitted the affidavit of John Uncapher, who was then assigned as a Staff Coordinator with the Domestic Operations Division at DEA Headquarters. Mr. Uncapher's staff was responsible for the DEA Warning Letter program. *See* Gov. Exh. 42, at 3. Under this program, DEA collects information regarding List I chemicals products that have been found at clandestine lab. sites and identifies the manufacturers of these products. *See Id.* The Government entered into evidence a list of 35 warning letters issued to PDK Laboratories, the manufacturer of Max Brand, a product which Respondent distributes. *See* Gov. Exh. 19. According to this exhibit, between January 5, 1999, and September 26, 2002, approximately 1.67 million pseudoephedrine tablets and 107,250 combination ephedrine tablets manufactured by this firm were found in numerous seizures of clandestine laboratories throughout the United States including Tennessee. The Government also introduced into evidence a list of 17 warning letters issued to BDI because their products, which Respondent also distributed, were found during seizures of clandestine laboratories. *See* Gov. Exh. 20.

The Government submitted into evidence the declaration of Jonathan Robbin, an expert in statistical analysis of demographic, economic, geographic and survey data. Based on his study of the latest available United States Economic Census of Retail Trade, Mr. Robbin concluded that "over 97% of all sales of non-prescription drug products occur in drug stores and pharmacies, supermarkets, large discount merchandisers and electronic shopping and mail order houses." Gov. Exh. 70, at 4. Moreover, sales of non-prescription drugs by convenience stores (including both those that sell and do not sell

gasoline), "account for only 2.3% of the overall sales of all convenience stores that handle the line and only 0.7% of the total sales of all convenience stores." *Id.*

Mr. Robbin further testified that based on his study of U.S. Government Economic Census Data, information obtained from the National Association of Convenience Stores, and commercially available point of sale transaction data, he constructed a model of the traditional market for retail sales of pseudoephedrine. *See id.* at 5. According to Mr. Robbin, sales of pseudoephedrine account for "only about 2.6%" of the sales of health and beauty care products in convenience stores and only "0.05% of total in-store (non-gasoline) sales." *Id.*

Mr. Robbin testified that "the normal expected retail sale of pseudoephedrine (Hcl) tablets in a convenience store may range between $ 0 and $ 40 per month, with an average of $ 20.60 per month." *Id.* at 7. Mr. Robbin also testified that "the expected sale of ephedrine (Hcl) tablets in a convenience store ranges between $ 0 and $ 25, with an average of $ 12.58." *Id.* at 7-8. Mr. Robbin further testified that a monthly retail sale of $ 40 of ephedrine or $ 60 of pseudoephedrine would "occur less than one in 1,000 times in random sampling." *Id.* Moreover, a monthly retail sale of $ 60 of ephedrine or $ 100 in pseudoephedrine would "occur about once in a million times in random sampling." *Id.*

The Investigation of Respondent

Respondent's initial registered location was 1319 Central Court, Hermitage, Tennessee. On July 19, 2001, Mr. Young wrote a letter to DEA's Nashville office informing it that Respondent had relocated its warehouse to 1320 Central Court, Hermitage, Tennessee, and requesting that DEA issue a registration for the new address. *See* Gov. Exh. 3. According to Mr. Young's testimony, Respondent had leased both the

1319 and 1320 locations for some period. When Respondent's lease for the 1319 location came up for renewal, Mr. Young decided to terminate it and vacate the premises as he was already leasing the 1320 space and had leased another premises (4708 Lebanon Pike) which he was using for an office and retail store. *See* Tr. 242-43. Mr. Young did not notify DEA, however, until after Respondent moved out of its then registered location. *Id.* at 244-45.

Because DEA's regulations provide that a "request for modification shall be handled in the same manner as an application for registration," 21 CFR 1309.61, on August 7, 2001, two DIs visited Respondent's 1320 Central Court facility to conduct an investigation. ALJ at 15. The DIs inspected the facility and obtained from Respondent lists of both its customers and suppliers. The DIs found that the List I chemical products were securely stored in a locked area of the warehouse. *See id.*

The DIs told Mr. Young that they would conduct an accountability audit. The DIs conducted an inventory of all List I chemical products on hand and obtained Mr. Young's signature on their inventory report. Tr. 39-40. The DIs also told Mr. Young that they needed to know what inventory was on Respondent's delivery trucks. *Id.* at 40. One of the DIs could not recall, however, whether Mr. Young had said there were List I chemical products on the trucks. *Id.* at 41. The DI later testified that Mr. Young had never gotten back to them regarding List I chemicals that may have been on the trucks. *Id.* at 131. In his testimony, Mr. Young confirmed that the DIs had asked him about "the truck inventory" and whether there were any "inventories on the truck." *Id.* at 254.

The DIs then requested the invoices necessary to conduct an accountability audit. Mr. Young told the DIs that the records were not kept at the warehouse but were at his

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office, which was located at 4706 Lebanon Pike.[4] The DIs then went to the office. *Id.* at 37.

The DI proceeded to perform a 30 day accountability audit[5] of three of the products – Ephedrine Plus 60 tablet bottles, Max Brand 60 tablet bottles, and Nyquil two tablet packets. Because there was no beginning inventory, the DIs assigned a value of zero for each of the products. *Id.* at 47. The DIs then examined both the hard copy purchase invoices from Respondent's suppliers and Respondent's hard copy sales records.[6] *Id.* at 51, 147. The audit determined that there were overages in the amount of 3,131 Ephedrine Plus bottles and 600 NyQuil packets. Gov. Exh. 12. The audit also found a shortage of 36 bottles of Max Brand Ephedrine. *Id.*

The ALJ found that "[t]he investigators did not contact Mr. Young to discuss the audit results" and noted that "Mr. Young testified that he was not aware of the audit results until three years after the August 7, 2001 visit." ALJ at 17.[7] The ALJ further found that Mr. Young then had his employees go back through his records and recalculate Respondent's sales, the employees found overages. *See id.*; *see also* Tr. 257-58.

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[4] The DIs further informed Mr. Young that under federal regulations, records of purchases over certain amounts must be maintained at the registered location. *See* Tr. 37-38. The record contains an invoice documenting a purchase from FDK Laboratories of 720 bottles containing 60 tablets of 2 way ephedrine, a product that contains 25 mg. of ephedrine hydrochloride per tablet. *See* Gov. Exh. 6. Respondent's purchase of this product did not, however, exceed the one kilogram threshold. *See* 21 CFR 1310.04(f)(1); Gov. Exh. 24.

[5] The audit actually covered the period from July 1, 2001, through August 7, 2001. *See* Gov. Exh. 12.

[6] There was a factual dispute as to whether Respondent informed the DIs as to the existence of his computerized records. The ALJ found that "whatever computerized records Respondent maintained showed only the dollar amount of the sale but not the products sold; this latter information was shown only on hard copy 'invoices.'" ALJ at 14; *see also* Tr. at 252. Because the accountability audit was based on the quantity and not dollar amount of the products, the dispute is immaterial.

[7] There is, however, conflicting testimony by Mr. Young that when the DIs were through with the audit, "we sat down and had a beer meeting out front, then a reference was made to a large overage in one category" and I told the DIs "you can't actually be over." Tr. at 233.

In October 2001, DEA modified Respondent's registration by changing the address of his registered location to 1320 Central Court. The DI verified that he had granted the modification because of the financial hardship Mr. Young was undergoing in maintaining three separate premises. Tr. at 33.

Approximately a year after the on-site inspection, one of the DIs conducted verification visits of three of Respondent's customers. ALJ at 18. The manager at each location verified that the store was a customer of Respondent; each of the managers also told the DI that they used more than one supplier of List I chemicals. *See id.* At two of the stores, the managers told the DI that they were attempting to identify customers who they believed were purchasing List I chemical products for illicit use and report them to law enforcement authorities. *See id.*

On September 19, 2003, Mr. Young requested another modification of the registration to change both the name on the registration and the address of its registered location to 4706 Lebanon Pike. On December 17, 2003, however, the instant Show Cause Order was issued. *See* ALJ at 17.

On February 20, 2004, two DIs and a Special Agent visited Respondent at its Lebanon Pike location to deliver a letter from Howard Davis, the Diversion Program Manager for DEA's Atlanta Field Division. The letter informed Respondent that he could not store listed chemicals at his new proposed location until DEA approved the change. Gov. Exh. 46. The letter further explained that DEA would not approve any modification until the Order to Show Cause was resolved. *Id.*

During the visit, Mr. Young told one of the DIs that no List I chemicals were being stored at the Lebanon Pike location. However, during the visit, one of the DIs

found a display rack containing 24 bottles and 5 packets of ephedrine products on a shelf in the office. ALJ at 17. Because the products were at a non-registered location, the DI immediately seized them. *Id.*

Mr. Young testified that the products were at the Lebanon Pike location because his son had taken them there to photograph them for a brochure to be used in marketing them to Respondent's customers. Tr. 277. Mr. Young testified that after the pictures were taken the products should have been immediately returned to the truck. *Id.* at 278.

As part of DEA's investigation, one of the DIs obtained from Respondent's suppliers copies of invoices documenting its purchases of List I chemical products from January 2003 through July 2004. Tr. at 166-75. According to the invoices from one supplier, CB Distributors, Respondent purchased 5,616 bottles of Rapid Action (60 tablet count), 576 bottles of Rapid Action (48 tablet count), 10,830 packets of Rapid Action (12 tablet count), 3,168 bottles of Mini Two Way (60 tablet count), 576 bottles of Mini Two Way (48 tablet count), 3,456 packets of Mini Two Way (6 tablet count), 15,708 bottles of Max Brand 2-Way (60 tablet count), 17,280 packets of Max Brand 2-Way (6 tablet count), and 1,584 bottles of Twin Tabs (60 tablet count). ALJ at 18.

The Government also introduced two invoices it had received from another of Respondent's suppliers, Sasser Distributing. The invoices show that on July 27, 2004, Respondent purchased 288 bottles of ephedrine products (60 tablet count), the next day, Respondent purchased another 144 bottles of Biotek Ephedrine (48 tablet count), as well

as an additional amount of Ephedrine Plus packets (6 tablet count). *See* Gov. Exhs. 52-53.[9]

As stated above, the Government entered into evidence the affidavit of Jonathan Robbin. According to the affidavit, DEA provided Mr. Robbin with a list of 801 wholesale transactions involving combination ephedrine and pseudoephedrine products made by Respondent to 97 Tennessee convenience stores between January 27, 2003, and November 22, 2004. Gov. Exh. 70, at 12. The affidavit further stated that during this period Respondent sold 17,271 bottles, each containing 60 tablets, and 24,520 packages, each containing six tablets, of combination ephedrine products. *See id.* The bottles held a total of 1,036,260 tablets and the packets held a total of 147,120 tablets. *Id.* Respondent also sold to 31 convenience stores, 1,435 bottles, each containing 60 tablets of Max Brand 30 mg. pseudoephedrine, for a total of 86,100 tablets of pseudoephedrine products. *Id.*

Using this data, Mr. Robbin calculated each store's implied average monthly retail sales and compared that to the normal expected retail sales discussed above.[10] *See id.* at 13. According to Mr. Robbin, only one of the 97 stores was selling near the normal expected sales range at 2.8 times expectation. *Id.* at 15. The next lowest store was selling over 20 times the expected sales range. *Id.* Mr. Robbin explained that in random sampling, sales over 20 times expectation "could occur only about three times in a billion raised to the fifth power." *Id.* Mr. Robbin further explained that "[t]he probability of an index equal to or greater than 20 is so small as to be near impossibility." *Id.* at 16.

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[9] During the August 2001 on-site inspection, the DIs received a supplier list from Mr. Young. Tr. 56. One of the DIs determined that at least two of Respondent's suppliers had received warning letters from DEA. *ALJ* n.18.

[10] Mr. Robbin's affidavit contains a detailed methodology, including the figure he used for the products' gross margin, to calculate the implied retail sales value of the products.

Finally, Mr. Robbin found that the top 94 stores had indexes over 25, the top 54 stores sold "over 100 times expectation," and the top sixteen sold "over 500 times expectation." *Id.* at 16.

Mr. Robbin explained that "[s]uch indexes are not possible in the normal commerce of these goods at ordinary convenience stores." *Id.* According to Mr. Robbin, because the average convenience store serves 120,000 shoppers per year, if combination ephedrine products were being purchased by customers to treat asthma (the purpose for which the FDA has approved them), three million persons would have to shop at the store in a year to account for sales 25 times the expected amount. *Id.* Mr. Robbin further explained that while it was possible that a single customer could purchase a store's entire monthly inventory, this amount of product would supply the person with enough of the drug to treat an asthmatic condition at recommended doses for two and one-quarter years. *Id.* Mr. Robbin explained that "[i]t is difficult to imagine . . . what such a shopper would do with all of this material every month except to resell or use it as a precursor chemical in the illicit manufacture of methamphetamine." *Id.* at 16-17. Mr. Robbin thus concluded that Respondent "frequently sells combination ephedrine . . . and single ingredient pseudoephedrine . . . products to these stores in extraordinary excess of normal or traditional demand by ordinary convenience store shoppers." *Id.* at 17.

Mr. Young submitted an affidavit challenging the factual basis of Mr. Robbin's findings. According to Mr. Young, he supplied records covering only the 365 day period from September 2003 through August 2004. Resp. Exh. 19, at 1. Mr. Young further stated that "the total number of stores serviced fluctuate[d] and was not a hard and fast 97 stores as stated by Mr. Robbin." *Id.*

Mr. Young also challenged Mr. Robbin's findings as to the monthly expected sales range of combination ephedrine and pseudoephedrine products in convenience stores. Mr. Young asserted that according to the March 28, 2005 edition of Convenience Store News, "the average c-store sold $ 5,462 worth of cold and cough remedies in 2003." *Id.* Mr. Young also asserted that according to the National Association of Convenience Stores State of the Industry Report for 2003, "the average c-store sold $ 2,980 of cough & cold remedies in 2003." *Id.* at 2. Mr. Young thus contends that "[these independent studies show average monthly sales of $ 250 to $ 450 per store per month for the c-store industry. This amount is 8 to 14 times greater than what Robin [sic] reports." *Id.* Mr. Young further asserted that Respondent's average per store sales of combination ephedrine products "is within the norms for the sale of these products to convenience stores that we have experienced in the 14 years that we have been in business." *Id.* at 4.

In support of his affidavit, Mr. Young also submitted into evidence a spreadsheet showing its List I chemical sales from September 2003 through August 2004. *See* Resp. Exh. 20. According to the spreadsheet, Respondent sold a total of $ 68,568.11 of List I chemical products to an average of 54 stores per month. *See id.* The spreadsheet also indicates that Respondent's average sale per store, per month, was $ 105.81, and calculates that the average retail sale per store, per month, was $ 154.00. *Id.* The spreadsheet also indicates that Respondent's sales of traditional branded products (such as Advil, Aleve, Tylenol, Dayquil and Nyquil that contain pseudoephedrine) amounted to only $1507 out of the total of $ 68,568, or approximately two percent of its List I chemical product sales. *Id.*

DISCUSSION

Section 304(a) of the Controlled Substances Act provides that a registration to distribute a list I chemical "may be suspended or revoked . . . upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. § 824(a)(4). In making this determination, Congress directed that I consider the following factors:

> (1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;
>
> (2) compliance by the applicant with applicable Federal, State, and local law;
>
> (3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;
>
> (4) any past experience of the applicant in the manufacture and distribution of chemicals; and
>
> (5) such other factors as are relevant to and consistent with the public health and safety.

Id. § 823(h).

"These factors are considered in the disjunctive." *Jay's Ideas*, 70 FR 33195, 33197 (2005). I may rely on any one or a combination of factors, and may give each factor the weight I deem appropriate in determining whether a registration should be revoked or an application for a modification of a registration should be denied. *See, e.g.*, *David M. Starr*, 71 FR 39367, 39368 (2006); *Energy Outlet*, 64 FR 14269 (1999). Moreover, I am "not required to make findings as to all of the factors." *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *Morall v. DEA*, 412 F.3d 165, 173-74 (D.C. Cir.

2005). My analysis of the factors in this case compels the conclusion that Respondent's continued registration would be inconsistent with the public interest.

Factor One – Maintenance of Effective Controls Against Diversion

I acknowledge that Respondent provides effective security against the theft of listed chemicals. Accurate recordkeeping is, however, another important control against diversion. *See* 21 CFR 1309.71(b)(8). As to this system, the record clearly indicates that Respondent does not maintain effective controls against diversion.

The accountability audit found that two of the products sold by Respondent had overages; the other product had a shortage. As the ALJ noted, the DIs used a zero opening inventory for each product because Respondent did not have an inventory. Using a zero opening inventory will result in an over-count if, in fact, a registrant had product on hand on the beginning date of the audit period. I note, however, that Mr. Young testified that he had his employees go back through his records and they too came up with overages. Tr. 257-58.

The DIs also found that there was a shortage of 26 Max Brand 60 tablet bottles. This is especially significant because the audit covered only a short period of time (approximately five weeks). Moreover, if, in fact, Respondent had product on hand on the beginning date of the audit period, assigning an inventory of zero would result in an undercount of the shortage.

I further note the testimony regarding whether there was inventory on the trucks. The ALJ noted that there was "somewhat inconsistent testimony about whether some List I chemicals were on" the trucks. *See* ALJ at 22. I am satisfied, however, that the DIs asked Respondent whether there were any List I chemicals on the trucks, *see* Tr. 40 &

254, and the fact remains that Respondent had no readily obtainable records showing the amount of inventory, if any, that was on the trucks. I therefore conclude that Respondent does not maintain effective controls against diversion. This factor thus supports a finding that Respondent's continued registration would be inconsistent with the public interest.

Factor Two – Compliance with Applicable Federal, State, and Local Laws

The record here demonstrates that Respondent committed several violations of federal law and regulations. First, in July 1001, Respondent moved its List I chemicals from the 1319 Central Court building, which was its registered location, to the 1320 Central Court building, without obtaining approval from DEA. This action violated 21 U.S.C. § 822(e) and 21 CFR 1309.25(a).

The ALJ also found that Respondent violated 21 CFR1310.04(c), by storing List I chemical records at its Lebanon Pike location, which was not registered. *See* ALJ at 23. The record does not, however, support this finding. While 21 CFR 1310.04(c) requires that records be maintained "at the regulated person's place of business where the transaction occurred," *id.*, the provision applies only to records which must be maintained under 21 CFR 1310.03. The only provision of that section which is pertinent here is the requirement that a regulated person keep a record of "a regulated transaction." *Id.* § 1310.03(a). The regulations establish that the threshold for transactions in combination ephedrine products between wholesale distributors is one kilogram. *Id.* § 1310.04(f)(1)(ii); *see also* Comprehensive Methamphetamine Control Act of 1996, Pub. L. No. 104-237, § 401(f), 110 Stat. 3099, 3110 (1996) (adopting one kilogram threshold for regulated transactions in combination ephedrine products between wholesale distributors).

The record contains only a single invoice conceivably documenting a regulated transaction between Respondent and one of its suppliers, PDK Laboratories, which had occurred at the time of the August 2001 inspection. This invoice indicates that on July 17, 2001, Respondent purchased 720 bottles containing 60 combination ephedrine tablets of 25 mg. ephedrine hydrochloride for a total of 43,200 tablets. *See* Gov. Exh. 6. This amount of product does not, however, exceed the one kilogram threshold because the hydrochloride constitutes approximately 18 percent of the chemical. As the Government's own exhibit demonstrates, the one kilogram threshold was equivalent to 48,826 combination ephedrine hcl tablets each containing 25 mg. ephedrine hcl. *See* Gov. Exh. 23. Because Respondent's purchase was more than 5000 tablets under this amount, and there is no other evidence indicating that Respondent engaged in additional purchases during the month, the record does not establish that Respondent violated 21 CFR 1310.04(c).

The record does, however, contain evidence establishing an additional violation of DEA regulations. During the February 2004 visit, the DIs found a display rack containing 24 bottles and 5 packets of combination ephedrine products at Respondent's Lebanon Pike store/office. Because Respondent's Lebanon Pike facility was not a registered location, Respondent's storage of the items at this location violated 21 U.S.C. § 822(e) and 21 CFR 1309.23(a). Most remarkably, Respondent committed this second violation after having been served with a Show Cause Order.

Because Respondent committed multiple violations of the CSA's provisions, I conclude that Respondent's record of compliance with federal law supports a finding that its continued registration would be inconsistent with the public interest.

Factor Three – The Record of Criminal Convictions

The record contains no evidence that Respondent's owner, or any employee, has been convicted of an offense under laws related to either controlled substances or listed chemicals. I thus conclude that this factor supports a finding that Respondent's continued registration would not be inconsistent with the public interest.

Factor Four – Past Experience in Distributing Listed Chemicals

It is undisputed that Respondent has distributed List I chemical products for several years. That experience is, however, characterized by several violations of the CSA, as well as the inability of Respondent to provide an accurate accounting of its products. Moreover, as described under factor five below, there is substantial evidence in the record establishing that Respondent's products have been diverted. Accordingly, this factor supports a finding that Respondent's continued registration would be inconsistent with the public interest.

Factor Five – Other Factors That Are Relevant to and Consistent With Public Health and Safety

The record here establishes – as do numerous agency precedents – that there is a substantial nexus between the sale of certain non-traditional List I chemical products by non-traditional retailers and the diversion of these products into the illicit production of methamphetamine. *See, e.g.*, *John Venuto*, 71 FR 39365, 39366 (2006); *Joey Enterprises*, 710 FR 76866, 76887 (2005); *TNT Distributors*, 70 FR 12729, 12730 (2005). Indeed, as noted recently in *TNT Distributors*, which also involved a Tennessee-based distributor of List I chemicals, "80 to 90 percent of ephedrine and pseudoephedrine being used [in Tennessee] to manufacture methamphetamine was being obtained from convenience stores." 70 FR at 12730.

Likewise in this case, there is undisputed testimony by a DEA Special Agent establishing that Tennessee-based methamphetamine cooks were purchasing large quantities of List I chemicals from smaller stores such as gas stations and convenience stores. Tr. at 12. Respondent's List I chemical sales were principally made to these types of retail establishments.

Moreover, Respondent's Exhibit 20, which was a compilation of its sales of List I chemical products for the period September 2003 through August 2004, establishes that 98 percent of its sales were of non-traditional products including those of several manufacturers who have received warning letters from this agency because their products have frequently been found during seizures of clandestine methamphetamine labs. Respondent's Exhibit 20 further establishes that during this period, its average sale per store, per month, was $ 103.61, which would result in an average retail sale per store, per month, of $ 184.

The ALJ found "persuasive" the affidavit of Mr. Robbin, the Government's expert witness who testified about the market for List I chemical products. ALJ at 25. Based on this evidence, the ALJ further concluded that "Respondent sold quantities of List I chemicals to convenience stores that far exceeded what the stores could reasonably be expected to sell to legitimate consumers." *Id.* The ALJ also rejected Mr. Young's assertion in his post-hearing affidavit challenging Mr. Robbin's testimony as to the normal expected sales of combination ephedrine and pseudoephedrine products in convenience stores. *See id.* According to Mr. Young, the average convenience store sold between $ 250 and $ 450 per store, per month, an amount that "is 8 to 14 times greater than what Robin [sic] reports." Resp. Exh. 19, at 2.

[illegible] to show that Respondent did not intend that it products be diverted, it is irrelevant.

As the ALJ observed, combination ephedrine products cannot be lawfully marketed over-the-counter as a cold and cough remedy and most of Respondent's sales were of this type of product. *See* ALJ at 23; 21 CFR 341.76. Moreover, products containing pseudoephedrine are only a subset of over-the-counter cold remedies. Respondent has produced no evidence establishing the percentage of over-the-counter cold remedies that include pseudoephedrine. I therefore credit Mr. Robbin's expert testimony as to the annual expected sales ranged of both ephedrine combination and pseudoephedrine products in non-traditional retailers.

Mr. Young also challenged the factual basis for Mr. Robbin's findings that were based on data supplied to the latter by DEA. According to Mr. Robbin's affidavit, the findings that were specific to Respondent were based on "a list supplied to the DEA by T. Young of BH wholesale transactions drawn from invoices to 97 convenience stores in Tennessee," which covered the period from January 27, 2003, through November 22, 2004. Govt. Exh. 70, at 12. Mr. Robbin further stated that the "[d]ata given for each transaction included invoice date, store name, a product description and number of units sold." *Id.* at 13. Mr. Young asserts, however, that he supplied DEA with "data from September 2003 thru August 2004," that the data "was for 365 days, not for 655 and the total number of stores serviced thatmate[d] and was not a head and fast 97 stores as stated by Mr. Robbin." Resp. Exh. 19, at 1.

The ALJ did not address this factual dispute. Mr. Robbin's declaration makes clear that he did not review the actual invoices but rather data provided him by the Government. The Government did not, however, submit into evidence the list of transactions referred to by Mr. Robbin or the documentary evidence upon which the list

Not Your Average Pot Proponent

SANTA CRUZ, Calif., May 24, 2004

(AP) What do you do when you sue U.S. Attorney General John Ashcroft and win? Fifty-one-year-old Valerie Corral, a sinewy 5-foot tall great-granddaughter of Italian immigrants, throws back her head laughing, her hands reaching to the clouds, hips wiggling, feet stomping.

"It's my happy dance!" she says, throwing her arms around her husband Mike.

She has also planted an acre of marijuana.

The decision that lets the crop remain is just one round in a long legal battle.

Last month, a federal judge in San Jose issued a preliminary injunction banning the **Justice Department**, including the **Drug Enforcement Administration**, from interfering with the Corrals' pot garden, set above an ocean bluff near Davenport, about an hour south of San Francisco. The injunction gives the judge time to reconsider his earlier decision to allow the garden to be uprooted.

Still, the Corrals call the injunction a victory.

They share their harvest through the first legally recognized, nonprofit medical marijuana club in America, which they founded in 1993. The club has about 250 seriously ill members who have prescriptions from their doctors to use marijuana to alleviate their suffering, increase their appetites and control their seizures. The marijuana is free.

The San Jose ruling is one of a number challenging federal restrictions on medical marijuana, which has consistently won support in national opinion polls since 1995 but has had a mixed record in state ballot measures.

This summer, the **U.S. Supreme Court** is expected to decide whether to hear another case that could undo or affirm the Corrals' right to grow pot — granted by state and local regulations, but denied by federal law. A second case in federal court in San Francisco — in which other medicinal-use growers seek to reclaim seized marijuana — could also affect the couple.

The Justice Department refused comment.

For now, the Corrals are the only people in the United States growing marijuana in their backyard backed by state law, a local ordinance and a federal judge's injunction. And Valerie Corral has become a heroine to proponents of medical marijuana.

"This could be the moment of the beginning of the end of this insane war against the sick," said Bruce Mirken of the Washington D.C.-based advocacy group **Marijuana Policy Project**. "And while the DEA and the Justice Department characterize Valerie as a common drug dealer, all you have to do is spend two minutes with her to know that's a lie."

During the past three decades, while sharing marijuana with sick people, Corral has watched — and in many cases held — 140 friends, ranging in age from 7 to 96, as they died of cancer, AIDS and other illnesses.

"It is the greatest honor to be asked by a person who is dying to sit with them," she said.

Reflection on those deaths has given her strength, she said — while battling the government, when federal agents pointed a rifle at her head, and when her motives have been called into question.

"John Ashcroft is not someone I would have chosen to tangle with, but I think of him, and George Bush, as lost souls," she said. "When I look at them, I think about how they are just people, ... and that makes them less fearsome. Ultimately we all make the same journey, and ultimately I hope they make theirs in peace."

In fact, Corral's compassion is grudgingly respected at the DEA's San Francisco office.

"I'm personally impressed with her desire to help deathly ill people," said spokesman Richard Meyer. "It's just that she makes it look like the way to help sick and dying people is to give them marijuana. And that's not the case.

"There's hundreds of ways to help these people. The DEA has a lot of compassion for those people who are sick and dying, but I think there are many, many ways to help them without giving them marijuana."

At DEA headquarters, authorities said the issue has nothing to do with Valerie Corral or compassion.

"This may be personal to her, but it's not personal to the DEA," said the agency's Will Glaspy in Washington, D.C. "The DEA's job is to enforce the Controlled Substance Act. Congress passed the laws and charged us with enforcing them. She is attempting to use the court system to get what she wants."

Valerie Corral's path to becoming a medical marijuana advocate began 31 years ago, the day a small airplane swooped low and buzzed a Volkswagen she was riding in through the Nevada desert. The car went out of control and was sent skidding, rolling and bouncing 365 feet through the dust, brush and rocks.

Corral's slight body was flung against the roof and doors, causing brain damage, epilepsy, and a lifetime of staggering migraines. She took prescription drugs but still suffered convulsions, shaking and grand mal seizures.

Then one day, Mike handed her a medical journal article that showed marijuana controlled seizures in mice. Since then, for 30 years, Valerie Corral says she has maintained a steady level of marijuana in her system.

Her legal challenges began in 1992, when the local sheriff arrested her for growing five marijuana plants. With Mike, she challenged the law, using the defense of necessity.

Prosecutors dismissed the case, saying they didn't think they could win before a sympathetic jury in liberal Santa Cruz. When the sheriff arrested the Corrals again in 1993, the district attorney said he had no intention of ever prosecuting them and told police to leave them alone.

A few years later, the Corrals helped draft California's landmark Compassionate Use Act, approved by voters in 1996, that allows patients with a doctor's recommendation to use marijuana. Similar laws in Alaska, Arizona, Colorado, Hawaii, Maine, Nevada, Oregon and Washington allow the infirm to receive, possess, grow or smoke marijuana for medical purposes without fear of state prosecution.

But the law did not provide complete protection from arrest.

While local authorities worked with the Corrals to protect them against theft and coordinate distribution, federal agents continued to assert that growing, using and distributing marijuana was illegal. To provide legal protection, the city of Santa Cruz deputized the Corrals in 2000 to function as medical marijuana providers.

But in September 2002, federal agents raided the Corrals' farm — just weeks before their annual harvest — taking the couple to jail and pulling up more than 150 plants.

The Corrals were never charged, but the raid prompted them to begin a legal challenge to the federal ban, aided by a team of attorneys including **Santa Clara University law professor Gerald Uelmen** and advocates at the **Drug Policy Alliance**, a non-profit Washington D.C.-based organization.

This is the case in which the San Jose judge recently ruled in their favor.

"Representing Valerie Corral, for me, is like representing Mother Teresa," said Uelmen, a constitutional law expert, calling her "one of the most compassionate people I've ever met."

And one who has led a movement to a new high.

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