No. 20-71433

In the United States Court of Appeals for the Ninth Circuit

SUZANNE SISLEY, M.D.; SCOTTSDALE RESEARCH INSTITUTE, LLC; BATTLEFIELD FOUNDATION, DBA FIELD TO HEALED; LORENZO SULLIVAN; KENDRICK SPEAGLE; GARY HESS,

Petitioners,

v.

U.S. DRUG ENFORCEMENT ADMINISTRATION; WILLIAM BARR, ATTORNEY GENERAL; TIMOTHY SHEA, ACTING ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION,

Respondents

EXCERPTS OF RECORD
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Exhibit B: Statement of Grounds

iii. History of cannabis evidences safety

Cannabis was criminalized in the 1930s, and against the advice of most major medical societies, the use of cannabis for any purpose, including medicinal, was criminalized in the United States by 1942.(307, 435,478) Prior to this, there were many cannabis-based prescription medications commercially manufactured by companies including Eli-Lilly, Parke Davis, and Sharp Dohme (now Merck Sharp Dohme).

Thus, over the past decades there have been further developments in opioid-based medicines while research in cannabinoid-based medicines was significantly slowed down. Today there are a multitude of opioid medicines widely available, in pills, patches, as well as for injection, inhalation, and implantation. The only form of a DEA-approved cannabinoid based medicine available in the United States is dronabinol (Marinol). According to research, potentially much of the morbidity and mortality caused by opioid toxicity over the past 70 years could have been reduced or prevented if cannabis had remained available on the United States pharmacopeia to serious illnesses.(35,37)

iv. The side effects of cannabis are milder than the other Schedule II drugs

As with any drug, cannabis is not without side effects. A patient does not need to be intoxicated to get a beneficial medical effect.(102) Cannabis may induce euphoria and, as such, may be psychologically addictive, but much less so than other Scheduled II drugs. There is no severe physical withdrawal syndrome associated with cannabis.(18,20) Cannabis addiction is amenable to treatment.(102) Cannabis may induce paranoia and disorientation, particularly in novice users, but again, less so than other Schedule II drugs.(11)

Many of the undesired psychoactive effects of cannabis are due to THC, which is among the reasons that dronabinol is not a suitable alternative (because dronabinol is 100 percent THC as opposed to natural cannabis which is only 15 percent THC).(11) However newer medicinal strains of cannabis are lower in THC and higher in the non-psychoactive, more therapeutic cannabinoids, such as CBD, and CBN. These compounds further improved the efficacy of cannabis.(18)

C. There are adequate and well-controlled studies proving the medical efficacy of cannabis

Regarding the degree and adequacy of well-controlled studies proving efficacy of cannabis as medicine, a review of the current scientific evidence is provided herein, followed by historical and societal perspectives. Regarding the accessibility and availability of these studies, all of the research studies cited herein, are available on the National Library of Medicine/PubMed (http://www.ncbi.nlm.nih.gov/pubmed).

i. Review of the current scientific evidence proves the medical efficacy of cannabis

Four reviews of modern human clinical studies with cannabis and cannabinoids in the United States and elsewhere have recently been published in peer-reviewed literature. (49,197, 471,569) Musty et al. reviewed seven state health department-sponsored clinical trials with data

from a total of 748 patients who received a dose of cannabis and 345 patients who received oral THC for the treatment of nausea and vomiting following cancer chemotherapy in Tennessee (1983), Michigan (1982), Georgia (1983), New Mexico (1983 and 1984), California (1989), and New York (1990).(471) To assess the evidence from these clinical trials, the authors systematically performed a meta-analysis of the individual studies, to assess possible beneficial effects. These trials were randomized, although it is not clear that they were truly blind. The authors found that patients who received a dose of cannabis experienced 70-100 percent relief from nausea and vomiting, while those who used oral THC experienced 76-88 percent relief.(471) Even judged using the strictest of evidence-based medicine (EBM) criteria, the evidence is convincing that cannabis does relieve nausea and vomiting in this setting. Bagshaw, et al. performed a systematic, comprehensive review of 80 human studies of cannabis and cannabinoids, and found similar conclusive evidence in support of cannabis use in the treatment of refractory nausea and appetite loss resulting from cancer treatment.(35)

Ben Amar et al., performed a meta-analytic review of all articles published on Medline and PubMed from inception of up till July 1, 2005.(49) The key words used were cannabis, marijuana, marihuana, hashish, hashich, haschich, cannabinoids, tetrahydrocannabinol, THC, dronabinol, nabilone, levonantradol, randomised, randomized, double-blind, simple blind, placebo-controlled, and human. The research also included studies published in English, French, and Spanish. For the final selection, the authors only included properly controlled clinical trials. Open label studies were excluded. Seventy-two controlled studies evaluating the therapeutic effects of cannabis and cannabinoids were identified. The forms of cannabis and approximate dosages were included as well as efficacy, and adverse effects. The authors concluded that on the basis of the reviewed studies, cannabinoids present significant therapeutic potential as antiemetic, appetite stimulants, analgesics, and also shows significant benefit in the treatment of multiple sclerosis, spinal cord injuries, Tourette's syndrome, epilepsy, and glaucoma.(49)

Rocha et al. performed a systematic review and metaanalysis identified 30 randomized, controlled clinical trials that evaluated the antiemetic efficacy of cannabinoids in comparison with conventional drugs and placebo.(569) A Cochrane-style meta-analysis of 18 studies, including 13 randomized, controlled clinical trials comparing cannabis to standard antiemetics for treatment of nausea and vomiting in cancer patients receiving chemotherapy, revealed a statistically significant patient preference for cannabis or its components versus a control drug, the latter being either placebo or an antiemetic drug such as prochlorperazine, domperidone, or alizapride.(49)

ii. Medicinal dosing paradigms are safe and effective and alternatives to smoking are recommended

Dosing paradigms for medicinal cannabis have been previously described.(16,105) With simple trial and error, most patients are able to get the right combination of cannabinoids that will address their symptoms and meet their needs. While research has not shown cannabis smoke definitely causes lung cancer, it can irritate bronchial mucosal membranes.(37,340)

In any case, cannabis does not need to be smoked to be effectively used as medicine. Cannabis can be vaporized. Cannabinoids are volatile and will vaporize at temperatures in the range of 250 degrees Fahrenheit, much lower than actual combustion.(193,438,698) Heated air

is drawn through cannabis and the active compounds vaporized, which are then inhaled. This rapid delivery of the cannabinoids allows for easy titration to desired effect, much as with smoking yet without health risks.(87,374,428) Additionally, cannabis can be ingested orally, or applied topically in a liniment.(105)

iii. Many known cannabinoids (not including THC) have therapeutic value with little or no cognitive or psychoactive side-effects; dronabinol (Marinol) is not an appropriate substitute for cannabis due to its 100 percent THC and lacking therapeutic cannabinoids

There are many known cannabinoids in the cannabis plant that have tremendous therapeutic value, yet have little or no cognitive or psychoactive effects.(11,18,102) The cannabinoids are lipophilic, 21 carbon terpenes, and include delta-9 THC and delta-8 THC, of which the THC produces the majority of psychoactive effects.(679) While the DEA considers cannabis a Schedule I drug, it classifies dronabinol (Marinol) as Schedule III. Dronabinol is 100 percent THC and is potentially very psychoactive. Natural cannabis typically would be no more than 15 percent THC by weight. Thus it is inconsistent that cannabis, with 15 percent THC, remains a Schedule I drug, while dronabinol, at 100 percent THC, is Schedule III.

In addition, many patients find dronabinol too sedating and associated with too many psychoactive effects due to its 100 percent THC. Dronabinol is not an appropriate substitute for natural cannabis because other major cannabinoids include cannabidiol (CBD) and cannabinol (CBN) in the natural substance, both of which significantly modify the effects THC and have distinct therapeutic and advantageous effects of their own. CBD appears to modulate and reduce any untoward effects of THC.(72,87,339,374,428,462,595,746) CBN appears to have distinct pharmacological properties that are quite different from cannabidiol.(72) CBN has significant anticonvulsant, sedative, and other pharmacological activities likely to interact with the effects of THC.(72) CBN may induce sleep and may provide some protection against seizures for epileptics.(339) Of relevance for pain management for serious illnesses, in addition to analgesia, the following dose-dependent pharmacologic actions have been observed in studies: muscle relaxation, anti-inflammatory effects, neuroprotection in ischemia and hypoxia, enhanced well-being, and anxiolysis.(16) The ratios of the various cannabinoids differ according to the plant strain, and, to some extent, how the plant is grown.(678)

Sharing Schedule I with cannabis are heroin, lysergic acid, and methamphetamine. Schedule II is a category of drugs considered to have a strong potential for abuse or addiction, but that also have legitimate medical use. Included here are opium, morphine, cocaine, and oxycodone. Schedule III drugs are felt to have even less abuse or addiction potential than Schedule I or II drugs and have a beneficial medical use. Included here are dronabinol, hydrocodone, amphetamine-based stimulants, and short-acting barbiturates. Schedule IV and V drugs are felt to have even less risks. Schedule IV drugs include benzodiazepines, while Schedule V drugs include antidiarrheals and antitussives that contain opioid derivatives. For further perspective, the DEA does not schedule carisoprodol (Soma) at all, implying that this agency does not consider it a dangerous drug. Carisoprodol is a widely used muscle relaxant whose active metabolite is the barbiturate meprobamate. Carisoprodol also shows serotonergic activity at higher levels and has produced overdose in humans. Abrupt cessation in patients taking large doses of carisoprodol will produce withdrawal, characterized by vomiting, insomnia,

tremors, psychosis, and ataxia. Given that dronabinol, being 100 percent THC and highly psychoactive, is Schedule III, and the potentially addictive drug carisoprodol is unscheduled, it is inconsistent that cannabis remains a Schedule I drug. Schedule II is entirely appropriate for cannabis.

Potential analgesic sites of action for cannabinoids have been identified at brain, spinal cord and peripheral levels.(87,374,428,595) There is strong data indicating that neurons in the rostroventral medulla and periaqueductal grey are involved the brain-mediated analgesic effects of cannabinoids.(213) There are also spinal mechanisms of analgesia, including cannabinergic inhibition of gamma amino butyric acid (GABA), glycine, and glutamate release. (122, 226, 304, 305, 464, 600, 636) There is also a growing body of evidence showing a peripheral analgesic action of cannabinoids, particularly if inflammation is present.(196,688) Animal studies have demonstrated analgesic effects of locally delivered cannabinoids at doses that would not be systemically effective.(196) The mechanisms of these peripheral analgesic actions are not completely understood but appear to be related to the anti-inflammatory effects of cannabinoids. Cannabinoids have profound effects on cytokine production, although the direction of such effects is variable and not always mediated by cannabinoid receptors. Another proposed mechanism for the anti-inflammatory actions is cannabinoid-induced increased production of eicosanoids that promote the resolution of inflammation. This differentiates cannabinoids from cyclooxygenase-2 inhibitors that suppress the synthesis of eicosanoids that promote the induction of the inflammatory process.(16,35)

D. Cannabis has been accepted by the medical community as meeting the current, modern accepted standards for what constitutes medicine

On November 10, 2009, the American Medical Association (AMA) voted to reverse its long-held position that cannabis remain a Schedule I substance. The AMA adopted a report drafted by the AMA Council on Science and Public Health (CSAPH) entitled, "Use of Cannabis for Medicinal Purposes," which affirmed the therapeutic benefits of marijuana and called for further research. The AMA CSAPH report concluded that, "short term controlled trials indicate that smoked cannabis reduces neuropathic pain, improves appetite and caloric intake especially in patients with reduced muscle mass, and may relieve spasticity and pain in patients with multiple sclerosis." Furthermore, the report urges that "the Schedule I status of marijuana be reviewed with the goal of facilitating clinical research and development of cannabinoid-based medicines, and alternate delivery methods."

The AMA's position change on medical cannabis followed a resolution adopted in 2008 by the American College of Physicians (ACP), the country's second largest physician group and the largest organization of doctors of internal medicine. The ACP resolution also called for reconsideration of moving medicinal cannabis out of schedule I after performing an "evidence-based review of the current science" on the medical efficacy of cannabis, which this report provides in part.

The Institute of Medicine (IOM), a very prestigious organization of clinical and basic science researchers, was among the first major physician based group to adopt a new stance, issuing the landmark publication, "Marijuana and Medicine" on April 7, 2003. This consensus

report addressed the scientific basis and the therapeutic effects of cannabis to treat a multitude of medical conditions. The IOM consensus book specifically evaluates how well cannabis meets all of the current, modern accepted standards for what constitutes "medicine." This document is available on the IOM website: http://iom.edu/Reports/2003/Marijuana-and-Medicine-Assessing-the-Science-Base.aspx

There is now consensus of medical opinion concerning medical acceptability of cannabis among the largest groups of physicians in the United States. The medical community has increasingly recommended cannabis as an accepted form of therapeutic medicine for multiple serious illnesses. Members of the medical community have adopted effective treatment protocols for certain conditions. The medical community continues to develop methods of safe, consistent and effective dose and potency customized to individual patients' needs.

Much research as described throughout this report has proven cannabis' effectiveness, and allowing patients to access and use cannabis for medical use consistently enjoys widespread support among clinicians. The available medical research indicates that cannabis is highly effective in treating a number of problems commonly encountered in medicine. Arguably, to reclassify it, only one accepted treatment modality is necessary: for example, treatment for neuropathic pain and wasting associated with HIV/AIDS, which is undisputable among any physician across the United States—that alone provides sufficient justification to reclassify cannabis for medical purposes. Many patients who are currently on long term opioids could potentially be treated with either cannabis alone or in combination with a lower dose of opioids (instead of far more harmful long-acting opioid medication).

From a pharmacological perspective, cannabinoids are considerably safer than opioids and have broad therapeutic applicability. Cannabis is a medicine that has proved efficacious and could be potentially very beneficial for patients and much safer than other "legal" options such as opioid based medicines. This is an opinion that doctors share across the county. Further doctors have developed dosing and potency applicability and methods for specific patients' condition, and these methods have become accepted and more widespread across the medical community in our nation and beyond.

E. The scientific evidence is widely available

The scientific evidence is replete and widely available. As the previous sections fully elucidate, the scientific evidence supports the rescheduling of cannabis for medical use. The evidence is widely available in complete form through published journals and on the internet just like any other medicinal drugs. The evidence is far more than anecdotal self-reported effects by patients. Double-blind placebo studies have shown effectiveness following the FDA's regulations to prove drug efficacy.

i. Scientific evidence regarding the safety and efficacy of cannabis is readily available directly from the National Library of Medicine

The scientific evidence regarding the safety and efficacy of cannabis is readily available directly from the National Library of Medicine (http://www.ncbi.nlm.nih.gov/pubmed/ also known as MEDLINE(R) or PubMed Central). This is the United States government's repository

for peer-reviewed scientific research. On this website the independently peer-reviewed research papers can be identified with the abstracts of research, a summarized form of a paper published in the medical literature. The full, complete data set can be accessed from the specific journal that the work is published in. For some journals there may be a small fee required to access this unless the person accessing the journal has a subscription or works at an institution with a group subscription.

There are now considerably more randomized, double-blinded, placebo-controlled clinical trials documenting the efficacy of cannabis for medicinal treatment of any number of conditions (pain, nausea, spasticity, glaucoma) than would typically be required of a standard prescription medication to obtain FDA approval for a given purpose (especially compared with the last time the FDA reviewed the matter in 2006). This is now being documented summarily in the Cochrane Library data base as well. There are several well done Cochrane reviews that summarize the multiple controlled, large scale, clinical trials that have been conducted with cannabis for efficacy as well as safety.(14) In fact, a simple word search on PubMed using just one keyword phrase "medical marijuana" reveals more than 2,389 published papers in peer-reviewed journals. Doing a search using the keyword "hydrocodone," the most widely prescribed opioid analgesic in the United States, reveals a total of only 508 published papers (search done November 27, 2011; 12:00 PST, English language literature only): *hydrocodone is the most commonly prescribed opioid medication in the United States, and the active ingredient in Vicodin; **active opioid ingredient in Percocet®; +active opioid ingredient in tapentadol®

ii. Table One compares the number of Medline citations for medical marijuana compared to other commonly prescribed opioid medications (as of 11/27/2011; 12:00 PST):

Medication (name/search term)	Number of Medline (peer reviewed) Citations
Medical marijuana	2,389
Hydrocodone*	508
Oxycodone**	1553
Tapentadol+	81

TABLE ONE

For the purposes of example, the results of a series of randomized, placebo-controlled FDA-approved clinical trials performed by regional branches of the University of California (UC) demonstrated that inhaled cannabis holds therapeutic value that is comparable to or better than conventional medications, particularly in the treatment of multiple sclerosis. These findings were publicly presented to the California legislature, and also appear online here: http://www.cmcr.ucsd.edu/images/pdfs/CMCR_REPORT_FEB17.pdf.

Further, the UC findings paralleled those previously reported by the American Medical Association's Council on Science and Public Health. The research on medicinal cannabis is subject to all the standard procedural protocols required for all medical research. This provides ample opportunity for peer members of the scientific community to fully vet and scrutinize the data demonstrating safety and efficacy of cannabis.

With respect to the Department of Health and Human Services (HHS) regarding the five cited elements required to make a determination of "currently accepted medical use" for medical

cannabis, all of these have been fulfilled as described herein. As noted above, there is a more complete scientific analysis of the chemical components found in cannabis than in the most commonly prescribed opioid medications. In fact, there are over four times more studies assessing the efficacy and safety of cannabis for medical use than there are for hydrocodone. These studies must pass through the same vetting process as any other study published in a peer reviewed journal. In fact, the data above is from only the peer reviewed journals accepted by the National Library of Medicine, which has its own stringent criteria for citing journal articles (see: http://www.ncbi.nlm.nih.gov/pubmed).

Research on the medical use of cannabis has unmistakably progressed to the point that it can be considered to have a "currently accepted medical use" as required by 21 U.S.C. 812(b)(2)(B)).

iii. With respect to a consensus of medical opinion, currently all of the following health organizations have issued statements in favor of medical cannabis

International and National Organizations

AIDS Action Council
AIDS Treatment News
American Academy of Family Physicians
American College of Physicians
American Medical Association
American Medical Student Association
American Nurses Association
American Preventive Medical Association
American Public Health Association
American Society of Addiction Medicine
Arthritis Research Campaign (United Kingdom)
Australian Medical Association (New South Wales) Limited
Australian National Task Force on Cannabis
Belgian Ministry of Health
British House of Lords Select Committee on Science and Technology
British House of Lords Select Committee on Science and Technology (Second Report)
British Medical Association
Canadian AIDS Society
Canadian Special Senate Committee on Illegal Drugs
Dr. Dean Edell (surgeon and nationally syndicated radio host)
French Ministry of Health
Health Canada
Kaiser Permanente
Lymphoma Foundation of America
The Montel Williams MS Foundation
Multiple Sclerosis Society (Canada)
The Multiple Sclerosis Society (United Kingdom)

Exhibit B: Statement of Grounds

National Academy of Sciences Institute Of Medicine (IOM)
National Association for Public Health Policy
National Nurses Society on Addictions
Netherlands Ministry of Health
New England Journal of Medicine
New South Wales (Australia) Parliamentary Working Party on the use of Cannabis for Medical Purposes
Dr. Andrew Weil (nationally recognized professor of internal medicine and founder of the National Integrative Medicine Council)

State and Local Organizations

Alaska Nurses Association
Being Alive: People With HIV/AIDS Action Committee (San Diego, CA)
California Academy of Family Physicians
California Medical Association
California Nurses Association
California Pharmacists Association
Colorado Nurses Association
Connecticut Nurses Association
Florida Governor's Red Ribbon Panel on AIDS
Florida Medical Association
Hawaii Nurses Association
Illinois Nurses Association
Life Extension Foundation
Medical Society of the State of New York
Mississippi Nurses Association
New Jersey State Nurses Association
New Mexico Medical Society
New Mexico Nurses Association
New York County Medical Society
New York State Nurses Association
North Carolina Nurses Association
Rhode Island Medical Society
Rhode Island State Nurses Association
San Francisco Mayor's Summit on AIDS and HIV
San Francisco Medical Society
Vermont Medical Marijuana Study Committee
Virginia Nurses Association
Washington State Medical Association
Washington State Pharmacy Assocaition
Whitman-Walker Clinic (Washington, DC)
Wisconsin Nurses Association

Exhibit B: Statement of Grounds

2. OTHER CURRENT SCIENTIFIC KNOWLEDGE (FACTOR THREE)

The third factor the Secretary must consider is the state of current scientific knowledge regarding cannabis. Thus, this section, in combination with the previous pharmacology section, discusses the chemistry, human pharmacokinetics, and medical uses of cannabis. In addition, there are a multitude of new randomized, controlled clinical trials using cannabis that have been published in the past five years, which are new since the previously cited (FDA 2006 report) metanalyses.(5,6,7,35,143,197,280,281,471,711) These investigations were done primarily in HIV-related painful neuropathy, spasticity in multiple sclerosis (MS), and appetite stimulation in HIV patients.

All of these recent studies have shown statistically significant improvements in pain relief, spasticity, and appetite in the cannabis-using groups compared with controls.(5,6,7,35, 143,197,280,281,471,711) A very recent systematic review and meta-analysis was done to evaluate the clinical effectiveness of analgesics in treating painful HIV-related sensory neuropathy (HIV-SN).(198) The Medline, Cochrane central register of controlled trials (www.clinicaltrials.gov, www.controlled-trials.com and the reference lists of retrieved articles) were all searched for prospective, double-blinded, randomized controlled trials investigating the pharmacological treatment of painful HIV-SN with 44 studies identified, 19 were RCTs. Of these, 14 fulfilled the inclusion criteria. Interventions demonstrating greater efficacy than placebo were cannabis, topical capsaicin, and recombinant human nerve growth factor (rhNGF), and of those three, cannabis had the strongest overall beneficial clinical effect. No superiority over placebo was reported in RCTs that examined amitriptyline, gabapentin, pregabalin, prosaptide, peptide-T, acetyl-L-carnitine, mexilitine, and lamotrigine.(198)

While nearly all of the published controlled clinical trials with cannabis conducted in the United States have shown statistically significant and measurable benefits in subjects receiving the treatment, there have been negative results.(121,198,299,536) Most notable perhaps was a study done by Greenberg, et al, in which 10 patients with spastic multiple sclerosis and 10 healthy controls showed a clinical improvement in pain and spasticity in some patients, but impairment in posture and balance was noted in the MS group.(299) Another study in 18 healthy females using a cannabis extract did not show an affect on heat pain thresholds in a sunburn model, but this hyperalgesia effect had not been previously seen nor has this been substantiated by another study.(563)

The vast majority of modern research indicates that cannabis has significant therapeutic efficacy in the treatment of a wide range of clinical applications. These include relief of pain associated with serious illnesses like cancer, spasticity, anorexia, nausea, glaucoma, and movement disorders. In addition, an emerging body of research suggests that the medicinal properties of cannabis may help the body in the setting of neurodegenerative disorders including ALS, Parkinson Disease, among others, as well as help against some types of malignant tumors.(3-5,13-16,30,31,37,72,102-109,122)

3. CANNABIS IS NOT AN IMMEDIATE PRECURSOR TO A CONTROLLED SUBSTANCE (FACTOR EIGHT)

The eighth factor the Secretary must consider is whether cannabis is an immediate precursor of a controlled substance. Cannabis is not an immediate precursor of another controlled substance. It is a controlled substance, and it would not metabolize into another controlled substance. Nothing more is required to address for this factor.

4. ACTUAL AND POTENTIAL FOR ABUSE (FACTOR ONE)

Generally, this factor (actual and potential for abuse) is similar to and best read together with the following sections that discuss the other factors required for this rule-making petition (dependence liability; pattern of abuse; and scope, duration and significance of abuse). The organization of this report reflects this grouping, while addressing each required factor independently for purposes of ensuring full analysis and compliance with the rule-making petition requirements.

This section discusses the issues involved with drug abuse, and begins with a review of the distinctions between the terms "addiction," "compulsive use," "abuse," "dependence," and "problems." These terms and related clinical and social concepts have evolved over time such that views of what was addiction a few decades ago no longer are the same in the general medical community today.

A. Background: definitions

Some researchers claim that cannabis is not particularly addictive. Experts assert that cannabis's addictive potential parallels caffeine's.(200,228) Hilts (1994) asked two prominent drug researchers to rank features of six common drugs: nicotine, caffeine, heroin, cocaine, alcohol, and cannabis.(200) Both experts ranked cannabis last in its ability to produce withdrawal, tolerance, and dependence. Another study had experts rank 18 drugs on how easily they 'hook' people and how difficult they are to quit. Cannabis ranked 14th, behind the legal drugs nicotine (ranked first), alcohol (ranked 8th), and caffeine (ranked 12th). (See chart in section C of this factor regarding "Addictiveness Ratings for Drugs of Abuse").

The results above reflect expert opinions. Other evidence also suggests that marijuana is not particularly addictive. For example, only a fraction of those who try cannabis eventually use it regularly. Nevertheless, some users still develop troubles related to the drug, and many request assistance in limiting their consumption.(573) In the face of these problems, the low ratings of addictive propensity seem confusing. This confusion may arise from diverse meanings for the word addiction.

The term 'addiction' developed to describe the repetition of a habit. Addiction initially did not necessarily involve drugs. Its Latin root, 'addictus,' means state, proclaim, or bind. The origin suggests an obvious, stated connection between addicted people and their actions. The word connotes surrender, and implies that an activity or substance has bound the person.(383) Addiction was usually treated as a bad habit, similar to biting one's nails compulsively. At the

beginning of the 20th century, at least in America, the term changed from a description of actions to a medical condition. This distinction may seem subtle, but converting a bad habit into a physiological disorder brings it into the domain of medical intervention. This medical approach implies that addiction is not just a troublesome activity; it is a personal condition. Medicine has transformed many troubling behaviors into biological illnesses, with many repercussions, including inconsistent and unclear clinical meaning.(225,671)

Some medical texts support the term 'addiction' as the proper expression for drug problems. This definition emphasizes preoccupation with the substance, compulsive use, and frequent relapses. People who spend considerable time and effort trying to obtain the drug appear preoccupied.

Compulsive use describes the subjective sense that one is forced to consume the drug. It need not mean intoxication at every moment. Compulsive use also can include consistent consumption under identical circumstances, such as using a drug at the same time each evening. Repeated use despite attempts to stop also typifies this definition of addiction. Proponents of this approach to defining problems emphasize loss of control. Loss of control implies that the initial use of the substance impairs the ability to stop. A tacit assumption in some medical settings suggests that these symptoms arise from a biological process, an interaction of a foreign chemical with internal physiology.(453) This approach may have inspired the disease model of addiction.

B. Background: the disease model of addiction

The disease model generates considerable emotion in many who investigate, treat, or experience drug problems. The controversy surrounding the model reflects the history of human reactions to personal difficulties as a moral issue or a moral model of addiction.

The moral model attributed troubles to ignoble thoughts, actions, or character. Some adherents to the moral model suggested that those with drug problems were weak-willed. The moral approach identified the initial source of the disorder as being inside the individual.

A shift to use of a disease model asserted that drug problems served as symptoms of an illness. This illness led people, through no fault of their own, to the problematic consumption of substances. The disease model minimized blaming addicts for symptoms beyond their control (e.g., few people fault people for contracting a disease like anthrax or influenza). No one tells people with these diseases to 'use willpower' to combat symptoms, whereas some believe resolving drug problems is a matter of willpower. The disease model suggests that condemnation wastes effort that could be better spent on therapy. This model underlies one of the most popular approaches to substance abuse treatment, the 12-step program.

Critics of the disease model suggest that viewing drug problems as a disease can have drawbacks. In an effort to minimize blaming people for addictive behavior, proponents of the disease model may have created another set of problems. The definition of disease has grown slippery. Addiction may not qualify because it does not parallel other illnesses. No bacteria or viruses lead to substance abuse the way they create anthrax or HIV/AIDS. Genes do not cause addiction in the direct way they produce Down Syndrome or hemophilia. The symptoms of

cancer do not flare up in certain environments the way that craving for liquor may increase in certain contexts. Despite these facts, some advocates of the disease model treat addiction as a purely biological phenomenon. This emphasis on biology can exclude important economic, societal, and psychological contributors.(524)

The opinion that drug problems reflect a medical disorder has certain drawbacks. The idea ignores social aspects of addiction, creates a dependence on medical treatments, and may lead to higher rates of relapse. Viewing addiction as a purely biological phenomenon minimizes established links between social class and drug problems.(34,448) This approach may blind people to the potential for limiting drug problems through social change. A purely biological approach may also lead people to rely inappropriately on medications rather than psychological treatment. Changing personal behavior is often difficult. Changing societal and cultural mores can prove even tougher. Prescribing medication for a disease is often more straightforward. The disease model also may contribute to higher rates of relapse because of a central idea about loss of control. A belief in this symptom, which describes an inability to use a drug in small amounts, may actually increase relapse rates.(419, 524)

Increases in the risk of relapse may serve as a prime example of a drawback associated with the disease model. Problem users frequently report that initial consumption of a drug invariably leads to using markedly more than they ever intended. Many assumed that a chemical process associated with the experience of intoxication impaired their ability to stop consumption. This loss of control became synonymous with addictive disease. Yet, alcoholics surreptitiously given alcohol do not show signs of uncontrolled drinking. In contrast, alcoholics who believe they have consumed alcohol after drinking a placebo do show less control over their drinking.(419) These results suggest that what people think is more important than what they consume.

In one relevant study, cannabis users in treatment reported about their relapses. Some used on a single occasion, considered it a ‘slip,’ and returned to abstinence quickly. Others considered the single use a sign of weak will or disease and ended up consuming markedly more.(651) These data suggest that this sort of loss of control likely arises from a psychological rather than a biological process. Many researchers view these data as evidence against the disease model.

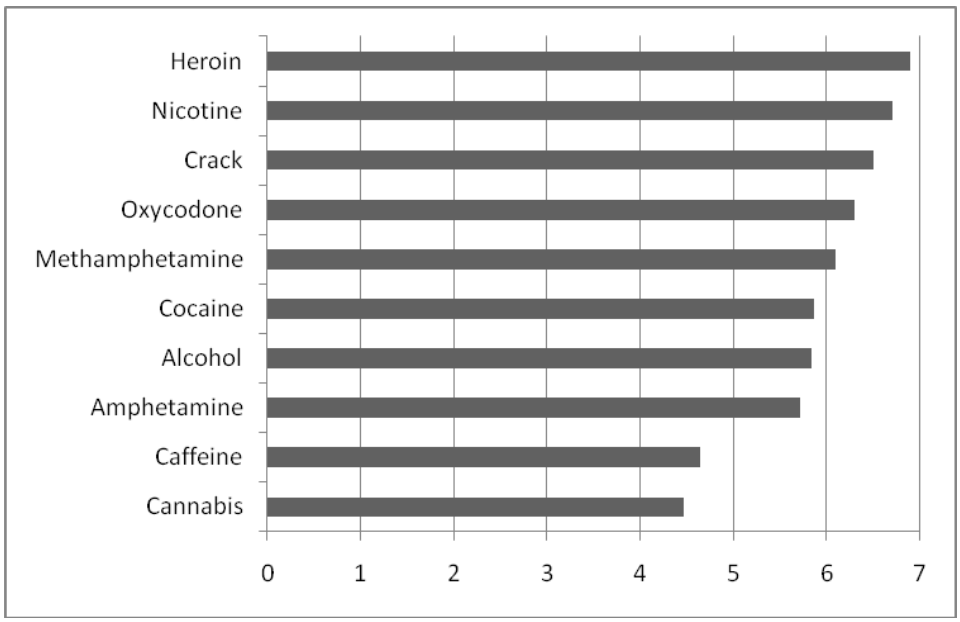
Other definitions of both addiction and disease have added to the controversy. Peele emphasizes tolerance, withdrawal, and craving as essential to addiction.(524) His work returns to the old definition of addiction, which can include actions that do not require chemicals. He extends the concept beyond drugs to nearly every behavior imaginable.(523) Yet he remains one of the most outspoken critics of the disease model. Tolerance, withdrawal, and craving all vary with features of the environment, suggesting that more than biology contributes to addictive behavior. Peele (1998) asserts that this evidence helps discredit the disease model. Other researchers argue that Peele misunderstands addiction.(710) The word may have so many different uses that it has lost its meaning. Thus, other terms have developed to describe trouble with drugs.

Exhibit B: Statement of Grounds

Because many define addiction quite broadly and disparately, some mental health professionals prefer the terms 'dependence' and 'abuse.' Others see these words as pejorative and judgmental compared to 'addiction.'(453) Oddly enough, the World Health Organization (WHO) proposed the word 'dependence' to avoid the derogatory aspects of the word 'addiction.'(195) Addiction may imply a purely physical, biological process that might neglect psychological contributors to drug problems.(245) Other terms have developed to focus on the observable behavior without hypothesizing an internal process or disease.

The foregoing discussion and debate provides background for the remaining discussion on this and the following three factors. In the end, regardless of the term applied or the clinical definition used, cannabis use, abuse, misuse, or dependence is within reasonable levels, especially as compared to other Schedule II drugs.

C. Cannabis use indicates a lower likelihood of addiction and abuse potential as compared to other substances (Table 2)



Addictiveness Ratings for Drugs of Abuse from 746 Drug Professionals.(250)

A survey of 746 mental health professionals and addictions researchers asked them to rate the addictiveness of various drugs on a seven-point scale with seven standing for extremely addictive. Participants included members of the National Association of Alcoholism and Drug Abuse Counselors, authors of papers published in peer-reviewed journals on substance abuse, and psychologists, social workers, licensed substance abuse counselors, and psychiatrists. The sample was evenly split among men and women. As the figure reveals, these experts rated licit and illicit drugs as more addictive than cannabis, with caffeine, amphetamine, alcohol, cocaine, methamphetamine, oxycodone, crack cocaine, nicotine and heroin receiving significantly higher scores. Effect sizes ranged from .18 standard deviations for caffeine to 1.53 standard deviations for heroin.

Exhibit B: Statement of Grounds

5. PSYCHIC OR PHYSIOLOGIC DEPENDENCE LIABILITY (FACTOR SEVEN)

Focusing on observable behavior has been a recurring theme for the Diagnostic and Statistical Manual (DSM) developed by the American Psychiatric Association (APA). This book attempts to define all psychiatric illnesses. Dependence and abuse appear in this work; addiction does not. Their definitions have gone through many revisions, and probably will continue to do so. The first version of the manual (the DSM I) appeared in 1952 (26); it is now in its fourth edition. Originally, the opinions of many mental health professionals contributed to the definition of any disorder. Gradually, researchers attempted to clarify the diagnoses based on science rather than opinion. Early versions of the dependence diagnosis simply required 'evidence of habitual use or a clear sense of need for the drug.'(27) This definition proved too subjective to diagnose reliably. Current definitions focus on a maladaptive pattern of use that leads to impairment or distress. Other symptoms are required for the diagnoses, as described below.

A. Cannabis has low relative dependence risk and does not reach the severity associated with other drugs

The DSM-IV defines drug dependence as a collection of any three of severe symptoms. All must create meaningful distress and occur within the same year. The diagnosis requires a certain amount of judgment on the clinician's part, but the symptoms tend to be obvious. Each symptom reflects the idea that a person requires the drug to function and makes maladaptive sacrifices to use it. The current diagnosis focuses on consequences, not the amount or frequency of consumption. In contrast, earlier versions of the DSM once employed the frequency of intoxication as a symptom. For example, the diagnosis of a disorder known as 'habitual excessive drinking' required intoxication 12 times per year.(27) This approach proved inexact, and failed to relate to the magnitude of difficulties. Thus, current diagnoses of drug dependence focus on negative consequences. They include tolerance and withdrawal, which were once considered the hallmarks of dependence. The additional symptoms are: use that exceeds initial intention, persistent desire for the drug or failed attempts to decrease consumption, loss of time related to use, reduced activities because of consumption, and continued use despite problems.

Tolerance is one of the hallmarks of physiological dependence. It occurs when repeated use of the same dose no longer produces as dramatic an effect. This symptom can indicate extensive use, and may motivate continued consumption. People do not grow tolerant to a drug, but to its effects. After repeated use, some of the effects of a drug may decrease while others may not. Tolerance to the desired effects of cannabis may encourage people to use more. Many people report using cannabis to enhance their moods.(628) Yet, tolerance develops to the mood-enhancing effect of THC.(278) This tolerance may lead people to use more to achieve the same emotional reactions. The increased use may coincide with a greater chance for problems. Ironically, tolerance to negative effects may also encourage more consumption. For example, using marijuana creates dry mouth, but this effect diminishes with use.(719) This negative effect may have inhibited use initially. People might stop using if their mouths became too dry. But once tolerance develops, their mouths do not grow as dry and they may use more. Thus,

tolerance to marijuana's effects may lead to increased consumption, and serves as a symptom of dependence.

The second symptom of dependence is withdrawal. Withdrawal refers to discomfort associated with the absence of the drug. Many drugs produce withdrawal, including the most common ones: caffeine, nicotine, and alcohol. The most notorious drug withdrawal may come from heroin. This opiate has a reputation for producing dramatic withdrawal symptoms. No two people experience withdrawal in the exact same way. Many assert that cannabis does not produce any withdrawal at all. It certainly does not create the dramatic symptoms characteristic of alcohol or heroin, and many users do not experience any problems after discontinuing use.(609) Nevertheless, people who are given synthetic THC for a few consecutive days report negative moods and disturbed sleep after they stop taking the drug.(278) People who use cannabis a few days in a row report more anxiety without the drug.(279) Cannabis can lead to withdrawal, and thus dependence, but it does not reach the severity of dependence associated with other drugs like alcohol or opiates.

The lack of flagrant, obvious cannabis withdrawal symptoms inspired the American Psychiatric Association to distinguish between types of dependence. Early versions of the diagnosis of dependence specifically noted that cannabis might cause problems in individuals who do not experience withdrawal.(14,27) The DSM-IV distinguishes between dependence with and without a physiological component. If tolerance or withdrawal appear among the three required symptoms, a diagnosis of physiological dependence is appropriate. Nevertheless, even without tolerance or withdrawal, individuals may receive a diagnosis of substance dependence without a physiological component. If they show three other symptoms, they will still receive the diagnosis. This change in procedure has made the diagnosis of marijuana dependence potentially more common.

A third symptom of dependence involves use that exceeds initial intention. This symptom suggests that individuals may plan to consume a certain amount of a drug, but once intoxication begins, they use markedly more. Use that exceeds intention was once known as loss of control. Many people misinterpreted the idea of loss of control, suggesting it meant an unstoppable compulsion to use the entire drug available. Use that exceeds intention specifically does not imply this dramatic, unconscious consumption. This symptom simply suggests that dependent users may have trouble using a small amount if they intend to.

Dependence also includes a fourth symptom: failed attempts to decrease use, or a constant desire for the drug. An inability to reduce drug consumption despite a wish to do so certainly suggests that the drug has altered behavior meaningfully. Yet, someone with no motivation to quit would likely never qualify for a failed attempt. Thus, people who have not attempted to quit may still qualify for this symptom if they show a persistent, continuous craving for the drug. An inability to stop or a constant desire suggests dependence.

A fifth symptom of dependence involves loss of time related to use. The time lost can be devoted to experiencing intoxication, recovering from it, or seeking drugs. Because marijuana is illegal, users may spend considerable time in search of it. People addicted to caffeine, nicotine, or alcohol may prove less likely to lose time in search of these substances. The number of hours

required to qualify for a meaningful loss of time is unclear, making this symptom seem subjective. Clear-cut cases include anyone whose day is devoted to finding drugs, getting intoxicated, and recovering. Anyone who spends a few hours each day on these activities would also qualify, depending on circumstances. In contrast, individuals who use cannabis for medical purposes would see increased productivity and might argue that they have lost little time in comparison with the medical benefits, so they would not likely qualify for this symptom. However, the subjective assessment of a meaningful amount of time may contribute to problems with the diagnosis of dependence.

The sixth symptom of dependence is reduced activities because of drug use. This symptom focuses on work, relationships, and leisure. The presence of this symptom suggests that the drug has taken over so much of daily life that the user would qualify as dependent. Any impairment in job performance because of intoxication, hangover, or devoting work hours to obtaining drugs would qualify for the symptom. Anyone who misses work habitually might qualify for reduced activities. Sufficient functioning at work, however, does not ensure against dependence. Even with stellar job performance, impaired social functioning can also indicate problems. If a user's only friends are also users and they only socialize while intoxicated, the substance has obviously had a marked impact on friendships. Recreational functioning is also important to the diagnosis. A user who formerly enjoyed hiking, reading, and theatre, but now spends all free time intoxicated would qualify for the symptom. This approach to the diagnosis implies that cannabis users who are not experiencing a multifaceted life can improve the way they function by using less, but it would not suggest that a medical cannabis user who improves performance would qualify.

The last symptom of dependence requires continued use despite problems. People who persist in using the drug despite obvious negative consequences would qualify for this symptom. Recurrent use regardless of continued occupational, social, interpersonal, psychological, or health trouble obviously shows dependence. Continued consumption in the face of conflicts with loved ones, employers, and family might qualify for this symptom. This creates an odd diagnostic situation because the symptom may vary with the person's environment. These interpersonal conflicts may arise from different interpersonal situations. This situation supports the idea that anyone who continues to use despite negative consequences must have a strong commitment to the drug, but members of a drug-oriented subculture might be less likely to be diagnosed with this symptom. Other problems need not involve people in the user's life. For example, anyone with emphysema who continues smoking tobacco would qualify for this symptom. People who report guilt or a loss of self-respect because of their drug use also qualify for this symptom. Those who continue using even when it leads them to have a negative view of themselves show a genuine sign of dependence. However, a medical cannabis user's quality of life would improve because of relief provided from their debilitating condition.

B. Conclusion: low risk of dependence does not reach the severity necessary to keep cannabis classified as a Schedule I substance

The seven symptoms of dependence do not indicate a risk to justify continued Schedule I placement of medical cannabis. Clearly risk is present, but it is significantly less than other legal and Schedule II drugs, especially for medical users of cannabis because performance would

likely improve in comparison with what a debilitating illness causes. Thus, reclassifying cannabis for medical use as a Schedule II is appropriate.

6. HISTORY AND CURRENT PATTERN OF ABUSE (FACTOR FOUR)

The fourth factor the Secretary must consider is the history and current pattern of abuse of cannabis. The history and current pattern of abuse can be confusing to estimate because a large percentage of United States citizens have tried marijuana at least once, but that is not as relevant to this analysis as the prevalence of use and misuse.

Some estimates suggest that over 40 percent of the nation has tried the plant. Rates were particularly high during peak eras of the 1970s.(14) For some age groups, trying marijuana is normative. For example, over 50 percent of those aged 18-25 report trying marijuana in their lifetimes, as has been the case each year from 2002-2010.(14) These reports from the National Study on Drug Use and Health (NSDUH) are available through the Substance Abuse and Mental Health Services Administration (SAMHSA) website: http://www.oas.samhsa.gov. Despite this prevalence, negative consequences remain rare. Most important, trying marijuana once should not be confused with a health problem, let alone a diagnosis of dependence or abuse.

A. Cannabis rates of dependence or abuse are remarkably low in comparison with other drugs

Rates of dependence or abuse are remarkably low. A survey of over 700 health professionals revealed that cannabis was considered less addictive than a host of other drugs, including the licit drugs alcohol, nicotine, and caffeine as well as Schedule II drugs like oxycodone, amphetamine, and methamphetamine.(250) The presence of marijuana dependence was extremely difficult to identify for many decades.(193) Recent work suggests that the diagnosis of both dependence and abuse remains extremely controversial. It is unfortunate that the term “dependence” is also used for illicit drugs with markedly more severe addictive potential and abuse dependence, including opiates. What qualifies as marijuana dependence lacks the severity and negative consequences common to dependence on alcohol or opiates.(128,193)

Even using these controversial diagnoses, rates of dependence and abuse are low. Interviews for the National Longitudinal Alcohol Epidemiologic Survey ([NLAES] and National Epidemiologic Survey on Alcohol and Related Conditions ([NESARC] each confirm that rates of dependence or abuse of cannabis have never exceed two percent in a given year.(138) These are huge studies, each with samples sizes over 40,000 people, employing extensive interviews with highly trained professionals. They likely create the most accurate estimates available. In contrast, alcohol abuse and dependence appears in seven to eight percent of the population in a given year.(138) The non-medical use of prescription drugs is markedly less common than using marijuana one time (approximately 10 percent), but over 20 percent of those people later qualify for a diagnosis of abuse.(428) Again, these SAMHSA-NSDUH reports are all available at: http://www.oas.samhsa.gov

B. Cannabis dependence causes much less severe negative consequences than other Schedule II drugs

Another important point to consider when interpreting data on marijuana problems involves a lack of focus on medical users. Currently, no large study of symptoms of dependence or abuse of marijuana focuses on patients with physician recommendations. At worst it is reasonable to generalize that if the two percent rate of dependence or abuse would generalize to medical users, then cannabis represents a far less harmful drug than other legal Schedule II substances.

One symptom of dependence involves time lost obtaining the drug. Obviously, a legitimate source of cannabis comparable to the pharmacies that provide Schedule II drugs would eliminate this symptom. In addition, given the low severity of the most common symptoms of dependence (like tolerance), it cannot be concluded that this risk always outweighs medical utility.

7. SCOPE, DURATION, AND SIGNIFICANCE OF ABUSE (FACTOR FIVE)

A subset of individuals may experience negative consequences from drugs that do not qualify for dependence but still lead to the diagnosis of substance abuse. This diagnosis requires significant impairment or distress directly related to the use of the drug. This dysfunction and strain are necessary to identify abuse. The diagnosis requires only one of the four symptoms that appear in the current criteria.(28) These symptoms include: interference with major obligations, intoxication in unsafe settings, legal problems, and continued use in the face of troubles. Each of these signs requires some interpretation on a diagnoser's part, but trained individuals apply the category reliably. Most experienced diagnosticians can agree who meets criteria for substance abuse and who does not.(694). This definition remains distinctly separate from dependence, which requires different symptoms and more of them. Although a diagnosis of abuse clearly serves as a sign of genuine troubles, many clinicians consider dependence more severe. Thus, those who qualify for dependence would not receive the less severe diagnosis of abuse.

The first symptom of abuse, interference with major obligations, requires impaired performance at work, home, or school. The idea that abuse requires interference with major obligations reflects concerns about optimal functioning. The impairment may arise because of intoxication, recovery from intoxication, or time devoted to searching for drugs. The definition is necessarily broad in order to apply to people with a variety of responsibilities. The symptom applies to employees who miss work or students who fail tests because of intoxication. One curious aspect of this symptom concerns the way some potential abusers arrange their lives to minimize the impact of their drug use on obligations. Anyone with few major obligations may become intoxicated more often or more severely without qualifying for the symptom.

The second symptom requires intoxication in an unsafe setting. The DSM specifically lists driving a car and operating machinery as hazardous situations where intoxication could create dangerous negative consequences.(632) Driving while intoxicated is unacceptable and qualifies as substance abuse.

Exhibit B: Statement of Grounds

The intoxicated performance of any task can lead to this diagnosis if impairment might create negative consequences. Driving a forklift or using power tools might qualify. Note that no negative consequences actually need to occur; their increased likelihood can qualify for abuse. Thus, those who drive intoxicated but never receive tickets or have accidents would still qualify for abuse because they have increased their likelihood of negative consequences.

The third symptom included in the diagnosis of substance abuse concerns legal problems. (76,266) The definition of this symptom makes users of legal drugs less likely to get a diagnosis of abuse than users of illegal drugs. Any arrest that arises from drug-impaired behavior, such as public intoxication or driving under the influence, clearly qualifies as abuse. Other legal problems qualify even if they do not arise from intoxication. If medical cannabis were rescheduled, the purchase and possession with the proper prescriptions would not be considered "abuse" alone, so legal problems that some individuals may currently experience should not be factored into an evaluation of the potential for abuse under the rescheduled drug.

The fourth symptom of drug abuse concerns consistent use despite problems. This symptom is identical to the last symptom of dependence (discussed under section 5. Psychic or Physiologic Dependence Liability). Note that recurrent use in the face of occupational, social, interpersonal, psychological, or health troubles qualifies as abuse. Medical use of cannabis that helps a patient withstand the effects of a serious illness, would obviously not qualify.

A. The prevalence and significance of potential abuse are limited for cannabis, especially in relation to other Schedule II substances

One of the most comprehensive studies of abuse and dependence began with interviews of over 42,000 people. This research focused on people who had used cannabis in the previous year, and revealed that 23 percent qualified for a diagnosis of abuse and six percent qualified for a diagnosis of dependence. Abuse appeared more often among rural users. Dependence appeared more often among users who were depressed.(257)

Other studies have concentrated on negative consequences rather than diagnoses. Recent, large-scale investigations focused on problems related to social functioning, health troubles, or psychological symptoms.(257) In a large sample of Americans, 85 percent of people who had used marijuana in the previous year reported none of these problems. Fifteen percent reported one, eight percent reported at least two, and four percent reported at least three negative consequences that they attributed to cannabis use. Thus, more than four out of five people who had used cannabis in the previous year reported no problems related to the drug.(482)

This information certainly helps provide estimates of marijuana problems, but the data raise questions. At first glance, it appears that 15 percent of marijuana users experience problems with the drug. However, the control group failed to account for people who did not use marijuana but also experience comparable social, medical, or psychological troubles. A meaningful control group that included people who never used marijuana would certainly help interpretations of this study. Some of the users in this study may have experienced these symptoms even if they had never used cannabis. Yet, the tacit assumption, that the cannabis

created the problems is not proved. If cannabis users reported more of these sorts of troubles than nonusers, the idea that cannabis caused the problems would be more supportable. The current approach, however, may overestimate marijuana's negative impact.

The limitations of this one study do not mean that cannabis does not cause problems. Other research supports the idea that a percentage of cannabis users experience troubles with the drug. Approximately nine percent of one group of users followed for five years developed negative consequences.(718) These researchers defined problems in four aspects of life. These included negative effects of the drug, problems controlling use, and interpersonal difficulties. They also included unfavorable opinions about use. Adverse opinions included feeling that marijuana use had grown excessive, guilt-inducing, or objectionable.

Unlike the NIDA study above, which focused on problems that could have occurred to anyone, this study identified troubles that concentrate more on marijuana. The nine percent of the sample labeled problem users experienced troubles in at least three of these domains. These studies both suggest that cannabis use is not harmless, and that some individuals experience negative consequences from the drug. Even those who may not qualify for addiction, abuse, or dependence might benefit from altering their marijuana consumption. A focus on problems may enhance the prevention of addiction, abuse, or dependence, however they are defined. However, the prevalence of associated problems is less than other legal medicine.

B. Conclusions

Cannabis is the most commonly consumed drug that is currently in Schedule I, with 200-300 million users worldwide. Approximately a third of Americans have tried the substance at least once. Less than five percent of Americans report using the drug every week. Estimating the exact number of users is difficult. The amounts that people consume are also hard to estimate. A variety of definitions of abuse and misuse of the drug exist. These include addiction, dependence, abuse, and problems. Addiction does not have a universal definition, making the term difficult to use scientifically. Abuse and dependence are diagnosed reliably and clearly can apply to problem marijuana users. Nevertheless, the abuse and dependence diagnoses may not provide the clear information one might learn from a simple list of marijuana problems. More to the point, cannabis problems are not particularly common, but six to nine percent of users report some difficulties with the drug, which is significantly less than other categories of legal Scheduled II and III drugs.

Exhibit B: Statement of Grounds

8. PUBLIC HEALTH RISK (FACTOR SIX)

This section will review and show that cannabis plays little role in producing social problems like amotivation, reckless driving, and aggression or hostility. Details of the relevant studies appear below.

A. Amotivational syndrome generally is not a dangerous side-effect, and data shows little correlation with cannabis use

Some concern has been expressed about the drug's long-term impact on motivation.(475-480) By the late 1960s, researchers coined the expression 'amotivational syndrome' to describe indifferent, apathic people who used marijuana, yet data has not proven that marijuana actually alters motivation. As a result, varied definitions and measurements of amotivational syndrome have led to some review of the concept.

To measure motivation or amotivational syndrome, some investigators have examined employment history and educational achievement, and others reviewed performance on laboratory tasks. Nearly all measurement strategies reflect generalized values about productivity. Many researchers tacitly assume that motivated people perform well in school, work hard for their employers, and persevere on laboratory tasks. Yet, there are many exceptions of the world's most famous achievers failing in these domains. People do not share all goals, or value the pursuit of objectives in the same way. Some cultures emphasize different values than others.(86)

The notion of amotivational syndrome can inadvertently pathologize behaviors that many people in other cultures find fulfilling.(467) For example, vacation time varies dramatically from country to country, reflecting different attitudes about leisure and productivity.(568) In addition, motivation and achievement do not necessarily lead to happiness or increased satisfaction in life. The idea of amotivational syndrome may present a false promise that accomplishments lead invariably to happiness.

Even within our society, the definitions of amotivational syndrome vary considerably. There is no formal diagnosis or established list of symptoms. Most researchers employ their own unique measures of motivation, making comparisons between studies difficult. Reports usually describe amotivation as a subtle shift in priorities. Achievement becomes less important; leisure becomes more important. Sufferers purportedly have few long-term goals or no concrete plans for attaining them. They may lose the ability to concentrate, endure frustration, and participate in life. Even if a cannabis-induced amotivational syndrome exists, its symptoms are far less problematic than the obvious problems associated with the abuse of other drugs. Chronic cannabis users rarely report the drastic financial, social, and occupational difficulties typical of addiction to opiates.

The purported symptoms of amotivational syndrome are hardly unique to cannabis use. Clinical depression often includes the fatigue, poor concentration, and apathy typical of amotivation. This overlap suggests that a subset of depressed people who use marijuana may

account for clinical observations of amotivational syndrome. People who are depressed or unmotivated may happen to use cannabis, giving the impression that the drug has created the symptoms. In fact, the links among depression, amotivation, and cannabis consumption are not straightforward.

Recent data reveal that cannabis consumption has no significant association with depression in adults. A subset of people who use marijuana to cope with problems show more depressive symptoms, but it is not clear that cannabis use caused their depression. People who first tried marijuana before age 16 showed more depression later in life, yet this relationship disappeared when the use of other drugs was taken into account.(261) A separate study revealed that measures of motivation correlated more with depression than with marijuana consumption, even among heavy users.(471) Thus, depression rather than cannabis may cause amotivational symptoms, and medical cannabis users feel less pain and are often less depressed as a result.

The idea that cannabis use diminishes motivation requires the same firm evidence of association, temporal antecedence, and isolation on the gateway effect. Marijuana must precede and correlate with amotivation to cause it. The symptoms also must not stem from some other contributor like personality, depression, or the use of another drug. Ensuring that amotivational syndrome arises from cannabis requires experiments. Researchers can randomly assign people to receive cannabis or placebo. This arrangement ensures that everyone is equally likely to end up in the group that uses cannabis, assuring that any identified deficits arise from cannabis rather than personality, depression, or other drug use.

In an alternative approach, participants work after use of a placebo and at other times after cannabis use. This strategy, known as a within-subjects design, ensures that all the people work both intoxicated and sober. Investigators can then compare each person's intoxicated performance to his or her own work in the absence of the drug. Under these circumstances, any identified impairment must stem from cannabis. Thus, laboratory experiments can rule out alternative explanations for the impact of cannabis on motivation. This type of research requires extensive time, effort, and funding. Cannabis use over many days should produce the lethargy and lack of ambition typical of the disorder. As the next section discusses, laboratory experiments on repeated daily exposure reveals no evidence for amotivaltional sydrome.

i. Laboratory performance does not indicate amotivational syndrome in cannabis users

In one of the first studies of chronic cannabis administration, researchers employed six men to build chairs for 70 days. They earned two dollars per chair initially, but went on strike twice and raised their fees. They had periods without cannabis, and weeks when they could purchase as much as they wanted. For 28 days the researchers required that they use at least two doses containing a total of 17 mg of THC. Generally, the men built fewer chairs and worked fewer hours when required to consume cannabis. They also built fewer chairs immediately after they went on strike and increased their wages. The men showed no other signs of amotivation.

This study supports the idea that intoxication can decrease productivity.(444) Yet, it is unclear if this would qualify as evidence for amotivational syndrome. Arranging for a strike to increase wages likely required motivation, organization, and drive. Making fewer chairs might

reflect lower motivation, but it more likely offers further evidence that intoxication impairs performance.

In another study of chronic administration, researchers paid 30 men to stay in the hospital for 94 days. They ingested no drugs for the first 11 days, used cannabis for the next 64, took a break from the drug for a week, used daily for nine more days, and then did not use the last three. They were paid for daily work on two different tasks. One required adding large numbers on a calculator. The other required answering textbook questions. Participants received ten cents for each correct answer on these two tasks. Acute intoxication and chronic exposure had no impact on any measure of performance. The men showed statistically comparable total responses, total correct responses, errors and time worked throughout the 94 day period.(135,136) These data offer no support for amotivational syndrome.

In another detailed experiment, 20 young men lived in a hospital for three months. They made belts for money, and used cannabis at various rates. The men were abstinent for certain periods, and could use as much as they chose at other times. On some days, researchers required that participants use a specific amount of cannabis, up to 30 mg of THC. Generally, the larger doses briefly reduced productivity. The men made fewer belts on days when they were forced to use high doses. People who used as much as they wanted initially performed more work than people who were forced to use larger amounts. Participants reportedly disliked the mandatory doses. Some even threatened to leave the experiment. However, over time, they developed tolerance, minimizing any effects on productivity, and they did not show overt signs of amotivational syndrome, including no decline in physical condition, personal hygiene, social functioning, or intellectual abilities. These signs remained absent even on days when the men made fewer belts.(96) Thus, the men in this study showed no symptoms of a motivational disorder. When they were required to use large doses of cannabis, they showed an initial drop in productivity, which quickly returned to normal.

The long-term studies discussed above offer little support for cannabis-induced losses of productivity. One standard way to manipulate motivation in the laboratory requires offering extra cash for good performance on tasks. In one study of marijuana's effects, researchers attempted to increase motivation and performance on simple tasks by offering financial incentives. On a reaction-time task, intoxicated people did not respond to this incentive as dramatically as the people who had not used cannabis. Offering extra money did not motivate people to react more quickly while intoxicated, but it did speed reaction times for people who were not intoxicated. The authors emphasize that this result offers little support for amotivational syndrome. Instead, these data mean that intoxicated people do not react to standard techniques for enhancing motivation.(538)

Two other studies performed in a residential laboratory revealed that intoxicated men were less likely to perform tasks that they disliked.(221-223) After using cannabis, these people spent less time on work and chores and more time on recreational activities. Articles often refer to these studies as evidence for amotivational syndrome. At worst, intoxication decreases a person's willingness to work on unappealing projects, but this effect hardly parallels the apathy typical of most definitions of amotivation. If these results qualify as evidence for amotivational

syndrome, then most psychoactive drugs could serve as a cause. In fact, anything that might create procrastination, including watching television, could serve as a source of amotivation.

Intoxication can impair performance on some tasks in some conditions. Nevertheless, the evidence lacks to prove clear amotivational syndrome. Many critics dismiss this laboratory evidence as irrelevant due reasons like short duration of exposure, yet that is not the case and there are other studies that demonstrate longer term exposure does not cause amotivation in animals.(630) The term often implies a failure to achieve in life, not simple deficits on laboratory tasks. To further test the role of cannabis in motivation, other investigators have examined marijuana's correlation with educational and work performance. Impairments on these life tasks appear more relevant to the idea of amotivational syndrome.

ii. Correlations with education and work do not support amotivational syndrome in cannabis users

Surveys of associations between drug use and job or school activities lack the experimental control found in the chronic administration studies. Investigators can only assume that cannabis use causes poor performance at work or school. Alternative explanations remain equally tenable. For example, poor adjustment in work or school might lead some people to use cannabis. A third factor may account for the association, too. Depressed people might perform poorly and choose to use cannabis. People with certain personality characteristics might choose to use marijuana and make school or work a low priority. Thus, a simple association between cannabis consumption and education or work does not prove that amotivational syndrome exists. Nevertheless, the absence of an association between cannabis and achievement might undermine arguments for cannabis-induced amotivation.

Parents and educators express understandable concern about marijuana, amotivational syndrome, and schoolwork. Research has focused on academic achievement in college and intoxicated school students. Contrary to popular belief, over half a dozen studies reveal that cannabis users and nonusers have comparable grades in college. One typical report surveyed 1,400 undergraduates, revealing no differences between users and nonusers on grades, changes in their majors, or number of colleges attended. Chronic users (those who used at least three times a week for three years) took more time off from their schooling, but were also more likely to plan to earn a graduate degree.(302)

Surprisingly, there is some evidence of improved academic performance in marijuana users than in nonusers, although no one has ever proposed that cannabis could help school performance.(239) Users and nonusers also show no differences in their orientations towards achievement, their extracurricular activities, or their participation in sports. Thus, research on college students provides no support for the idea of amotivational syndrome.(751)

Although cannabis consumption in college has no link to school performance, high school students who use cannabis have lower grades and quit school more often. Cannabis users in school also spend less time on their homework and miss more days of school.(347) At first glance, this association between cannabis and school performance seems consistent with the idea of amotivation. Perhaps cannabis destroys motivation in young teens, so an age restriction

would be appropriate. Yet, data do not support this restricted form of amotivational syndrome, either. Most heavy users earned lower grades prior to their cannabis consumption, suggesting that other factors besides cannabis might have caused the poorer performance.(621,622) For example, high school students who use cannabis heavily also tend to use alcohol and other illicit substances. These results suggest that drugs other than cannabis might lower grades.(276)

Cannabis alone probably does not cause poor school performance. Instead, the regular consumption of cannabis in school serves as part of a general pattern of deviance. Heavy users appear more unconventional in general. They are more critical of society, less involved in church and school, and more involved in delinquent acts. They often behaved this way before they ever discovered cannabis.(171) Because these young people showed these qualities before using cannabis, the drug seems an unlikely cause of amotivational syndrome in high school students. Thus, depressed, unmotivated, unconventional adolescents may choose to use marijuana, but the drug does not appear to create their deviance. Nonetheless, the DEA should apply age restrictions for the medical use of the cannabis.

Two contradictory attitudes have developed about marijuana's impact on job performance. Many people believe the drug destroys motivation and detracts from efficiency, yet others use the drug to enhance their work, which can be said in the case of many medical cannabis users who continue working while suffering a debilitating illness because cannabis helps.

The results seem to depend upon the type of job involved. People who perform repetitive, simple tasks may turn to cannabis to relieve from painful jobs. For example, laborers in India increased their ganja consumption 50 percent during the harvest season.(125) In Jamaica, farm hands who used cannabis actually worked harder than those who did not.(137,515) Perhaps marijuana makes monotonous physical labor more bearable. In contrast, jobs that require complex or rapid decisions likely suffer during intoxication.(119) Thus, the acute effects of cannabis on performance may vary dramatically with different jobs and the condition of the user.

The enduring lack of initiative that defines amotivational syndrome requires more than brief changes in work performance during intoxication. Wages, hours, and employment history may serve as better indices of motivation on the job. Research performed in countries where workers frequently use cannabis has shown little difference between heavy users, occasional users, and abstainers. These groups had comparable forms of employment in Costa Rica and Jamaica.(73,110)

In the United States, where cannabis consumption is less prevalent, the impact of the drug on wages, hours, and job turnover still does not support the idea of amotivational syndrome. Data actually suggest some positive links between cannabis consumption and work, but only for adults. One survey of over 8,000 adults who held a variety of jobs showed higher wages with increased use.(344) Other studies of employment histories and drug use reveal that marijuana users do not appear to lose their jobs more often than nonusers, even though employers are more likely to fire users of other illicit drugs.(494, 517)

iii. Summary for amotivational syndrome

Laboratory studies of humans and primates offer little support for amotivational syndrome for cannabis users. Employment data show no links between cannabis use and lower wages, poor work performance, or job turnover. School performance does not vary with cannabis consumption in college students. High school students who use cannabis do worse in school, but most performed poorly before they used cannabis, and many used other drugs that likely contributed to their lower grades more than cannabis. Nonetheless, appropriate age restrictions are necessary. Employment data show no links between cannabis use alone and lower wages, poor work performance, or job turnover in adults.

Self-reports in heavy users show that a percentage of people think cannabis affects their motivation, but consumption of other drugs or the presence of physical and emotional problems more likely are the cause of their lack of motivation. More importantly, these were not medical users who clearly indicate a beneficial therapeutic experience when using cannabis for severe medical conditions. Additionally, no studies show pervasive lethargy, dysphoria, and apathy appear in all heavy users. Thus, the evidence for a cannabis-induced amotivational syndrome is weak. Yet, a subset of depressed users may show the symptoms of amotivational syndrome.(185) These people would likely benefit from cognitive-behavioral treatments for depression, which can improve mood, motivation, and achievement.

B. Cannabis use has risks similar to other legal Schedule II substances

i. Overview

Amotivational syndrome is not the only social problem attributed to marijuana. The drug's potential role in auto accidents has also generated considerable concern. In 1997, traffic accidents in the U.S. numbered 16 million and caused 43,000 deaths. Comparable numbers of crashes and fatalities have likely occurred in more recent years.(84) These statistics raise an understandable concern about impaired driving. Many drugs can increase highway mishaps. Alcohol is the most common and notorious cause of accidents. Common antidepressants, antihistamines, and tranquilizers also reduce driving skill.(566)

Cannabis intoxication clearly alters thought and memory, leading many researchers to investigate its role in highway fatalities. Data supports that marijuana does not significantly contribute to accidents.(413, 669) Research on cannabis and traffic safety relies on two approaches: epidemiological studies of crashes and laboratory experiments with intoxicated drivers. In general, studies reveal that marijuana has no effect on culpability for fatal crashes if a driver's age and blood alcohol concentration are taken into account. There is no data regarding whether marijuana intoxication increases the chances of other more minor accidents. Regardless, driving while intoxicated is never acceptable and cannot be tolerated.

Laboratory experiments using driving simulators and actual performance on the road reveal that motorists intoxicated with cannabis compensate for the drug's cognitive effects. They drive more slowly, leave more space between cars, and take fewer risks. Nevertheless, dangerous situations might require rapid responses to avoid an accident, and recent work reveals

that the combination of alcohol and cannabis can meaningfully increase driving problems. Given marijuana's proven ability to impair attention and rapid responses, users must avoid driving while intoxicated.(485) Driving after consuming alcohol, particularly in combination with cannabis or any other drug, legal or illegal, even antihistamines, is extremely dangerous and ill-advised. These risks are similar to other Schedule II drugs.

ii. Epidemiological studies

Nearly a dozen studies from all around the globe report the frequent presence of THC in the bloodstreams of motorists involved in accidents that caused death or injury. It is important to note that depending on the study, as many as 84 percent of these users were intoxicated with alcohol at the time. Ethanol's detrimental effect on driving is well established, and seems the most parsimonious explanation for these mishaps.

For example, data from over 1,000 drivers involved in fatal accidents in Australia revealed that cannabis was present in 11 percent of them. Ratings of the accident reports revealed that drivers who had consumed alcohol or the combination of alcohol and cannabis were culpable more often than drivers who were free of drugs.(181).

Curiously, many studies of cannabis and traffic safety found that the odds of causing death or injury were slightly lower in cannabis users than in people who had not consumed drugs.(41) For example, the study of Australian motorists mentioned above showed that users of cannabis were 30 percent less likely to cause accidents as drivers who had not used any drug. A study of over 300 drivers involved in fatal crashes in California focused on motorists who tested positive for cannabis but no other drug. Unexpectedly, they were half as likely to be responsible for accidents as those who were free of substances.(730) Another investigation of over 1,800 fatal crashes in the U.S. found that drivers who used only cannabis were 70 percent as likely to have caused an accident as the drug-free group.(680)

Although, driving while intoxicated on any psychoactive substance is a problem, none of these estimates revealed statistically significant increases in causes of accidents as a result of using cannabis alone. Nevertheless, as the next section discusses, the consistency of these results raises interesting questions in which laboratory research provides a potential explanation.

iii. Laboratory experiments

Another approach to answering questions about cannabis and traffic safety involves randomly assigning motorists to ingest THC or placebo before driving. This approach has several advantages over epidemiological work. Critics might argue that epidemiological studies of THC's presence in crashes may create a confounding bias. They assert that people who choose to use marijuana and drive may be more disinhibited than those who do not drive during cannabis intoxication. Thus, any epidemiological evidence for elevated THC rates in drivers involved with accidents may simply reflect an underlying driving deficit correlated with the propensity to use cannabis before operating a motor vehicle.

Laboratory experiments can bypass this problem in two ways. First, researchers can randomly assign drivers to receive cannabis or placebo. This arrangement ensures that good and bad drivers are equally likely to end up in the group that uses marijuana before driving. Random

assignment assures that any identified deficits arise from intoxication rather than a biased sample. In an alternative approach, participants drive once after using a placebo and again after using cannabis. This technique, known as a within-subjects design, ensures that all the people drive both intoxicated and sober. Then, investigators can compare each individual's performance while intoxicated to his or her own performance in the absence of the drug. Again, under these circumstances, any identified impairment must stem from intoxication. Thus, laboratory experiments rule out alternative explanations for marijuana's impact on driving (and provide a safe laboratory environment for the test).

A review of over a dozen of these experiments reveals three findings. First, after using marijuana, people drive more slowly. In addition, they increase the distance between their cars and the car in front of them. Third, they are less likely to attempt to pass other vehicles on the road. All of these practices can decrease the chance of crashes and certainly limit the probability of injury or death if an accident does occur. These three habits may explain the slightly lower risk of accidents that appears in the epidemiological studies. These results contrast dramatically to those found for alcohol. Alcohol intoxication often increases speed and passing while decreasing following distance, and markedly raises the chance of crashes.(632)

Additional work has confirmed these effects.(555,556) One recent, comprehensive paper reported four different experiments examining the impact of THC and alcohol alone and in combination.(555) Men and women used cannabis containing zero, 100, 200, or 300 micrograms of THC per kilogram of body weight. The active doses correspond to approximately one-half, one, or one-and-a-half of a cannabis dose for a 150 pound person. Participants drank placebos or enough alcohol to maintain breath alcohol concentrations of approximately .04 percent (this dose corresponds approximately to drinking two beers quickly on an empty stomach for a 150 pound man). Participants then drove in different places on separate occasions, including a deserted stretch of road, in regular highway traffic, and on city streets. A driving instructor in a specially equipped training car, sat beside them, rating their performance (a second wheel and controls allowed the instructor to drive if needed). These studies have advantages over research that employs driving simulators because performance in a real car in regular traffic likely better generalizes to other driving situations.

In other tests, participants performed two different driving tasks. One task, the road-tracking test, simply involved maintaining a constant speed of 90 kilometers (roughly 55 miles) per hour and staying within a designated lane.(556) The other task, the car-following test, involved maintaining a constant distance behind a vehicle that altered its speed and acceleration. Marijuana produced two consistent effects. First, the drug significantly increased lateral movement within the traffic lane. That is, participants' cars weaved from side to side within the lane more after using cannabis than placebo. Second, cannabis caused drivers to increase their distance from the vehicle in front of them during the car-following test. Marijuana did not alter any other way that the drivers handled the vehicle, maneuvered through traffic, or turned the car. In contrast, alcohol not only increased lateral movement in the lane, it also impaired vehicle handling and maneuvers. The two drugs combined produced the most impairment.(556)

Thus, although traffic accidents kill thousands each year and driving while intoxicated with cannabis is not tolerable, its role alone in reckless driving is markedly smaller than once

believed. Epidemiological research reveals that those who test positive for cannabis and no other drug do not cause accidents any more often than people who are drug free. Laboratory research shows that cannabis intoxication increases lateral motion within the traffic lane but does not impair handling, maneuvering, or turning. Obviously, no one should operate dangerous machinery of any kind under the influence of cannabis or other psychoactive drugs. Nevertheless, the impact of cannabis alone on reckless driving appears extremely small. Although traffic fatalities remain a serious social problem, cannabis use alone does not appear to be a significant causative factor.

C. Cannabis use does not increase aggression

i. Overview

In addition to concerns about loss of motivation and reckless driving, many people fear that cannabis intoxication can lead to hostility. Summaries of studies on marijuana and aggression may reveal these biases more than any other area of research. Interpretations of this literature are incredibly disparate. One author's evidence for marijuana's connection to violence serves as another author's proof that the drug does not cause aggression.

An interpretation of a study of murderers illustrates this point. In this research, interviews with 268 incarcerated murderers revealed that 72 of them had used cannabis within a day of the homicide. Of these 72, 18 claimed that marijuana contributed to the murder in some way. Fifteen of these 18 were intoxicated with other drugs at the time.(643) The researchers reported these facts clearly, but interpretations of their meaning vary dramatically. One review cites this study as an example of cannabis leading to violence.(667) Another uses it as an illustration of the rarity of cannabis-induced hostility, emphasizing how other drugs account for the relationship between cannabis and aggression.(751) Thus, any interpretations of data from this field require a close reading of the original studies.

People have assumed drugs lead to violence at least since the seventeenth century, and certainly intoxication, withdrawal, and chronic use of alcohol and stimulants clearly increase aggressive acts.(358) Despite evidence for increased aggression that is otherwise associated with other drugs, the vast majority of work shows that cannabis does not induce hostility. This research includes the standard series of case studies, correlational reports, and laboratory experiments.

Each of these research approaches has strengths and weaknesses, but the general conclusions remain the same: direct links between cannabis intoxication and violence do not appear in the general population. A few studies show correlations between marijuana consumption and violent acts, but these links frequently stem from personality characteristics or the use of other drugs. People who are violent or who use drugs that lead to violence often also use cannabis, but it is not clear that the cannabis use causes the violence.

Laboratory studies also find no link between THC intoxication and violence. Most people who ingest THC before performing a competitive task in the laboratory do not show more aggression than people who receive placebos; occasionally they show decreased hostility. Numerous scientific panels sponsored by various governments invariably report that marijuana does not lead to violence.(751)

Exhibit B: Statement of Grounds

ii. Historical precedent

Cannabis use dates back more than a thousand years. There have been many differing reports about cannabis throughout history, some supportive of its medical use, and some reports have focused on its negative, or in most cases, perceived negative side-effects.(114) Harry Anslinger, the first head of the Federal Bureau of Narcotics, cited the negative history as evidence of marijuana-induced aggression.(69) Modern authors still suggest that the drug leads to hostility.(613) It is clear that this misunderstanding stems from biases and poor interpretations of history and individual case studies.

Some of the most sensationalistic case studies came from the Bureau of Narcotics in the 1930s that told of users who committed heinous crimes. Many times the details did not reveal if the crime actually occurred during marijuana intoxication or some other issue. Yet, some focused on marijuana's link to violence. A classic example concerned a Florida murder case from 1933. Initial newspaper reports attributed the murders to the drug, and Harry Anslinger used the case as an example for many years. Despite these reports of this event, further investigation revealed that the murderer suffered from a serious psychotic, mental illness, and many members of his family also struggled with psychotic disorders. He may have had a history of violence prior to his drug use, yet none of these possibilities appeared in press.(350) A close look at another case study that the Bureau of Narcotics frequently cited revealed that the criminal had claimed to use marijuana when, in fact, he had not.(80)

iii. Crime

A more scientific way to investigate marijuana's alleged link to violence appeared in studies of crime rates. Researchers have looked for an association between violent crime and cannabis consumption for at least 70 years. This association does not prove that marijuana causes aggression, but any theory linking cannabis and violence would suggest that the two should covary. Early studies of military personnel, arrestees, and patients in mental hospitals revealed no relationship between cannabis and violent crime.

One typical study examined rates of aggressive crime in military prisoners. Marijuana users were no more likely to commit crimes of violence than nonusers.(79) Some studies revealed fewer antisocial behaviors in cannabis users than in users of other drugs.(2) Later research confirmed these findings. For example, a study of 109 delinquent juveniles revealed that violent offenses had no link with cannabis consumption, but significant associations with cocaine and amphetamine use.(627)

A few recent studies reported small but statistically significant associations between marijuana consumption and violence in select groups of adolescents. Yet, the effects were extremely small, meaning that the amount of violence increased only a little as the amount of cannabis consumption increased a lot. (Correlations were approximately .20 and only reached statistical significance because of the large sample sizes). These studies asked teens about their marijuana use as well as the frequency of their aggressive acts, but failed to assess if they were intoxicated when they were hostile. Thus, they alone do not support the idea that cannabis causes violence. Instead, a subset of teens may choose both to use marijuana and behave aggressively because of an underlying personality characteristic or tendency.(1, 665, 725, 726) People who have trouble inhibiting themselves might engage in both cannabis consumption and

violent behavior, yet neither one caused the other. The use of other drugs, including alcohol, may be a more likely explanation for the aggression. In fact, when one group of researchers included previous violence and alcohol consumption in their analyses, the links between marijuana and aggression disappeared.(725)

Other studies suggest that these small links between cannabis consumption and hostility do not mean that marijuana intoxication leads to aggression. For example, a group of adolescents charged with violent crimes reported that cannabis was likely to decrease aggressiveness.(685) Less than four percent of people report that they think marijuana makes them angry or hostile.(272, 608) Research participants have lower scores on questionnaires designed to assess hostility, anger, and aggressiveness if they answer after using cannabis.(2) Yet, some of the most compelling evidence that the drug does not increase hostility stems from laboratory work that actually measures belligerent behavior.

iv. Laboratory research

A sophisticated way to examine marijuana's impact on aggression requires providing THC to participants in the laboratory. Few people behave in a hostile fashion in a formal setting, so most studies provoke participants to see if they will aggress in response. A popular paradigm uses a competitive game. The participant competes against an opponent to provide a faster, correct response. The winner of each trial can give the loser a mild electric shock. (A later version of the task allows the winner to take money or points from the loser). In fact, the opponent is bogus and the results are fixed. The participant loses a specified number of times. The experimenter makes it seem as if the opponent provides increasing or heavy penalties in an effort to provoke aggression. This paradigm may seem an absurd analogue to hostile interactions in everyday life, yet former prisoners with histories of aggressive acts do behave more aggressively in this game. Frustration, drug withdrawal, and other conditions that should increase violence also increase aggression in the game.(124) Laboratory studies using this paradigm find that marijuana intoxication rarely heightens hostile responses. Participants gave stronger shocks when intoxicated with alcohol, but THC had no impact. A high dose of THC actually lowered aggression, despite the provocation inherent in the task.(472, 679) These results suggest that cannabis intoxication does not increase aggression in a normal population.

v. Conclusion: cannabis alone does not cause aggression

Cannabis intoxication does not lead to aggression in the general population. Self-reports of experienced users suggest that the drug makes them feel calm rather than hostile and unfriendly. History and research on crime reveals little impact of cannabis on violence. The vast majority of laboratory research shows that cannabis intoxication does not increase hostility and action. Associations between cannabis and aggression arise in small subsets of the population, usually involving individuals experiencing other unrelated co-occurring conditions. The drug's general absence of an impact on hostility has led every major commission report to conclude that cannabis does not increase aggression.

D. Conclusions on public health factor

Some have concerns that cannabis creates meaningful social problems, including amotivational syndrome, reckless driving, and aggression. However, research in each of these domains reveals that these concerns are unfounded. Evidence for a cannabis-induced amotivational syndrome is lacking. A subset of depressed users may have inspired a few case studies that report apathy, indifference, and dysphoria, but cannabis likely does not cause these symptoms. The drug does not correlate with low grades in college students. High school students who use marijuana have lower grades, but their poor school performance occurred prior to their consumption of cannabis. Cannabis users do not show worse performance on the job, more frequent unemployment, or lower wages. In addition, long-term exposure to cannabis in the laboratory fails to show any meaningful or consistent impact on productivity.

Clearly, no one should drive while intoxicated. Yet links between cannabis use and reckless driving are weak, and usually stem from co-occurring alcohol consumption. People with THC but no alcohol in their blood do not have higher rates of culpability for traffic accidents than drug-free drivers. Laboratory experiments that administer THC and placebo to motorists reveal an increased weaving within the lane that accompanies intoxication. Yet, these drivers also spontaneously slow their speed, increase their following distance, and rarely attempt to pass other cars. In contrast, alcohol, even at relatively low doses, clearly impairs driving.

The association between cannabis intoxication and aggression is also unlikely. Most studies of violent crime show no link to marijuana use or small correlations that suggest a few aggressive people also happen to use cannabis. Laboratory research on general samples shows no increases in aggression during intoxication. Concerns about productivity, impaired driving, and hostility are certainly important, but restricting marijuana consumption seems to have little impact on these social problems.

Exhibit B: Statement of Grounds

CONCLUSION AND POSSIBLE FUTURE DIRECTIONS

The United States Justice Department remains committed to the enforcement of the Controlled Substances Act. Because the department "is also committed to making efficient and rational use of its limited investigative and prosecutorial resources," and must appropriately reclassify drug substances when medical and scientific evidence requires as presented in this report, the DEA after the FDA scientific review, following the eight-factor analysis and evidence presented here, should reclassify cannabis as a Schedule II substance.(682)

The Obama administration has acknowledged the "compassionate use" that some states' electorates have provided for. While cannabis is not a benign drug, mounting scientific evidence and consensus of medical opinion support rescheduling to Schedule II, the most highly regulated schedule.

Some very ill people have had very difficult times finding safe and reliable sources, and some have had to fight long court battles to defend themselves for the use of a compound that irrefutably works to help relieve painful symptoms from serious illnesses like treatment for HIV/AIDS wasting syndrome, amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease, and multiple sclerosis (MS).

On multiple occasions the DEA has studied the medicinal properties of cannabis. A DEA Administrative Law Judge concluded that, "the evidence clearly shows that marijuana is capable of relieving the distress of great numbers of very ill people, and doing so with safety under medical supervision…it would be unreasonable, arbitrary and capricious for the DEA to continue to stand between those sufferers and the benefits of this substance."(40) However, the DEA overruled the opinion, and then denied two subsequent petitions despite the mounting scientific evidence. Since the last FDA review in 2006, the scientific process has identified and clarified even more of the therapeutic effects of cannabis through ongoing research and assessment of available data. This petition presents this further evidence. It is now time for the DEA to reschedule the substance.

There are other possible futures and ways to make the medicinal use of cannabis viable for patients in need while addressing public health issues. Concerns are often raised about lack of quality control in using medicinal cannabis, including lack of dosing paradigms, safe methods of use, and inability to safely access cannabis. One possible future would be to allow for the legal, regulated growth of cannabis for medicinal use. It is now a relatively easy and affordable task to use DNA analysis via polymerase chain reaction (PCR) and gel electrophoresis testing to provide an extremely accurate characterization of a plant's genetic make-up. Accurate analytical kits are available that would make this accessible to even small scale farmers. These techniques would also foster the creation of unique genetic hybrids grown specifically to maximize therapeutic medicinal potential.

At the pharmacy level it is now possible to easily and inexpensively perform quantitative analysis to identify the levels of cannabinoids, including chemical and physical properties, such as chemical reactivity, solubility, molecular weight, melting point, etc. via techniques such as gas

Exhibit B: Statement of Grounds

chromatography-mass spectrometry (GC-MS), mass selective detectors (MSD), operating in either electron ionization (EI) or negative-ion chemical ionization (NICI) mode. These methods are fully validated, and the validated parameters included linearity, selectivity, accuracy, precision, and extraction efficiency. Thus cannabis plants could be grown under controlled settings, with harvesting of the flowers, which after proper drying, would be quantitatively evaluated for specific cannabinoid levels.

These dried, cured flowers would then go to a compounding pharmacist. Pharmaceutical compounding is a longstanding traditional role for pharmacists. It is a process by which a pharmacist combines ingredients into a customized medication for an individual patient. Compounding is now increasingly offered by community pharmacies as a specialized service. Studies have shown that pharmacists providing compounding reported that this has increased the quality of pharmaceuticals and improves collaboration between the patient, physician, and pharmacist, while empowering the patient and improving professional satisfaction of the physician and pharmacist.(422) This would allow safe access to a medicine with proven efficacy and acceptable safety, in a manner that does not endanger the patient and allows for reasonable regulatory oversight.

The evidence presented in this report proves the addiction, dependence, abuse and misuse potential are all low compared with other Schedule II drugs. Like other controlled substances in schedule II or III, the public health concerns remain, but none that outweigh the fact that cannabis is a medically acceptable drug for patients with serious conditions. Cannabis does not present a potential for abuse to justify remaining a Schedule I substance. It remains that no one should drive a vehicle intoxicated, and children should not use cannabis – both statements are true for almost all other Schedule II substances. There are well researched accepted medical uses; there are ways to safely administer the drug; and, there are effective non-smoking methods like vaporization, oral ingestion or topical application. The DEA and FDA should use this rule-making process to clarify appropriate use standards, including age restrictions.

The National Academy of Sciences, Institute of Medicine perhaps sums it up best (715): "Marijuana is not, to be sure, a completely benign substance. It is a powerful drug that affects the body and mind in a variety of ways. However, except for the damage caused by smoking [*which this petition clearly describes non-smoking methods for medical use*], its adverse effects resemble those of many approved medications." [Italics added]

Current federal rules preclude the adoption of reasonable and workable frameworks for providing access to patients while maintaining the ability of law enforcement agencies to address non-medical/illegal distribution and use of cannabis. The situation has become untenable. The solution lies with the federal government. The DEA should initiate rulemaking proceedings to reclassify medical cannabis as a Schedule II drug so qualifying patients who follow law may obtain the medication they need through the traditional and safe method of physician prescribing and pharmacy dispensing.

Exhibit B: Statement of Grounds

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His research has focused on the relationships between chronic pain, quality of life, and physical function in amyotrophic lateral sclerosis (ALS), and other NMDs. He has authored over 150 peer-reviewed papers, publishing the first article on cannabis as a treatment for ALS. He is past recipient of the Best Research Paper Award from the American Academy of PM&R and the Excellence in Research Writing Award from the Association of Academic Physiatrists, as well as the Excellence in Clinic Care Award from the Muscular Dystrophy Association.

He maintains clinical faculty appointments at the University of Washington and UCD Schools of Medicine. He is a diplomat of the American Board of Physical Medicine and Rehabilitation, the Neuromuscular Medicine subspecialty of the American Board of Psychiatry and Neurology (founding member), and the American Board of Electrodiagnostic Medicine.

Exhibit B: Statement of Grounds

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ii Mitch Earleywine, Ph.D.

Dr. Mitch Earleywine is Professor of Clinical Psychology at the University at Albany, State University of New York, where he teaches courses on drugs and human behavior, substance abuse treatment, and clinical research methods.

He received his Bachelor's degree from Columbia University and his Ph.D. from Indiana University. He joined the faculty at the University of Southern California for 14 years before moving to Albany in 2005.

He has received 20 teaching commendations, including the coveted General Education Teaching Award from the University of Southern California and the Chancellor's Award for Excellence in Teaching from the State University of New York system. He has over 100 publications on personality, motivation, and substance abuse.

iii Jason T. McGill, JD

Mr. McGill is the Executive Policy Advisor for Health Care for Washington State Governor Chris Gregoire's Executive Policy Office. He is a lifelong Washingtonian and earned both a Bachelor of Arts in Business Administration and a law degree from Seattle University, with a focus in health law. He later earned an executive management certificate from the University of Washington, Evans School of Public Affairs.

He worked in private law practice for several years before joining the Washington State Attorney General's Office where he was lead counsel and represented the healthcare related programs of the state Department of Labor and Industries. He became the Medical Administrator for the Department of Labor and Industries. In that capacity he was an Executive Management Team member and responsible for setting strategic vision, management of nursing and healthcare policy staff in partnership with the Medical Director and Associate Medical Directors of the agency.

U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator *Springfield, VA 22152*

August 11, 2016

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Governor of Rhode Island
82 Smith Street
Providence, Rhode Island 02903

The Honorable Jay R. Inslee
Governor of Washington
P.O. Box 40002
Olympia, Washington 98504-0002

Mr. Bryan A. Krumm
[redacted]

Dear Governor Raimondo, Governor Inslee, and Mr. Krumm:

The enclosed materials provide the legal and factual bases for our decision, in response to your petitions, regarding the rescheduling of marijuana.[1] I will get to that decision, but I will first highlight broader considerations with respect to (1) the law regarding drug scheduling and (2) the current state of marijuana research.

The Law Regarding Drug Scheduling:

The Controlled Substances Act (CSA) mandates that scheduling decisions be based on medical and scientific data and other data bearing on the relative abuse potential of the drug. Under the CSA, the Food and Drug Administration (FDA), in consultation with the National Institute on Drug Abuse (NIDA), reviews, analyzes, and assesses that data and its medical and scientific conclusions legally bind the Drug Enforcement Administration (DEA).

The FDA and the DEA make a determination based on a full review of the relevant scientific and medical literature regarding marijuana. That process, too, is outlined in the enclosed materials.

A substance is placed in Schedule I if it has no currently accepted medical use in treatment in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse. These criteria are set by statute.

[1] Governors Raimondo and Inslee succeeded petitioner Governors Chafee and Gregoire, respectively.

Schedule I includes some substances that are exceptionally dangerous and some that are less dangerous (including marijuana, which is less dangerous than some substances in other schedules). That strikes some people as odd, but the criteria for inclusion in Schedule I is not relative danger.

In that sense, drug scheduling is unlike the Saffir-Simpson scale or the Richter scale. Movement up those two scales indicates increasing severity and damage (for hurricanes and earthquakes, respectively); not so with drug scheduling. It is best not to think of drug scheduling as an escalating "danger" scale – rather, specific statutory criteria (based on medical and scientific evidence) determine into which schedule a substance is placed.

Marijuana Research:

Research is the bedrock of science, and we will – as we have for many years – support and promote legitimate research regarding marijuana and its constituent parts. For instance, DEA has never denied an application from a researcher to use lawfully produced marijuana in a study determined by the Department of Health and Human Services (HHS) to be scientifically meritorious.

In fact, during the last two plus years, the total number of individuals and institutions registered with DEA to research marijuana, marijuana extracts, derivatives, and tetrahydrocannabinols (THC) has more than doubled, from 161 in April 2014 to 354 at present. Some of the ongoing research includes studies of the effects of smoked marijuana on human subjects. Folks might be surprised to learn that we support this type of research. But, we do.

DEA and NIDA have also increased the amount of marijuana available for research. Indeed, we consistently meet legitimate demand by researchers for marijuana. Currently, NIDA is filling requests for research marijuana in an average of 25 days.

We will continue to work with NIDA to ensure that there is a sufficient supply of marijuana and its derivatives (in terms of quantity and the variety of chemical constituents) to support legitimate research needs. This includes approving additional growers of marijuana to supply researchers. Details of this proposal to support legitimate research will be published in the Federal Register.

Further, in December 2015, we waived certain regulatory requirements for researchers conducting FDA-authorized clinical trials on cannabidiol (CBD), a constituent part of marijuana. These waivers, when granted, enable researchers to modify or expand the scope of their studies more easily. Currently, there are 90 researchers registered with the DEA to conduct CBD research on human subjects. We have approved every waiver application that has been submitted by these researchers – to date, a total of 47.

If, for instance, CBD proves to be safe and effective for the treatment of a specific medical condition, such as childhood epilepsy (some trials have shown promise), that would be a wonderful and welcome development. But we insist that CBD research – or any research – be sound, scientific, and rigorous before a product can be authorized for medical use. That is specifically – and properly – the province of the FDA.

DEA continues to work on other measures to support marijuana research. For instance, DEA is building an online application system for researchers to apply for Schedule I research registrations, including for marijuana. DEA also is drafting clear guidance to assist Schedule I researchers in that application process.

The Decision:

The FDA drug approval process for evaluating potential medicines has worked effectively in this country for more than 50 years. It is a thorough, deliberate, and exacting process grounded in science, and properly so, because the safety of our citizens relies on it.[2]

Using established scientific standards that are consistent with that same FDA drug approval process and based on the FDA's scientific and medical evaluation, as well as the legal standards in the CSA, marijuana will remain a schedule I controlled substance. It does not have a currently accepted medical use in treatment in the United States, there is a lack of accepted safety for its use under medical supervision, and it has a high potential for abuse.

If the scientific understanding about marijuana changes – and it could change – then the decision could change. But we will remain tethered to science, as we must, and as the statute demands. It certainly would be odd to rely on science when it suits us and ignore it otherwise.

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[2] The FDA's scientific assessment determines the safety and efficacy of drugs intended for human consumption. The FDA's team, charged with conducting that assessment, consists of clinical pharmacologists, epidemiologists, toxicologists, physicians, chemists, statisticians and other scientists, working together to ensure approved drugs are safe and effective. As our partners at HHS note, "[An] expert [in this discipline] is an individual qualified by scientific training and experience to evaluate the safety and effectiveness of a drug." Although medical doctors are highly trained and qualified to treat patients with FDA-approved drugs, as HHS notes, "[m]edical practitioners who are not experts in evaluating drugs are not qualified to determine whether a drug is generally recognized as safe or effective or meets NDA (New Drug Application) requirements." 57 FR 10499. Simply put, evaluating the safety and effectiveness of drugs for their intended use is a highly specialized endeavor undertaken by the FDA's Center for Drug Evaluation and Research.

The DEA and FDA continue to believe that scientifically valid and well-controlled clinical trials conducted under investigational new drug applications are the proper way to research all potential new medicines, including marijuana. Furthermore, we believe that the drug approval process is the proper way to assess whether a product derived from marijuana or its constituent parts is safe and effective for medical use.

We fully support legitimate medical and scientific research on marijuana and its constituent parts and we will continue to seek ways to make the process for those researchers more efficient and effective.

Sincerely,

Chuck Rosenberg
Acting Administrator

Enclosures

The Quest for Drug Control

Politics and Federal Policy in a Period of Increasing Substance Abuse, 1963–1981

David F. Musto, M.D., and Pamela Korsmeyer

Yale University Press

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To the memory of
Donald J. Cohen
1940–2001

that its agents had implicated Mr. Tack or Mr. Torrijos in its briefings of the House subcommittee. A bureau spokesman, who confirmed this, was unable to explain the conflict with the subcommittee's report, which said that bureau agents had 'confirmed' information about the 'involvement[‘] of the Panamanian officials."[65]

The policies that had begun in 1969 and had seemed logical and effective methods to reduce the flow of heroin into the United States through diplomatic pressure on the countries where opium originated had become, by 1972, a far more complex and confusing collection of initiatives the real results of which were difficult to identify. Whatever credence policy makers gave at first to Nixon's statement that drug control should be given priority over other foreign policy considerations[66] had dissipated in the face of the imperatives of the war in Southeast Asia, interagency conflict, and the inherent complexity of the drug phenomenon.

LAW AND ORDER THROUGH NARCOTICS CONTROL: THE COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970

Along with foreign policy initiatives aimed at controlling supplies of opiates at their sources, Richard Nixon's planners and staff began to add a second level to emerging anti-drug policy—domestic law enforcement. The effort to enact effective legislation against drug trafficking and use had its origins both in the political circumstances of the Nixon campaign and in basic beliefs about the relationship between crime and drugs that had had at least some currency among bureaucrats and policy makers since before the Harrison Act of 1914. Richard Nixon may have felt some pressure to emphasize the crime issue by the threat to his conservative base of support posed by the candidacy of George Wallace; and the belief Nixon shared with many of his advisors that a strong relationship existed between crime and drug use fit neatly into the efforts to reform narcotics laws that had begun in the Johnson administration. During 1967 and 1968 the staff of the National Commission on Reform of Federal Criminal Laws had worked on a new federal criminal code that built on the work of the Katzenbach Commission and laid the groundwork for the penalty structure for drug offenses that would emerge over the coming year.

At the outset of Nixon's first term, in January 1969, the White House and the Justice Department, principally Michael R. Sonnenreich, deputy chief counsel

of the Bureau of Narcotics and Dangerous Drugs, and John W. Dean III, then deputy assistant attorney general, undertook to recast the Johnson-era initiative into what would become a sweeping consolidation and rationalization of the drug control laws that had been accumulating since 1909. The measure they drafted opened various possibilities for controversy and political difficulty that were not lost on its supporters.[67] The early drafts of the bill provided for generally lower penalties for narcotics offenses: mandatory minimum terms for first offenses relating to traffic in narcotics and marijuana were eliminated; all penalties relating to marijuana were reduced; simple possession offenses were classified as misdemeanors; and the death penalty was eliminated.

Another important component of the proposed new measure was that it established four classifications, or schedules, for narcotics, dangerous drugs, and cannabis according to abuse potential and usefulness in legitimate medical practice. The ultimate responsibility for assigning a substance to one category or another was to lie with the attorney general. This provision, at least theoretically, created the possibility that the attorney general could, in effect, legalize a given substance by simply reclassifying it—however difficult it might be to imagine John Mitchell doing such a thing—and was eventually modified to require congressional approval for reclassification of a Schedule I substance or removal of a substance from the list. Initially, the only counterbalance to the possibility that the bill would be regarded as "soft" was a section that allowed the court "to double the penalty otherwise authorized on a finding that the person convicted was involved in a continuing criminal enterprise."[68] Soft or not, the bill was clearly designed to deal with the drug abuse problem through criminal justice.

Opposition to the emerging legislation among the health professionals at the Department of Health, Education, and Welfare was fierce. In early May, the department submitted a report to the Budget Bureau registering its opposition to the direction that the legislation was taking and suggesting a number of changes that would make the bill more compatible with its view of the drug problem as a scientific and public health matter.[69] HEW objected to empowering the attorney general to license manufacturers, researchers, and health practitioners and to classify dangerous substances according to the new schedules. Qualified approval for the more lenient penalty structure was expressed in the document, but suggestions for further relief for recidivists and addicts prosecuted for simple possession were favored. The HEW document also reopened an old debate about the advisability of Reorganization Plan 1 of 1968, which

had moved the regulatory and enforcement functions of the Bureau of Drug Abuse Control from HEW to the new Bureau of Narcotics and Dangerous Drugs in Justice.

From the point of view of the Justice Department, a fundamental difference in perspective between Justice and HEW was that "it is a *policy* determination as to whether nor not a drug should be controlled. At that point in time, since the control of the drug will require enforcement, it is necessary to evaluate that recommendation, *along with practical problems of enforcement,* to determine whether the drug should be placed under control. This is not something that the Secretary of Health, Education and Welfare is as qualified to perform as is the Attorney General [emphasis original]."[70]

While HEW supported the most lenient possible sanctions, there was opposition from other quarters. Congressman Richard H. Poff (R., VA) warned Attorney General Mitchell that "Congress is in no temper to buy this penalty structure. An attempt to make the sale might poison the rest of the reform package. Yes, the present penalty structure is disjointed. However, I would recommend that Congress be asked to use its own judgment in correcting present penalty conflicts, inconsistencies and inequities. In other words, you could leave the penalty definitions in Title V blank and in the message invite Congress to make its own decisions."[71]

Michael Sonnenreich defended the Justice Department draft penalty structure. "From the point of view of halting illicit drug traffic, simple possession is the least meaningful enforcement tool in terms of agent time, court time, and the Bureau's overall mission. . . . As to [people caught in possession of dangerous drugs], maximum flexibility in sentencing should be maintained."[72] Sonnenreich did offer the possibility of amending the section on continuing criminal enterprise to prohibit suspension of sentence and probation for such offenses.

Pressure to complete the bill and get it to Congress was intense. In addition to anticipation among the public and the legislative branch of government generated by speculation and commentary in the press, the Supreme Court had handed down a decision in the case of *Leary v. U.S.* (395 US 6) that endangered the legal basis of marijuana prohibition in taxation law. If the federal government was to retain control over this drug and perhaps others, new legislation based on interstate commerce law had to be promulgated. A decision to finalize the measure at a leadership meeting to be held on 8 July was made at the urging of John Dean.[73] Notes on the meeting prepared for the President's Meeting

> the only area of controversy in the discussion [of the narcotics bill] was over penalties. It appeared that in some areas Justice Department felt it was most feasible to reduce penalties for drugs like marijuana for the simple reason that it was almost impossible to get convictions for the stronger penalties. However, the President argued on the political basis that it would be unwise for the Administration to appear to be reducing in any way the penalties for drug users or especially dope peddlers. It was generally agreed that any change in the sentences regarding penalties would be left up to the wisdom of the Congress. The Administration would not take responsibility for this by including it in any message or legislation.[74]

Meanwhile, various senators and congressmen were busy introducing bills that took every conceivable approach to the problem of drug abuse. It is curious that members of Congress of both parties agreed with the administration that controlling the use and abuse of narcotics and dangerous drugs was a pressing necessity. At the time, the Gallup Organization was reporting that a mere 1 percent of the population considered drugs to be the "most important problem facing the country today" (39 percent cited Vietnam, 15 percent student unrest, 12 percent race relations).[75] The fact that the Vietnam War was cited as the most important problem by a wide margin probably had a depressing effect on other percentages, but the White House was relying on a survey that excluded Vietnam as an issue, and even so, drugs (in this case including alcohol) were named by only 3 percent of the respondents.[76] In the face of this apparently low public alarm about drug abuse, the enthusiasm for narcotics legislation on the part of elected officials may be a bit hard to understand. Again, as pointed out with respect to Johnson's anti-drug initiatives and the observations of such Nixon advisors as Moynihan and Ehrlichman, the explanation probably lies in the fact that such legislation did respond to a broad but low-intensity public unease. Drug control bills offered the opportunity for politicians to express concern for the poor and the wretched (narcotics addicts) *and* for middle-class youth, whose misguided but understandable attempts at rebellion required both compassion and correction, while *simultaneously* lowering the boom on criminals. Differences among competing measures were differences of emphasis—in some cases more power was accorded to law enforcement agencies, in others, to reliance on the health bureaucracy.

Probably the most significant of the drug measures introduced prior to the administration's bill was that sponsored by Senator Thomas Dodd (D., CT), on 18 April (S. 1895). Dodd's proposal appears to have been based on the Justice Department drafts but was intended to establish a joint committee drawn from the National Institute of Mental Health and the attorney general's office to

study alternative marijuana laws and would increase the staff of both the BNDD and the Bureau of Customs, two measures also suggested by the Katzenbach Commission. There were other technical differences between the two documents, particularly having to do with classification of drugs, that made Dodd's version unacceptable to the administration.[77]

Another proposal, introduced by Senator Frank Moss (D., UT), called for the establishment of a presidential commission to study marijuana use and abuse and to render a report within two years (S. 2590). Later, in August, the Justice Department in consultation with Senator Dodd's staff would develop an amendment to the administration's bill that would establish such a commission through a combination of some of the features of Dodd's bill with some from Senator Moss's version. This amendment turned out to be a thorn in the side of the administration. Nixon's staff was ultimately unable to control the activities and conclusions of the commission, and a considerable effort at political damage control had to be mounted.

THE CONTROLLED DANGEROUS SUBSTANCES ACT OF 1969: INITIAL CONGRESSIONAL ACTION

On 14 July 1969 President Nixon announced a national "war on drugs." His "Special Message to the Congress on Control of Narcotics and Dangerous Drugs" was a prelude to introducing the new legislation that would be the first battle plan of the war. (The bill was formally introduced in the Senate on 16 July by Everett Dirksen [R., IL] as S. 2637.) And so began a sixteen-month process of legislative give-and-take, political maneuvering, and bureaucratic jockeying.

The president seemed to acknowledge the less-than-complete public agreement with respect to the size and importance of the drug problem in saying, "A national awareness of the gravity of the situation is needed: a new urgency and concerted national policy are needed at the Federal level to begin to cope with this growing menace to the general welfare of the United States." He went on to draw the parallel between narcotics use and crime in no uncertain terms, saying, "Narcotics have been cited as a primary cause of the enormous increase in street crimes over the last decade. . . . An addict can be forced to commit two or three burglaries a day to maintain his habit."[78]

Senate Bill 2637 had three main purposes, according to testimony of Attorney General Mitchell before the Senate Subcommittee to Investigate Juvenile Delinquency, of which Senator Dodd was the chair. The measure was meant to "[1] provide more meaningful regulation over legitimate sources of drugs, [2] to strengthen law enforcement against illicit drug traffic, and [3] to eliminate some of the inconsistencies in the present regulation of drugs."[79] It also increased Justice Department involvement in drug education and research. As had been recommended by Congressman Poff and in line with the decision reached in the 8 July meeting, the administration maintained a penalty structure in the final legislative proposal that closely followed existing federal law, though abolishing the death penalty where it had been applicable to sales of heroin to minors. President Nixon's advisors were open to further revisions in the penalty structure but, in the furtherance of strong law enforcement, included in the bill what was known as the "no-knock" provision. This title allowed federal narcotics officers to enter premises without warning if first they obtained a warrant stating that they had reason to believe that evidence would be destroyed if they announced their presence and purpose. Although several states had similar laws, giving federal agents "no-knock" authority was extremely controversial. Liberals denounced the provision, and the administration complained that "the only thing that was reported in the media was that we would be kicking in doors without announcing authority and purpose."[80] Interestingly, this item had appeared previously in Senate Bill 1895 introduced by Senator Dodd, a Democrat.

The professionals at HEW rallied to oppose the measure that seemed to confer ownership of the drug issue on the Department of Justice once and for all. They allied themselves with those members of Congress, such as Senator Harold E. Hughes (D., IA) and Senator Ralph Yarborough (D., TX), who objected to treating drug abuse solely as a subject of criminal law rather than principally as an object of public health. Always careful to identify their remarks as personal and not indicative of administration thought, HEW officials advocated the greatest possible relaxation of the penalty structure, an increased emphasis on marijuana research, and expansion of addiction treatment and urged that drug abuse education be the responsibility of HEW and not Justice.

Criticism from HEW executives (for example, Stanley Yolles, director of the National Institute of Mental Health, and Sidney Cohen, director of NIMH's Division of Narcotic Abuse and Drug Addiction),[81] from a number of prominent senators, and from the press, and possibly the bitter experience of Operation Intercept (the administrations' first attempt at high-profile border interdiction), eventually led to a modification of the administration's tentative penalty structure along the lines of the original Justice Department draft. It fell

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to John Ingersoll, director of the Bureau of Narcotics and Dangerous Drugs, to present the new structure to Congress, which he did on 20 October in testimony before the Senate Subcommittee to Investigate Juvenile Delinquency. In spite of Congressman Poff's warning, the net effect of the new version was to ameliorate considerably the punitive nature of the bill. Mandatory minimum sentences were removed (except in the case of a continuing criminal enterprise), and possession of narcotics and dangerous drugs was classified as a misdemeanor rather than a felony.[82] The problem then faced by the White House was how to prevent the more flexible penalties from doing just what they had feared when the measure was being discussed in the Spring—make the administration appear to be "soft" on narcotics. John Ehrlichman instructed Egil Krogh to "get with Jeb Magruder immediately to coordinate the Administration's justification for reducing narcotics penalties for first offense to a misdemeanor so that the rationale will be easily understood by the average newspaper reader. It may be that Ingersoll or even the Attorney General should have a press conference on this right away in order to make a full explanation. As it is now, it looks like we're coming down soft on narcotics and we should scotch this immediately."[83]

A bipartisan leadership meeting to which representatives of the print media were invited was convened on 23 October. At the meeting, Ingersoll stoutly defended the proposition that "we will see more and better enforcement of the law under the new approach than at the present."[84] He also emphasized the importance of "no-knock" authority for his agents and the bureau's plans to attack drug trafficking at its highest levels as international conspiracies. This policy of concentrating the bureau's resources on long-term strategies to undermine high-level trafficking at the expense of more immediate and visible action against narcotics-related street crime (an approach advocated by both the Prettyman and Katzenbach Commissions) would later prove to be a point of political vulnerability for Ingersoll himself, but the administration's immediate need had been met. The impression of less-than-forceful commitment to punishing narcotics offenders, made all the more perilous by the very recent and embarrassing unraveling of Operation Intercept, had been contained.

OPERATION INTERCEPT: SORTIE AND RETREAT

In March of 1969 a Special Presidential Task Force Relating to Narcotics, Marihuana, and Dangerous Drugs had met for the first time. Its declared purpose was to "conduct a comprehensive study of marihuana with specific emphasis

on the Mexican border problem."[85] Subcommittees on health, resources, and enforcement met during April and May, and a report was completed by early June. According to the transmittal letter to the president from Treasury Secretary David Kennedy and Attorney General Mitchell, the report was "a direct result of your pledge to the American people on September 16, 1968, at Anaheim, California."[86] The work of the task force had very likely been spurred on by rising public concern about unrest on college campuses across the nation.[87] May 1969 had seen widespread student disturbances, some provoked by arrests of students on drug charges, some related to the civil rights movement, and some related to antiwar protests. It was widely believed that students were quickly becoming the primary consumers of cannabis and that students were causing a lot of trouble.

In hindsight, the *Task Force Report* seems to serve these sorts of beliefs rather than to present objective analysis of a situation or a selection of policy alternatives. According to the report, cannabis use among young people was growing at a truly startling rate. It pointed out that in "1967 alone there were over 2,000 more arrests for marihuana violations than in the previous six years alone."[88] In dealing with the old questions of whether marijuana use leads to addiction to other drugs and whether there is a link between marijuana and crime, its authors engaged in some curious logical leaps. To wit:

> The evidence [tends] to show that only five percent of habitual marihuana users progress to heroin addiction. . . .
>
> In view of the foregoing, it must be concluded that regular and continuous use of *cannabis* can and does produce psychological dependency and marked susceptibility to progression to stronger reality concealing drugs.[89]

And this:

> The President's Commission on Law Enforcement and Administration of Justice has observed:
>
> > One likely hypothesis is that, given the accepted tendency of marihuana to release inhibitions, the effect of the drug will depend on the individual and the circumstances. It might, but certainly will not necessarily or inevitably lead to aggressive behavior or crime. The response will depend more on the individual than the drugs.
> >
> > While perhaps it cannot be statistically proven that marihuana or other dangerous drugs may be the cause of originating crime, nevertheless the use of marihuana or dangerous drugs is related to increased criminal activity.[90]

The first recommendation offered in the *Task Force Report* was that smuggling across the Mexican border should be brought under control through

strict inspection and surveillance, more enforcement personnel, better detection equipment, and more funding for intelligence and evidence gathering. (These measures corresponded closely to those promised by candidate Nixon in his Anaheim address.) A second feature of the proposed attack on marijuana smuggling was to encourage Mexico to take stronger enforcement and crop control measures within its own borders. Third, the report urged more effective prosecution and punishment of violators. President Nixon concurred "in the basic conclusions and in the essential recommendations of the report" and ordered "immediate steps calculated to make a frontal attack on the narcotic, marihuana and dangerous drug traffic across the Mexican border."[91]

The end result of the deliberations of the action task force created by this presidential directive was Operation Intercept, a massive attempt to throttle cross-border drug traffic. How the plan was actually formulated is not clear from documents in the National Archives. In any case, the political and social atmosphere of the summer of 1969, as policy makers went about their work, was as charged as it had been in the spring. The "war on drugs" officially began on July 14; a month later the news media carried the spectacle of upward of 400,000 young people celebrating sex and drugs and rock 'n' roll at a massive gathering at Bethel, New York, to be remembered as "Woodstock." (Although one estimate put the number of pot smokers at the festival at "90% of those present," the police made "fewer than 100 arrests on narcotics charges.")[92]

News of a plan to declare Tijuana and possibly other border towns off-limits to military personnel (as the task force had recommended) began leaking to the press in late August, alarming business people on both sides of the border and inspiring the Mexican authorities to increase drug control efforts. On 9 September a detailed report on Operation Intercept appeared on the front page of the *New York Times* alongside a report on President Nixon's meeting with Mexican President Gustavo Díaz Ordaz at the new Amistad Dam on the Rio Grande. The article quoted extensively from the *Task Force Report,* including the observation that, should soldiers and sailors be forbidden to visit border towns, "the effect on the local economy would be substantial. Such action could be considered as an inducement for better drug control along the border."[93] White House planners found themselves scrambling to organize an announcement of the operation on their own terms. Herbert G. Klein, Nixon's director of communications, assured the president in a memo dated 13 September that "we have things in good order now"; the whole press corps had been brought up-to-date by Assistant Attorney General Richard Kleindienst and Eugene Rossides, assistant secretary of the treasury for enforcement, at a

press conference the previous day.[94] A series of briefings was scheduled for the coming week in preparation for the official launch of the program. Klein told the president, "I am sure we will have some complaints because of the economic losses this will create along the border by virtually stopping tourism. I think the theme on the major war on narcotics has such power though that 'Operation Intercept' will be widely applauded by the public. I think we will earn the support from the community along the border through these briefings."[95]

Operation Intercept was officially begun at 2:30 P.M. on Sunday, 21 September 1969, under the operational control of Myles Ambrose, commissioner of Customs, and the general direction of Richard Kleindienst and Eugene Rossides. The following day Secretary Kennedy of Treasury and Attorney General Mitchell briefed the press on the first day of the operation and indicated that it would continue for some time.

Meanwhile, the 1,700-mile border with Mexico from San Diego to Brownsville, Texas, was clogged with irate travelers, and business owners were furious. The U.S.-Mexican Border Cities Association protested, and the Mexican government and press expressed indignation. Radio Station KVOZ in Laredo, Texas, complained bitterly. "In spite of a unanimous chorus of criticism from at least three Congressmen who represent this area . . . in spite of comments of protest from the Mexican Government—including the President himself. In spite of numerous calls, telegrams and letters into Washington to every conceivable bureau of government that might alter or review Operation Intercept—the attitude has been one of unbending inflexibleness."[96]

To judge from this evidence, the optimism expressed by Herbert Klein had not proven to be justified. Closer to the mark was a report done in the Budget Bureau that reached Egil Krogh's desk on 29 September. That document sharply criticized the original *Task Force Report* as "a grossly inadequate basis for Presidential decision and the policy line laid down in the Report seems likely to result in embarrassment to the President in an area of extreme importance to him."[97]

Nevertheless, the administration remained committed to the operation. A progress report submitted by Commissioner Ambrose on 6 October showed that Customs had made eleven seizures of narcotics at border ports that included 14½ ounces of heroin, ¼ ounce of cocaine, and small quantities of other substances.[98] He reported forty-five seizures of marijuana, peyote, and hashish (1,830 pounds 36 ounces of marijuana plus 9,892 cigarettes and 7 seeds, 60 pounds of peyote, and 78½ ounces of hashish). In addition, two marine

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seizures were accomplished, yielding 165 pounds of marijuana, 1,000 "pills," and small amounts of LSD, cocaine, and hashish. Searches of aircraft turned up another 1,000 pounds of marijuana. Ambrose's assessment of the effects of the operation on public opinion and upon the supply of marijuana and other drugs within the United States was rather different from what one might gather from the radio and newspaper reports cited above.

> Throughout the border community (United States and Mexico), the general populace supports Operation Intercept; but retail merchants have been very vocal in their criticism, citing as their main complaint loss of business up to 65 percent. It is important to note, however, that local exchange banks, which rely heavily upon monies tendered by the firms claiming the reduction of sales, report only a 1 percent reduction in volume of money exchanged.
>
> Civic groups such as the P.T.A., Rotary, Lions, and Chambers of Commerce in Mexico and the United States have supported Intercept and have proposed that Mexico join the effort by starting a cleanup of the Mexican border area. In addition, at least one of the Mexican Federal Judicial prosecutors has unofficially endorsed the program as required and long overdue to point up to the central government the urgent need for enforcement emphasis in the Mexican border communities. Numerous other Mexican officials have offered their support on a local level.[99]

And further:

> Information has been obtained from narcotic enforcement offices (city, state, and federal) regarding marihuana, heroin, and dangerous drugs availability throughout the United States from Honolulu to New York, Miami to Chicago, and along the border. It was consistently reported that Mexican marihuana is virtually unavailable or in very limited supply, and significantly higher in price.
>
> Mexican heroin is also very scarce in most communities sampled, and the price is markedly higher. Local police in some areas have reported that dangerous drugs are largely being obtained by the use of false prescriptions.[100]

But even before this report reached the president, moves were under way to arrive at some sort of understanding between the United States and Mexico to reduce the most damaging effects of Operation Intercept. A meeting of officials from both countries was held on 8 October, but U.S. representatives refused to accede to Mexican appeals to open the border. Then overnight everything changed.

Planners were caught between opinion leaders to their left who felt that the whole thing was a fiasco and those on the right who might see a change in policy as capitulation. It is also likely that they realized that, believing such input

as the assessments of Herbert Klein and Commissioner Ambrose, the executive branch had miscalculated the willingness of the public to suffer discomfort and delays in the name of marijuana control. They had not sufficiently appreciated the implications of the BOB report or the poll data that indicated fairly low public concern about drug issues, nor had they correctly assessed the possibilities for extremely negative reaction on the Mexican side of the border. As so often happens, a complex environment had resulted in imperfect decision making. The resolution that was chosen and announced on 10 October was to rename the effort "Operation Cooperation." U.S. border interdiction efforts would be scaled back, and Mexico promised to undertake stronger control measures of its own.

It is possible that this frustrating experience eased the way for the administration's changed position on marijuana penalties in the Comprehensive Drug Abuse Prevention and Control Act. The obvious danger of appearing to retreat from a commitment to an uncompromising fight against drug abuse focused on marijuana may have lent further support to then emerging plans for eradication of heroin as a clearer, more reliable policy objective.

THE COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970: THE POLITICS OF PASSAGE

The fall of 1969 saw a number of events that bore directly or indirectly on the drug abuse issue. Reports of drug-related deaths appeared in the media, a massive antiwar protest at which marijuana was openly consumed took place in November, and in December President Nixon hosted a Governors' Conference at which drug abuse was the main topic under discussion. Also at this time, the animosity of the White House staff toward HEW had solidified. Egil Krogh had complained as early as July of the leaks and sandbagging tactics he thought were the modus operandi of the professionals in that department.[101] Consistent with a generalized effort to control the cabinet bureaucracy from the White House, by December he and his colleagues were embarked on a difficult and complex course of action designed to make both formation and implementation of drug policy functionally effective and politically reliable through reorganization as well as through the new legislation.[102]

On 16 December a revised bill, S. 3246, was reported out of the Senate Judiciary Committee. The new measure combined the administration bill (S. 2637) and the Dodd proposal (S. 1895). It also revised the penalty structure according

to the new administration recommendations and according to "the harmfulness, abuse characteristics and their social implications of the several classes of drugs. For example, to impose the same high mandatory penalties for marihuana-related offenses as for LSD and heroin offenses is inequitable in the face of a considerable amount of evidence that marihuana is significantly less harmful and dangerous than LSD or heroin."[103]

During January 1970 the Senate wrangled over the "no-knock" provision, which it finally approved over the strenuous objections of Senator Sam J. Ervin, Jr. (D., NC). Senator Harold Hughes (D., IA) continued his support of HEW as the principal locus of drug abuse control and as ultimate arbiter of the classification of dangerous substances, in opposition to his Democratic colleague, Senator Dodd. He also favored further reductions in the penalties for drug possession, but the amendments he introduced were defeated. On 28 January the Senate unanimously approved the Controlled Dangerous Substances Act. At that point, the measure included (1) reduction of the penalty for simple possession of narcotics to a misdemeanor punishable with up to one year in jail and a maximum fine of $5,000; (2) the "no-knock" provision; (3) a four-level drug classification system; and (4) authorization for a commission to study marijuana use and abuse.

The bill was still profoundly disturbing to health professionals both within and outside the government. They felt that it would imperil the authority of the health bureaucracy in the field of substance abuse and possibly even expose individual health practitioners and scientists to criminal prosecution or at least to both major and minor interference from law enforcement organizations. In April the American Medical Association objected to Justice Department registration and recordkeeping requirements that affected the activities of physicians and researchers, and to giving the attorney general the ultimate authority to classify drugs.[104] Later (June), physicians and scientists on the staff of NIMH and other HEW institutes signed a letter to Representative John Jarman (D., OK), chair of the House Subcommittee on Public Health and Welfare, that reiterated these objections.[105] The position of the Department of Justice was that the proposed law was meant only as a law enforcement measure, not as an all-encompassing solution to the drug problem, and that "researchers are not *sui generis* and must be held to the same high standards of others engaged in handling controlled dangerous substances."[106]

The administration did what it could to contribute to the ultimate triumph of Justice as the agency responsible for the bulk of narcotics control efforts. As will be discussed in greater detail, what was perceived at the White House as re-

President Nixon and Elvis Presley discuss drug policy while presidential aide Egil Krogh takes notes, December 1970. (Nixon Project, National Archives.)

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calcitrance and disloyalty at HEW precipitated the departure under duress of three of that department's leaders in May and June. Public concern about both drug abuse and crime was rising at the time, which fact served to strengthen further the nearly instinctive preference of both the president and his staff for dealing with the Justice Department over HEW. The situation was made even more difficult by the fact that Republicans had a history of opposing transfer of drug control authority to Justice: they had, by and large, voted against moving all drug-related agencies (including HEW's BDAC) into the Justice Department in 1968, whereas Democrats had generally favored this reorganization. One possible explanation for this is that Republicans feared placing such responsibilities in the hands of President Johnson's attorney general, Ramsey Clark.[107] They had no such fears with respect to John Mitchell.[108]

In the House of Representatives, the conflict between proponents of locating the major thrust of drug control efforts in the Justice Department and advocates of the primacy of the health bureaucracy continued unabated through the spring and summer of 1970. The administration's bill had been introduced in the House in September 1969 as two bills (H.R. 13742 and H.R. 13743) because of disagreements over which committee should receive it, Ways and Means—which could be expected to favor Justice—or Interstate Commerce, whose health subcommittee was determined to include a title granting expanded research, education, and treatment resources to HEW. Both committees held hearings and executive sessions on the bills beginning in February 1970 while the Justice Department maneuvered to help Ways and Means gain control of the issue and to thwart Democratic support of HEW in the commerce committee. The situation was summed up by a Justice Department official as follows:

> [The health subcommittee of Interstate Commerce] displayed an antagonism toward the Administration's approach to drug control. Congressman Rogers, supported by other Democrats, indicated a clear intent to minimize the Attorney General's role in any legislation they acted upon.
>
> After a considerable lack of progress in getting the subcommittee to see our viewpoint in executive sessions, two steps became necessary:
>
> 1. Introduction of S. 3246 in a slightly revised version (H.R. 17463) by Chairman [Wilbur] Mills, at the Attorney General's request [6 May 1970]. . . .
>
> The real turning point occurred in July, 1970, when the Attorney General met with Chairman Mills and received the latter's promise to schedule hearings on H.R. 17463 and give the Department what it needed. Cooperation became more pronounced in the Commerce Subcommittee, which finally recommended to the full Committee a clean bill (H.R. 18583) on 7/22/70, just two days after Ways and Means began its hearings on H.R. 17463.[109]

The bill (H.R. 18583), containing elements of all three of its predecessors, was reported out of committee on 10 September. The measure still contained Title I, dealing with research and rehabilitation resources for the National Institute of Mental Health, and it divided narcotics and dangerous drugs into five schedules instead of the original four. This seems to have occurred because of Senator Dodd's insistence on including Librium and Valium among the dangerous drugs and because of pressure from the manufacturer of those drugs, Hoffman LaRoche, which did not want its products put into the same schedule as amphetamines and barbiturates.[110]

The Comprehensive Drug Abuse Prevention and Control Act of 1970 was finally approved by the conference of both houses on 13 October after some weeks of new attempts to include amendments favorable to HEW. One of these called for the creation of a new Institute for the Prevention and Treatment of Drug Abuse and Drug Dependence. The amendment was defeated, but the idea of the institute became a sort of "thing that wouldn't die": it came up again when the administration sought legislation creating the Special Action Office for Drug Abuse Prevention and, as will be seen, eventually took shape as the National Institute on Drug Abuse. The legislation in its final form did not include Librium or Valium at all, and the administration had to accede to inclusion of Title I, granting new money to community mental health centers administered by HEW and authorizing a number of grants for research and education. It was signed by the president on 27 October 1970.

With this legislation on the books, administration policy makers could devote their energies to the third aspect of drug abuse control—treatment and rehabilitation. The next major effort at crime control through a drive against drugs, the Office of Drug Abuse Law Enforcement, would emerge in late 1971. Its development would be motivated by organizational and political necessities similar to those that led to the establishment of the Special Action Office of Drug Abuse Prevention.

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1971," Box 32, Egil Krogh files, WHSF, Nixon Presidential Materials Staff, National Archives.

52. F. Belair, Jr., "C.I.A. Identifies 21 Opium Refineries," *New York Times,* 6 June 1971.
53. F. Belair, Jr., "C.I.A. Identifies 21 Opium Refineries," *New York Times,* 6 June 1971.
54. A.W. McCoy, *The Politics of Heroin: CIA Complicity in the Global Drug Trade* (Brooklyn, NY: Lawrence Hill Books, 1991), p. 385.
55. "Use of heroin by U.S. servicemen in Vietnam has allegedly reached crisis proportions and threatens to disrupt the Administration's Vietnamization policy." Undated memorandum bearing title "Drugs," folder: "[FY19]73 Initiatives [1971]," Box 32, Egil Krogh files, WHSF, Nixon Presidential Materials Staff, National Archives. "[President:] Maybe the war hypo's narcotics—may find answers earlier—A by-product of war. Must have an answer—will kill us re foreign policy." Papers of the Nixon White House, 1969–1974, Part III: John Erlichman: Notes of Meetings with the President 1969–1973, Microfiche (Frederick, MD: University Publications of America, 10 June 1971, 3-32-E10.
56. J. Ingersoll, Testimony, Narcotics Research, Rehabilitation and Treatment, Hearings, U.S. Congress, House of Representatives, Select Committe on Crime, 92nd Congress, 1st Session, 2, 3, 4, and 23 June 1971, pp. 345–389.
57. This imperative is recorded in John Ehrlichman's meeting notes from 27 May 1971 (Papers of the Nixon White House, 1969–1974, Part III: John Ehrlichman: Notes of Meetings with the President, 1969–1973, Microfiche [Frederick, MD: University Publications of America, 1987–1991], 3-32-E10), 28 May (3-32-F13), and 10 June (3-34-A13) and was publicly expressed by the president in a news conference reported in the *New York Times* on 2 June. The 10 June notes also indicate that the president expressed the opinion that a higher percentage of students at Ivy League schools used drugs than did soldiers in Vietnam. Egil Krogh observed that the drugs of choice in the two situations were not the same.
58. See, for example, Ehrlichman meeting notes dated 10 June 1971 in which John Ingersoll, director of BNDD, is referred to as "pedestrian," which is followed by the remark "Maybe he has to go" and the comment "No confidence in HEW." Papers of the Nixon White House, 1969–1974, Part III: John Erlichman: Notes of Meetings with the President, 1969–1973, Microfiche (Frederick, MD: University Publications of America, 1987–1991), 10 June 1971, 3-34-A13.
59. Memorandum, from Egil Krogh to the president through John Ehrlichman, 27 May 1971, folder: "Meeting with President, Top Civilian and Military Leaders, Thursday, June 3, 1971," Box 32, Egil Krogh files, WHSF, Nixon Presidential Materials Staff, National Archives.
60. Telephone conversation with Walter Minnick, June 1994.
61. Telephone conversation with Walter Minnick, June 1994.
62. Briefing by Nelson Gross cited in Task Force on Federal Heroin Addiction Programs, *Federal Drug Abuse Programs* (Washington, DC: Drug Abuse Council, 1972), p. 26.
63. Letter, Egil Krogh for Robert G. Neumann, 19 January 1972, "Chron Files 1972–73," Box 5, Egil Krogh files, WHSF, Nixon Presidential Materials Staff, National Archives.
64. B. Welles, "House Member Charges Narcotics Smuggling Inquiry Touches 'Highest Levels' of Panama Government," *New York Times,* 16 March 1972.

65. B. Welles, "House Member Charges Narcotics Smuggling Inquiry Touches 'Highest Levels' of Panama Government," *New York Times,* 16 March 1972.
66. Memorandum, Richard M. Nixon for John Ehrlichman, John Mitchell, Henry Kissinger, and Elliot Richardson (in Secretary Rogers's absence), 22 September 1969, folder: "Heroin/Turkey—1969," Box 30, Egil Krogh files, WHSF, Nixon Presidential Materials Staff, National Archives.
67. Memorandum, Will Wilson to the Attorney General, 13 March 1969, folder: "Administration Drug Bill [4 of 5]," Box 27, John W. Dean III files, WHSF, Nixon Presidential Materials Staff, National Archives.
68. Memorandum, Will Wilson for the Attorney General, 13 March 1969, folder: "Administration Drug Bill [4 of 5]," Box 27, John W. Dean III files, WHSF, Nixon Presidential Materials Staff, National Archives.
69. Summary of HEW Staff Views on Justice Draft Bill, "Controlled Dangerous Substances Act of 1969," folder: "Administration Drug Bill [3 of 5]," Box 27, John W. Dean III files, WHSF, Nixon Presidential Materials Staff, National Archives.
70. Memorandum, M.R. Sonnenreich for John W. Dean III, 7 May 1969, folder: "Administration Drug Bill [4 of 5]," Box 27, John W. Dean III files, WHSF, Nixon Presidential Materials Staff, National Archives. Emphasis in original.
71. Letter, Richard H. Poff for John N. Mitchell, 21 May 1969, folder: "Administration Drug Bill [3 of 5]," Box 27, John W. Dean III files, WHSF, Nixon Presidential Materials Staff, National Archives.
72. Memorandum, Michael R. Sonnenreich to John W. Dean III, 9 June 1969, file: "Administration Drug Bill [3 of 5]," Box 27, John W. Dean III files, WHSF, Nixon Presidential Materials Staff, National Archives.
73. Memorandum, John W. Dean III for the Attorney General, 2 July 1969, folder: "Administration Drug Bill [4 of 5]," Box 27, John W. Dean III files, WHSF, Presidential Materials Staff, National Archives.
74. Memorandum, Patrick J. Buchanan for the President, 8 July 1969, folder: "Beginning July 6th," Box 78, President's Office files, President's Meeting files, WHSF, Nixon Presidential Materials Staff, National Archives.
75. Gallup Organization, National Adult Survey, 27 May 1969.
76. Loose sheet of opinion poll data, Box 12, President's Handwriting file, President's Office file, WHSF, Nixon Presidential Materials Staff, National Archives.
77. Memorandum, M. Sonnenreich for J.W. Dean, 22 April 1969, folder: "Administration Drug Bill [3 of 5]," Box 27, John W. Dean III files, WHSF, Nixon Presidential Materials Staff, National Archives.
78. "Text of Nixon's Message to Congress Proposing 10 Steps in Fight on Narcotics," *New York Times,* 15 July 1969, p. 18.
79. *Congressional Quarterly Almanac* (Washington, DC: Congressional Quarterly News Features, 1969), p. 707.
80. Michael R. Sonnenreich, "The Controlled Dangerous Substances Act of 1969, *Status Quo Ante* or Beyond?" in *Communication and Drug Abuse: Proceedings of the Second Rutgers Symposium on Drug Abuse,* ed. J.R. Wittenborn et al. (Springfield, IL: Charles C. Thomas, 1969), p. 497.

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81. *Congressional Quarterly Almanac* (Washington, DC: Congressional Quarterly News Features, 1969), p. 708.
82. U.S. Congress, Senate, 91st Congress, 1st Session, Report No. 91-613, Controlled Dangerous Substances Act of 1969 (Washington, DC: GPO, 1969), esp. p. 1 and p. 8.
83. Memorandum, John Ehrlichman for Bud Krogh, 20 October 1969, folder: "Oversized Attachments OA2776—Part I," Box 59, Egil Krogh files, WHSF, Nixon Presidential Materials Staff, National Archives.
84. *Public Papers of the Presidents of the United States: Richard Nixon* (Washington, DC: Federal Register Division, National Archives and Records Service, 1974), p. 834.
85. Task Force Report: Narcotics, Marijuana and Dangerous Drugs—Findings and Recommendations, 6 June 1969, folder: "Ex FG 221-28 Narcotics, Marijuana and Dangerous Drugs [1969–70]," Box 5, FG221 Task Forces, WHCF, Nixon Presidential Materials Staff, National Archives.
86. Letter, David M. Kennedy and John N. Mitchell for the President, 6 June 1969, folder: "Ex FG 221-28 Narcotics, Marijuana and Dangerous Drugs [1969–70]," Box 5, FG 221 Task Forces, WHCF, Nixon Presidential Materials Staff, National Archives.
87. In May of 1969, 15 percent of those polled by Gallup cited this as the nation's most important problem, up from 3 percent in January and 11 percent in February.
88. Special Presidential Task Force Relating to Narcotics, Marijuana and Dangerous Drugs, *Task Force Report: Narcotics, Marijuana and Dangerous Drugs—Findings and Recommendations,* 6 June 1969, p. 7, folder: "Ex FG 221-28 Narcotics, Marijuana and Dangerous Drugs [1969–70]," Box 5, FG 221 "Task Forces," WHCF, Nixon Presidential Materials Staff, National Archives.
89. Special Presidential Task Force Relating to Narcotics, Marijuana and Dangerous Drugs, *Task Force Report: Narcotics, Marijuana and Dangerous Drugs—Findings and Recommendations,* 6 June 1969, p. 7, folder: "Ex FG 221-28 Narcotics, Marijuana and Dangerous Drugs [1969–70]," Box 5, FG 221 "Task Forces," WHCF, Nixon Presidential Materials Staff, National Archives, p. 12.
90. Special Presidential Task Force Relating to Narcotics, Marijuana and Dangerous Drugs, *Task Force Report: Narcotics, Marijuana and Dangerous Drugs—Findings and Recommendations,* 6 June 1969, p. 7, folder: "Ex FG 221-28 Narcotics, Marijuana and Dangerous Drugs [1969–70]," Box 5, FG 221 "Task Forces," WHCF, Nixon Presidential Materials Staff, National Archives, p. 15.
91. Memorandum, Richard Nixon for various cabinet officers, 27 June 1969, folder: "Ex FG 221-28 Narcotics, Marijuana and Dangerous Drugs [1969–70]," Box 5, FG 221 "Task Forces," WHCF, Nixon Presidential Materials Staff, National Archives.
92. *Time,* 29 August 1969, p. 32.
93. F. Belair, "Mexico Is Asked to Help Combat Drug Smuggling." *New York Times,* 9 September 1969, p. 1; Special Presidential Task Force Relating to Narcotics, Marihuana and Dangerous Drugs, *Task Force Report: Narcotics, Marijuana and Dangerous Drugs—Findings and Recommendations,* 6 June 1969, folder: "Ex FG 221-28 Narcotics, Marijuana and Dangerous Drugs [1969–70], Box 5, FG 221 "Task Forces," WHCF, Nixon Presidential Materials Staff, National Archives.
94. Memorandum, Herbert G. Klein for the president, 13 September 1969, folder: "[Ex] HE5-1 7/1/69–12/31/69," Box 17, Subject Files, HE (Health), WHCF, Nixon Presidential Materials Staff, National Archives.

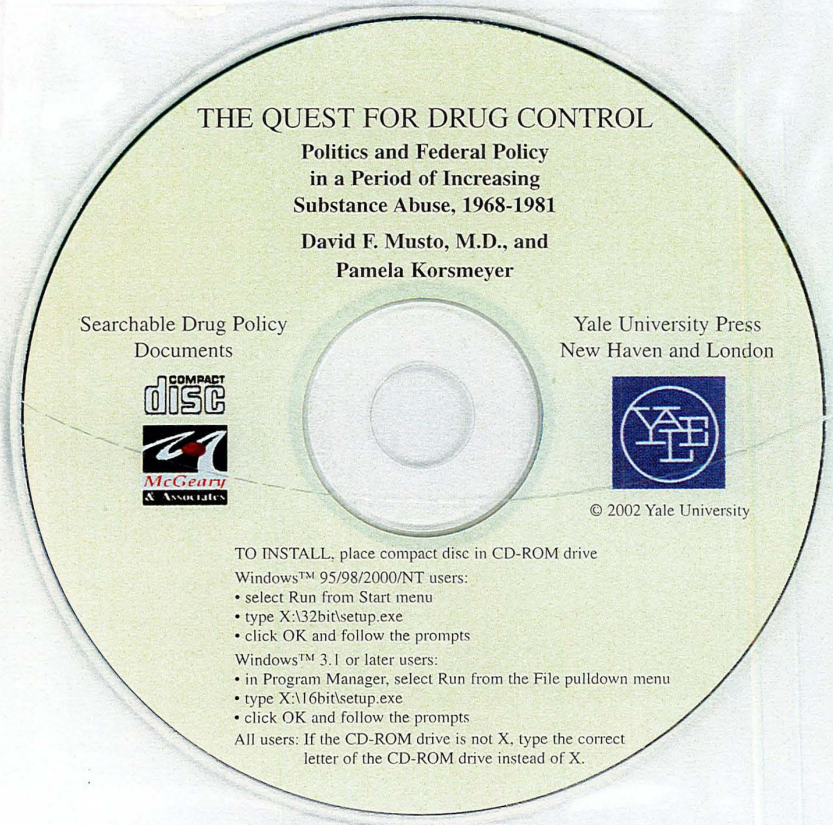
95. Memorandum, Herbert G. Klein for the president, 13 September 1969, folder: "[Ex] HE5-1 7/1/69–12/31/69," Box 17, Subject Files, HE (Health), WHCF, Nixon Presidential Materials Staff, National Archives.
96. Transcript, The Streets of Laredo, Radio Station KVOZ, 1 October 1969, folder: "[Ex] HE 5-1 7/1/69–12/31/69," Box 17, Subject Files, HE (Health), WHCF, Nixon Presidential Materials Staff, National Archives.
97. Memorandum with attachment, Tom Whitehead for Egil Krogh, 29 September 1969, folder: "Anti-Smuggling Supplem. Appropriats. [1969]," Box 30, Egil Krogh files, WHSF, Nixon Presidential Materials Staff, National Archives.
98. Report, Myles J. Ambrose for Mr. Richard G. Kleindienst, Deputy Attorney General, Mr. Eugene T. Rossides, Assistant Secretary of the Treasury, Co-Chairmen, The President's Task Force on Narcotics, Marihuana and Dangerous Drugs, 6 October 1969, folder: "Report to the President on Operation Intercept," Box 53, Egil Krogh files, WHSF, Nixon Presidential Materials Staff, National Archives.
99. Report, Myles J. Ambrose for Mr. Richard G. Kleindienst, Deputy Attorney General, Mr. Eugene T. Rossides, Assistant Secretary of the Treasury, Co-Chairmen, The President's Task Force on Narcotics, Marihuana and Dangerous Drugs, 6 October 1969, folder: "Report to the President on Operation Intercept," Box 53, Egil Krogh files, WHSF, Nixon Presidential Materials Staff, National Archives, p. 11.
100. Report, Myles J. Ambrose for Mr. Richard G. Kleindienst, Deputy Attorney General, Mr. Eugene T. Rossides, Assistant Secretary of the Treasury, Co-Chairmen, The President's Task Force on Narcotics, Marihuana and Dangerous Drugs, 6 October 1969, folder: "Report to the President on Operation Intercept," Box 53, Egil Krogh files, WHSF, Nixon Presidential Materials Staff, National Archives, p. 12.
101. Memorandum, Egil Krogh for John Ehrlichman and Kenneth Cole, 28 July 1969, folder: "Oversized Attachments OA 2776—Part I," Box 59, Egil Krogh files, WHSF, Nixon Presidential Materials Staff, National Archives.
102. A number of authors have discussed Nixon's abandonment of his cabinet beginning toward the end of 1969. See especially Shirley Ann Warshaw, "The Implementation of Cabinet Government During the Nixon Administration," in *Richard M. Nixon: Politician, President, Administrator,* ed. L. Friedman and W.E. Levantrosser (New York: Greenwood Press, 1991), pp. 331–350; Tom Wicker, *One of Us: Richard Nixon and the American Dream* (New York: Random House, 1991); and Michael Genovese, *The Nixon Presidency: Power and Politics in Turbulent Times* (New York: Greenwood Press, 1990), pp. 24, 29, 30, 32, 73.
103. U.S. Congress, Senate, 91st Congress, 1st Session, Report No. 91-613, Controlled Dangerous Substances Act of 1969 (Washington, DC: GPO, 1969), p. 1.
104. Memorandum, M.R. Sonnenreich for John W. Dean III, 28 April 1970, folder: "Administration Drug Bill [4 of 5]," Box 27, John W. Dean III files, WHSF, Nixon Presidential Materials Staff, National Archives.
105. "200 HEW Scientists Urge Defeat of Drug-Control Bill," *Hospital Tribune,* 1 June 1970.

106. Memorandum, M.R. Sonnenreich to Egil Krogh, 2 February 1970, folder: "(Controlled Dangerous Substances Act?)," Box 39, Egil Krogh files, WHSF, Nixon Presidential Materials Staff, National Archives.
107. Handwritten notes, [May 1970], folder: "Administration Drug Bill [5 of 5]," Box 28, John W. Dean III files, WHSF, Nixon Presidential Materials Staff, National Archives.
108. *Food Drug and Cosmetics Report,* 11 May 1970, folder: "Administration Drug Bill [4 of 5]," Box 27, John W. Dean III files, WHSF, Nixon Presidential Materials Staff, National Archives. See also Memorandum, President's Advisory Council on Executive Organization, 27 January 1970, folder: "LEN 1-2-2," Box 42, PACEO files, WHCF, Nixon Presidential Materials Staff, National Archives: "Underlying the opposition to the 1968 reorganization was the desire of the Treasury appropriations committees in Congress to retain supervision of narcotics matters and the belief, particularly among Republicans, that the Justice Department under Attorney General Ramsey Clark was soft on crime. The vote on the reorganization followed party lines. 166 Republicans opposed the reorganization and only 8 supported it. 192 Democrats supported the reorganization and 24 opposed it. It was approved 200 to 190."
109. Memorandum, Stanley Ebner for Wallace H. Johnson, 30 September 1970, folder: "Administration Drug Bill [2 of 5]," Box 2, John W. Dean III files, WHSF, Nixon Presidential Materials Staff, National Archives.
110. Memorandum, John Dean for the Attorney General, 10 September 1970, folder: "Administration Drug Bill [2 of 5]," Box 2, John W. Dean III files, WHSF, Nixon Presidential Materials Staff, National Archives.

CHAPTER 3. THE FIRST NIXON ADMINISTRATION: TREATMENT AND REHABILITATION

1. It is also true that in late 1969 the administration needed to justify its retreat from the harsh penalty structure it had originally included in the Comprehensive Drug Abuse Prevention and Control Act.
2. P. Grose, "Governors See Simulated 'Trip' at Nixon Presentation on Drugs," *New York Times,* 4 December 1969.
3. Memorandum, John G. Veneman, Acting Secretary of HEW for the President, 13 November, 1969, folder: "Oversized Attachments OA 2776, Part I," Box 59, Egil Krogh files, WHSF, Nixon Presidential Materials Staff, National Archives.
4. Memorandum, Egil Krogh for John Ehrlichman, 4 December 1969, folder: "Oversized Attachments OA 2776—Part I," Box 59, Egil Krogh files, WHSF, Nixon Presidential Materials Staff, National Archives.
5. Of the six issues cited as the most important problem facing the United States at the time by respondents to the Gallup survey, drugs moved from fifth place in January 1970 to third place in December. The Vietnam War remained in first place throughout the year. The cost of living declined from second to fourth place. The civil rights movement and crime began the year in third and fourth place respectively and ended the period tied for fifth. Student unrest occupied sixth place in January and second place in December.
6. Memorandum, Egil Krogh for John Ehrlichman and Kenneth Cole, 28 July 1969, folder: "Oversized Attachments OA 2776—Part I," Box 59, Egil Krogh files, WHSF, Nixon Presidential Materials Staff, National Archives.

7. Memorandum, Bud Wilkinson for Egil Krogh, 26 February 1970, folder: "LEN 6-4 [1 of 2]," Box 44, PACEO files, WHCF, Nixon Presidential Materials Staff, National Archives.
8. Memorandum for the record, 26 March 1970, "Drug Abuse Study Interview, Mr. Jim Atwater, Special Assistant to the President, Interviewer: Mr. John J. Cohressen," folder: "LEN 6-4 [1 of 2]," Box 44, PACEO files, WHCF, Nixon Presidential Materials Staff, National Archives: "Mr. Atwater related that HEW's funds had been frozen as part of the cut down on federal spending, and that subsequently, BoB or someone decided that the funds could be unfrozen. Bud Wilkinson, and apparently Bud Krogh, had withheld permission to release funds for the programs because they found that the NIMH and OE [Office of Education] programs were not formulated within the Administration's thinking. NIMH had not clarified exactly what they had wanted to do; their thinking appeared to change easily; and each new idea was dependent on unclear variables. OE had a plan to set up six intensive drug education programs in communities with significant drug abuse problems as an experiment to decide what in fact was the best approach to preventive education. Here political considerations entered into having a campaign which would go into many more communities across the Country."
9. Memorandum, Charles Wilkinson to Egil Krogh, 26 February 1970, folder: "LEN 12-3," Box 45, PACEO files, WHCF, Nixon Presidential Materials Staff, National Archives.
10. Memorandum for the record, from the Drug Abuse Study Group of PACEO, 13 April 1970, folder: "LEN 6-4 [1 of 2]," Box 44, PACEO files, WHCF, Nixon Presidential Materials Staff, National Archives.
11. Memorandum, Drug Abuse Study Group for the President's Advisory Council on Executive Organization, 20 May 1970, folder: "LEN 13-3 [1 of 3]," Box 49, PACEO files, WHCF, Nixon Presidential Materials Staff, National Archives.
12. Memorandum, Drug Abuse Study Group for the President's Advisory Council on Executive Organization, 20 May 1970, folder: "LEN 13-3 [1 of 3]," Box 49, PACEO files, WHCF, Nixon Presidential Materials Staff, National Archives.
13. Memorandum, Drug Abuse Study Group for the President's Advisory Council on Executive Organization, 20 May 1970, folder: "LEN 13-3 [1 of 3]," Box 49, PACEO files, WHCF, Nixon Presidential Materials Staff, National Archives.
14. Memorandum, Drug Abuse Study Group for the President's Advisory Council on Executive Organization, 20 May 1970, folder: "LEN 13-3 [1 of 3]," Box 49, PACEO files, WHCF, Nixon Presidential Materials Staff, National Archives.
15. Memorandum for the record, 6 April 1970, folder: "LEN 6-4 [2 of 2]," Box 44, PACEO files, WHCF, Nixon Presidential Materials Staff, National Archives.
16. Health Program Analysis: Five-Year Program Plan for the Prevention and Treatment of Narcotic and Drug Abuse, August 1967, folder: "Len 12-8," Box 49, PACEO files, WHCF, Nixon Presidential Materials Staff, National Archives.
17. R.D. Lyons, "U.S. Health Aide Is Out in Dispute," *New York Times,* 3 June 1970, p. 1.
18. R.D. Lyons, "U.S. Health Aide Is Out in Dispute," *New York Times,* 3 June 1970, p. 1.


THE QUEST FOR DRUG CONTROL
Politics and Federal Policy
in a Period of Increasing
Substance Abuse, 1968-1981
David F. Musto, M.D., and
Pamela Korsmeyer
Searchable Drug Policy
Documents
COMPACT
disc
McGeary
& Associates
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TO INSTALL, place compact disc in CD-ROM drive
Windows™ 95/98/2000/NT users:
• select Run from Start menu
• type X:\32bit\setup.exe
• click OK and follow the prompts
Windows™ 3.1 or later users:
• in Program Manager, select Run from the File pulldown menu
• type X:\16bit\setup.exe
• click OK and follow the prompts
All users: If the CD-ROM drive is not X, type the correct
letter of the CD-ROM drive instead of X.

UNITED STATES GOVERKNMENT DEPARTMENT OF JUSTICE

Memorandum

To : Mr. John W. Dean, III
Associate Deputy Attorney General
DATE: April 17, 1970

FROM : Mr. Michael R. Sonnenreich
Deputy Chief Counsel

SUBJECT: Proposed Changes in S.3246, the Controlled Dangerous Substances Act.

As a follow up to my memorandum of April 8, 1970, enclosed is a final copy of those changes which I feel need to be made in S.3246, the Controlled Dangerous Substances Act.

1. On page 6, beginning with line 20, delete all through line 22.

2. On page 7, beginning with line 21, delete all through line 2 on page 8 and insert in lieu thereof the following:

> "'Dispense' means to distribute a controlled dangerous substance to an ultimate user or human research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for such distribution. 'Dispenser' is a practitioner who distributes a controlled dangerous substance to an ultimate user or human research subject.".

3. On page 8, beginning with line 3, delete all through line 5 and insert in lieu thereof the following:

> "'Distribute' means the actual, constructive, or attempted transfer of a controlled dangerous substance, whether or not there exists an agency

relationship. 'Distributor' means a person who actually or constructively transfers, or attempts to transfer, a controlled dangerous substance, whether or not there exists an agency relationship.".

4. On page 12, line 3, immediately after the word "States" change the period to a comma and insert thereafter the words "except as otherwise provided herein.".

5. On page 14, line 21, immediately after the word "use" insert the words "in treatment".

6. On page 14, line 25, delete the word "substances" and insert in lieu thereof the word "opiates".

7. On page 15, line 19, delete the word "Diethyliambutene" and insert in lieu thereof the word "Diethylthiambutene". On line 22, delete the word "Dimethyliambutene" and insert in lieu thereof the word "Dimethylthiambutene".

8. On page 17, beginning with line 1, delete all through line 17 and insert in lieu thereof the following:

(1) Acetorphine.
(2) Acetyldihydrocodeine.
(3) Benzylmorphine.
(4) Codeine methylbromide.
(5) Codeine-N-Oxide.
(6) Cyprenorphine.
(7) Desomorphine.
(8) Dihydro codeine.
(9) Dihydro morphine.
(10) Etorphine.
(11) Heroin.
(12) Hydromorphinol.
(13) Methyldesorphine.
(14) Methylhydromorphine.
(15) Morphine methylbromide.
(16) Morhpine methylsulfonate.
(17) Morphine-N-Oxide.
(18) Myrophine.
(19) Nicocodeine.
(20) Nicomorphine.
(21) Normorphine.
(22) Pholcodine.

(23) Thebacon.

9. On page 18, line 11, delete the word "Tetrahydrocannabinol" and insert in lieu thereof the word "Tetrahydrocannabinols".

10. On page 19, beginning with line 3, delete all through line 13 and insert in lieu thereof the following:

"(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate;

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause 1, except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identifical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecogine.".

11. On page 20, line 23, delete the words "well documented and approved" and insert in lieu thereof the words "currently accepted".

12. On page 25, line 24, delete the word "fifty" and insert in lieu thereof the words "one hundred".

13. On page 26, line 8, immediately after the word "grams" insert a period and delete all thereafter through line 9.

14. On page 41, line 14, delete the words "United States" and insert in lieu thereof the words "continental United States, State of Hawaii, or Puerto Rico from any insular possession or other place subject to the jurisdiction of the United States, or to import or bring into the United States, as defined in subsection 102(z), from any place,".

15. On page 48, beginning with line 1, delete all through line 3, and insert in lieu thereof the following:

> "(2) to import or bring into the continental United States, State of Hawaii, or Puerto Rico from any insular possession or other place subject to the jurisdiction of the United States, or to import or bring into the United States, as defined in subsection 102(z), from any place, a controlled dangerous substance classified in schedules I or II or a narcotic drug classified in schedules III or IV;".

16. On page 50, line 25, delete the words "title II" and insert in lieu thereof "title III".

17. On page 55, line 9, delete the words "(2) or (3)," and insert in lieu thereof the words "(2), (3), or (4),".

On line 10, delete the words "(2) or (3)," and insert in lieu thereof the words "(2), (3), or (4),".

18. On page 56, line 6, immediately after the word "purposes" insert the words "of this section or for purposes".

19. On page 57, lines 16 and 17, delete the words "the commission of the" and insert in lieu thereof the words "his conviction for that".

20. On page 58, line 12, delete the word "an" and substitute in lieu thereof the words "a United States".

21. On page 63, line 4, delete the word "sentences" and insert in lieu thereof the word "sentence".

22. On page 83, line 15, immediately after the word "for" delete the hyphen.

23. On page 88, line 15, immediately after the semicolon delete the word "and". On line 17, delete the period and insert in lieu thereof a semicolon immediately followed by the word "and". Between lines 17 and 18 insert a new subparagraph which reads as follows:

> "(g) an evaluation of the efficacy of existing marihuana laws.".

24. On page 103, line 17, insert new section 908 which reads as follows:

"REPUBLISHING OF SCHEDULES

Sec. 908. The schedules set out in section 202 of this Act shall be up-dated and republished on a semi-annual basis for two years from the effective date of this Act and thereafter on an annual basis.".

25. On page 103, line 18, renumber "Sec. 908" as "Sec. 909". Appropriate changes should be made in the table of contents on page 3 by renumbering "Sec. 908. Effective Date" as "Sec. 909. Effective Date." New section 908 should be reflected as "Sec. 908. Republishing of Schedules.".

Controlled substance	Drug code	Schedule
AH-7921 (3,4-dichloro-N-[(1-dimethylamino)cyclohexylmethyl]benzamide))	9551	I
Acetylmethadol	9601	I
Allylprodine	9602	I
Alphacetylmethadol except levo-alphacetylmethadol	9603	I
Alphameprodine	9604	I
Alphamethadol	9605	I
Betacetylmethadol	9607	I
Betameprodine	9608	I
Betamethadol	9609	I
Betaprodine	9611	I
Dextromoramide	9613	I
Dipipanone	9622	I
Hydroxypethidine	9627	I
Noracymethadol	9633	I
Norlevorphanol	9634	I
Normethadone	9635	I
Racemoramide	9645	I
Trimeperidine	9646	I
1-Methyl-4-phenyl-4-propionoxypiperidine	9661	I
Tilidine	9750	I
Para-Fluorofentanyl	9812	I
3-Methylfentanyl	9813	I
Alpha-methylfentanyl	9814	I
Acetyl-alpha-methylfentanyl	9815	I
Beta-hydroxyfentanyl	9830	I
Beta-hydroxy-3-methylfentanyl	9831	I
Alpha-methylthiofentanyl	9832	I
3-Methylthiofentanyl	9833	I
Thiofentanyl	9835	I
Methamphetamine	1105	II
Methylphenidate	1724	II
Amobarbital	2125	II
Pentobarbital	2270	II
Secobarbital	2315	II
Glutethimide	2550	II
Nabilone	7379	II
1-Phenylcyclohexylamine	7460	II
Phencyclidine	7471	II
Phenylacetone	8501	II
1-Piperidinocyclohexanecarbonitrile	8603	II
Alphaprodine	9010	II
Dihydrocodeine	9120	II
Ecgonine	9180	II
Ethylmorphine	9190	II
Levomethorphan	9210	II
Levorphanol	9220	II
Meperidine	9230	II
Dextropropoxyphene, bulk (non-dosage forms)	9273	II
Levo-alphacetylmethadol	9648	II
Noroxymorphone	9668	II
Racemethorphan	9732	II
Alfentanil	9737	II
Remifentanil	9739	II
Sufentanil	9740	II
Carfentanil	9743	II
Tapentadol	9780	II

The company plans to import the listed controlled substances for the manufacture of analytical reference standards and distribution to their research and forensic customers. Approval of permit application will occur only when the registrant's activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Dated: August 9, 2019.

Neil D. Doherty,

Acting Assistant Administrator.

[FR Doc. 2019–18455 Filed 8–26–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Applications: Bulk Manufacturers of Marihuana

ACTION: Notice of applications.

SUMMARY: The Drug Enforcement Administration (DEA) is providing

notice of certain applications it has received from entities applying to be registered to manufacture in bulk a basic class of controlled substances listed in schedule I. Prior to making decisions on these pending applications, DEA intends to promulgate regulations that govern the program of growing marihuana for scientific and medical research under DEA registration. In addition, this notice informs applicants that they may withdraw their applications if they no longer need to obtain a registration because of the recent amendments made by the Agriculture Improvement Act of 2018 to the definition of marihuana to no longer include ''hemp'' as defined by law.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefor, may file written comments on or objections to the issuance of the proposed registration on or before October 28, 2019.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152–2639. To ensure proper handling of comments, please reference ''Docket No. DEA–392'' in all correspondence, including attachments.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act (CSA) prohibits the cultivation and distribution of marihuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes specified in 21 CFR 1301.33(a), DEA is providing notice that the entities identified below have applied for registration as bulk manufacturers of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic classes, and applicants therefor, may file written comments on or objections to the issuance of the requested registrations, as provided in this notice. This notice does not constitute any evaluation or determination of the merits of the applications submitted.

The applicants plan to manufacture bulk active pharmaceutical ingredients (APIs) for product development and distribution to DEA-registered researchers. If their applications for registration are granted, the registrants would not be authorized to conduct other activity under those registrations, aside from those coincident activities specifically authorized by DEA regulations. DEA will evaluate the applications for registration as bulk manufacturers for compliance with all applicable laws, treaties, and regulations and to ensure adequate safeguards against diversion are in place.

In particular, in accordance with the criteria specified in 21 U.S.C. 823(a), DEA is required, among other things, to maintain ''effective controls against diversion . . . by limiting the . . . bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.'' 21 U.S.C. 823(a); *see* Lyle E. Craker;—Denial of Application, 74 FR 2101, 2118–23, 2127–33 (2009) (''[A]n applicant seeking to become registered to bulk manufacture a schedule I or II controlled substance bears the burden of demonstrating that the existing registered bulk manufacturers of a given schedule I or II controlled substance are unable to produce an adequate and uninterrupted supply of that substance under adequately competitive conditions.''), *pet. for rev. denied, Craker* v. *DEA,* 714 F.3d 17, 27–29 (1st Cir. 2013); *see also* Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 FR 53846, 53847 (Aug. 12, 2016) (''As subsection 823(a)(1) provides, DEA is obligated to register only the number of bulk manufacturers of a given schedule I or II controlled substance that is necessary to 'produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.' '').

Thus, in accordance with the criteria of section 823(a), DEA anticipates evaluating the applications and, of those applications that it finds are compliant with relevant laws, regulations, and treaties, granting the number that the agency determines is necessary to ensure an adequate and uninterrupted supply of the controlled substances at issue under adequately competitive conditions. By registering these additional growers in accordance with the criteria of section 823(a), DEA anticipates that additional strains of marihuana will be produced and made available to researchers. This should facilitate research, advance scientific understanding about the effects of marihuana, and potentially aid in the development of safe and effective drug products that may be approved for marketing by the Food and Drug Administration.

The applicants noticed below applied to become registered with DEA to grow marihuana as bulk manufacturers subsequent to a 2016 DEA policy statement that provided information on how it intended to expand the number of registrations, and described in general terms the way it would oversee those additional growers. Therein, DEA recognized the need to move past the single grower system and register additional growers. DEA has received 33 pending applications, as listed below; the most recent was filed in May 2019. Because the size of the applicant pool is unprecedented in DEA's experience, the Agency has determined that adjustments to its policies and practices with respect to the marihuana growers program are necessary to fairly evaluate the applicants under the 823(a) factors, including 823(a)(1).

In addition, since publication of the 2016 policy statement, the Department of Justice, in consultation with other federal agencies, has been engaged in a policy review process to ensure that the marihuana growers program is consistent with applicable laws and treaties. That review process remains ongoing; however, it has progressed to the point where DEA is able to issue Notices of Application. Over the course of this policy review process, the Department of Justice has also determined that adjustments to DEA's policies and practices related to the marihuana growers program may be necessary. Accordingly, before DEA completes this evaluation and registration process, DEA intends to propose regulations in the near future that would supersede the 2016 policy statement and govern persons seeking to become registered with DEA to grow marihuana as bulk manufacturers, consistent with applicable law.

DEA notes that, as the result of a recent amendment to federal law, certain forms of cannabis no longer require DEA registration to grow or manufacture. The Agriculture Improvement Act of 2018, Public Law 115–334, which was signed into law on December 20, 2018, changed the definition of marihuana under the CSA. As amended, the definition of marihuana no longer includes ''hemp,'' which is defined as ''the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.'' 7 U.S.C. 1639*o*(1). Pursuant to the amended definition, cannabis plant material which contains 0.3 percent or less delta-9 tetrahydrocannabinol (THC) on a dry

weight basis is not a controlled substance and does not require a DEA registration to grow. Accordingly, if any of the below-listed applicants have applied for a DEA registration exclusively for the purpose of growing cannabis that contains no more than 0.3 percent delta-9 THC on a dry weight basis, including cannabis that contains cannabidiol (CBD) and falls below the delta-9 THC threshold, the applicants no longer require DEA registration for that purpose. If desired, these applicants may respond in writing with a request to withdraw their applications. Upon receipt of a request to withdraw an application that is received no later than November 1, 2019, DEA will refund all related application fees paid by the applicant.

In addition, any listed applicants who no longer wish to obtain registration for any other reason may also request to withdraw their application in writing, and DEA will refund all related application fees paid by the applicant, provided the withdrawal is received no later than November 1, 2019. Applicants who wish to withdraw their application may do so by sending a letter to: Drug Enforcement Administration, Attn: Regulatory/DRG, 8701 Morrissette Drive, Springfield, VA 22152–2639.

List of Applications Received

In accordance with 21 CFR 1301.33(a), DEA is providing notice that on the following dates, the following entities applied to be registered as bulk manufacturers of the following basic classes of controlled substances:

Date	Applicant	Address	Controlled substance	Drug Code	Sch.
2/6/17	7218737 Delaware Inc	50 Otis Street, Westborough, MA 01581.	Marihuana	7360	I
5/11/17	A and C Laboratories	155 Federal Street, Suite 700, Boston, MA 02110.	Marihuana extract, Marihuana, Tetrahydrocannabinols.	7350, 7360, 7370	I
2/14/18	Abatin Cultivation Center	2146 Queens Chapel Rd., Washington, DC 20018.	Marihuana extract, Marihuana	7360	I
12/30/16.	Annac Medical Center LLC	5172 W Patrick Lane, Suite 100, Las Vegas, NV 89117–8911.	Marihuana extract, Marihuana	7350, 7360	I
1/4/18	Battelle Memorial Institute	1425 Plain City—Gorgesville Road, Bldg. JS–1–009, Powell, OH 43065–9647.	Marihuana, Tetrahydrocannabinols	7360, 7370	I
3/16/17	Biopharmaceutical Research Company, LLC.	11045 Commercial Parkway, Castroville, CA 95012–3209.	Marihuana extract	7350	I
11/2/16	Cannamed Pharmaceuticals, Inc	27120 Ocean Gateway, Salisbury, MD 21803.	Marihuana extract, Marihuana, Tetrahydrocannabinols.	7350, 7360, 7370	I
3/13/17	Columbia Care NY, LLC	Eastman Business Park, Bldg. 12, 4th Floor, 1669 Lake Ave., Rochester, NY 14615.	Marihuana extract	7350	I
5/3/18	Contract Pharmacal Corp	135 Adams Avenue, Hauppauge, NY 11788.	Marihuana extract, Marihuana, Tetrahydrocannabinols.	7350, 7360, 7370	I
8/2/17	Confederated Tribes of the Colville	P.O. Box 150, 21 Colville Street, Nespelem, WA 99155.	Marihuana,	7360	I
11/10/16.	Fraunhofer USA	Center for Molecular Biotechnology, 9 Innovation Way, Newark, DE 19711.	Marihuana extract	7350	I
7/31/14	Gary Gray DBA Complex Pharmacist Owner.	P.O. Box 2522, 1721 W Burrel Ave., Visalia, CA 93279–2522.	Marihuana, Tetrahydrocannabinols	7360, 7370	I
10/22/18.	GB Sciences, Inc. DBA GB Sciences Nevada, LLC.	3550 W Teco Ave., Las Vegas, NV 89118–6876.	Marihuana extract, Marihuana, Tetrahydrocannabinols.	7350, 7360, 7370	I
4/27/17	Green Leaf Inc	4614 Halibut Point Rd., Sitka, AK 99835.	Marihuana extract, Marihuana, Tetrahydrocannabinols.	7350, 7360, 7370	I
11/23/16.	Hawaii Agriculture Research Institute	94–340 Kunia Road, Kunia, HI 96759–0100.	Marihuana extract	7350	I
8/30/16	Hemp CBD LLC	190 Eagle Ford Dr., Pleasanton, TX 78064.	Marihuana, Tetrahydrocannabinols	7360, 7370	I
5/22/17	JT Medical, LLC	598 South Juniata St., Box 311, Lewistown, PA 17044–0311.	Marihuana extract, Marihuana	7350, 7360	I
5/5/17	Maridose LLC	23378 Barlake Dr., Boca Raton, FL 33433.	Marihuana, Tetrahydrocannabinols	7360, 7370	I
10/3/16	MCRGC LLC	811 Western Ave., Manchester, ME 04351.	Marihuana extract, Marihuana, Tetrahydrocannabinols.	7350, 7360, 7370	I
9/12/16	Medpharm Research, LLC	4880 Havana St., Denver, CO 80239.	Marihuana extract, Marihuana	7350, 7360	I
12/27/18.	MMJ Biopharma Cultivation	14930 Reflection Key Circle, Apt. 2511, Fort Myers, FL 33907.	Marihuana, Tetrahydrocannabinols	7360, 7370	I
1/17/17	Modern Pharmacy, LLC	123 Alton Rd., Miami Beach, FL 33139.	Marihuana extract, Marihuana	7350, 7360	I
4/5/17	National Center for Development of Natural Products.	The University of Mississippi, 135 Coy Waller Lab Complex, P.O. Box 1848, University, MS 38677.	Marihuana extract	7350	I

Date	Applicant	Address	Controlled substance	Drug Code	Sch.
5/2/19	Nuvue Pharma, LLC	4740 Dillion Drive, Pueblo, CO 81008–2112.	Marihuana	7360	I
3/31/17	Pharmacann LLC	1010 Lake St., 2nd Fl., Oak Park, IL 60301–1132.	Marihuana	7360	I
11/8/16	PS Patients Collective, Inc	36555 Bankside Drive, Cathedral City, CA 92234.	Marihuana, Tetrahydrocannabinols	7360, 7370	I
1/13/17	Scientific Botanical Pharmaceutical, Inc.	1225 W Deer Valley Rd., Phoenix, AZ 85027.	Marihuana extract, Marihuana, Tetrahydrocannabinols.	7350, 7360, 7370	I
11/29/16.	Scottsdale Research Institute	1225 W Deer Valley Rd., Phoenix, AZ 85027.	Marihuana extract	7350	I
10/3/16	The Giving Tree Wellness Center	21617 N 9th Avenue, Phoenix, AZ 85027.	Marihuana	7360	I
9/21/18	Trail Blazin' Productions	2005 Division St., Bellingham, WA 98226.	Marihuana	7360	I
2/21/17	Ultra Rich CBD	30 Rockcreek Rd., Orovada, NV 89425.	Marihuana extract	7350	I
11/1/17	University of California, Davis	One Shields Avenue, EH&S Hoagland Hall 276, Davis, CA 95616.	Marihuana	7360	I
2/22/17	University of Massachusetts	80 Campus Center Way, Amherst, MA 01003–9246.	Marihuana extract	7350	I

Dated: August 22, 2019.

Neil D. Doherty,

Acting Assistant Administrator, Deputy Assistant Administrator.

[FR Doc. 2019–18456 Filed 8–26–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; National Medical Support Notice—Part B

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting the Employee Benefits Security Administration (EBSA) sponsored information collection request (ICR) titled, ''National Medical Support Notice—Part B,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before September 26, 2019.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* website at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201907-1210-001* (this link will only become active on the day following publication of this notice) or by contacting Frederick Licari by telephone at 202–693–8073, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–EBSA, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW, Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Frederick Licari by telephone at 202–693–8073, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the National Medical Support Notice—Part B information collection. Section 609 of the Employee Retirement Income Security Act (ERISA) and regulations at 29 CFR 2590.609–2 establish a National Medical Support Notice to provide group health benefits coverage pursuant to Qualified Medical Child Support Orders. Part B, Medical Support Notice to Plan Administrator, is a notice from an employer to a benefits plan administrator to implement coverage of children under ERISA covered group health plans. ERISA section 609(a) authorizes this information collection. *See* 29 U.S.C. 1169(a).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB under the PRA approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1210–0113.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on August 31, 2019. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on March 27, 2019 (84 FR 11573).

Interested parties are encouraged to send comments to the OMB, Office of

GUIDANCE DOCUMENT

Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices

Guidance for Industry

JANUARY 2009

Final

Issued by:

(/regulatory-information/search-fda-guidance-documents/good-reprint-practices-distribution-medical-journal-articles-and-medical-or-scientific-reference)
Office of the Commissioner, Office of Policy, Legislation, and International Affairs, Office of Policy

Additional copies are available from:
Office of Policy, Office of the Commissioner
Food and Drug Administration
White Oak Building 1, Room 4305
10903 New Hampshire Avenue
Silver Spring, MD, 20993
301-796-4830.

This guidance document represents the Food and Drug Administration's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, please contact the appropriate FDA staff.

I. Introduction

This guidance is intended to describe the Food and Drug Administration's (FDA or Agency) current thinking regarding "Good Reprint Practices" with regard to the distribution by a drug or medical device manufacturer (or representative)[1] of medical journal articles and scientific or

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medical reference publications (referred to generally as medical and scientific information) that discuss unapproved new uses[2] for approved drugs[3] or approved or cleared medical devices marketed in the United States to healthcare professionals and healthcare entities.[4]

FDA's guidance documents do not establish legally enforceable rights or responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

Section 401 of the Food and Drug Administration Modernization Act (FDAMA) (21 U.S.C. § 360aaa, § 551, Federal Food, Drug, and Cosmetic Act (FD&C Act)), described certain conditions under which a drug or medical device manufacturer could choose to disseminate medical and scientific information discussing unapproved uses of approved drugs and cleared or approved medical devices to healthcare professionals and certain entities (including pharmacy benefits managers, health insurance issuers, group health plans, and Federal or State governmental agencies). FDAMA section 401 provided that, if these conditions were met, dissemination of such journal articles or reference publications would not be considered as evidence of the manufacturer's intent that the product be used for an unapproved new use. FDA implementing regulations were codified at 21 CFR Part 99.

In 2000, subsequent to a decision by the United States Court of Appeals for the District of Columbia Circuit, FDA published a Notice (65 Fed. Reg. 14286, March 16, 2000) clarifying the applicability of the FDAMA section 401 provision and the FDA implementing regulations. In that Notice, FDA stated that the statute and implementing regulations constituted a "safe harbor" for a manufacturer that complies with them before and while disseminating journal articles and reference publications about "unapproved new uses" of approved or cleared products. If a manufacturer complied with the FDAMA provision, the distribution of such journal articles or reference publications would not be used as evidence of an intent that the product distributed by the manufacturer be used for an unapproved use. The Notice also stated that if a manufacturer chose to disseminate materials but not proceed under FDAMA section 401, that failure would not constitute an independent violation of law but could be used as evidence of a manufacturer's intent that the product be used for an unapproved use.

FDAMA section 401 ceased to be effective on September 30, 2006, and the implementing regulations are no longer applicable. In light of the statute's sunset, FDA is providing its current views on the dissemination of medical journal articles and medical or scientific reference publications on unapproved uses of approved drugs and approved or cleared medical devices to healthcare professionals and healthcare entities.

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III. Purpose

As explained in FDA's March 16, 2000 Notice, the FD&C Act and FDA's implementing regulations generally prohibit manufacturers of new drugs or medical devices from distributing products in interstate commerce for any intended use that FDA has not approved as safe and effective or cleared through a substantial equivalence determination (e.*g*., FD&C Act §§ 505(a), 502(o), 501(f)(1)(B), 301(a) and (d); 21 U.S.C. §§ 355, 352(o), 351(f)(1)(B), 331(a) and (d)). The Agency recognizes the value of having new indications and intended uses for products approved or cleared by FDA and encourages sponsors of medical products to seek such approvals or clearances. An approved new drug that is marketed for an unapproved use is an unapproved new drug with respect to that use. (FD&C Act §§ 505(a), 301(d), 21 U.S.C. 355(a), 331(d)). An approved drug that is marketed for an unapproved use (whether in labeling or not) is misbranded because the labeling of such drug does not include "adequate directions for use" (FD&C Act § 502(f); 21 U.S.C. § 352(f); 21 CFR 201.100(c)(1)). Similarly, a medical device that is promoted for a use that has not been approved or cleared by FDA is adulterated and misbranded.

FDA does recognize, however, the important public health and policy justification supporting dissemination of truthful and non-misleading medical journal articles and medical or scientific reference publications on unapproved uses of approved drugs and approved or cleared medical devices to healthcare professionals and healthcare entities. Once a drug or medical device has been approved or cleared by FDA, generally, healthcare professionals may lawfully use or prescribe that product for uses or treatment regimens that are not included in the product's approved labeling (or, in the case of a medical device cleared under the 510(k) process, in the product's statement of intended uses). These off-label uses or treatment regimens may be important and may even constitute a medically recognized standard of care. Accordingly, the public health may be advanced by healthcare professionals' receipt of medical journal articles and medical or scientific reference publications on unapproved new uses of approved or cleared medical products that are truthful and not misleading.

FDA's legal authority to determine whether distribution of medical or scientific information constitutes promotion of an unapproved "new use," or whether such activities cause a product to violate the FD&C Act has not changed. In recognition of the public health value to healthcare professionals of receiving truthful and non-misleading scientific and medical information, FDA is providing recommendations concerning "Good Reprint Practices" for the dissemination of medical journal articles and medical or scientific reference publications on unapproved uses of drugs and medical devices.[5]

IV. Agency Recommendations for Good Reprint Practices

Scientific and medical information that concerns the safety or effectiveness of an approved drug or approved or cleared medical device for an unapproved new use that is not included in the product's approved labeling or statement of intended uses (including unapproved new uses of approved drugs and approved or cleared devices) is often published in journal articles or

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reference publications. These publications are often distributed by manufacturers to healthcare professionals or healthcare entities. When a manufacturer disseminates such medical and scientific information, FDA recommends that the following principles of "Good Reprint Practices" be followed.

A. Types of Reprints/Articles/Reference Publications

A scientific or medical journal article that is distributed should:

- be published by an organization that has an editorial board that uses experts who have demonstrated expertise in the subject of the article under review by the organization and who are independent of the organization to review and objectively select, reject, or provide comments about proposed articles; and that has a publicly stated policy, to which the organization adheres, of full disclosure of any conflict of interest or biases for all authors, contributors, or editors associated with the journal or organization;
- be peer-reviewed and published in accordance with the peer-review procedures of the organization; and
- not be in the form of a special supplement or publication that has been funded in whole or in part by one or more of the manufacturers of the product that is the subject of the article.

A scientific or medical reference publication that is distributed should not be:

- primarily distributed by a drug or device manufacturer, but should be generally available in bookstores or other independent distribution channels (e.g. subscription, Internet) where medical textbooks or periodicals are sold;
- written, edited, excerpted, or published specifically for, or at the request of, a drug or device manufacturer; or
- edited or significantly influenced by a drug or device manufacturer or any individuals having a financial relationship with the manufacturer.

The information contained in the scientific or medical journal article or reference publication should address adequate and well-controlled clinical investigations that are considered scientifically sound by experts with scientific training and experience to evaluate the safety or effectiveness of the drug or device. These can include historically controlled studies, pharmacokinetic (PK) and pharmacodynamic (PD) studies, and meta-analyses if they are testing a specific clinical hypothesis.[6]

The information must not:

- be false or misleading. For example, a distributed journal article or reference text should not be characterized as definitive or representative of the weight of credible evidence derived from adequate and well-controlled clinical investigations if it is inconsistent with

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that weight of credible evidence or a significant number of other studies contradict the article or reference text's conclusions; should not have been withdrawn by the journal or disclaimed by the author; and should not discuss a clinical investigation where FDA has previously informed the company that the clinical investigation is not adequate and well-controlled; or

- pose a significant risk to the public health, if relied upon.

The following publications are examples of publications that would not be considered consistent with the "Good Reprint Practices" outlined in this guidance:

- letters to the editor;
- abstracts of a publication;
- reports of Phase 1 trials in healthy subjects; or
- reference publications that contain little or no substantive discussion of the relevant investigation or data.

B. Manner in which to Disseminate Scientific and Medical Information

Scientific or medical information that is distributed should:

- be in the form of an unabridged reprint, copy of an article, or reference publication;
- not be marked, highlighted, summarized, or characterized by the manufacturer in any way (except to provide the accompanying disclosures discussed in this section);
- be accompanied by the approved labeling for the drug or medical device;
- be accompanied, when such information exists, by a comprehensive bibliography of publications discussing adequate and well-controlled clinical studies published in medical journals or medical or scientific texts about the use of the drug or medical device covered by the information disseminated (unless the information already includes such a bibliography);
- be disseminated with a representative publication, when such information exists, that reaches contrary or different conclusions regarding the unapproved use; especially those in cases where the conclusions of articles or texts to be disseminated have been specifically called into question by another published article(s) or text(s); and
- be distributed separately from information that is promotional in nature. For example, if a sales representative delivers a reprint to a physician in his office, the reprint should not be physically attached to any promotional material the sales representative uses or delivers during the office visit and should not be the subject of discussion between the sales representative and the physician during the sales visit.[7] Similarly, while reprints may be distributed at medical or scientific conferences in settings appropriate for scientific

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exchange, reprints should not be distributed in promotional exhibit halls or during promotional speakers' programs.

The journal reprint or reference publication should be accompanied by a prominently displayed and permanently affixed statement disclosing:

- that the uses described in the information have not been approved or cleared by FDA, as applicable to the described drug or medical device;
- the manufacturer's interest in the drug or medical device that is the subject of the journal reprint or reference text;
- any author known to the manufacturer as having a financial interest in the product or manufacturer or who is receiving compensation from the manufacturer, along with the affiliation of the author, to the extent known by the manufacturer, and the nature and amount of any such financial interest of the author or compensation received by the author from the manufacturer;[8]
- any person known to the manufacturer who has provided funding for the study; and
- all significant risks or safety concerns known to the manufacturer concerning the unapproved use that are not discussed in the journal article or reference text.

V. Summary

FDA recognizes that the public health can be served when health care professionals receive truthful and non-misleading scientific and medical information on unapproved uses of approved or cleared medical products. Accordingly, if a manufacturer follows the recommendations described in Section IV of this guidance, FDA does not intend to consider the distribution of such medical and scientific information in accordance with the recommendations in this guidance as establishing intent that the product be used for an unapproved new use.[9] However, if a manufacturer engages in other conduct that unlawfully promotes an unapproved use of a medical product -- whether or not the manufacturer also engages in conduct in conformance with the recommendations in this guidance -- such other conduct may result in enforcement action.

Footnotes

[1] As used in this guidance, the term "manufacturer" means a person who manufactures a drug or device or who is licensed by such person to distribute or market the drug or device. The term may also include the sponsor of the approved, licensed, or cleared drug or device.

[2] The terms "unapproved new use", "unapproved use", and "off-label use" are used interchangeably in this guidance to refer to a use of an approved or cleared medical product that is not included in the product's approved labeling or statement of intended uses.

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[3] As used in this guidance, the terms "drug" and "device" includes biological products licensed under Section 351(a) of the Public Health Service Act. *See* 42 U.S.C. § 262(j).

[4] "Healthcare entity" includes hospitals, professional medical organizations, drug formulary committees, and health plans.

[5] FDA has elsewhere stated its views on the dissemination of information regarding unapproved uses in response to requests for scientific or medical information initiated solely by health care professionals. Such prior FDA statements include: 62 Fed. Reg. 64073, 64086, 64091(December 3, 1997), Guidance for Industry, *Industry-Supported Scientific and Educational Activities*, (November 1997) at 64099, available at http://www.fda.gov/cder/guidance/isse.htm and 59 Fed. Reg. 59820, 59823 (November 18, 1994).

[6] In the case of medical devices, journal articles or reference publications discussing significant non-clinical research may be consistent with this guidance.

[7] To the extent that the recipients of such information have questions, the sales representative should refer such questions to a medical/scientific officer or department (see footnote 5), and the officer or department to which the referral is made should be separate from the sales and/or marketing departments.

[8] For purposes of this recommendation, an "author" includes any individual, whether credited in the publication or not, who meets the standards for authorship set forth in the guidelines of the International Committee on Medical Journal Editors' *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication*, section II.A.

[9] Given the sunset of FDAMA § 401, the other elements that comprised § 401 which are not specifically described in this guidance are no longer applicable.

Submit Comments

Submit comments on this guidance document electronically via docket ID: FDA-2013-S-0610 (https://www.regulations.gov/docket?D=FDA-2013-S-0610) - Specific Electronic Submissions Intended For FDA's Dockets Management Staff (i.e., Citizen Petitions, Draft Proposed Guidance Documents, Variances, and other administrative record submissions)

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Rockville, MD 20852

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All comments should be identified with the title of the guidance.

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No. 20-71433

In the United States Court of Appeals
for the Ninth Circuit

SUZANNE SISLEY, M.D.; SCOTTSDALE RESEARCH INSTITUTE, LLC; BATTLEFIELD FOUNDATION, DBA FIELD TO HEALED; LORENZO SULLIVAN; KENDRICK SPEAGLE; GARY HESS,

Petitioners,

v.

U.S. DRUG ENFORCEMENT ADMINISTRATION; WILLIAM BARR, ATTORNEY GENERAL; TIMOTHY SHEA, ACTING ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION,

Respondents

DECLARATION OF MATTHEW C. ZORN

My name is Matthew C. Zorn. I am over the age of 21, of sound mind, and capable of making this declaration. My address is 811 Main Street, Suite 4100, Houston, Texas 77002. I declare under penalty of perjury that the foregoing is true and correct. I am of sound mind, and capable of making this declaration. I have personal knowledge of the facts stated herein.

1. I am an attorney of Yetter Coleman LLP, in Houston, Harris County, Texas. I am licensed to practice law in the State of Texas. I am one of the attorneys for petitioners in *Suzanne Sisley, M.D. v. U.S. Drug Enforcement Administration*, which is pending in the Ninth Circuit Court of Appeals, Case No. 20-71433. I have personal knowledge of the facts stated in this declaration.

2. Included in the Excerpts of Record ("ER") is a true and correct copy of the January 3, 2020 Stephen Zyskiewicz petition.

3. Included in the ER is the DEA Determination denying the Zyskiewicz petition.

4. Included in the ER is a true and correct copy of an email from Stephen Zyszkiewicz to Shane Pennington, dated May 4, 2020.

5. Included in the ER is a true and correct copy of the Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53,688 (Aug. 12, 2016), which was attached to the May 4, 2020 e-mail and April 22, 2020 e-mails. *See* ER 3-4.

6. Included in the ER is a true and correct copy of the Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53,767 (Aug. 12, 2016) *See* ER 3-4.

7. Included in the ER is a true and correct copy of the Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10,499 (Mar. 26, 1992).

8. Included in the ER is a true and correct copy of excerpts from the book R. Bogomolny, M. Sonnenreich & A. Roccograndi, *A Handbook on the 1970 Federal Drug Act: Shifting the Perspective* (Charles C. Thomas 1975) ("Handbook").

9. Included in the ER is a true and correct copy of excerpts from *Commerce, Justice, Science, and Related Agencies Appropriations for Fiscal Year 2019 Hearings*, Subcommittee of the Committee of Appreciations (Apr. 25, 2018).

10. Included in the ER is a true and correct copy of the Letter from bipartisan Members of Congress to Attorney General Sessions and DEA Acting Administrator Dhillon dated September 28, 2018.

11. Included in the ER is a true and correct of excerpts from *Hearing Before the House Committee on the Judiciary*, 116th Cong., 1st Sess. (Feb. 8, 2019).

12. Included in the ER is a true and correct copy of Proposed Recommendations to the Drug Enforcement Administration Regarding the Scheduling Status of Marihuana and Its

Components and Notice of a Public Hearing, 47 Fed. Reg. 28,141 (June 29, 1982).

13. Included in the ER is a true and correct copy of the Schedules of Controlled Substances; Scheduling of 3, 4-Methylenedioxymethamphetamine (MDMA) Into Schedule I of the Controlled Substances Act; Remand, 53 Fed Reg. 5156 (Feb. 22, 1988).

14. Included in the ER is a true and correct copy of the Marijuana Scheduling Petition; Denial of Petition, 54 Fed. Reg. 53,767 (Dec. 29, 1989).

15. Included in the ER is a true and correct copy of the Notice of Denial of Petition, 66 Fed. Reg. 20,038 (Apr. 18, 2001).

16. Included in the ER is a true and correct copy of the Lyle E. Craker; Denial of Application, 74 Fed. Reg. 2,101 (Jan. 14, 2009).

17. Included in the ER is a true and correct copy of the Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552 (July 8, 2011).

18. Included in the ER is a true and correct copy of the Applications to Become Registered Under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 Fed. Reg. 53,846 (Aug. 12, 2016).

19. Included in the ER is a true and correct copy of the Controls to Enhance the Cultivation of Marihuana for Research in the United States, 85 Fed. Reg. 16,292 (Mar. 23, 2020).

20. Included in the ER is a true and correct copy of 116 Cong. Rec. 972-980 (1970).

21. Included in the ER is a true and correct copy of 116 Cong. Reg. 36882 (1970).

22. Included in the ER is a true and correct copy of excerpts from *Controlled Dangerous Substances, Narcotics and Drug Control Laws: Hearings before the Committee on Ways and Means, House of Representatives*, 91st Cong., 2d Sess. (1970).

23. Included in the ER is a true and correct copy of the Letter from bipartisan Senators to Attorney General Jeff Sessions re: Marijuana Research Manufacture Applications NIDA Monopoly dated July 25, 2018.

24. Included in the ER is a true and correct copy of the Letter from bipartisan Members of Congress to Hon. Jeff Sessions dated August 31, 2018.

25. Included in the ER is a true and correct copy of the Letter from Democratic Senators to Secretary Azar, Director of ONDCP Carroll, and DEA Acting Administrator Dhillon dated December 11, 2019.

26. Included in the ER is a true and correct copy of Amended Petition for a Writ of Mandamus filed in *In re Scottsdale Research Institute, LLC*, No. 19-1120 (D.C. Cir. June 11, 2019), Doc. # 1792237.

27. Included in the ER is a true and correct copy of the Letter from bipartisan Members of Congress to DEA Acting Administrator Shea dated August 18, 2020.

28. Included in the ER is a true and correct copy of the Order, *In re Scottsdale Research Institute, LLC*, No. 19-1120 (D.C. Cir. Oct. 18, 2019) Doc. # 1811363.

29. Included in the ER is a true and correct copy of excerpts from *Alcoholism and Narcotics, Hearings on Inquiry into the Problem of Alcoholism and Narcotics (Part 5)*, 91st Cong., 2d Sess. (1970) (statements of Dr. Norris and Sen. Hughes).

30. Included in the ER is a true and correct copy of the *In the Matter of Marijuana Rescheduling Petition*, Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of Administrative Law Judge, Docket No. 86-22 (DOJ Sept. 6, 1988).

31. Included in the ER is a true and correct copy of the press release, Drug Enforcement Administration, *DEA announces steps necessary to improve access to marijuana research* (Aug. 26, 2019).

32. Included in the ER is a true and correct copy of excerpts from *Crime in America—Illicit and Dangerous Drugs, Hearings pursuant to H. Res. 17*, 91st Cong., 1st Sess. (1969).

33. Included in the ER is a true and correct copy of L. Sacco et. al, *The Marijuana Policy Gap and the Path Forward*, Congressional Research Service (Mar. 10, 2017).

34. Included in the ER is a true and correct copy of L. Sacco, *Schedule I Status of Marijuana*, Congressional Research Service (Sept. 11, 2020).

35. Included in the ER is a true and correct copy of B. Erickson, *Cannabis research stalled by federal inaction*, 98 Chem.& Eng. News (June 29, 2020) *available at* https://cen.acs.org/biological-chemistry/natural-products/Cannabis-research-stalled-federal-inaction/98/i25.

36. Included in the ER is a true and correct copy of the FDA Drug Bulletin, Vol. 12, No. 1 (Apr. 1982).

37. Included in the ER is a true and correct copy of the Letter from bipartisan Senators and Members of Congress of the Attorney General Barr, dated Dec. 6, 2019.

38. Included in the ER is a true and correct copy of H. Rep. No. 91-1444 (Part 1) (1970) ("House Report").

39. Included in the ER is a true and correct copy of excerpts from *Part 1, Drug Abuse Control Amendments—1970, Hearing on H.R. 11701 and H.R. 13743*, 91st Cong., 2d Sess. (Feb. and Mar. 1970).

40. Included in the ER is a true and correct copy of excerpts from *Part 2, Drug Abuse Control Amendments—1970, Hearings on H.R. 11701 and H.R. 13743*, 91st Cong., 2d Sess. (Feb. and Mar. 1970).

41. Included in the ER is a true and correct copy of the Response to Mandamus Petition, *In re Scottsdale Research*, No. 19-1120 (D.C. Cir. Aug. 28, 2019), Doc. # 1803993.

42. Included in the ER is a true and correct copy of the Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499-02 (Mar. 26, 1992).

43. Included in the ER is a true and correct copy of *NORML v. DEA*, 1980 U.S. App. LEXIS 13099 (D.C. Cir. Oct. 16, 1980).

44. Included in the ER is a true and correct copy of the OLC Memo, *Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs*, 42 Op. O.L.C. -- (DOJ June 6, 2018).

45. Included in the ER is a true and correct copy of the article Tyler Kingkade, *One doctor vs. the DEA: Inside the battle to study marijuana in America* (Apr. 29, 2020), *available at* https://www.nbcnews.com/news/us-news/one-doctor-vs-dea-inside-battle-study-marijuana-america-n1195436.

46. Included in the ER is a true and correct copy of excerpts from the book G. Posner, *Pharma: Greed, Lies, and the Poisoning of America* (Avid Reader Press / Simon & Schuster 2020).

47. Included in the ER is a true and correct copy of excerpts from the book M. Sonnenreich et al., Handbook of Federal Narcotic and Dangerous Drug Laws (DOJ Jan. 1969) (eBook *available* for free *at* https://books.google.com/books?id=ytW7AAAAIAAJ).

48. Included in the ER is a true and correct copy of excerpts from *Federal Drug Abuse and Drug Dependence Prevention, Treatment, and Rehabilitation Act of 1970, Hearings Before the Special Subcommittee on Alcoholism and Narcotics of the Comm. on Labor and Public Welfare on S. 3562, Pt. 2*, 91st Cong., 2d Sess. (Mar. 1970).

49. Included in the ER is a true and correct copy of Anna L. Schwabe, et al., Research grade marijuana supplied by the National Institute on Drug Abuse is genetically divergent from commercially available Cannabis (Pre-Print), *available at* https://www.biorxiv.org/content/10.1101/592725v1.full.pdf

50. Included in the ER is a true and correct copy of S. Rep. No. 91-613 (1969) ("Senate Report").

51. Included in the ER is a true and correct copy of an Order in *In re Scottsdale Research Institute, LLC,* No. 19-1120 (D.C. Cir. July 29, 2019), Doc. # 1799597.

52. Included in the ER is a true and correct copy of pages from Webster's New Twentieth Century Dictionary (2d ed. 1970).

53. Included in the ER is a true and correct copy of National Conference of State Legislatures, State Medical Marijuana Laws & Table 1 (Mar. 10, 2020) *available at* https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx.

54. Included in the ER is a true and correct copy of the Settlement Agreement in *Scottsdale Research Institute, LLC v. U.S. Drug Enf't Admin.*, 2:20-cv-00605-PHX-JJT (D. Ariz. Apr. 28, 2020).

55. Included in the ER is a true and correct copy of the Rulemaking Petition to Reclassify Cannabis for Medical Use from a Schedule I Controlled Substance to a Schedule II submitted by former Governors Lincoln Chafee and Christine Gregoire dated November 30, 2011.

56. Included in the ER is a true and correct copy of a Letter from DEA Acting Administrator Rosenberg to Gov. Raimondo, Gov. Inslee, and Krumm (Aug. 11, 2016).

57. Included in the ER is a true and correct copy of excerpts from the book D. Musto & P. Korsmeyer, *The Quest for Drug Control: Politics and Federal Policy in a Period of Increasing Substance Abuse, 1968-1981* (Yale Univ. 2002) ("Musto").

58. Included in the ER is a true and correct copy of a PDF printout of an April 17, 1970 memorandum from Michael R. Sonnenreich to John W. Dean, III, that I personally printed out from the full-text database of archival material contained on the CD-ROM accompanying Musto.

59. Included in the ER is a true and correct copy of the Bulk Manufacturer of Controlled Substances Applications: Bulk Manufacturers of Marihuana, 84 Fed. Reg. 44922 (Aug. 27, 2019).

60. Included in the ER is a true and correct copy of FDA, *Good Reprint Practices* (Jan. 2009), http://www.fda.gov/RegulatoryInformation/Guidances/ucml25126.htm.

Under 28 U.S.C. § 1746, I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed in Harris County, State of Texas, on the 29th day of September, 2020.

Matthew C. Zorn

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

SUZANNE SISLEY, M.D. ET AL., *Petitioners,* v. U.S. DRUG ENFORCEMENT ADMINISTRATION, ET AL., *Respondents.*	)	No. 20-71433

DECLARATION OF SUZANNE SISLEY, M.D.

1. I am the President and Founder of Scottsdale Research Institute, LLC ("SRI"). SRI is an Arizona based limited liability company and clinical trials site dedicated to advancing the state of medical care through rigorous research. It is located at 5436 E Tapekim Rd., Cave Creek, AZ 85331 and our website is at http://www.sriresearch.org/. SRI strives to conduct high quality, controlled scientific studies to ascertain the general medical safety and efficacy of cannabis products and examine forms of cannabis administration. SRI does not encourage recreational use of cannabis.

2. I am also a physician licensed to practice medicine in the State of Arizona and am in good standing. I completed my medical degree at the University of Arizona College of Medicine and did my residency at Good

Samaritan Regional Medical Center in the fields of Internal Medicine and Psychiatry. I also served as Clinical Faculty at St. Joseph's Hospital and Medical Center at the MercyCare Adult Medicine Clinic for indigent patients.

3. I have received many honors and awards for my work, both in private practice and in research. For example, in 2001, I won the UA's Leo B. Hart Humanitarian Award from the University of Arizona College of Medicine. I also received the Arizona Medical Association's highest honor, the President's Distinguished Service Award.

4. I have received significant support from patient rights organizations including veteran groups around the country, such as the American Legion. In September 2016, the American Legion passed a resolution in support of our research, urging the DEA to license privately-funded cannabis production to enable safe and efficient cannabis drug development.[1]

Private Practice

5. My private practice of Internal Medicine & Psychiatry has always had a focus on treating veterans as well as underserved populations across Arizona. I treat over 400 patients per month, averaging about 20 patients

[1] See https://archive.legion.org/bitstream/handle/20.500.12203/5763/2016N011.pdf. See also B. Bender, American Legion to Trump: Allow marijuana research for vets, Politico (May 20, 2017).

per day, primarily over telemedicine. The demographic breakdown of my practice is approximately 40% military veterans, 20% police and fire, and 40% patients enrolled with 8 different Native American tribes based in Arizona. My specialties include treating chronic pain, opioid dependence and PTSD.

6. My research interests are directly influenced by my experiences in private practice. More than a decade ago, I began noticing intractable PTSD and a suicide epidemic among veterans first-hand. PTSD is a mental health condition experienced by some who go through traumatic events. Symptoms vary from individual to individual. Common symptoms include anxiety, insomnia, depression, and nightmares. Currently there are limited approved pharmaceutical remedies for PTSD. Only two anti-depressants are approved by the FDA to treat PTSD.2

7. Many of my veteran clients with PTSD did not respond to conventional medications. Some clients told me that using cannabis helped alleviate their symptoms.3 For many, cannabis was the only drug that worked, reversing insomnia or easing depression and anxiety. Patients told

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2 See https://www.youtube.com/watch?v=Idujb84MwPE ("Weed 3") at 3:30 (April 19, 2015).

3 See Weed 3 at 5:00.

me that cannabis effectively quelled nightmares, flashbacks, and hypervigilance.

8. This first-hand experience inspired me to conduct clinical trials on the safety and efficacy of cannabis use to suppress treatment resistant PTSD, which I discussed in CNN's "Weed 3: The Marijuana Revolution,"[4] an April 19, 2015 special report by CNN's chief medical correspondent Dr. Sanjay Gupta.

The Road to Clinical Trials

9. I struggled for seven years to get approval from four different federal agencies to conduct clinical trials of cannabis as a treatment for PTSD symptoms in veterans.

10. In 2009, I began collaborating with the Multidisciplinary Association for Psychedelic Studies (MAPS) on a proposal for the FDA. On Nov. 11, 2010, MAPS' clinical research team submitted our protocol to the FDA, and FDA approval came in April 2011.

[4] Although the video does not appear to be available from CNN, the video is widely available online, for example on YouTube at https://www.youtube.com/watch?v=Idujb84MwPE. I am introduced in the video at 3:30, and our struggle to obtain all the necessary government permissions begins at 5:30.

11. On July 30, 2012, we submitted the protocol to the University of Arizona Institutional Review Board (IRB), which approved the study in October 2012.

12. Shortly after FDA approval, we sent the proposal to NIDA and PHS for approval. After a series of rejections, we finally obtained approval from these agencies around March 2014. That approval was critical because it allowed us to be able to purchase federally legal cannabis from NIDA, the only source of cannabis legal for use in federally regulated research.

13. On April 17, 2014, NIDA informed us that it did not have the cannabis we needed for our study. Shortly after that, NIDA told us that it would have to grow the cannabis we needed for our protocol.

14. In June 2014, I was released by the University of Arizona. They chose not to renew my contract of employment and two other subcontracts. My assistant professorship was terminated. Without an academic appointment, I was unable to continue my research with the university. I discussed this in an interview with CNN's Sanjay Gupta in July 2014.[5]

15. On November 2, 2015, we submitted our protocol to the DEA. As part of the approval process, the DEA inspected SRI. In April 2016, the DEA

[5] The interview is available at https://www.cnn.com/2014/07/12/health/marijuana-researcher-arizona/index.html.

approved my Schedule I license to do research with cannabis, which is still active. That license removed the last barrier to the study.

16. Our phase II clinical trials titled "Placebo-Controlled, Triple-Blind, Randomized Crossover Pilot Study of the Safety and Efficacy of Four Different Potencies of Smoked Marijuana in 76 Veterans with Chronic, Treatment-Resistant Posttraumatic Stress Disorder (PTSD)" began in early 2017, and we concluded it in early 2019. SRI treated 76 participants as part of the study. MAPS sponsored the study and it was funded with a $2.1 million grant from the Colorado Department of Public Health and Environment. The study's protocol is available online.[6]

NIDA Cannabis

17. On August 10, 2016, NIDA approved SRI's request to order 6.3kg of cannabis for our clinical trials. We had requested multiple cannabis strains with varying levels of THC and CBD, including high THC, high CBD, balanced THC/CBD, and placebo. On August 25, 2016, I received the first shipment. The cannabis arrived frozen, in dried bulk form. SRI tested the cannabis at a DEA-licensed laboratory.

[6] See https://www.sriresearch.org/MJP1-A6V1-FINAL-16MAR2017-Web%20(1).html.

18. The NIDA cannabis SRI received looked nothing like commercial grade medical cannabis one can buy from dispensaries states where medicinal cannabis is legal. NIDA cannabis consistently appears to have extraneous material like sticks, stems, and seeds. Many packages looked like the green powder shown below from a 2017 article on pbs.org that I am quoted in:[7]

19. I am also quoted in a 2017 Washington Post article titled "Government marijuana looks nothing like the real stuff. See for yourself," where a side by side comparison of commercial medicinal cannabis and NIDA cannabis can be seen:[8]

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[7] See C. Hellerman "Scientists say the government's only pot farm has moldy samples — and no federal testing standards," PBS (Mar. 8, 2017) (https://www.pbs.org/newshour/nation/scientists-say-governments-pot-farm-moldy-samples-no-guidelines). I took this picture.

[8] See C. Ingraham and T. Chappell, "Government marijuana looks nothing like the real stuff. See for yourself," Washington Post (Mar. 13, 2017) (https://www.washingtonpost.com/news/wonk/wp/2017/03/13/gov

20. In my opinion, both as a researcher and physician, the quality of this cannabis SRI had to use for its clinical trials had an adverse impact on the study results and sometimes on the study subjects. It is also my opinion that the poor quality of this cannabis would have an adverse impact on *any* safety and efficacy study.

21. For example, while conducting SRI's clinical trial, I noticed that bronchial irritation was a common complaint among the study subjects. I believe this side effect could have been mitigated if not eliminated had SRI been able to grow and use its own cannabis (which would have only contained the flowering tops of the plant without the extraneous plant material that can burn more harshly and cause excessive mucosal irritation) or simply if SRI could have used other cannabis that did not have extraneous material and excessively high levels of mold.

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ernment-marijuana-looks-nothing-like-the-real-stuff-see-for-yourself/?utm_term=.2dcae33401d3/).

22. Thus, NIDA cannabis was not only inadequate for the Phase II trial we just completed, but will be inadequate for further studies, such as Phase III clinical trials or other Phase II clinical trials. The presence of sticks, stems, and seeds and significant mold makes this drug unsuitable for clinical research in certain patient populations.

Application to DEA

23. On October 1, 2016, I submitted SRI's application for registration under the Controlled Substances Act. Shortly after, I submitted answers to a supplemental questionnaire.

24. Between the time I filed my application and August 2019, I followed up with the DEA numerous times. I believe I called DEA five times between June 2017 to August 2018. I called both DEA's local office in Arizona and DEA's national office. Each time I called to check in on the status of my application, I was told that nothing regarding my application status had changed.

25. DEA was always very polite but never offered any explanation for the delay. The local DEA office told me that they had no idea when the application would be processed.

26. In an August 30, 2018 e-mail, I wrote to DEA:

> I have contacted my local DEA office regularly asking them the status of our application over the past two years and continue to

> get a vague response saying they have no idea when the application will ever be processed.
>
> Can you provide us another update from the national office on when the applications will be evaluated?
>
> I know we've discussed this on the phone several times over the last few years and I continue to hear from you that you are unsure of when this application above will be assessed. So given the continual uncertainty from your office, I've stopped inquiring with national office because this seemed futile.

27. DEA's Unit Chief Regulatory Unit promptly responded to my August 30, 2018 e-mail. He stated: "The status of the application remains unchanged. The DEA and DOJ are discussing applications involving the bulk manufacture of drug code 7360 for research purposes."

28. DEA's inability to share details about SRI's application confused me. I have had nothing but positive experiences with DEA employees and have maintained good working relationships with local DEA staff. That continues to this day.

29. In Spring 2019, having still heard nothing from DEA substantively responding to my inquiries, I sought legal representation to assist me with the processing of my application. The recent NBCNews article entitled, "One doctor vs. the DEA: Inside the battle to study marijuana in

America," summarizes SRI's successful legal actions against DEA and the current research situation.[9]

30. As of the time of this declaration, SRI's 2016 application to cultivate marijuana to support its clinical research remains pending.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 24, July 2020.

Suzanne Sisley, M.D.

[9] https://www.nbcnews.com/news/us-news/one-doctor-vs-dea-inside-battle-study-marijuana-america-n1195436.

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

SUZANNE SISLEY, M.D. ET AL.,	)	
Petitioners,	)	
v.	)	No. 20-71433
U.S. DRUG ENFORCEMENT ADMINISTRATION, ET AL.,	)	
Respondents.	)	

DECLARATION OF GARY HESS

1. My name is Gary Hess. I am a 42-year-old veteran. I live and work in Louisiana.

2. I served in the Marine Corps from 1998 to 2008, both enlisted and as an officer. As an Infantry Officer from 2004-2008, I saw the heaviest levels of fighting in Iraq. I served as a Mobile Assault Platoon Commander, Scout Sniper Employment Officer, and the Assistant Operations Officer for the Special Operations Training Group.

3. Following my service, I have had a successful career serving as COO for a federal contracting firm, creating and managing an award-winning start-up; and most recently, and serving as the CEO of an Oil and Gas Firm in Southern Louisiana. I currently manage a veteran's non-profit.

4. In 2008, I was honorably discharged with disabilities consisting of Traumatic Brain Injury, chronic pain, and PTSD, among others. I suffered these wounds in combat. For example, while serving in Iraq, I was occupying a house that was hit with a vehicle-born improvised explosive device, decapitating one of the Marines I was with and wounding the remaining three, including myself. Multiple members of my platoon ended their own lives after they returned to civilian life.

5. After 11 years of honorable service, multiple awards for valor, and significant combat trauma, I entrusted the VA to help manage my injuries, as well as the wounds of the Marines who served under my command. I reached out to the VA for help, but it has not been able to effectively treat my symptoms. From 2009 to 2017, I was prescribed the pharmaceutical "combat cocktail." It was a failure.

6. After trying medicinal marijuana, my most distressing and untreatable symptoms abated.

7. I am not able to get medicinal marijuana from the VA nor will the VA discuss medicinal marijuana with me.

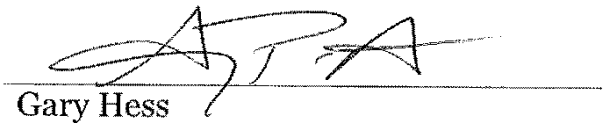
8. In fact, in 2010, after my brother revealed his marijuana use as a self-medicating therapeutic platform to manage his PTSD symptoms, the VA

withheld medications from him, forcing my brother to seek and pay for private care outside of the VA as his health continued to degrade.

9. My struggle is current, it is real, and it is daily.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 28, September 2020.



Gary Hess

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

SUZANNE SISLEY, M.D. ET AL.,	)	
Petitioners,	)	
v.	)	No. 20-71433
U.S. DRUG ENFORCEMENT ADMINISTRATION, ET AL.,	)	
Respondents.	)	

DECLARATION OF KENDRIC SPEAGLE

1. My name is Kendric Speagle. I am a Navy veteran and live in Scottsdale, Arizona. I am CEO of a biotechnology company located in Scottsdale, Arizona that takes new compounds from preclinical development to FDA proof of concept.

2. I joined the Navy in 1993 when I was 19 years old. During my 4 years of service, I worked as an aviation logistician onboard the aircraft carrier USS George Washington, which was forward deployed in the Persian Gulf enforcing No Fly Zones in Southern Iraq and in the Adriatic Sea leading NATO missions over Bosnia Herzegovina.

3. In my late 30's, I began having severe fluctuations in the intra-ocular pressure of my right eye, consistent with glaucoma. I immediately

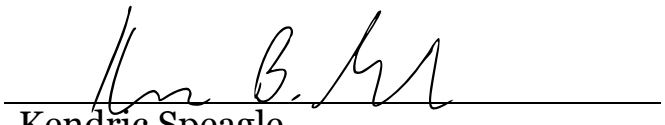
reached out to the VA and inquired about using marijuana to reduce the eye pressure and the painful symptoms. I was told that the VA was legally hamstrung in its ability to either recommend cannabis or provide marijuana for medical purposes. I had surgery and took multiple medications, but nothing seemed to reduce the painful pressure in my right eye.

4. I discovered that marijuana successfully, immediately, and drastically reduced the intra-ocular pressure and pain. Unfortunately, it was too late to prevent an acute episode of glaucoma, which left the muscles in the iris of my right eye completely dead.

5. I believe that had the VA been less encumbered by DEA's classification of marijuana as a schedule I drug, I would have avoided years of pain, and might have the ability to see clearly today.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 28, September 2020.



Kendric Speagle

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

SUZANNE SISLEY, M.D. ET AL., *Petitioners,* v. U.S. DRUG ENFORCEMENT ADMINISTRATION, ET AL., *Respondents.*	)	No. 20-71433

DECLARATION OF L. LORENZO SULLIVAN

1. My name is L. Lorenzo Sullivan. I am currently 73 years old and live in Phoenix, AZ.

2. I retired from a career as an Investment Banker, Registered Investment Advisor and owner, with two partners, of an NASD licensed firm. I have held executive positions with several Fortune 500 companies, including AT&T and AM International. I formerly served on the Board of a private adoption agency, Christian Family Care of Arizona.

3. I am also a US Army veteran, honorably discharged, having served 3 years of active duty, including two years in the Republic of Vietnam. I was a door gunner on medical evacuation helicopters with the 1st Cavalry Division.

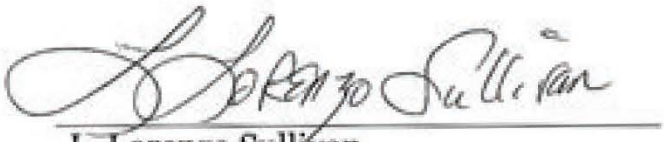
4. I suffer from PTSD. I'm classified by the VA as 85% unemployable and receive disability compensation based on this determination. I have had considerable difficulties with the numerous medications prescribed by the VA. A retired heart surgeon suggested that I explore what potential medicinal cannabis may have for me.

5. Although I am entitled to medical care through the VA, when I attempted to have a conversation with my VA doctor in the mental health department, I was quickly told the VA could not help me. The VA indicated it could not even discuss the risks and benefits of using cannabis with me. Because no VA doctor would discuss the issue with me, I have had to educate myself.

6. I understand that as long as medicinal cannabis remains a Schedule I drug, VA health care providers may not recommend or prescribe it to me or other veterans in treatment.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 24, July 2020.



L. Lorenzo Sullivan