Written Statement of

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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.