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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e. Dr. John Morgan, psychopharmacologist, Board-certified in Internal Medicine, full Professor and Director of Pharmacology at the City University of New York;

f. Dr. Phillip Jobe, neuropsychopharmacologist with a practice in Illinois and former Professor of Pharmacology and Psychiatry at the Louisiana State University School of Medicine in Shreveport, Louisiana, from 1974 to 1984;

g. Dr. Arthur Kaufman, formerly a general practitioner in Maryland, currently Vice-President of a private medical consulting group involved in the evaluation of the quality of care of all the U.S. military hospitals throughout the world, who has had extensive experience in drug abuse treatment and rehabilitation programs;

h. Dr. J. Thomas Ungerleider, a full Professor of Psychiatry at the University of California in Los Angeles with extensive experience in research on the medical use of drugs;

i. Dr. Andrew Weil, ethnopharmacologist, Associate Director of Social Perspectives in Medicine at the College of Medicine at the University of Arizona, with extensive research on medicinal plants; and

j. Dr. Lester Grinspoon, a practicing psychiatrist and Associate Professor at Harvard Medical School.

36. Certain law enforcement authorities have been outspoken in their acceptance of marijuana as an antiemetic agent. Robert T. Stephan, Attorney General of the State of Kansas, and himself a former cancer patient, said of chemotherapy in his affidavit in this record: "The treatment becomes a terror." His cancer is now in remission. He came to know a number of health care professionals whose medical judgment he respected. They had accepted marijuana

as having medical use in treatment. He was elected Vice President of the National Association of Attorneys General (NAAG) in 1983. He was instrumental in the adoption by that body in June 1983 of a resolution acknowledging the efficacy of marijuana for cancer and glaucoma patients. The resolution expressed the support of NAAG for legislation then pending in the Congress to make marijuana available on prescription to cancer and glaucoma patients. The resolution was adopted by an overwhelming margin. NAAG's President, the Attorney General of Montana, issued a statement that marijuana does have accepted medical uses and is improperly classified at present. The Chairman of NAAG's Criminal Law and Law Enforcement Committee, the Attorney General of Pennsylvania, issued a statement emphasizing that the proposed rescheduling of marijuana would in no way affect or impede existing efforts by law enforcement authorities to crack down on illegal drug trafficking.

37. At least one court has accepted marijuana as having medical use in treatment for chemotherapy patients. On January 23, 1978 the Superior Court of Imperial County, California issued orders authorizing a cancer patient to possess and use marijuana for therapeutic purposes under the direction of a physician. Another order authorized and directed the Sheriff of the county to release marijuana from supplies on hand and deliver it to that patient in such form as to be usable in the form of cigarettes.

38. During the period 1978-1980 polls were taken to ascertain the degree of public acceptance of marijuana as effective in treating cancer and glaucoma patients. A poll in Nebraska brought slightly over 1,000 responses - 83% favored making marijuana available by prescription, 12% were opposed, 5% were undecided. A poll in Pennsylvania elicited 1,008 responses - 83.1% favored availability by prescription, 12.2% were opposed, 4.7% were undecided. These

two surveys were conducted by professional polling companies. The Detroit Free Press conducted a telephone poll in which 85.4% of those responding favored access to marijuana by prescription. In the State of Washington the State Medical Association conducted a poll in which 80% of the doctors belonging to the Association favored controlled availability of marijuana for medical purposes.

Discussion

From the foregoing uncontroverted facts it is clear beyond any question that many people find marijuana to have, in the words of the Act, an "accepted medical use in treatment in the United States" in effecting relief for cancer patients. Oncologists, physicians treating cancer patients, accept this. Other medical practitioners and researchers accept this. Medical faculty professors accept it. Nurses performing hands-on patient care accept it.

Patients accept it. As counsel for CCA perceptively pointed out at oral argument, acceptance by the patient is of vital importance. Doctors accept a therapeutic agent or process only if it "works" for the patient. If the patient does not accept, the doctor cannot administer the treatment. The patient's informed consent is vital. The doctor ascertains the patient's acceptance by observing and listening to the patient. Acceptance by the doctor depends on what he sees in the patient and hears from the patient. Unquestionably, patients in large numbers have accepted marijuana as useful in treating their emesis. The have found that it "works". Doctors, evaluating their patients, can have no basis more sound than that for their own acceptance.

Of relevance, also, is the acceptance of marijuana by state attorneys-

general, officials whose primary concern is law enforcement. A large number of them have no fear that placing marijuana in Schedule II, thus making it available for legitimate therapy, will in any way impede existing efforts of law enforcement authorities to crack down on illegal drug trafficking.

The Act does not specify by whom a drug or substance must be "accepted [for] medical use in treatment" in order to meet the Act's "accepted" requirement for placement in Schedule II. Department of Justice witnesses told the Congress during hearings in 1970 preceeding passage of the Act that "the medical profession" would make this determination, that the matter would be "determined by the medical community." The Deputy Chief Counsel of BNDD, whose office had written the bill with this language in it, told the House subcommittee that "this basic determination . . . is not made by any part of the federal government. It is made by the medical community as to whether or not the drug has medical use or doesn't".[7]

No one would seriously contend that these Justice Department witnesses meant that the entire medical community would have to be in agreement on the usefulness of a drug or substance. Seldom, if ever, do all lawyers agree on a point of law. Seldom, if ever, do all doctors agree on a medical question. How many are required here? A majority of 51%? It would be unrealistic to attempt a plebescite of all doctors in the country on such a question every time it arises, to obtain a majority vote.

In determining whether a medical procedure utilized by a doctor is actionable as malpractice the courts have adopted the rule that it is acceptable

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7 Drug Abuse Control Amendments - 1970: Hearings on H.R. 11701 and H.R. 13743 Before the Subcommittee on Public Health and Welfare of the House Committee on Interstate and Foreign Commerce, 91st Congress, 2d Sess. 678, 696, 718 (1970) (Statement of John E. Ingersoll, Director, BNDD).

for a doctor to employ a method of treatment supported by a respectable minority of physicians.

In Hood v. Phillips, 537 S.W. 2d 291 (1976) the Texas Court of Civil Appeals was dealing with a claim of medical malpractice resulting from a surgical procedure claimed to have been unnecessary. The court quoted from an Arizona court decision holding that

> a method of treatment, as espoused and used by . . . a respectable minority of physicians in the United States, cannot be said to be an inappropriate method of treatment or to be malpractice as a matter of law even though it has not been accepted as a proper method of treatment by the medical profession generally.

Ibid. at 294. Noting that the Federal District court in the Arizona case found a "respectable minority" composed of sixty-five physicians throughout the United States, the Texas court adopted as "the better rule" to apply in its case, that

> a physician is not guilty of malpractice where the method of treatment used is supported by a respectable minority of physicians.

Ibid.

In Chumbler v. McClure, 505 F.2d 489 (6th Cir. 1974) the Federal courts were dealing with a medical malpractice case under their diversity jurisdiction, applying Tennessee law. The Court of Appeals said:

> . . . The most favorable interpretation that may be placed on the testimony adduced at trial below is that there is a division of opinion in the medical profession regarding the use of Premarin in the Treatment of cerebral vascular insufficiency, and that Dr. McClure was alone among neurosurgeons in Nashville in using such therapy. The test for malpractice and for community standards is not to be determined solely by a plebiscite. Where two or more schools of thought exist among competent members of the medical profession concerning proper medical treatment for a given ailment, each of which is supported by responsible

> medical authority, it is not malpractice to be among the minority in a given city who follow one of the accepted schools.

505 F.2d at 492 (Emphasis added). See, also, Leech v. Bralliar, 275 F.Supp. 897 (D.Ariz., 1967).

How do we ascertain whether there exists a school of thought supported by responsible medical authority, and thus "accepted"? We listen to the physicians.

> The court and jury must have a standard measure which they are to use in measuring the acts of a doctor to determine whether he exercised a reasonable degree of care and skill; they are not permitted to set up and use any arbitrary or artificial standard of measurement that the jury may wish to apply. The proper standard of measurement is to be established by testimony of physicians, for it is a medical question.

Hayes v. Brown, 133 S.E. 2d. 102(Ga., 1963) at 105.

As noted above, there is no question but that this record shows a great many physicians, and others, to have "accepted" marijuana as having a medical use in the treatment of cancer patients' emesis. True, all physicians have not "accepted" it. But to require universal, 100% acceptance would be unreasonable. Acceptance by "a respectable minority" of physicians is all that can reasonably be required. The record here establishes conclusively that at least "a respectable minority" of physicians has "accepted" marijuana as having a "medical use in treatment in the United States." That others may not makes no difference.

The administrative law judge recommended this same approach for determining whether a drug has an "accepted medical use in treatment" in The Matter Of MDMA Scheduling, Docket No. 84-48. The Adminstrator, in his first final rule in that proceeding, issued on October 8, 1986[8], declined to adopt this approach. He

8 51 Fed. Reg. 36552 (1986).

ruled, instead, that DEA's decision on whether or not a drug or other substance had an accepted medical use in treatment in the United States would be determined simply by ascertaining whether or not "the drug or other substance is lawfully marketed in the United States pursuant to the Federal Food, Drug and Cosmetic Act of 1938 . . . ."[9]

The United States Court of Appeals for the First Circuit held that the Administrator erred in so ruling.[10] That court vacated the final order of October 8, 1986 and remanded the matter of MDMA's scheduling for further consideration. The court directed that, on remand, the Administrator would not be permitted to treat the absence of interstate marketing approval by FDA as conclusive evidence on the question of accepted medical use under the Act.

In his third final rule[11] on the matter of the scheduling of MDMA the Administrator made a series of findings of fact as to MDMA, the drug there under consideration, with respect to the evidence in that record. On those findings he based his last final rule in the case.[12]

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9 Ibid., at 36558.

10 Grinspoon v. Drug Enforcement Administration, 828 F.2d 881 (1st. Cir., 1987).

11 53 Fed. Reg. 5156 (1988). A second final rule had been issued on January 20, 1988. It merely removed MDMA from Schedule I pursuant to the mandate of the Court of Appeals which had voided the first final rule placing it there. Subsequently the third final rule was issued, without any further hearings, again placing MDMA in Schedule I. There was no further appeal.

12 In neither the first nor the third final rule in the MDMA case does the Administrator take any cognizance of the statements to the Congressional committee by predecessor Agency officials that the determination as to "accepted medical use in treatment" is to be made by the medical community and not by any part of the federal government. See page 27, above. It is curious that the Administrator makes no effort whatever to show how the BNDD representatives were mistaken or to explain why he now has abandoned their interpretation. They wrote that language into the original bill.

That third final rule dealing with MDMA is dealing with a synthetic, "simple", "single-action" drug. What might be appropriate criteria for a "simple" drug like MDMA may not be appropriate for a "complex" substance with a number of active components. The criteria applied to MDMA, a synthetic drug, are not appropriate for application to marijuana, which is a natural plant substance.

The First Circuit Court of Appeals in the MDMA case told the Administrator that he should not treat the absence of FDA interstate marketing approval as conclusive evidence of lack of currently accepted medical use. The court did not forbid the Administrator from considering the absence of FDA approval as a factor when determining the existence of accepted medical use. Yet on remand, in his third final order, the Administrator adopted by reference 18 of the numbered findings he had made in the first final order. Each of these findings had to do with requirements imposed by FDA for approval of a new drug application (NDA) or of an investigational new drug exemption (IND). These requirements deal with data resulting from controlled studies and scientifically conducted investigations and tests.

Among those findings incorporated into the third final MDMA order from the first, and relied on by the Administrator, was the determination and recommendation of the FDA that the drug there in question was not "accepted". In relying on the FDA's action the Administrator apparently overlooked the fact that the FDA clearly stated that it was interpreting "accepted medical use" in the Act as being equivalent to receiving FDA approval for lawful marketing under the FDCA. Thus the Administrator accepted as a basis for his MDMA third final rule the FDA recommendation which was based upon a statutory interpretation which the Court.

of Appeals had condemned.

The Administrator in that third final rule made a series of further findings. Again, the central concern in these findings was the content of test results and the sufficiency or adequacy of studies and scientific reports. A careful reading of the criteria considered in the MDMA third final order reveals that the Administrator was really considering the question: Should the drug be accepted for medical use?; rather than the question: Has the drug been accepted for medical use? By considering little else but scientific test results and reports the Administrator was making a determination as to whether or not, in his opinion, MDMA ought to be accepted for medical use in treatment.

The Agency's arguments in the present case are to the same effect. In a word, they address the wrong question. It is not for this Agency to tell doctors whether they should or should not accept a drug or substance for medical use. The statute directs the Administrator merely to ascertain whether, in fact, doctors have done so.

The MDMA third final order mistakenly looks to FDA criteria for guidance in choosing criteria for DEA to apply. Under the Food, Drug and Cosmetic Act the FDA is deciding - properly, under that statute - whether a new drug should be introduced into interstate commerce. Thus it is appropriate for the FDA to rely heavily on test results and scientific inquiry to ascertain whether a drug is effective and whether it is safe. The FDA must look at a drug and pass judgement on its intrinsic qualities. The DEA, on the other hand, is charged by 21 U.S.C. § 812(b)(1)(B) and (2)(B) with ascertaining what it is that other people have done with respect to a drug or substance: "Have they accepted it?;" not "Should they accept it?"

In the MDMA third final order DEA is actually making the decision that doctors have to make, rather than trying to ascertain the decision which doctors have made. Consciously or not, the Agency is undertaking to tell doctors what they should or should not accept. In so doing the Agency is acting beyond the authority granted in the Act.

It is entirely proper for the Administrator to consider the pharmacology of a drug and scientific test results in connection with determining abuse potential. But abuse potential is not in issue in this marijuana proceeding.

There is another reason why DEA should not be guided by FDA criteria in ascertaining whether or not marijuana has an accepted medical use in treatment. These criteria are applied by FDA pursuant to Section 505 of the Federal Food, Drug and Cosmetic Act (FDCA), as amended.[13] When the FDA is making an inquiry pursuant to that legislation it is looking at a synthetically formed new drug. The marijuana plant is anything but a new drug. Uncontroverted evidence in this record indicates that marijuana was being used therapeutically by mankind 2000 years before the Birth of Christ.[14]

Uncontroverted evidence further establishes that in this country today "new drugs" are developed by pharmaceutical companies possessing resources sufficient to bear the enormous expense of testing a new drug, obtaining FDA approval of its efficacy and safety, and marketing it successfully. No company undertakes the investment required unless it has a patent on the drug, so it can recoup its development costs and make a profit. At oral argument Government counsel conceded that "the FDA system is constructed for pharmaceutical companies. I won't

13 21 U.S.C. § 355.

14 Alice M. O'Leary, direct, par. 9.

deny that."[15]

Since the substance being considered in this case is a natural plant rather than a synthetic new drug, it is unreasonable to make FDA-type criteria determinative of the issue in this case, particularly so when such criteria are irrelevant to the question posed by the Act: Does the substance have an accepted medical use in treatment?

Finally, the Agency in this proceeding relies in part on the FDA's recommendation that the Administrator retain marijuana in Schedule I. But, as in the MDMA case, that recommendation is based upon FDA's equating "accepted medical use" under the Act with being approved for marketing by FDA under the Food, Drug and Cosmetic Act, the interpretation condemned by the First Circuit in the MDMA case. See Attachment A, p.24, to exhibit G-1 and exhibit G-2.

The overwhelming preponderance of the evidence in this record establishes that marijuana has a currently accepted medical use in treatment in the United States for nausea and vomiting resulting from chemotheraphy treatments in some cancer patients. To conclude otherwise, on this record, would be unreasonable, arbitrary and capricious.

15 Tr. XV-37.

VI.

ACCEPTED MEDICAL USE IN TREATMENT

- GLAUCOMA

Findings of Fact

The preponderance of the evidence establishes the following facts with respect to the accepted medical use of marijuana in the treatment of glaucoma.

1. Glaucoma is a disease of the eye characterized by the excessive accumulation of fluid causing increased intraocular pressure, distorted vision and, ultimately, blindness. In its early stages this pressure can sometimes be relieved by the administration of drugs. When such medical treatment fails adequately to reduce the intraocular pressure (IOP), surgery is generally resorted to. Although useful in many cases, there is a high incidence of failure with some types of surgery. Further, serious complications can occur as a result of invasive surgery. Newer, non-invasive procedures such as laser trabeculoplasty are thought by some to offer much greater efficacy with fewer complications. Unless the IOP is relieved and brought to a satisfactory level by one means or another, the patient will go blind.

2. Two highly qualified and experienced ophthalmologists in the United States have accepted marijuana as having a medical use in treatment for glaucoma. They are John C. Merritt, M.D. and Richard D. North, M.D. Each of them is both a clinician, treating patients, and a researcher. Dr. Merritt is also a professor of ophthalmology. Dr. North has served as a medical officer in ophthalmology for the Department of Health, Education and Welfare and has worked with the Public Health Service and FDA.

3. Dr. Merritt's experience with glaucoma patients using marijuana medicinally includes one Robert Randall and, insofar as the evidence here establishes per petitioners' briefs, an unspecified number of other patients, something in excess of 40.

4. Dr. North has treated only one glaucoma patient using marijuana medicinally - the same Robert Randall mentioned immediately above. Dr. North had monitored Mr. Randall's medicinal use of marijuana for nine years as of May 1987.

5. Dr. Merritt has accepted marijuana as having an important place in the treatment of "End Stage" glaucoma. "End Stage" glaucoma, essentially, defines a patient who has already lost substantial amounts of vision; available glaucoma control drugs are no longer able adequately to reduce the intraocular pressure (IOP) to prevent further, progressive sight loss; the patient, lacking additional IOP reductions, will go blind.

6. Robert S. Hepler, M.D., is a highly qualified and experienced ophthalmologist. He has done research with respect to the effect of smoking marijuana on glaucoma. In December 1975 he prescribed marijuana for the same Robert Randall mentioned above as a research subject. Dr. Hepler found that large dosages of smoked marijuana effectively reduced Robert Randall's IOP into the safe range over an entire test day. He concluded that the only known alternative to preserve Randall's sight which would avoid the significant risks of surgery is to include marijuana as part of Randall's prescribed medical regimen. He further concluded in 1977 that, if marijuana could have been legally prescribed, he would have prescribed it for Randall as part of Randall's regular glaucoma maintenance program had he been Randall's personal physician.

Nonetheless, in 1987 Dr. Hepler was of the opinion that marijuana did not have a currently accepted medical use in the United States for the treatment of glaucoma.

7. Four glaucoma patients testified in these proceedings. Each has found marijuana to be of help in controlling IOP.

8. In 1984 the treatment of glaucoma with Cannabis was the subject of an Ophthalmology Grand Rounds at the University of California, San Francisco. A questionnaire was distributed which queried the ophthalmologists on cannabis therapy for glaucoma patients refractory to standard treatment. Many of them have glaucoma patients who have asked about marijuana. Most of the responding ophthalmologists believed that THC capsules or smoked marijuana need to be available for patients who have not benefitted significantly from standard treatment.

9. In about 1978 an unspecified number of persons in the public health service sector in New Mexico, including some physicians, accepted marijuana as having medical use in treating glaucoma.

10. A majority of an unspecified number of ophthalmologists known to Arthur Kaufman, M.D., who was formerly in general practice but now is employed as a medical program administrator, accept marijuana as having medical use in treatment of glaucoma.

11. In addition to the physicians identified and referred to in the findings above, the testimony of patients in this record establishes that no more than three or four other physicians consider marijuana to be medically useful in the treatment of glaucoma in the United States. One of those physicians actually wrote a prescription for marijuana for a patient, which, of course, she was unable to have filled.

12. There are test results showing that smoking marijuana has reduced the IOP in some glaucoma patients. There is continuing research underway in the United States as to the therapeutic effect of marijuana on glaucoma.

Discussion

Petitioners' briefs fail to show that the preponderance of the evidence in the record with respect to marijuana and glaucoma establishes that a respectable minority of physicians accepts marijuana as being useful in the treatment of glaucoma in the United States.

This conclusion is not to be taken in any way as criticism of the opinions of the ophthalmologists who testified that they accept marijuana for this purpose. The failure lies with petitioners. In their briefs they do not point out hard, specific evidence in this record sufficient to establish that a respectable minority of physicians has accepted their position.

There is a great volume of evidence here, and much discussion in the briefs, about the protracted case of Robert Randall. But when all is said and done, his experience presents but one case. The record contains sworn testimony of three ophthalmologists who have treated Mr. Randall. One of them tells us of a relatively small number of other glaucoma patients whom he has treated with marijuana and whom he knows to have responded favorably. Another of these three doctors has successfully treated only Randall with marijuana. The third testifies, despite his successful experience in treating Randall, that marijuana does not have an accepted use in such treatment.

In addition to Robert Randall, Petitioners point to the testimony of three other glaucoma patients. Their case histories are impressive, but they contribute

little to the carrying of Petitioner's burden of showing that marijuana is accepted for medical treatment of glaucoma by a respectable minority of physicians. See pages 26-29, above.

Petitioners have placed in evidence copies of a number of newspaper clippings reporting statements by persons claiming that marijuana has helped their glaucoma. The administrative law judge is unable to give significant weight to this evidence. Had these persons tesified so as to have been subject to cross-examination, a different situation would be presented. But these newspaper reports of extra-judicial statements, neither tested by informed inquiry nor supported by a doctor's opinion, are not entitled to much weight. They are of little, if any, materiality.

Beyond the evidence referred to above there is little other "hard" evidence, pointed out by petitioners, of physicans accepting marijuana for treatment of glaucoma. Such evidence as that concerning a survey of a group of San Francisco ophthalmologists is ambiguous, at best. The relevant document establishes merely that most of the doctors on the grand rounds, who responded to an inquiry, believed that the THC capsules or marijuana ought to be available.

In sum, the evidence here tending to show that marijuana is accepted for treatment of glaucoma falls far, far short of the quantum of evidence tending to show that marijuana is accepted for treatment of emesis in cancer patients. The preponderance of the evidence here, identified by petitioners in their briefs, does not establish that a respectable minority of physicians has accepted marijuana for glaucoma treatment.

VII.

ACCEPTED MEDICAL USE IN TREATMENT

- MULTIPLE SCLEROSIS, SPASTICITY

AND HYPERPARATHYROIDISM

Findings Of Fact

The preponderance of the evidence clearly establishes the following facts with respect to marijuana's use in connection with multiple sclerosis, spasticity and hyperparathyroidism.

1. Multiple sclerosis is the major cause of neurological disability among young and middle-aged adults in the United States today. It is a life-long disease. It can be extremely debilitating to some of its victims but it does not shorten the life span of most of them. Its cause is yet to be determined. It attacks the myelin sheath, the coating or insulation surrounding the message-carrying nerve fibers in the brain and spinal cord. Once the myelin sheath is destroyed, it is replaced by plaques of hardened tissue known as sclerosis. During the initial stages of the disease nerve impulses are transmitted with only minor interruptions. As the disease progresses, the plaques may completely obstruct the impulses along certain nerve systems. These obstructions produce malfunctions. The effects are sporadic in most individuals and the effects often occur episodically, triggered either by malfunction of the nerve impulses or by external factors.

2. Over time many patients develop spasticity, the involuntary and abnormal contraction of muscle or muscle fibers. (Spasticity can also result from serious injuries to the spinal cord, not related to multiple sclerosis.)

3. The symptoms of multiple sclerosis vary according to the area of

the nervous system which is affected and according to the severity of the disease. The symptoms can include one or more of the following: weakness, tingling, numbness, impaired sensation, lack of coordination, disturbances in equilibrium, double vision, loss of vision, involuntary rapid movement of the eyes (nystagmus), slurred speech, tremors, stiffness, spasticity, weakness of limbs, sexual dysfunction, paralysis, and impaired bladder and bowel functions.

4. Each person afflicted by multiple sclerosis is affected differently. In some persons, the symptoms of the disease are barely detectable, even over long periods of time. In these cases, the persons can live their lives as if they did not suffer from the disease. In others, more of the symptoms are present and acute, thereby limiting their physical capabilities. Moreover, others may experience sporadic, but acute, symptoms.

5. At this time, there is no known prevention or cure for multiple sclerosis. Instead, there are only treatments for the symptoms of the disease. There are very few drugs specifically designed to treat spasticity. These drugs often cause very serious side effects. At the present time two drugs are approved by FDA as "safe" and "effective" for the specific indication of spasticity. These drugs are Dantrium and Lioresal baclofen.

6. Unfortunately, neither Dantrium nor Lioresal is a very effective spasm control drug. Their marginal medical utility, high toxicity and potential for serious adverse effects make these drugs difficult to use in spasticity therapy.

7. As a result, many physicians routinely prescribe tranquilizers, muscle relaxants, mood elevators and sedatives such as Valium to patients experiencing spasticity. While these drugs do not directly reduce spasticity

they may weaken the patient's muscle tone, thus making the spasms less noticeable. Alternatively, they may induce sleep or so tranquilize the patient that normal mental and physical functions are impossible.

8. A healthy, athletic young woman named Valerie Cover was stricken with multiple sclerosis while in her early twenties. She consulted several medical specialists and followed all the customary regimens and prescribed methods for coping with this debilitating disease over a period of several years. None of these proved availing. Two years after first experiencing the symptoms of multiple sclerosis her active, productive life - as an athlete, Navy officer's wife and mother - was effectively over. The Social Security Administration declared her totally disabled. To move about her home she had to sit on a skateboard and push herself around. She spent most of her time in bed or sitting in a wheelchair.

9. An occasional marijuana smoker in her teens, before her marriage, she had not smoked it for five years as of February 1986. Then a neighbor suggested that marijuana just might help Mrs. Cover's multiple sclerosis, having read that it had helped cancer patient's control their emesis. Mrs. Cover acceded to the suggestion.

10. Just before smoking the marijuana cigarette produced by her neighbor, Mrs. Cover had been throwing up and suffering from spasms. Within five minutes of smoking part of the marijuana cigarette she stopped vomiting, no longer felt nauseous and noticed that the intensity of her spasms was significantly reduced. She stood up unaided.

11. Mrs. Cover began smoking marijuana whenever she felt nauseated. When she did so it controlled her vomiting, stopped the nausea and increased her

appetite. It helped ease and control her spasticity. Her limbs were much easier to control. After three months of smoking marijuana she could walk unassisted, had regained all of her lost weight, her seizures became almost nonexistent. She could again care for her children. She could drive an automobile again. She regained the ability to lead a normal life.

12. Concerned that her use of this illegal substance might jeopardize the career of her Navy officer husband, Mrs. Cover stopped smoking marijuana several times. Each time she did so, after about a month, she had retrogressed to the point that her multiple sclerosis again had her confined to bed and wheelchair or skateboard. As of the Spring of 1987 Mrs. Cover had resumed smoking marijuana regularly on an "as needed" basis. Her multiple sclerosis symptoms are under excellent control. She has obtained a full-time job. She still needs a wheelchair on rare occasions, but generally has full use of her limbs and can walk around with relative ease.

13. Mrs. Cover's doctor has accepted the effectiveness of marijuana in her case. He questioned her closely about her use of it, telling her that it is the most effective drug known in reducing vomiting. Mrs. Cover and her doctor are now in the process of filing an Investigational New Drug (IND) application with FDA so that she can legally obtain the marijuana she needs to lead a reasonably normal life.

14. Martha Hirsch is a young woman in her mid-thirties. She first exhibited symptoms of multiple sclerosis at age 19 and it was diagnosed at that time. Her condition has grown progressively worse. She has been under the care of physicians and hospitalized for treatment. Many drugs have been prescribed for her by her doctors. At one point in 1983 she listed the drugs that had been

prescribed for her. There were 17 on the list. None of them has given her the relief from her multiple sclerosis symptoms that marijuana has.

15. During the early stages in the development of her illness Ms. Hirsch found that smoking marijuana improved the quality of her life, keeping her spasms under control. Her balance improved. She seldom needed to use her cane for support. Her condition lately has deteriorated. As of May 1987 she was experiencing severe, painful spasms. She had an indwelling catheter in her bladder. She had lost her locomotive abilities and was wheelchair bound. She could seldom find marijuana on the illegal market and, when she did, she often could not afford to purchase it. When she did obtain some, however, and smoked it, her entire body seemed to relax, her spasms decreased or disappeared, she slept better and her dizzy spells vanished. The relaxation of her leg muscles after smoking marijuana has been confirmed by her personal care attendant's examination of them.

16. The personal care attendant has told Ms. Hirsch that she, the attendant, treats a number of patients who smoke marijuana for relief of multiple sclerosis symptoms. In about 1980 another patient told Ms. Hirsch that he knew many patients who smoke marijuana to relieve their spasms. Through him she met other patients and found that marijuana was commonly used by many multiple sclerosis patients. Most of these persons had told their doctors about their doing so. None of those doctors advised against the practice and some encouraged it.

17. Among the drugs prescribed by doctors for Ms. Hirsch was ACTH. This failed to give her any therapeutic benefit or to control her spasticity. It did produce a number of adverse effects, including severe nausea and vomiting which, in turn, were partly controlled by rectally administered anti-emetic

drugs.

18. Another drug prescribed for her was Lioresal, intended to reduce her spasms. It was not very effective in so doing. But it did cause Ms. Hirsch to have hallucinations. On two occasions, while using this drug, Ms. Hirsch "saw" a large fire in her bedroom and called for help. There was no fire. She stopped using that drug. Ms. Hirsch has experienced no adverse reactions with marijuana.

19. Ms. Hirsch's doctor has accepted marijuana as beneficial for her. He agreed to write her a prescription for it, if that would help her obtain it. She has asked him if he would file an IND application with FDA for her. He replied that the paperwork was "overwhelming". He indicated willingness to help in this undertaking after Ms. Hirsch found someone else willing to put the paperwork together.

20. When Greg Paufler was in his early twenties, employed by Prudential Insurance Company, he began to experience the first symptoms of multiple sclerosis. His condition worsened as the disease intensified. He had to be hospitalized. He lost the ability to walk, to stand. Diagnosed as having multiple sclerosis, a doctor prescribed ACTH for him, an intensive form of steroid therapy. He lost all control over his limbs and experienced severe, painful spasms. His arms and legs became numb.

21. ACTH had no beneficial effects. The doctor continued to prescribe it over many months. ACTH made Paufler ravenously hungry and he began gaining a great deal of weight. ACTH caused fluid retention and Paufler became bloated, rapidly gaining weight. His doctor thought Paufler should continue this steroid therapy, even though it caused the adverse effects mentioned plus the possiblity of sudden heart attack or death due to respiratory failure. Increased dosages

of this FDA-approved drug caused fluid to press against Paufler's lungs making it difficult for him to breathe and causing his legs and feet to become swollen. The steroid therapy caused severe, intense depression marked by abrupt mood shifts. Throughout, the spasms continued and Paufler's limbs remained out of control. The doctor insisted that ACTH was the only therapy likely to be of any help with the multiple sclerosis, despite its adverse effects. Another, oral, steroid was eventually substituted.

22. One day Paufler became semi-catatonic while sitting in his living room at home. He was rushed to the hospital emergency room. He nearly died. Lab reports indicated, among other things, a nearly total lack of potassium in his body. He was given massive injections of potassium in the emergency room and placed on an oral supplement. Paufler resolved to take no more steroids.

23. From time to time, prior to this point, Paufler had smoked marijuana socially with visiting friends, seek some relief from his misery in a temporary "high". He now began smoking marijuana more often. After some weeks he found that he could stand and then walk a bit. His doctor dismissed the idea that marijuana could be helpful with multiple sclerosis, and Paufler, himself, was skeptical at first. He began discontinuing it for a while, then resuming.

24. Paufler found that when he did not smoke marijuana his condition worsened, he suffered more intense spasms more frequently. When he smoked marijuana, his condition would stabilize and then improve; spasms were more controlled and less severe; he felt better; he regained control over his limbs and could walk totally unaided. His vision, often blurred and unfocused, improved. Eventually he began smoking marijuana on a daily basis. He ventured outdoors. He was soon walking half a block. His eyesight returned to normal.

His central field blindness cleared up. He could focus well enough to read again. One evening he went out with his children and found he could kick a soccer ball again.

25. Paufler has smoked marijuana regularly since 1980. Since that time his multiple sclerosis has been well controlled. His doctor has been astonished at Paufler's recovery. Paufler can now run. He can stand on one foot with his eyes closed. The contrast with his condition, several years ago, seems miraculous. Smoking marijuana when Paufler feels an attack coming on shortens the attack. Paufler's doctor has looked Paufler in the eye and told him to keep doing whatever it is he's doing because it works. Paufler and his doctor are exploring the possbility of obtaining a compassionate IND to provide legal access to marijuana for Paufler.

26. Paufler learned in about 1980 of the success of one Sam Diana, a multiple sclerosis patient, in asserting the defense of "medical necessity" in court when charged with using or possessing marijuana. He learned that doctors, researchers and other multiple sclerosis patients had supported Diana's position in the court proceeding.

27. Irwin Rosenfeld has been diagnosed as having Pseudo Pseudo Hypoparathyroidism. This uncommon disease causes bone spurs to appear and grow all over the body. Over the patient's lifetime hundreds of these spurs can grow, any one of which can become malignant at any time. The resulting cancer would spread quickly and the patient would die.

28. Even without development of a malignancy, the disease causes enormous pain. The spurs press upon adjacent body tissue, nerves and organs. In Rosenfeld's case, he could neither sit still nor lie down, nor could he walk,

without experiencing pain. Working in his furniture store in Portsmouth, Virginia, Mr. Rosenfeld was on his feet moving furniture all day long. The lifting and walking caused serious problems as muscles and tissues rubbed over the spurs of bone. He tore muscles and hemorrhaged almost daily.

29. Rosenfeld's symptoms first appeared about the age of ten. Various drugs were prescribed for him for pain relief. He was taking extremely powerful narcotics. By the age of 19 his therapy included 300 mg. of Sopor (a powerful sleeping agent) and very high doses of Dilaudid. He was found to be allergic to barbiturates. Taking massive doses of pain control drugs, as prescribed, made it very difficult for Rosenfeld to function normally. If he took enough of them to control the pain, he could barely concentrate on his schoolwork. By the time he reached his early twenties Rosenfeld's monthly drug intake was between 120 to 140 Dilaudid tablets, 30 or more Sopor sleeping pills and dozens of muscle relaxants.

30. At college in Florida Rosenfeld was introduced to marijuana by classmates. He experimented with it recreationally. He never experienced a "high" or "buzz" or "floating sensation" from it. One day he smoked marijuana while playing chess with a friend. It had been very difficult for him to sit for more than five or ten minutes at a time because of tumors in the backs of his legs. Suddenly he realized that, absorbed in his chess game, and smoking marijuana, he had remained sitting for over an hour - with no pain. He experimented further and found that his pain was reduced whenever he smoked marijuana.

31. Rosenfeld told his doctor of his discovery. The doctor opined that it was possible that the marijuana was relieving the pain. Something

certainly was - there was a drastic decrease in Rosenfeld's need for such drugs as Dilaudid and Demerol and for sleeping pills. The quality of pain relief which followed his smoking of marijuana was superior to any he had experienced before. As his dosages of powerful conventional drugs decreased, Rosenfeld became less withdrawn from the world, more able to interact and function. So he has continued to the present time.

32. After some time Rosenfeld's doctor accepted the fact that the marijuana was therapeutically helpful to Rosenfeld and submitted an IND application to FDA to obtain supplies of it legally for Rosenfeld. The doctor has insisted, however, that he not be publicly identified. After some effort the IND application was granted. Rosenfeld is receiving supplies of marijuana from NIDA. Rosenfeld testified before a committee of the Virginia legislature in about 1979 in support of legislation to make marijuana available for therapeutic purposes in that State.

33. In 1969, at age 19, David Branstetter dove into the shallow end of a swimming pool and broke his neck. He became a quadraplegic, losing control over the movement of his arms and legs. After being hospitalized for 18 months he returned home. Valium was prescribed for him to reduce the severe spasms associated with his condition. He became mildly addicted to Valium. Although it helped mask his spasms, it made Branstetter more withdrawn and less able to take care of himself. He stopped taking Valium for fear of the consequences of long-term addiction. His spasms then became uncontrollable, often becoming so bad they would throw him from his wheelchair.

34. In about 1973 Branstetter began smoking marijuana recreationally. He discovered that his severe spasms stopped whenever he smoked marijuana.

Unlike Valium, which only masked his symptoms and caused him to feel drunk and out of control, marijuana brought his spasmodic condition under control without impairing his faculties. When he was smoking marijuana regularly he was more active, alert and outgoing.

35. Marijuana controlled his spasms so well that Branstetter could go out with friends and he began to play billiards again. The longer he smoked marijuana the more he was able to use his arms and hands. Marijuana also improved his bladder control and bowel movements.

36. At times the illegal marijuana Branstetter was smoking became very expensive and sometimes was unavailable. During periods when he did not have marijuana his spasms would return, preventing Branstetter from living a "normal" life. He would begin to shake uncontrollably, his body would feel tense, and his muscles would spasm.

37. In 1979 Branstetter was arrested and convicted of possession of marijuana. He was placed on probation for two years. During that period he continued smoking marijuana and truthfully reportd this, and the reason for it, to his probation officer whenever asked about it. No action was taken against Branstetter by the court or probation authorities because of his continuing use of marijuana, except once in the wake of his publicly testifying about it before the Missouri legislature. Then, although adverse action was threatened by the judge, nothing was actually done.

38. In 1981 Branstetter and a friend, a paraplegic, participated in a research study testing the therapeutic effects of synthetic THC on spasticity. Placed on the THC Branstetter found that it did help control his spasms but appeared to became less effective with repeated use. Also, unlike marijuana,

synthetic THC had a powerful mind-altering effect he found annoying. When the study ended the researcher strongly suggested that Branstetter continue smoking marijuana to control his spasms.

39. None of Branstetter's doctors have told him to stop smoking marijuana while several, directly and indirectly, have encouraged him to continue. Branstetter knows of almost 20 other patients, paraplegics, quadraplegics and multiple sclerosis sufferers, who smoke marijuana to control their spasticity.

40. In 1981 a State of Washington Superior Court judge, sitting without a jury, found Samuel D. Diana not guilty of the charge of unlawful possession of marijuana. In so doing the judge upheld Diana's defense of medical necessity. Diana had been a multiple sclerosis patient since at least 1973. He testified that smoking marijuana relieved his symptoms of double vision, tremors, unsteady walk, impaired hearing, tendency to vomit in the mornings and stiffness in the joints of his hands and legs.

41. Among the witnesses was a physician who had examined defendant Diana before and after he had used marijuana. This doctor tesified that marijuana had been effective therapeutically for Diana, that other medication had proven ineffective for Diana and that, while marijuana may have some detrimental effects, Diana would receive more benefit than harm from smoking it. The doctor was not aware of any other drug that would be as effective as marijuana for Mr. Diana. Other witnesses included three persons afflicted with multiple sclerosis who tesified in detail as to marijuana's beneficial effect on their illness.

42. In acquitting defendant Diana of unlawful possession of marijuana the trial judge found that the three requirements for the defense of medical necessity had been established, namely: defendant's reasonable belief that his

use of marijuana was necessary to minimize the effects of multiple sclerosis; the benefits derived from its use are greater than the harm sought to be prevented by the controlled substances law; and no drug is as effective as marijuana in minimizing the effects of the disease in the defendant.

43. Denis Petro, M.D., is a neurologist of broad experience, ranging from active practice in neurology to teaching the subject in medical school and employment by FDA as a medical officer reviewing IND's and NDA's. He has also been employed by pharmaceutical companies and has served as a consultant to the State of New York. He is well acquainted with the case histories of three patients who have successfully utilized marijuana to control severe spasticity when other, FDA-approved drugs failed to do so. Dr. Petro knows of other cases of patients who, he has determined, have effectively used marijuana to control their spasticity. He has heard reports of additional patients with multiple sclerosis, paraplegia and quadriplagia doing the same. There are reports published in the literature known to Dr. Petro, over the period at least 1970 - 1986, of clinical tests demonstrating that marijuana and THC are effective in controlling or reducing spasticity in patients.

44. Large numbers of paraplegic and quadriplegic patients, particularly in Veterans Hospitals, routinely smoke marijuana to reduce spasticity. While this mode of treatment is illegal, it is generally tolerated, if not openly encouraged, by physicians in charge of such wards who accept this practice as being of benefit to their patients. There are many spinal cord injury patients in Veterans Hospitals.

45. Dr. Petro sought FDA approval to conduct research with spasticity patients using marijuana. FDA refused but, for reasons unknown to him, allowed

him to make a study using synthetic THC. He and colleagues made such a study. They concluded that synthetic THC effected a significant reduction in spasticity among multiple sclerosis patients, but study participants who had also smoked marijuana reported consistently that marijuana was more effective.

46. Dr. Petro accepts marijuana as having a medical use in the treatment of spasticity in the United States. If it were legally available and he was engaged in an active medical practice again, he would not hesitate to prescribe marijuana, when appropriate, to patients afflicted with uncontrollable spasticity.

47. Dr. Petro presented a paper to a meeting of the American Academy of Neurology. The paper was accepted for presentation. After he presented it Dr. Petro found that many of the neurologists present at this most prestigious meeting were in agreement with his acceptance of marijuana as having a medical use in the treatment of spasticity.

48. Dr. Andrew Weil, a general medicine practitioner in Tucson, Arizona, who also teaches at the University of Arizona College of Medicine, accepts marijuana as having a medical use in the treatment of spasticity. In multiple sclerosis patients the muscles become tense and rigid because their nerve supply is interrupted. Marijuana relieves this spasticity in many patients, he has found. He would prescribe it to selected patients if it were legally available.

49. Dr. Lester B. Collins, III, a neurologist, then treating about 20 multiple sclerosis patients a year, seeing two or three new ones each year, stated in 1983 that he had no doubt that marijuana worked symptomatically for some multiple sclerosis patients. He said that it does not alter the course of

the disease but it does relieve the symptoms of spasticity.

50. Dr. John P. Morgan, board certified in internal medicine, Professor of Medicine and Director of Pharmacology at CCNY Medical School in New York and Associate Professor of Medicine and Pharmacology at Mt. Sinai School of Medicine, accepts marijuana as having medical use in treatment in the United States. If he were practicing medicine and marijuana were legally available he would prescribe it when indicated to patients with legitimate medical needs.

Discussion

Based upon the rationale set out in pages 26 to 34, above, the administrative law judge concludes that, within the meaning of the Act, 21 U.S.C. § 812(b)(2)(B), marijuana "has a currently accepted medical use in treatment in the United States" for spasticity resulting from multiple sclerosis and other causes. It would be unreasonable, arbitrary and capricious to find otherwise. The facts set out above, uncontroverted by the Agency, establish beyond question that some doctors in the United States accept marijuana as helpful in such treatment for some patients. The record here shows that they constitute a significant minority of physicians. Nothing more can reasonably be required. That some doctors would have more studies and test results in hand before accepting marijuana's usefulness here is irrelevant.

The same is true with respect to the hyperparathyroidism from which Irvin Rosenfeld suffers. His disease is so rare, and so few physicians appear to be familiar with it, that acceptance by one doctor of marijuana as being useful in treating it ought to satisfy the requirement for a significant minority. The Agency points to no evidence of record tending to establish that marijuana is

not accepted by doctors in connection with this most unusual ailment. Refusal to acknowledge acceptance by a significant minority, in light of the case history detailed in this record, would be unreasonable, arbitrary and capricious.

VIII.

ACCEPTED SAFETY FOR USE UNDER MEDICAL SUPERVISION

With respect to whether or not there is "a lack of accepted safety for use of [marijuana] under medical supervision", the record shows the following facts to be uncontroverted.

Findings of Fact

1. Richard J. Gralla, M.D., an oncologist and Professor of Medicine who was an Agency witness, accepts that in treating cancer patients oncologists can use the cannabinoids with safety despite their side effects.

2. Andrew T. Weil, M.D., who now practices medicine in Tucson, Arizona and is on the faculity of the College of Medicine, University of Arizona, was a member of the first team of researchers to perform a Federal Government authorized study into the effects of marijuana on human subjects. This team made its study in 1968. These researchers determined that marijuana could be safely used under medical supervision. In the 20 years since then Dr. Weil has seen no information that would cause him to reconsider that conclusion. There is no question in his mind but that marijuana is safe for use under appropriate medical supervision.

3. The most obvious concern when dealing with drug safety is the possibility of lethal effects. Can the drug cause death?

4. Nearly all medicines have toxic, potentially lethal effects. But marijuana is not such a substance. There is no record in the extensive medical literature describing a proven, documented cannabis-induced fatality.

5. This is a remarkable statement. First, the record on marijuana encompasses 5,000 years of human experience. Second, marijuana is now used daily by enormous numbers of people throughout the world. Estimates suggest that from twenty million to fifty million Americans routinely, albeit illegally, smoke marijuana without the benefit of direct medical supervision. Yet, despite this long history of use and the extraordinarily high numbers of social smokers, there are simply no credible medical reports to suggest that consuming marijuana has caused a single death.

6. By contrast aspirin, a commonly used, over-the-counter medicine, causes hundreds of deaths each year.

7. Drugs used in medicine are routinely given what is called an LD-50. The LD-50 rating indicates at what dosage fifty percent of test animals receiving a drug will die as a result of drug induced toxicity. A number of researchers have attempted to determine marijuana's LD-50 rating in test animals, without success. Simply stated, researchers have been unable to give animals enough marijuana to induce death.

8. At present it is estimated that marijuana's LD-50 is around 1:20,000 or 1:40,000. In layman terms this means that in order to induce death a marijuana smoker would have to consume 20,000 to 40,000 times as much marijuana as is contained in one marijuana cigarette. NIDA-supplied marijuana cigarettes weigh approximately .9 grams. A smoker would theoretically have to consume nearly 1,500 pounds of marijuana within about fifteen minutes to induce a lethal response.

9. In practical terms, marijuana cannot induce a lethal response as a result of drug-related toxicity.

10. Another common medical way to determine drug safety is called the therapeuic ratio. This ratio defines the difference between a therapeutically effective dose and a dose which is capable of inducing adverse effects.

11. A commonly used over-the-counter product like aspirin has a therapeutic ratio of around 1:20. Two aspirins are the recommended dose for adult patients. Twenty times this dose, forty aspirins, may cause a lethal reaction in some patients, and will almost certainly cause gross injury to the digestive system, including extensive internal bleeding.

12. The therapeutic ratio for prescribed drugs is commonly around 1:10 or lower. Valium, a commonly used prescriptive drug, may cause very serious biological damage if patients use ten times the recommended (therapeutic) dose.

13. There are, of course, prescriptive drugs which have much lower therapeutic ratios. Many of the drugs used to treat patients with cancer, glaucoma and multiple sclerosis are highly toxic. The therapeutic ratio of some of the drugs used in antineoplastic therapies, for example, are regarded as extremely toxic poisons with therapeutic ratios that may fall below 1:1.5. These drugs also have very low LD-50 ratios and can result in toxic, even lethal reactions, while being properly employed.

14. By contrast, marijuana's therapeutic ratio, like its LD-50, is impossible to quantify because it is so high.

15. In strict medical terms marijuana is far safer than many foods we commonly consume. For example, eating ten raw potatoes can result in a toxic response. By comparison, it is physically impossible to eat enough marijuana to induce death.

16. Marijuana, in its natural form, is one of the safest therapeutically

active substances known to man. By any measure of rational analysis marijuana can be safely used within a supervised routine of medical care.

17. Some of the drugs most widely used in chemotherapy treatment of cancer have adverse effects as follows:

> Cisplatin, one of the most powerful chemo-therapeuic agents used on humans - may cause deafness; may lead to life-threatening kidney difficulties and kidney failure; adversely affects the body's immune system, suppressing the patient's ability to fight a host of common infections.
>
> Nitrogen Mustard, a drug used in therapy for Hodgkins disease - nauseates; so toxic to the skin that, if dropped on the skin, this chemical literally eats it away along with other tissues it contacts; if patient's intravenous lead slips during treatment and this drug gets on or under the skin the patient may suffer serious injury including temporary, and in extreme cases, permanent, loss of use of the arm.
>
> Procarbizine, also used for Hodgkins disease - has known psychogenic, i.e., emotional, effects.
>
> Cytoxin, also known as Cyclophosphanide - suppresses patient's immune system response; results in serious bone marrow depletion; studies indicate this drug may also cause other cancers, including cancers of the bladder.
>
> Adriamycan, has numerous adverse effects; is difficult to employ in long term therapies because it destroys the heart muscle.

While each of these agents has its particular adverse effects, as indicated above, they also cause a number of similar, disturbing adverse effects. Most of these drugs cause hair loss. Studies increasingly indicate all of these drugs may cause other forms of cancer. Death due to kidney, heart or respiratory failure is a very real possibility with all of these agents and the margin for error is minimal. Similarly, there is a danger of overdosing a patient weakened by his cancer. Put simply, there is very great risk associated with the medical

use of these chemicals agents. Despite these high risks, all of these drugs are considered "safe" for use under medical supervision and are regularly administered to patients on doctor's orders in the United States today.

18. There have been occasional instances of panic reaction in patients who have smoked marijuana. These have occurred in marijuana-naive persons, usually older persons, who are extremely anxious over the forthcoming chemotherapy and troubled over the illegality of their having obtained the marijuana. Such persons have responded to simple person-to-person communication with a doctor and have sustained no long term mental or physical damage. If marijuana could be legally obtained, and administered in an open, medically-supervised session rather than surreptitiously, the few instances of such adverse reaction doubtless would be reduced in number and severity.

19. Other reported side effects of marijuana have been minimal. Sedation often results. Sometimes mild euphoria is experienced. Short periods of increased pulse rate and of dizziness are occasionally experienced. Marijuana should not be used by persons anxious or depressed or psychotic or with certain other health problems. Physicians could readily screen out such patients if marijuana were being employed as an agent under medical supervision.

20. All drugs have "side effects" and all drugs used in medicine for their therapeutic benefits have unwanted, unintended, sometimes adverse effects.

21. In medical treatment "safety" is a relative term. A drug deemed "safe" for use in treating a life-threatening disease might be "unsafe" if prescribed for a patient with a minor ailment. The concept of drug "safety" is relative. Safety is measured against the consequences a patient would confront in the absence of therapy. The determination of "safety" is made in terms of

whether a drug's benefits outweigh its potential risks and the risks of permitting the disease to progress.

22. In the context of glaucoma therapy, it must be kept in mind that glaucoma, untreated, progressively destroys the optic nerve and results in eventual blindness. The danger, then, to patients with glaucoma is an irretrievable loss of their sight.

23. Glaucoma is not a mortal disease, but a highly specific, selectively incapacitating condition. Glaucoma assaults and destroys the patient's most evolved and critical sensory ability, his or her vision. The vast majority of patients afflicted with glaucoma are adults over the age of thirty. The onset of blindness in middle age or later throws patients into a wholely alien world. They can no longer do the work they once did. They are unable to read a newspaper, drive a car, shop, walk freely and do all the myriad things sighted people take for granted. Without lengthy periods of retaining, adaptation and great effort these individuals often lose their sense of identity and ability to function. Those who are young enough or strong-willed enough will regain a sense of place, hold meaningful jobs, but many aspects of the life they once took for granted cannot be recaptured. Other patients may never fully adjust to their new, uncertain circumstances.

24. Blindness is a very grave consequence. Protecting patients from blindness is considered so important that, for ophtholmologists generally, it justifies the use of toxic medicines and uncertain surgical procedures which in other contexts might be considered "unsafe." In practice, physicians often provide glaucoma patients with drugs which have many serious adverse effects.

25. There are only a limited number of drugs available for the

treatment of glaucoma. All of these drugs produce adverse effects. While several government witnesses lightly touched on the side effects of these drugs, none provided a full or detailed description of their known adverse consequences.

26. The adverse physical consequences resulting from the chronic use of commonly employed glaucoma control drugs include a vast range of unintended complications from mild problems like drug induced fevers, skin rashes, headaches, anorexia, asthma, pulmonary difficulties, hypertension, hypotension and muscle cramps to truly serious, even life-threatening complications including the formation of cataracts, stomach and intestinal ulcers, acute respiratory distress, increases and decreases in heart rate and pulse, disruption of heart function, chronic and acute renal disease, and bone marrow depletion.

27. Finally, each FDA-approved drug family used in glaucoma therapy is capable of producing a lethal response, even when properly prescribed and used. Epinephrine can lead to elevated blood pressure which may result in stroke or heart attack. Miotic drugs suppress respiration and can cause respiratory paralysis. Diuretic drugs so alter basic body chemistry they cause renal stones and may destroy the patient's kidneys or result in death due to heart failure. Timolol and related beta-blocking agents, the most recently approved family of glaucoma control drugs, can trigger severe asthma attacks or cause death due to sudden cardiac arrhythmias often producing cardiac arrest.

28. Both of the FDA-approved drugs used in treating the symptoms of multiple sclerosis, Dantrium and Lioresal, while accepted as "safe" can, in fact, be very dangerous substances. Dantrium or dantrolene sodium carries a boxed warning in the Physician's Desk Reference (PDR) because of its very high toxicity. Patients using this drug run a very real risk of developing sympto-

matic hepatitis (fatal and nonfatal). The list of sublethal toxic reactions also underscores just how dangerous Dantrium can be. The PDR, in part, notes Dantrium commonly causes weakness, general malaise and fatigue and goes on to note the drug can also cause constipation, GI bleeding, anorexia, gastric irritation, abdominal cramps, speech disturbances, seizure, visual disturbances, diplopia, tachycardia, erratic blood pressure, mental confusion, clinical depression, renal disturbances, myalgia, feelings of suffocation and death due to liver failure.

29. The adverse effects associated with Lioresal baclofen are somewhat less severe, but include possibly lethal consequences, even when the drug is properly prescribed and taken as directed. The range of sublethal toxic reactions is similar to those found with Dantrium.

30. Norman E. Zinberg, M.D., one of Dr. Weil's colleagues in the 1968 study mentioned in finding 2, above, accepts marijuana as being safe for use under medical supervision. If it were available by prescription he would use it for appropriate patients.

31. Lester Grinspoon, M.D., practicing psychiatrist, researcher and Associate Professor of Medicine at Harvard Medical School, accepts marijuana as safe for use under medical supervision. He believes its safety is its greatest advantage as a medicine in appropriate cases.

32. Tod H. Mikuriya, M.D., a psychiatrist practicing in Berkley, California who treats substance abusers as inpatients and outpatients, accepts marijuana as safe for use under medical supervision.

33. Richard D. North, M.D., who has treated Robert Randall for glaucoma with marijuana for nine years, accepts marijuana as safe for use by his patient

under medical supervision. Mr. Randall has smoked ten marijuana cigarettes a day during that period without any evidence of adverse mental or physical effects from it.

34. John C. Merritt, M.D., an expert in ophthalmology, who has treated Robert Randall and others with marijuana for glaucoma, accepts marijuana as being safe for use in such treatment.

35. Deborah B. Goldberg, M.D., formerly a researcher in oncology and now a practicing physician, having worked with many cancer patients, observed them, and heard many tell of smoking marijuana successfully to control emesis, accepts marijuana as proven to be an extremely safe anti-emetic agent. When compared with the other, highly toxic chemical substances routinely prescribed to cancer patients, Dr. Goldberg accepts marijuana as clearly safe for use under medical supervision. (See finding 17, above.)

36. Ivan Silverberg, M.D., board certified in oncology and practicing that specialty in the San Francisco area, has accepted marijuana as a safe anti-emitic when used under medical supervision. Although illegal, it is commonly used by patients in the San Francisco area with the knowledge and acquiesence of their doctors who readily accept it as being safe for such use.

37. It can be inferred that all of the doctors and other health care professionals referred to in the findings in Sections V, VI and VII, above, who tolerate or permit patients to self-addminister illegal marijuana for therapeutic benefit, accept the substance as safe for use under medical supervision.

Discussion

The Act, at 21 U.S.C. § 812(b)(1)(C), requires that marijuana be retained in Schedule I if "[t]here is a lack of accepted safety for use of [it] under medical supervision." If there is no lack of such safety, if it is accepted that this substance can be used with safety under medical supervision, then it is unreasonable to keep it in Schedule I.

Again we must ask - "accepted" by whom? In the MDMA proceeding the Agency's first Final Rule decided that "accepted" here meant, as in the phrase "accepted medical use in treatment", that the FDA had accepted the substance pursuant to the provisions of the Food, Drug and Cosmetic Act. 51 Fed. Reg. 36555 (1986). The Court of Appeals held that this was error. On remand, in its third Final Rule on MDMA, the Agency made the same ruling as before, relying essentially on the same findings, and on others of similar nature, just as it did with respect to "accepted medical use." 53 Fed. Reg. 5156 (1988).

The administrative law judge finds himself constrained not to follow the rationale in that MDMA third Final Order for the same reasons as set out above in Section V with respect to "accepted medical use" in oncology. See pages 30 to 33. Briefly, the Agency was looking primarily at the results of scientific tests and studies rather than at what physicians had, in fact, accepted. The Agency was wrongly basing its decision on a judgement as to whether or not doctors ought to have accepted the substance in question as safe for use under medical supervision. The criteria the Agency applied in the MDMA third Final Rule are inappropriate. The only proper question for the Agency here is: Have a significant minority of physicians accepted marijuana as safe for use under medical supervision?

The gist of the Agency's case against recognizing marijuana's acceptance as safe is to assert that more studies, more tests are needed. The Agency has presented highly qualified and respected experts, researchers and others, who hold that view. But, as demonstrated in the discussion in Section V above, it is unrealistic and unreasonable to require unanimity of opinion on the question confronting us. For the reasons there indicated, acceptance by a significant minority of doctors is all that can reasonably be required. This record makes it abundantly clear that such acceptance exists in the United States.

Findings are made above with respect to the safety of medically supervised use of marijuana by glaucoma patients. Those findings are relevant to the safety issue even though the administrative law judge does not find accepted use in treatment of glaucoma to have been shown.

Based upon the facts established in this record and set out above one must reasonably conclude that there is accepted safety for use of marijuana under medical supervision. To conclude otherwise, on this record, would be unreasonable, arbitrary and capricious.

IX.

CONCLUSION AND RECOMMENDED DECISION

Based upon the foregoing facts and reasoning, the administrative law judge concludes that the provisions of the Act permit and require the transfer of marijuana from Schedule I to Schedule II. The judge realizes that strong emotions are aroused on both sides of any discussion concerning the use of marijuana. Nonetheless it is essential for this Agency, and its Administrator, calmly and dispassionately to review the evidence of record, correctly apply the law, and act accordingly.

Marijuana can be harmful. Marijuana is abused. But the same is true of dozens of drugs or substances which are listed in Schedule II so that they can be employed in treatment by physicians in proper cases, despite their abuse potenial.

Transferring marijuana from Schedule I to Schedule II will not, of course, make it immediately available in pharmacies throughout the country for legitimate use in treatment. Other government authorities, Federal and State, will doubtless have to act before that might occur. But this Agency is not charged with responsibility, or given authority, over the myriad other regulatory decisions that may be required before marijuana can actually be legally available. This Agency is charged merely with determining the placement of marijuana pursuant to the provisions of the Act. Under our system of laws the responsibilities of other regulatory bodies are the concerns of those bodies, not of this Agency.

There are those who, in all sincerety, argue that the transfer of marijuana

to Schedule II will "send a signal" that marijuana is "OK" generally for recreational use. This argument is specious. It presents no valid reason for refraining from taking an action required by law in light of the evidence. If marijuana should be placed in Schedule II, in obedience to the law, then that is where marijuana should be placed, regardless of misinterpretation of the placement by some. The reasons for the placement can, and should, be clearly explained at the time the action is taken. The fear of sending such a signal cannot be permitted to override the legitimate need, amply demonstrated in this record, of countless suffers for the relief marijuana can provide when prescribed by a physician in a legitimate case.

The evidence in this record clearly shows that marijuana has been accepted as 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 DEA to continue to stand between those sufferers and the benefits of this substance in light of the evidence in this record.

The administrative law judge recommends that the Administrator conclude that the marijuana plant considered as a whole has a currently accepted medical use in treatment in the United States, that there is no lack of accepted safety for use of it under medical supervision and that it may lawfully be transferred from Schedule I to Schedule II. The judge recommends that the Administrator transfer marijuana from Schedule I to Schedule II.

Dated: SEP 6 1988

Francis L. Young
Administrative Law Judge

CERTIFICATION OF SERVICE

This is to certify that the undersigned on SEP 6 1988 , caused a copy of the foregoing to be delivered to

Madeleine R. Shirley, Esq.
Office of Chief Counsel
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1405 I Street, N.W.
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and caused a copy to be mailed, postage paid, to each of the following:

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Dianne L. Martin
Hearing Clerk

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Drug Enforcement Administration

DEA Headquarters

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August 26, 2019

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FOR IMMEDIATE RELEASE

DEA announces steps necessary to improve access to marijuana research

WASHINGTON – The Drug Enforcement Administration today announced that it is moving forward to facilitate and expand scientific and medical research for marijuana in the United States. The DEA is providing notice of pending applications from entities applying to be registered to manufacture marijuana for researchers. DEA anticipates that registering additional qualified marijuana growers will increase the variety of marijuana available for these purposes.

Over the last two years, the total number of individuals registered by DEA to conduct research with marijuana, marijuana extracts, derivatives and delta-9-tetrahydrocannabinol (THC) has increased by more than 40 percent from 384 in January 2017 to 542 in January 2019. Similarly, in the last two years, DEA has more than doubled the production quota for marijuana each year based on increased usage projections for federally approved research projects.

"I am pleased that DEA is moving forward with its review of applications for those who seek to grow marijuana legally to support research," said Attorney General William P. Barr. "The Department of Justice will continue to work with our colleagues at the Department of Health and Human Services and across the Administration to improve research opportunities wherever we can."

"DEA is making progress in the program to register additional marijuana growers for federally authorized research, and will work with other relevant federal agencies to expedite the necessary next steps," said DEA Acting Administrator Uttam Dhillon. "We support additional research into marijuana and its components, and we believe registering more growers will result in researchers having access to a wider variety for study."

This notice also announces 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, which was signed into law on Dec. 20, 2018, changed the definition of marijuana to exclude "hemp"—plant material that contains 0.3 percent or less delta-9 THC on a dry weight basis. Accordingly,

hemp, including hemp plants and cannabidiol (CBD) preparations at or below the 0.3 percent delta-9 THC threshold, is not a controlled substance, and a DEA registration is not required to grow or research it.

Before making decisions on these pending applications, DEA intends to propose new regulations that will govern the marijuana growers program for scientific and medical research. The new rules will help ensure DEA can evaluate the applications under the applicable legal standard and conform the program to relevant laws. To ensure transparency and public participation, this process will provide applicants and the general public with an opportunity to comment on the regulations that should govern the program of growing marijuana for scientific and medical research.

Notice of Application.

Who We Are+
What We Do+
Resources+
Doing Business with the DEA+
Policies+

United States Drug Enforcement Administration
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CRIME IN AMERICA—ILLICIT AND DANGEROUS DRUGS

HEARINGS

BEFORE THE

SELECT COMMITTEE ON CRIME
HOUSE OF REPRESENTATIVES

NINETY-FIRST CONGRESS

FIRST SESSION

PURSUANT TO

H. Res. 17

A RESOLUTION CREATING A SELECT COMMITTEE TO CONDUCT STUDIES AND INVESTIGATIONS OF CRIME IN THE UNITED STATES

OCTOBER 23, 24, 25, AND 27, 1969, SAN FRANCISCO, CALIF.

Printed for the use of the Select Committee on Crime

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cotics and Dangerous Drugs is also accompanied by an attorney, Anthony J. Roccograndi.

I might say that this paraphernalia down front is not part of Chairman Pepper's apothecary. That is going to be explained.

I would like to say a brief word about each of these gentlemen who is going to appear as our witnesses.

John L. Kelly is the deputy director in Los Angeles for the Bureau of Narcotics and Dangerous Drugs. His region includes Hawaii. He has been with the Bureau of Narcotics for 19 years and, before assuming his present position, was agent in charge in San Francisco for the Bureau of Narcotics and Dangerous Drugs.

Mr. Addario has had an outstanding career in the law enforcement area. He started in 1959 with the Philadelphia Police Department, at which time he joined the Narcotics Bureau as a criminal investigator in Philadelphia and New York.

Mr. Currie is a native San Franciscan. He has been with the San Francisco Police Department for 33 years. For the past 6 years, Lieutenant Currie has been in charge of the Narcotics Detail of the Department. Lieutenant Currie is not here yet.

Matthew O'Connor is sitting on the left. He is the San Francisco area supervisor for the California Bureau of Narcotics Enforcement. He has been with that bureau for 21 years and served in the capacity of supervisor for 11 years. He is well informed on the drug scene in California and elsewhere. He was recently elected president of the California Narcotics Enforcement Association at Philadelphia.

I might say, Mr. Chairman, before we ask these gentlemen questions, that each of them and each of the departments involved here have been exceedingly helpful to the committee in this investigation. Indeed, I believe that without their cooperation, we would not have been able to put the hearings together as quickly as we have.

I would like to start out by asking each of the agency representatives to describe the size of their narcotic enforcement agency, what areas their enforcement efforts cover, and what their general activities are.

Could you start on that, Mr. Kelly, representing the Bureau of Narcotics and Dangerous Drugs? Then we will hear from the State agency and then, hopefully, the city of San Francisco if Lieutenant Currie is here by that time.

STATEMENT OF JOHN L. KELLY, DEPUTY REGIONAL DIRECTOR IN LOS ANGELES, BUREAU OF NARCOTICS AND DANGEROUS DRUGS, ACCOMPANIED BY DANIEL J. ADDARIO, SPECIAL AGENT IN CHARGE, SAN FRANCISCO DISTRICT OFFICE, BUREAU OF NARCOTICS AND DANGEROUS DRUGS; ANTHONY J. ROCCOGRANDI, ATTORNEY AT LAW; NORBERT CURRIE, LIEUTENANT IN CHARGE OF THE NARCOTICS DETAIL, SAN FRANCISCO POLICE DEPARTMENT; AND MATTHEW M. O'CONNOR, SAN FRANCISCO AREA SUPERVISOR, CALIFORNIA BUREAU OF NARCOTIC ENFORCEMENT

Mr. KELLY. Yes, sir.

First I would like to thank this committee for this invitation to appear before them.

Mr. WIGGINS. I am not being critical of you. I just want a copy of it if I can have it.

Mr. Kelly, have you in the Federal agency on the Federal side made any recommendation on this?

Mr. KELLY. I was just in the process of asking our legal adviser here.

Mr. ADDARIO. This is Mr. Roccograndi, our legal counsel from the Bureau of Narcotics and Dangerous Drugs.

Mr. WIGGINS. What I am getting at is, if you have recommendations, I would like you to file those recommendations with the committee and if you have not, I would like those at least under our jurisdiction on the Federal side to put together your thoughts and file them with the committee.

Mr. ROCCOGRANDI. Sir, I think those thoughts have been put together in Mr. Nixon's proposal which is incorporated in S. 2637, currently before Senator Dodd's committee.

Mr. PEPPER. Would you please repeat that?

Mr. ROCCOGRANDI. Legislation which would make the equipment you see before you contraband and subject to forfeiture is currently incorporated in the administration's proposal, S. 2637, which was before Senator Dodd's Subcommittee on Juvenile Delinquency.

Mr. WIGGINS. It is still there.

Thank you.

Mr. WATSON. Pursuing that one step further, is it not true that any contrivance used in the illegal manufacture of any commodity is subject to contraband laws? You are not telling me that it is legal for these pills to be manufactured in these various places, because the law requires that every manufacturer be licensed. The manufacturer using this machine was not licensed, was it?

Mr. ROCCOGRANDI. No, sir.

Mr. WATSON. And not being licensed, any contrivance or machinery used in the illegal processes is subject to contraband.

Mr. ROCCOGRANDI. I am afraid not, sir. It is subject to seizure but it is not forfeitable as contraband. In many instances, the machinery and equipment can be reclaimed by its former owner.

Mr. WATSON. Are you telling me that it is subject to seizure but you cannot keep it? Is that correct?

Mr. ROCCOGRANDI. Yes, sir, in most cases under present law.

Mr. KURRUS. Does that machine have any purpose other than putting out illegal pills? Where do you buy a machine like that? That is a pretty complicated looking piece of equipment. Is that a custom-made job, so to speak?

Mr. ADDARIO. Your biggest manufacture of tableting machines is an outfit called Stokes in Philadelphia. That particular machine looks like a combination of a homemade-type thing. That is not what you would call a standardized type of tableting machine.

Mr. KURRUS. Would Stokes in Philadelphia sell a tableting machine or a pill-making machine to anybody who just wanted to buy one?

Mr. ADDARIO. Again, with the proper letterhead and various other Dun & Bradstreet ratings, I am sure just about anyone could get a tableting machine.

Mr. KURRUS. What's a machine like that worth?

Mr. ADDARIO. That is about $400.

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The Marijuana Policy Gap and the Path Forward

Updated March 10, 2017

Congressional Research Service
https://crsreports.congress.gov
R44782

CRS REPORT
Prepared for Members and
Committees of Congress

Summary

Under federal law, the cultivation, possession, and distribution of marijuana are illegal, except for the purposes of sanctioned research. States, however, have established a range of laws and policies regarding marijuana's medical and recreational use. Most states have deviated from an across-the-board prohibition of marijuana, and it is now more so the rule than the exception that states have laws and policies allowing for some cultivation, sale, distribution, and possession of marijuana—all of which are contrary to the federal Controlled Substances Act (CSA). As of March 2017, nearly 90% of the states, as well as Puerto Rico and the District of Columbia, allow for the *medical use* of marijuana in some capacity. Also, eight states and the District of Columbia now allow for some *recreational use* of marijuana. These developments have spurred a number of questions regarding their potential implications for federal law enforcement activities and for the nation's drug policies as a whole.

Thus far, the federal response to state actions to decriminalize or legalize marijuana largely has been to allow states to implement their own laws on marijuana. The Department of Justice (DOJ) has nonetheless reaffirmed that marijuana growth, possession, and trafficking remain crimes under federal law irrespective of states' positions on marijuana. Rather than targeting individuals for drug use and possession, federal law enforcement has generally focused its counterdrug efforts on criminal networks involved in the drug trade.

While the majority of the American public supports marijuana legalization, some have voiced apprehension over possible negative implications. Opponents' concerns include, but are not limited to, the potential impact of legalization on (1) marijuana use, particularly among youth; (2) road incidents involving marijuana-impaired drivers; (3) marijuana trafficking from states that have legalized it into neighboring states that have not; and (4) U.S. compliance with international treaties. Proponents of legalization have been encouraged by potential outcomes that could result from marijuana legalization, including a new source of tax revenue for states and a decrease in marijuana-related arrests. Many of these potential implications are yet to be fully measured.

Given the current marijuana policy gap between the federal government and many of the states, there are a number of issues that Congress may address. These include, but are not limited to, issues surrounding availability of financial services for marijuana businesses, federal tax treatment, oversight of federal law enforcement, allowance of states to implement medical marijuana laws and involvement of federal health care workers, and consideration of marijuana as a Schedule I drug under the CSA. The marijuana policy gap has widened each year for some time. It has only been a few years since states began to legalize recreational marijuana, but over 20 years since they began to legalize medical marijuana. In addressing state-level legalization efforts and considering marijuana's current placement on Schedule I, Congress could take one of several routes. It could elect to take no action, thereby upholding the federal government's current marijuana policy. It may also decide that the CSA must be enforced in states and not allow them to implement conflicting laws on marijuana. Alternatively, Congress could choose to reevaluate marijuana's placement as a Schedule I controlled substance.

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Introduction

Marijuana is the most commonly used illicit drug in the United States.[1] It is a psychoactive drug that generally consists of leaves and flowers of the cannabis sativa plant. Its history dates back thousands of years, but in the United States, it became popular as a recreational drug in the early 20th century.[2] The THC[3] content of marijuana is dependent on both the variety of the cannabis plant and the part used.[4] Under federal law, cannabis and its derivatives are classified as Schedule I controlled substances—thus prohibiting their possession, cultivation, or distribution—under the Controlled Substances Act (CSA), regardless of its THC content, unless specifically exempted or listed in another schedule (see "Controlled Substances Act").

The percentage of the population 12 and older currently using (past month use of) marijuana has generally increased over the last several years—from 6.9% in 2010 to 8.3% in 2015.[5] The rate of past-month marijuana use among youth (aged 12-17), however, has remained relatively unchanged over this period (7.0%).[6] Youth also generally perceive that obtaining marijuana—if they desire it—is relatively easy.[7] Indeed, marijuana is available throughout the United States; 34% of state and local law enforcement agencies that were surveyed by the Drug Enforcement Administration (DEA) reported an increase in availability over the last year, and 62% reported that availability had remained the same.[8]

This report provides a background on federal marijuana policy and an overview of state trends with respect to marijuana decriminalization and legalization—for both medical and recreational

[1] In 2015, an estimated 22.2 million individuals in the United States aged 12 or older (8.3% of this population) were current (past month) users of marijuana. See Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, *Results from the 2015 National Survey on Drug Use and Health: Detailed Tables*, September 2016, Tables 1.1A and 1.1B, http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015.htm. Hereinafter, *Results from 2015 NSDUH*.

[2] David F. Musto, *The American Disease: Origins of Narcotic Control*, 3rd ed. (New York: Oxford University Press, 1999), p. 219.

[3] THC stands for delta-9-tetrahydrocannabinol, the primary psychoactive chemical compound, or cannabinoid, in marijuana.

[4] Industrial hemp is a variety of the cannabis plant that has low THC content and is cultivated for use in the production of a wide range of products. THC levels for hemp are generally less than 1%. For further information about hemp, see CRS Report RL32725, *Hemp as an Agricultural Commodity*, by Renée Johnson. While hemp is mentioned in this report, it largely focuses on marijuana.

[5] For each year from 2010 to 2014, the estimated percentage of the population currently using marijuana was 6.9%, 7.0%, 7.3%, 7.5%, and 8.4% respectively. The difference between each year's estimate (2010 – 2013) and the 2014 estimate (8.4%) is statistically significant at the .05 level. For 2014 to 2015, however, the percentage dropped from 8.4% to 8.3%; this change is not statistically significant at the .05 level. See Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, *Results from 2015 NSDUH*; and *Results from the 2014 National Survey on Drug Use and Health: Summary of National Findings*, September 2015, p. 6 (hereinafter, *Results from 2014 NSDUH*). Of note, some warn of potential bias in drug usage survey data because of misreporting by respondents. See Beau Kilmer, Jonathan P. Caulkins, and Gregory Midgette, et al., *Before the Grand Opening: Measuring Washington State's Marijuana Market in the Last Year Before Legalized Commercial Sales*, RAND Drug Policy Research Center, 2013.

[6] Results from *2015 NSDUH*, Table 1.2B; and *Results from 2014 NSDUH*.

[7] Nearly half of surveyed youth indicated that marijuana would be "fairly easy" or "very easy" to obtain if desired. *Results from the 2015 NSDUH*, Table 3.1B.

[8] Based on assessments from 1,444 local, state, and tribal law enforcement agencies that responded to the DEA's 2016 National Drug Threat Survey. U.S. Drug Enforcement Administration, *2016 National Drug Threat Assessment Summary,* DEA-DCT-DIR-001-17, November 2016 (hereinafter, *2016 National Drug Threat Assessment Summary*).

uses. It then analyzes relevant issues for federal law enforcement and the implications of state marijuana legalization. The report also outlines a number of related policy questions that Congress may confront, including legalization in the District of Columbia, financial services for marijuana businesses, the medical nature of marijuana, oversight of federal law enforcement, and evaluation of marijuana as a Schedule I drug.

Controlled Substances Act

Marijuana is currently listed as a Schedule I controlled substance under the CSA.[9] This indicates that the federal government has determined that

> (A) The drug or other substance has a high potential for abuse.
>
> (B) The drug or other substance has no currently accepted medical use in treatment in the United States.
>
> (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.[10]

Controlled Substances Act (CSA)

The CSA was enacted as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[11] It regulates the manufacture, possession, use, importation, and distribution of certain drugs, substances, and precursor chemicals. Under the CSA, there are five schedules under which substances may be classified—Schedule I being the most restrictive. Substances placed onto one of the five schedules are evaluated on

- actual or relative potential for abuse;
- known scientific evidence of pharmacological effects;
- current scientific knowledge of the substance;
- history and current pattern of abuse;
- scope, duration, and significance of abuse;
- risk to public health;
- psychic or physiological dependence liability; and
- whether the substance is an immediate precursor of an already scheduled substance.

U.S. federal drug control policies—specifically those positions relating to marijuana—continue to generate debates among policymakers, law enforcement officials, scholars, and the public. Even before the federal government's move in 1970 to criminalize the manufacture, distribution, dispensation, and possession of marijuana,[12] there were significant discussions over marijuana's place in American society.

Evolution of Public Opinion

Changes in state and local marijuana laws are coupled with a general shift in public attitudes toward the substance. In 1969, 12% of the surveyed population supported legalizing marijuana;

[9] For more information on the CSA, see the text box, "Controlled Substances Act (CSA)."

[10] 21 U.S.C. §812(b)(1).

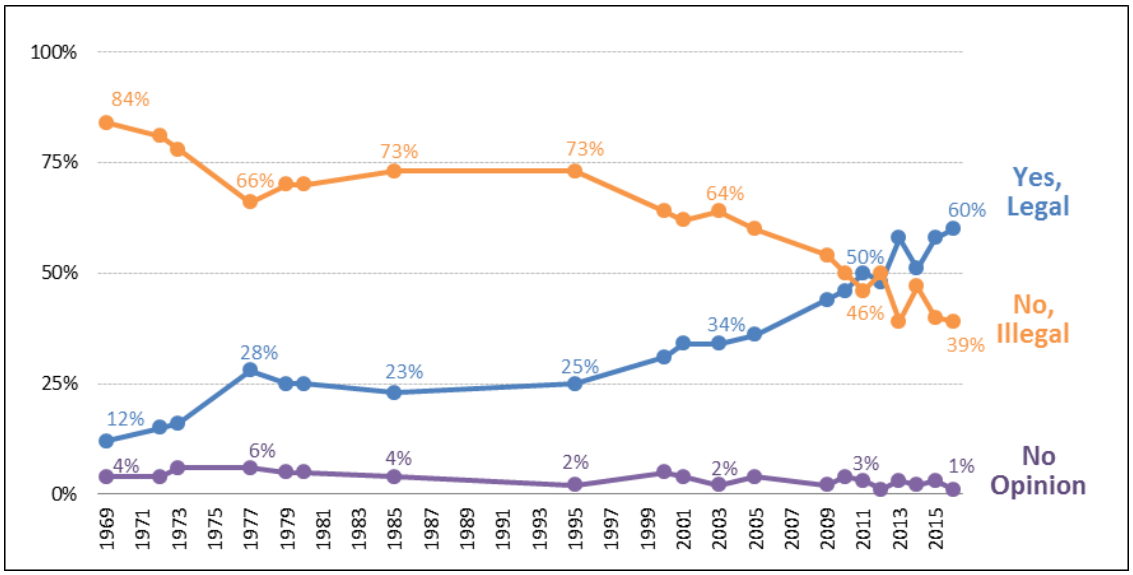
[11] P.L. 91-513; 21 U.S.C. §801 et. seq. For additional information on the CSA, see CRS Report RL34635, *The Controlled Substances Act: Regulatory Requirements*, by Brian T. Yeh; and CRS Report RL30722, *Drug Offenses: Maximum Fines and Terms of Imprisonment for Violation of the Federal Controlled Substances Act and Related Laws*, by Brian T. Yeh.

[12] 21 U.S.C. §§812 and 841.

today, 60% of surveyed adults feel that marijuana should be legalized.[13] Support for legalization has more than doubled over the last 20 years. In addition, nearly 60% of respondents indicate that the federal government should not enforce federal marijuana prohibition laws in those states that allow for its use.[14]

Figure 1. Views on Legalization of Marijuana

Percentage of Americans who support or are against legalizing marijuana, 1969-2016



Source: CRS presentation of Gallup data. Gallup News Service, *Gallup Poll Social Series: Crime*, http://www.gallup.com.

Notes: Question: "Do you think marijuana should be made legal or not?" Sample sizes vary from year to year. 2016 data are based on telephone interviews conducted October 5-9, 2016, with a random sample of 1,017 adults aged 18 and older living in the United States.

Marijuana as Medicine

As mentioned, marijuana's placement on Schedule I of the CSA means that it has no currently accepted medical use according to the federal government. Under federal law, marketing a drug as medicine requires approval from the Food and Drug Administration (FDA).[15] While most states have laws allowing for medicinal use of marijuana, the FDA has not approved marijuana, any drug containing marijuana, or any drug containing a plant-derived chemical constituent of marijuana for medicinal use. The FDA has, however, approved two drugs containing synthetic

[13] The poll question is "Do you think marijuana should be made legal or not?" See Art Swift, *Support for Legal Marijuana Use Up to 60% in U.S.*, Gallup, October 19, 2016 (based on poll data from October 2016). For purposes of this question, it does not distinguish between medical and recreational marijuana. Of note, in August 2016, the Pew Research Center found similar levels of support for marijuana legalization among American adults. See Abigail Geiger, *Support for marijuana legalization continues to rise*, Pew Research Center, article based on Aug. 23-Sept. 2 Pew Research Center survey, October 12, 2016, http://www.pewresearch.org.

[14] Pew Research Center for the People & the Press, *In Debate Over Legalizing Marijuana, Disagreement Over Drug's Dangers*, April 14, 2015 (based on poll data from March 2015).

[15] Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. §§301 et seq.). For more information CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by Susan Thaul.

THC.[16] In addition, drugs containing plant-derived THC and/or cannabidiol (CBD, a nonpsychoactive chemical component of marijuana) are in the drug development and approval process.[17] See **Appendix A** for further discussion of these drugs.

Individuals use marijuana to treat medical issues such as lack of appetite, nausea, chronic pain, spasticity, anxiety, and other maladies; however, the efficacy of this treatment is unclear from available scientific evidence.[19] While some individuals report (both anecdotally and in scientific studies) benefits and alleviation of symptoms from use of marijuana, reports are inconsistent. Some have argued that the scientific field has been unable to robustly determine the medicinal value and merits of marijuana due to regulatory restrictions on quality, quantity, and use of marijuana in scientific research.[20]

Risks Associated with Marijuana Use

The FDA's eight-factor analysis includes an assessment of risks associated with marijuana use. Marijuana is known to affect the central nervous system, the cardiovascular system, the respiratory system, and the immune system. Its effects may vary according to how it is consumed (e.g., inhaled or ingested), how much of it is consumed, how often it is consumed, and over what time frame it is consumed.

Some of marijuana's most widely recognized effects are among the reasons people use it recreationally: it can reduce inhibition, improve mood, enhance sensory perception, and heighten imagination (among other effects). Some common effects are more problematic: it can cause dizziness, confusion, ataxia (i.e., uncoordinated movements), delusions, and agitation (among other effects). Marijuana's acute effects can impair an individual's ability to perform daily activities, such as studying or driving. Chronic use of marijuana can lead to abuse or dependence and, in the case of heavy chronic use, the potential for withdrawal (with symptoms like insomnia, weight loss, and irritability).[18]

Scientific Evaluations of Medical Marijuana Effects

Recent evaluations conducted separately by the FDA and the National Academies of Sciences, Engineering, and Medicine (the National Academies) illustrate the challenge of meeting the required standard of evidence for demonstrating effective medical use. While taking different approaches to their evaluations, both the FDA and the National Academies have found that the current evidence base falls short. According to the FDA, "no published studies conducted with marijuana meet the criteria of an adequate and well-controlled efficacy study," and "the criteria for adequate safety studies [have] also not been met."[21] According to the National Academies,

[16] These drugs are Nabilone, an antiemetic (to reduce nausea or prevent vomiting) for patients receiving chemotherapy for cancer, and Dronabinol, both an antiemetic for patients on chemotherapy and an appetite stimulant for patients with AIDS-related weight loss. See **Appendix A** for additional information regarding FDA-approved drugs.

[17] Department of Health and Human Services, Food and Drug Administration, *FDA and Marijuana: Questions and Answers*, http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm#determinations. For an explanation of the FDA's drug development and approval process, see http://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm.

[18] Department of Justice, Drug Enforcement Administration, "Denial of Petition to Initiate Proceedings to Reschedule Marijuana," 81 *Federal Register* 53687-53766 and 53767-53845, August 12, 2016.

[19] Penny F. Whiting, Robert F. Wolff, and Sophan Deshpande, et al., "Cannabinoids for Medical Use," *Journal of the American Medical Association*, vol. 313, no. 24 (June 2015), pp. 2456-2473.

[20] See, for example, Chapter 15 of National Academies of Sciences, Engineering, and Medicine, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*, Washington, DC, 2017, p. S-1, doi: 10.17226/24625.

[21] Department of Justice, Drug Enforcement Administration, "Denial of Petition to Initiate Proceedings to Reschedule Marijuana," 81 *Federal Register* 53687-53766 and 53767-53845, August 12, 2016. The criteria for adequate and well-controlled studies are defined under 21 C.F.R. §314.126.

"conclusive evidence regarding the short- and long-term health effects (harms and benefits) of cannabis use remains elusive."[22] These studies are discussed in more detail in **Appendix A**.

Federal Regulation of Marijuana Research

Individuals who seek to conduct research on any controlled substance must do so in accordance with the CSA and other federal laws.[23] For all controlled substances, individuals must obtain a registration issued by the Attorney General, as delegated to the DEA[24] in accordance with associated rules and regulations issued by the Attorney General.[25] Also, DEA regulations require *all* registrants to comply with strict storage requirements for controlled substances.[26]

Some have argued that federal regulation of marijuana research unnecessarily impedes the clinical trials that are required for FDA approval, and the Obama Administration simplified some small steps within the larger process. In recent years, the federal government has attempted to make marijuana research easier.

- In June 2015, HHS eliminated one step in obtaining research-grade marijuana for research that is not funded by the National Institutes of Health.[27]
- In December 2015, the DEA announced a waiver to make it easier for researchers conducting clinical trials with CBD to modify their research protocols and obtain more CBD than was initially approved.[28]
- In August 2016, the DEA announced a new policy intended to increase the number of approved sources of research-grade marijuana.[29]

Prior to the August 2016 change, some contended that marijuana provided to researchers was "both qualitatively and quantitatively inadequate."[30] The DEA's recent policy change

[22] National Academies of Sciences, Engineering, and Medicine, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*, Washington, DC, 2017, p. S-1, doi: 10.17226/24625.

[23] For regulatory requirements under the CSA, see CRS Report RL34635, *The Controlled Substances Act: Regulatory Requirements*, by Brian T. Yeh.

[24] As authorized under 21 U.S.C. §871, the Attorney General may delegate any of his/her control and enforcement functions under the CSA to any officer or employee of the Department of Justice—many of these functions are performed by the DEA.

[25] See 21 U.S.C. §822. This requirement is also described under 21 CFR 1301.11(a): Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§1301.22 through 1301.26.

[26] For the purposes of ensuring the secure storage and distribution of *all* controlled substances, all applicants and registrants must generally "provide effective controls and procedures to guard against theft and diversion of controlled substances." See 21 C.F.R. §1301.71.

[27] Department of Health and Human Services, "Announcement of Revision to the Department of Health and Human Services Guidance on Procedures for the Provision of Marijuana for Medical Research as Published on May 21, 1999," 80 *Federal Register* 35960-35961, June 23, 2015.

[28] Department of Justice, Drug Enforcement Administration, "DEA Eases Requirements for FDA-Approved Clinical Trials on Cannabidiol," press release, December 23, 2015.

[29] Department of Justice, Drug Enforcement Administration, "Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the U.S.," 81 *Federal Register* 53846-53848, August 12, 2016.

[30] Marc Kaufman, "Federal Marijuana Monopoly Challenged," *Washington Post*, December 12, 2005; and Department of Justice, Drug Enforcement Administration, "Lyle E. Craker; Denial of Application," 74 *Federal Register* 2101, January 14, 2009.

may appease those researchers seeking better quality and quantity of marijuana. For broader discussion of this issue, see **Appendix A**.

Current Federal Status of Marijuana and the Policy Gap with States

While the federal government maintains marijuana's current placement as a Schedule I controlled substance, states have established a range of laws and policies regarding its medical and recreational use. These developments have spurred a number of questions regarding potential implications for federal drug enforcement activities and for the nation's drug policies as a whole. In 1970, the CSA placed the control of marijuana under federal jurisdiction *regardless* of state regulations and laws, and its status has remained unchanged under federal law for nearly 50 years. For more background on federal marijuana policy and the history of how marijuana came to be illegal in the United States, see **Appendix B**.

Select Consequences of Marijuana Use Under Federal Law

Marijuana use may subject an individual to a number of consequences under federal law regardless of whether that individual has been convicted of a marijuana-related offense. For example, marijuana users may lose their ability to purchase and possess a firearm, or be barred from living in public housing. Under the Gun Control Act, it is unlawful to possess, ship, transport, receive, or dispose of any firearm or ammunition to any person "who is an unlawful user of or addicted to any controlled substance" as defined by the CSA.[31] In addition, federal law also establishes that "illegal drug users" are ineligible for federally assisted housing.[32] The law requires public housing agencies and owners of federally assisted housing to establish standards that would allow the agency or owner to prohibit admission to, or terminate the tenancy or assistance of, any such applicant or tenant.[33]

DEA Rejection of Petitions to Reschedule

There has been mounting public pressure for the DEA to reevaluate marijuana as a Schedule I controlled substance. Over the years, several entities have submitted petitions to reschedule marijuana.[34] In August 2016, after a five-year evaluation process done in conjunction with the Food and Drug Administration (FDA), the DEA rejected two petitions submitted by two state governors and a New Mexico health provider, respectively, to move marijuana to a less-restrictive schedule under the CSA.[35] Consistent with past practice,[36] the rejections were based on a conclusion by both the FDA and DEA that marijuana continues to meet the criteria for inclusion

[31] See 18 U.S.C. §§922(g)(3), 924(a)(2) and 27 C.F.R. §478.11.

[32] 42 U.S.C. §§13661-13662.

[33] For a broader discussion of legal consequences of marijuana use, see CRS Report R43435, *Marijuana: Medical and Retail—Selected Legal Issues*, by Todd Garvey, Charles Doyle, and David H. Carpenter.

[34] Any interested party may petition the Administrator of the DEA to initiate rulemaking proceedings to reschedule a controlled substance. See 21 U.S.C. §811(a) and 21 C.F.R. §1308.43(a) for relevant rules and regulations.

[35] In 2011, the governors of Rhode Island and Washington petitioned the DEA to have marijuana and "related items" removed from Schedule I of the CSA and rescheduled as medical cannabis in Schedule II. In 2009, Bryan Krumm, a health provider in New Mexico, petitioned the DEA to have marijuana removed from Schedule I of the CSA and rescheduled in any schedule other than Schedule I.

[36] The DEA has previously denied petitions to reschedule marijuana. For example, in 2002 a petition was filed to have marijuana removed from Schedule I and rescheduled as cannabis in Schedule III, IV, or V. In 2011, the DEA rejected the petition. See Drug Enforcement Administration, "Denial of Petition to Initiate Proceedings to Reschedule Marijuana," 76 *Federal Register* 40552-40589, July 8, 2011.

on Schedule I—namely that it has a high potential for abuse, has no currently accepted medical use, and lacks an accepted level of safety for use under medical supervision.[37]

It is important to note that both Congress and the Administration have the power to alter marijuana's status as a Schedule I substance. Congress could amend the CSA to move marijuana to a lower schedule or remove it entirely from control. The Administration could also make such changes on its own, though it is bound by the CSA to evaluate a substance prior to altering its scheduling status.[38]

Trends in States

Over the past few decades, most states have deviated from an across-the-board prohibition of marijuana, and as of March 2017, nearly 90% of the states, as well as Puerto Rico and the District of Columbia, allowed for the *medical use* of marijuana in some capacity.[39] Also, eight states and the District of Columbia now allow for the *recreational use* of marijuana.[40] It is now more so the rule than the exception that states have laws and policies allowing for some manufacturing, sale, distribution, and possession of marijuana—all of which are contrary to the CSA, except for the purposes of sanctioned research.[41] Evolving state-level positions on marijuana include decriminalization initiatives, legal exceptions for medical use, and legalization of certain quantities for recreational use. See **Figure 2** at the end of this section for the various marijuana policies of states.

Decriminalization and legalization initiatives in the states reflect growing public support for the legalization of marijuana. As mentioned, just prior to passage of the CSA in 1970, 12% of surveyed individuals aged 18 and older felt that marijuana should be made legal. In 2016, more than half (60%) of surveyed U.S. adults expressed that marijuana should be legalized.[42]

Decriminalization

Marijuana *decriminalization* differs markedly from *legalization*. A state decriminalizes conduct by removing the accompanying criminal penalties; however, civil penalties remain. If, for instance, a state decriminalizes the possession of marijuana in small amounts,[43] possession of it

[37] See Drug Enforcement Administration, "Denial of Petition to Initiate Proceedings to Reschedule Marijuana," 81 *Federal Register* 53767-53845, August 12, 2016; and Drug Enforcement Administration, "Denial of Petition to Initiate Proceedings to Reschedule Marijuana," 81 *Federal Register* 53687-53766, August 12, 2016.

[38] Federal rulemaking proceedings to add, delete, or change the schedule of a drug or substance may be initiated by the Attorney General (through the DEA), by the Secretary of Health and Human Services, or by petition from any interested person; 21 U.S.C. §811(a). Congress may change the scheduling status of a drug or substance through legislation.

[39] National Conference of State Legislatures, *State Medical Marijuana Laws*, November 2016. Some states allow broad access to medical marijuana while others have more narrow conditions under which access is granted. For example, in Alabama medical marijuana may only be dispensed by the University of Alabama and only to treat a person with an epileptic condition under certain conditions. Also, some states allow cannabidiol (CBD)-only medical marijuana. CBD is a chemical compound of marijuana.

[40] States have established rules surrounding marijuana use—see "Recreational Legalization" for a discussion of state regulations.

[41] The notable exception is the distribution of marijuana for research purposes.

[42] Art Swift, *Support for Legal Marijuana Use Up to 60% in U.S.*, Gallup, October 19, 2016 (based on poll data from October 2016).

[43] Typically one ounce or less, but the amount varies from state to state.

still violates state law, but possession of quantities within the specified *small amount* is considered a civil offense and subject to a civil penalty, not criminal prosecution. By decriminalizing possession of marijuana in small amounts, states are *not legalizing* its possession. In addition, as these initiatives generally relate to the *possession* (rather than the manufacture or distribution) of small amounts of marijuana, decriminalization initiatives do not impede federal law enforcement's priority of targeting high-level drug offenders, or so-called "big fish," rather than individual users.

Decriminalization initiatives by the states do not appear to be at odds with the CSA because both maintain that possessing marijuana is in violation of the law. For example, individuals in possession of small amounts of marijuana in Nebraska—a state that has decriminalized possession of small amounts—are in violation of both the CSA and Nebraska state law. The difference lies in the associated penalties for these federal and state violations. Under the CSA, a person convicted of simple possession (first offense) of marijuana may be punished with up to one year imprisonment and/or fined not more than $1,000.[44] Under Nebraska state law, a person in possession (first offense) of an ounce or less of marijuana is subject to a civil penalty of not more than $300.[45]

In recent years, several states have decriminalized the possession of small amounts of marijuana; however, some of these states continue to treat possession of small amounts of marijuana as a criminal offense under specific circumstances. In New York, for example, the possession of small amounts of marijuana is still considered a crime when it is "open to public view."[46] In 2015, just over 21,000 individuals in New York were arrested for criminal possession of marijuana in the fifth degree, a misdemeanor.[47]

Decriminalization in Cities

Several cities have officially or unofficially decriminalized marijuana possession regardless of what has occurred at the state level. In November 2014, New York City (NYC) Mayor de Blasio and NYC Police Commissioner Bratton announced a change in marijuana enforcement policy; individuals found to be in possession of marijuana (25 grams or less)[48] *may* be eligible to receive a summons instead of being arrested.[49] The New York City Police Department (NYPD) issues so-called "pot tickets" for those in possession of 25 grams or less. In 2016, however, preliminary data indicated that marijuana possession arrests were increasing in NYC compared to 2015—this increase could be the result of changes in NYPD arrest policies; this remains unclear.[50]

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[44] 21 U.S.C. §844.

[45] Also, the judge may order the offender to attend a drug use and abuse education course. See §28-416 of the Nebraska Revised Statutes.

[46] NY Pen. Law §221.10.

[47] State-level arrest data provided to CRS by the New York State Department of Criminal Justice Services.

[48] Under NY Pen. Law §221.10, a person is guilty of criminal possession of marihuana in the fifth degree when he knowingly and unlawfully possesses "1. marihuana in a public place ... and such marihuana is burning or open to public view; or 2. one or more preparations, compounds, mixtures or substances containing marihuana and... are of an aggregate weight of more than twenty-five grams."

[49] City of New York, *Transcript: Mayor de Blasio, Police Commissioner Bratton Announce Change in Marijuana Policy*, November 10, 2014.

[50] City-level arrest data provided to CRS by the New York State Department of Criminal Justice Services. Also see Jennifer Fermino, John Annese, and Ginger Adams Otis, "NYPD cracks down on marijuana possession in NYC, sees big uptick in arrests for carrying pot," *New York Daily News*, June 2, 2016.

Just as there are disparities in state and federal laws and policies, some cities' decriminalization initiatives run contrary to the laws and policies of the states. In Pennsylvania, the state government has not decriminalized marijuana possession, but Pittsburgh, Philadelphia, State College, and Harrisburg have all decriminalized possession in some form. In 2016, Harrisburg's city council unanimously voted to make possession of 30 grams or less of marijuana punishable by a $75 fine and public use punishable by a $150 fine.[51]

Medical Marijuana Exceptions

In 1996, California became the first state to amend its drug laws to allow for the medicinal use of marijuana. As of March 2017, over half of the states, the District of Columbia, Puerto Rico, and Guam have comprehensive policies allowing for the medicinal use of marijuana.[52] Seventeen additional states allow for so-called "limited access medical marijuana," which refers to cannabis with low THC content or CBD oil.[53]

As noted, the CSA does not distinguish between the medical and recreational use of marijuana. Under the CSA, marijuana has "no currently accepted medical use in treatment in the United States,"[54] and states' allowance of its use for medical purposes is at odds with the federal position. Federal law enforcement has investigated, arrested, and prosecuted individuals for medical marijuana-related offenses regardless of whether they are in compliance with state law; however, federal law enforcement emphasizes the investigation and prosecution of growers and dispensers over individual users of medical marijuana. Federal enforcement priorities are discussed further in "Federal Response to State Divergence."

Recreational Legalization

In contrast to marijuana *decriminalization* initiatives wherein civil penalties remain for violations involving marijuana possession, marijuana *legalization* measures remove all state-imposed penalties for specified activities involving marijuana. Until 2012, the recreational use of marijuana had not been legal in any U.S. state since prior to the passage of the CSA in 1970. In November 2012, citizens of Colorado and Washington voted to legalize, regulate, and tax small amounts of marijuana for recreational use.[55] In November 2014, legalization initiatives also passed in Alaska, Oregon, and the District of Columbia (DC), further expanding the disparities between federal and state marijuana laws. Later, in November 2016, recreational legalization initiatives passed in Massachusetts, California, Maine, and Nevada.

These recreational legalization initiatives all legalized the possession of specific quantities of marijuana by individuals aged 21 and over and (with the exception of DC) set up state-administered regulatory schemes for the sale of marijuana;[56] however, there are variations among

[51] Christine Vendel, "It's official: Harrisburg council reduces penalties for pot possession," *Penn Live*, July 5, 2016; and City of Harrisburg, City Council.

[52] Several states are implementing recently enacted laws. National Conference of State Legislatures, *State Medical Marijuana Laws*, November 2016.

[53] As previously mentioned, CBD is a chemical compound in marijuana. Unlike THC, it does not have a psychoactive component.

[54] 21 U.S.C. §812(b)(1).

[55] For more detail regarding both Washington Initiative 502 and Colorado Amendment 64, see CRS Report R43034, *State Legalization of Recreational Marijuana: Selected Legal Issues*, by Todd Garvey and Brian T. Yeh

[56] Regulatory schemes include restrictions and requirements for licensing the production, processing, and retail of marijuana, and procedures for the issuance of licenses.

the initiatives. For example, Colorado, Alaska, Oregon, Massachusetts, Nevada, Maine, California, and DC allow for individuals to grow their own marijuana plants while Washington does not. These legalization initiatives also specify that many actions involving marijuana remain crimes. For example, in Washington, as well as other states, the operation of a motor vehicle while under the influence of marijuana remains a crime.[57] In some states such as Colorado, individuals over the age of 21 may grow small amounts of marijuana for personal use, but marijuana may not be consumed "openly and publicly or in a manner that endangers others."[58] In an example of city-level initiatives breaking from state-level policies, in November 2016, the city of Denver voted to allow designated areas where public consumption of marijuana would be allowed.[59] **Figure 2** highlights the status of marijuana laws by state.

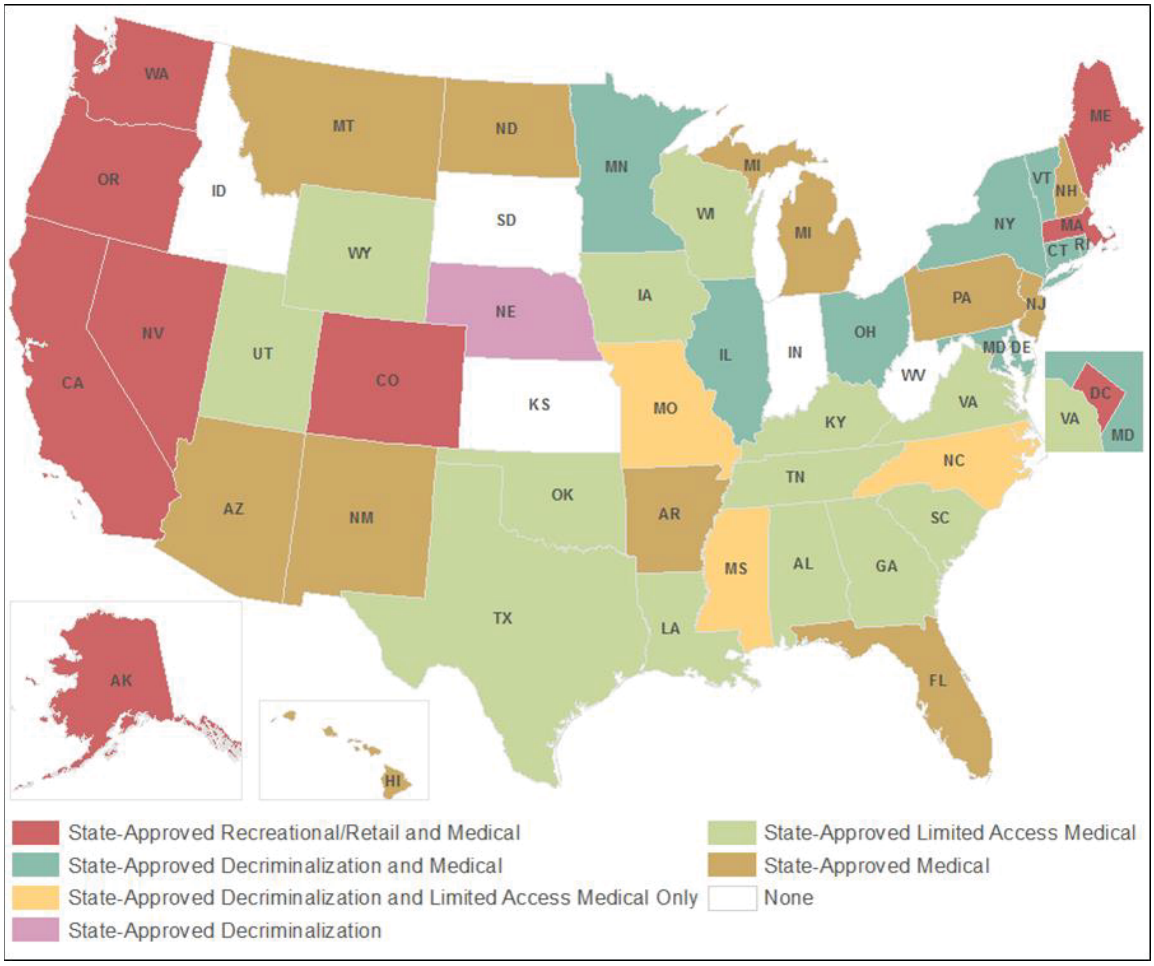
[57] Washington Initiative 502, http://sos.wa.gov/_assets/elections/initiatives/i502.pdf.

[58] Colorado Amendment 64, http://www.leg.state.co.us/LCS/Initiative%20Referendum/1112initrefr.nsf/c63bddd6b9678de787257799006bd391/cfa3bae60c8b4949872579c7006fa7ee/$FILE/Amendment%2064%20-%20Use%20&%20Regulation%20of%20Marijuana.pdf. For information on the Colorado regulatory system, see the website of the Colorado Department of Revenue, Marijuana Enforcement Division: https://www.colorado.gov/pacific/enforcement/marijuanaenforcement.

[59] Denver Initiated Ordinance 300, https://www.denvergov.org/content/dam/denvergov/Portals/778/documents/VoterInfo/Sample_Ballot/2016GeneralComboSampleBallotWatermark.pdf.

Figure 2. Map of State Marijuana Laws

March 2017



Source: CRS presentation of data from the National Conference of State Legislatures and the Drug Enforcement Administration.

Notes: Limited-access medical marijuana refers to cannabis with low THC content or cannabidiol (CBD) oil. "State-approved" refers to either state laws that (1) allow for recreational and/or medical marijuana and/or (2) decriminalize the possession of marijuana in small amounts.

Federal Response to State Divergence

Enforcement Focused on Traffickers

Rather than targeting individuals for drug use and possession, federal law enforcement has generally focused its counterdrug efforts on criminal networks involved in the drug trade. Notably, federal policing efforts on marijuana enforcement appear consistent with this position. Federal marijuana enforcement efforts have largely been focused on *traffickers and distributors* of illicit drugs, rather than the low-level users; rather, arrests for marijuana *possession* offenses are largely made by state and local police.[60] President Obama once noted that "[it] would not

[60] For a discussion of drug enforcement in the United States, see CRS Report R43749, *Drug Enforcement in the United*

make sense from a prioritization point of view for us to focus on recreational drug users in a state that has already said that under state law that's legal."[61] While it is not yet clear how the Trump Administration will proceed with drug enforcement priorities, the White House press secretary indicated there may be increased enforcement against recreational marijuana, and stated that there is a "big difference" between medical and recreational marijuana.[62]

Department of Justice Guidance Memos for U.S. Attorneys

After some states began to legalize the medical use of marijuana, the Department of Justice (DOJ) reaffirmed that marijuana growth, possession, and trafficking remain crimes under federal law irrespective of how individual states may change their laws and positions on marijuana.[63] DOJ has clarified federal marijuana policy through several memos providing direction for U.S. Attorneys in states that allow the medical use of marijuana. In the so-called "Ogden Memo" of 2009, former Deputy Attorney General David Ogden reiterated that combating major drug traffickers remains a central priority and stated:

> [t]he prosecution of significant traffickers of illegal drugs, including marijuana, and the disruption of illegal drug manufacturing and trafficking networks continues to be a core priority in the [Justice] Department's efforts against narcotics and dangerous drugs, and the Department's investigative and prosecutorial resources should be directed towards these objectives. As a general matter, pursuit of these priorities should not focus federal resources in your States on individuals whose actions are in clear and unambiguous compliance with existing state laws providing for the medical use of marijuana.[64]

In a follow-up memorandum to U.S. Attorneys, former Deputy Attorney General James Cole restated that enforcing the CSA remained a core priority of DOJ, even in states that had legalized medical marijuana. He clarified that "[t]he Ogden Memorandum was never intended to shield such activities from federal enforcement action and prosecution, even where those activities purport to comply with state law."[65]

In his memo, Deputy Attorney General Cole warned those who might assist medical marijuana dispensaries in any way. He stated that "[p]ersons who are in the business of cultivating, selling or distributing marijuana, *and those who knowingly facilitate such activities* [emphasis added], are in violation of the Controlled Substances Act, regardless of state law."[66] This has been interpreted by some to mean, for example, that building owners and managers are in violation of the CSA by allowing medical marijuana dispensaries to operate in their buildings.[67] Deputy

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States: History, Policy, and Trends, by Lisa N. Sacco.

[61] "Marijuana Not High Obama Priority," *ABC Nightline*, December 14, 2012.

[62] The White House, Office of the Press Secretary, *Press Briefing by Press Secretary Sean Spicer, 2/23/2017, #15*, February 22, 2017, https://www.whitehouse.gov/the-press-office/2017/02/23/press-briefing-press-secretary-sean-spicer-2232017-15.

[63] United States Attorney's Office, "Statement From U.S. Attorney's Office on Initiative 502," press release, December 5, 2012.

[64] Deputy Attorney General David W. Ogden, *Memorandum for Selected United States Attorneys*, U.S. Department of Justice, Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana, Washington, DC, October 19, 2009, pp. 1-2.

[65] Deputy Attorney General James M. Cole, *Memorandum for United States Attorneys*, U.S. Department of Justice, Guidance Regarding the Ogden Memo in Jurisdictions Seeking to Authorize Marijuana for Medical Use, Washington, DC, June 29, 2011, p. 2.

[66] Ibid.

[67] Jennifer Medina, "U.S. Attorneys in California Set Crackdown on Marijuana," *New York Times*, October 8, 2011, p.

Attorney General Cole further warned that "[t]hose who engage in transactions involving the proceeds of such activity [cultivating, selling, or distributing of marijuana] may be in violation of federal money laundering statutes and other federal financial laws."[68] This warning may be one reason why medical marijuana dispensaries have had difficulty accessing bank services.[69] In an August 2013 memorandum, Deputy Attorney General Cole stated that while marijuana remains an illegal substance under the CSA, DOJ would focus its resources on the "most significant threats in the most effective, consistent, and rational way."[70] The memo outlined eight enforcement priorities for DOJ:

- Preventing the distribution of marijuana to minors;
- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
- Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;
- Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
- Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;
- Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and
- Preventing marijuana possession or use on federal property.[71]

In a February 2014 memorandum, Deputy Attorney General Cole further reinforced these enforcement priorities, specifically as they relate to the prosecution of marijuana-related financial crimes. The memo directed the U.S. Attorneys that "in determining whether to charge individuals or institutions with ... [certain financial] offenses based on marijuana-related violations of the CSA, prosecutors should apply the eight enforcement priorities described in the August 29 guidance."[72]

In October 2014, DOJ released another memo to the U.S. Attorneys that reiterated the applicability of the eight enforcement priorities to their marijuana efforts in Indian country.[73] It responded to the American Indian tribes' requests for guidance on CSA enforcement on tribal

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[68] Deputy Attorney General James M. Cole, *Memorandum for United States Attorneys*, U.S. Department of Justice, Guidance Regarding the Ogden Memo in Jurisdictions Seeking to Authorize Marijuana for Medical Use, Washington, DC, June 29, 2011, p. 2.

[69] John Ingold, "Last Bank Shuts Doors on Colorado Pot Dispensaries," *The Denver Post*, October 1, 2011; Jonathan Martin, "Medical-Marijuana Dispensaries Run Into Trouble at the Bank," *The Seattle Times*, April 29, 2012.

[70] Deputy Attorney General James M. Cole, *Memorandum for all United States Attorneys*, U.S. Department of Justice, Guidance Regarding Marijuana Enforcement, Washington, DC, August 29, 2013, p. 1.

[71] Ibid., pp. 1-2.

[72] Deputy Attorney General James M. Cole, *Memorandum for All United States Attorneys*, U.S. Department of Justice, Guidance Regarding Marijuana Related Financial Crimes, Washington, DC, February 14, 2014, p. 2.

[73] Executive Office for United States Attorneys, *Policy Statement Regarding Marijuana Issues in Indian Country*, October 28, 2014.

lands. DOJ reiterated that the August 2013 Cole memo does not prohibit the federal government from enforcing federal law in Indian Country, and adds the following:

> The eight priorities in the Cole Memorandum will guide United States Attorneys' marijuana enforcement efforts in Indian Country, including in the event that sovereign Indian Nations seek to legalize the *cultivation or use* of marijuana in Indian Country [emphasis added].[74]

Unlike the Cole memo, DOJ did not specifically refer to *distribution* and regulation of marijuana. It was unclear whether distribution of marijuana would be tolerated on tribal lands should tribal governments seek to legalize and distribute marijuana. Despite the lack of clarity, some tribes moved forward with plans to grow and sell marijuana at tribe-owned stores on tribal lands.[75] Since the memo was released, the DEA has led marijuana enforcement actions on tribal lands,[76] but it remains unclear whether legal marijuana will be tolerated on tribal land as it has been tolerated in states.

Monitoring Enforcement Priorities

In a review of the DOJ memoranda, the Government Accountability Office (GAO) concluded that "DOJ has not historically devoted resources to prosecuting individuals whose conduct is limited to possession of small amounts of marijuana for personal use on private property. Rather, DOJ has left such lower-level or localized marijuana activity to state and local law enforcement authorities through enforcement of their own drug laws."[77] GAO has recommended that DOJ monitor the effects of state-level marijuana legalization initiatives relative to the eight DOJ enforcement priorities. This evaluation noted that DOJ has used a number of tools to help assess these effects. For instance, DOJ indicated to GAO that U.S. Attorneys were in contact with officials in states such as Colorado and Washington that had legalized marijuana. In addition, DOJ reported that it relies upon information from sources such as "federal surveys on drug use; state and local research; and feedback from federal, state, and local law enforcement."[78] Notably, DOJ has reportedly not been documenting its specific monitoring process, and GAO has recommended that DOJ develop a "clear plan" for how it will monitor and document the effects of state marijuana legalization on federal enforcement priorities.[79]

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[74] Monty Wilkinson, *Memorandum*, U.S. Department of Justice, Policy Statement Regarding Marijuana Issues in Indian Country, Washington, DC, October 28, 2014.

[75] "Native American Tribes Approve Plan to Grow and Sell Marijuana in Oregon," *The New York Times*, December 19, 2015; Noelle Crombie, "Warm Springs Tribes Launch Ambitious Pot Venture, Hope for Economic Windfall," *The Oregonian - Oregon Live*, April 29, 2016; John Gillie, "Two Marijuana Retailers Opening Soon in City that Still Bans Cannabis Sales," *The News Tribune*, January 28, 2017; and Jackie Valley, "Las Vegas Paiutes' Newest Venture: Medical Marijuana," *Las Vegas Sun*, March 1, 2016.

[76] Steven Nelson, "DEA Raid on Tribe's Cannabis Crop Infuriates and Confuses Reformers," *U.S. News & World Report*, October 26, 2015; and Cary Spivak, "Milwaukee Journal Sentinel," November 18, 2015.

[77] U.S. Government Accountability Office, *State Marijuana Legalization: DOJ Should Document Its Approach to Monitoring the Effects of Legalization*, GAO-16-1, December 2015, p. 9.

[78] Ibid., p. 27.

[79] Ibid.

Federal Enforcement in States: Directives through Federal Appropriations[80]

Over the past several years, Congress has included provisions in appropriations acts that prohibit DOJ from using appropriated funds to prevent certain states and the District of Columbia[81] from "implementing their own State laws that authorize the use, distribution, possession, or cultivation of medical marijuana."[82] The current appropriations provision is in effect until April 28, 2017.[83] Courts have interpreted the appropriation provision to restrict DOJ from using appropriated funds (1) to take legal action directly against states and (2) to initiate criminal prosecutions of state officials for any action related to the implementation of a state medical marijuana law.[84] Several federal courts also have interpreted the provision as prohibiting DOJ from prosecuting individuals who, while strictly complying with the laws of one of the states covered by the appropriations provisions, have allegedly distributed, possessed, or cultivated medical marijuana in violation of *federal* law.[85] Although the appropriations provision restricts DOJ's ability to expend funds to enforce federal law, at least one court has made clear that the provision "does not provide immunity from prosecution for federal marijuana offenses."[86]

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[80] This section was contributed by Todd Garvey, Legislative Attorney, Congressional Research Service. For a more detailed analysis of this issue, see CRS Legal Sidebar WSLG1451, *District Court Holds Appropriations Language Limits Enforcement of Federal Marijuana Prohibition*, by Todd Garvey.

[81] The provision specifically lists 43 jurisdictions: Alabama, Alaska, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, Wisconsin, Wyoming, the District of Columbia, Guam, and Puerto Rico.

[82] See, for example, P.L. 113-235, §538 (2014) and P.L. 114-113, §542 (2015).

[83] P.L. 114-254, §101(1).

[84] See, for example, United States v. Marin All. for Med. Marijuana, 139 F. Supp. 3d 1039, 1044 (E.D. Cal. 2015) (citing the DOJ's interpretation that the appropriation provision prohibits "federal actions that interfere with a state's promulgation of regulations implementing its statutory provisions, or with its establishment of a state licensing scheme.").

[85] See, for example, United States v. McIntosh, 833 F.3d 1163, 1177 (9th Cir. 2016) (holding that the 2015 appropriations restriction "prohibits DOJ from spending funds from relevant appropriations for the prosecution of individuals who engaged in conduct permitted by the State Medical Marijuana Laws [of California, Oregon, and Washington] and who fully comply with such laws); United States v. Daleman, No. 1:11-CR-00385-DAD-BAM, 2017 U.S. Dist. LEXIS 23213 (E.D. Cal. Feb. 17, 2017) (denying defendant's motion to enjoin the Department of Justice from using funds for his prosecution because defendant failed to establish that he "*strictly* complied with all relevant conditions imposed by state law on the use, distribution, possession, and cultivation of medical marijuana.") (emphasis in original); *Marin All. for Med. Marijuana,* 139 F. Supp. at 1040 (holding that the 2015 appropriations provision bars DOJ from using appropriated funds to enforce an injunction prohibiting a medical marijuana dispensary from engaging in activities that are compliant with California's medical marijuana law).

[86] *McIntosh*, 833 F.3d at 1179, n. 5 ("The CSA prohibits the manufacture, distribution, and possession of marijuana. Anyone in any state who possesses, distributes, or manufactures marijuana for medical or recreational purposes (or attempts or conspires to do so) is committing a federal crime. The federal government can prosecute such offenses for up to five years after they occur.... Congress could restore funding tomorrow, a year from now, or four years from now, and the government could then prosecute individuals who committed offenses while the government lacked funding. Moreover, a new president will be elected soon, and a new administration could shift enforcement priorities to place greater emphasis on prosecuting marijuana offenses."). See also United States v. Nixon, 839 F.3d 885, 886 (9th Cir. 2016) (per curiam) (holding that the appropriations provision does not "impact[] the ability of a federal district court to restrict the use of a medical marijuana as a condition of probation.").

Financial Services for Marijuana Businesses[87]

As explained below, so long as marijuana remains classified as a Schedule I controlled substance under federal law, financial institutions and their directors, officers, employees, and owners could be subject to severe criminal and administrative sanctions[88] for providing financial services to marijuana businesses, even if those businesses are operating in compliance with state law.[89] A consequence of these legal risks is that many financial institutions reportedly have been unwilling to provide financial services to state-authorized marijuana businesses.[90]

Bank Secrecy Act[91] and Federal Anti-Money Laundering Laws

Federal law classifies marijuana as a Schedule I controlled substance.[92] As a result, it is a federal crime to grow, sell, or merely possess the drug.[93] In addition to facing the prospect of a federal criminal prosecution, imprisonment, and criminal fines, those who violate the federal CSA may suffer a number of additional adverse consequences under federal law.[94] For example, federal authorities may confiscate any property used to grow marijuana or facilitate its sale or use, as well as all proceeds derived from the sale of marijuana.[95] When financial institutions provide financial services to business customers, they generally are not directly involved in the sale, possession, or distribution of their customers' products. However, financial institutions commonly acquire the *proceeds* from the sale of their customers' products. To the extent that a bank acquires such proceeds with the knowledge that they are derived from the sale of marijuana in violation of federal law, the proceeds potentially could be confiscated by federal authorities,[96] even when the underlying actions are permissible under state law.[97] For example, if a bank originates a loan to a

[87] This section was contributed by David H. Carpenter, Legislative Attorney, Congressional Research Service.

[88] See, for example, United States v. HSBC Bank USA, N.A., No. 12-CR-763, 2013 U.S. Dist. LEXIS 92438, 31-38 (E.D. N.Y. July 1, 2013) (approving a deferred prosecution agreement with a financial institution for, among other things, "fail[ing] to implement an effective [anti-money laundering] program to monitor suspicions transactions ... [which] permitted Mexican and Colombian drug traffickers to launder at least $881 million in drug trafficking proceeds through HSBC Bank USA undetected"; the agreement "imposes upon HSBC significant, and in some respect extraordinary, measures," including the forfeiture of $1.256 billion, remedial measures, and the admission of criminal violations).

[89] *McIntosh*, 833 F.3d at 1179, n. 5.

[90] Steve Leblanc, "Can Sen. Elizabeth Warren help fix banking issues for the cannabis industry?," *Associated Press*, January 3, 2017, available at http://www.thecannabist.co/2017/01/03/elizabeth-warren-marijuana-banking/70517/; Lisa Lambert, "Got bank? Election could create flood of marijuana cash with no place to go," *Reuters*, October 31, 2016, available at http://www.reuters.com/article/us-usa-marijuana-banks-idUSKBN12V0D5.

[91] The "Bank Secrecy Act" is commonly used to refer to Titles I and II of the Act of October 26, 1970, P.L. 91-508, 84 Stat. 1114–24 (1970).

[92] 21 U.S.C. §812(c), Sch.I(c)(10).

[93] Ibid. §§841-890.

[94] Ibid. For a detailed description of the CSA's civil and criminal provisions, see CRS Report RL30722, *Drug Offenses: Maximum Fines and Terms of Imprisonment for Violation of the Federal Controlled Substances Act and Related Laws*, by Brian T. Yeh.

[95] 18 U.S.C. §§981(a)(1)(A), 982(a)(1). For information on the procedural requirements and potential defenses associated with asset forfeiture, see CRS Report 97-139, *Crime and Forfeiture*, by Charles Doyle.

[96] Ibid. §981(a)(1)(C) ("The following property is subject to forfeiture to the United States ... (C) Any property, real or personal, which constitutes or is derived from proceeds traceable to ... any offense constituting 'specified unlawful activity' (as defined in section 1956(c)(7) of this title) [i.e., the list of predicate offenses for money laundering (18 U.S.C. §1956)], or a conspiracy to commit such offense.").

[97] *McIntosh*, 833 F.3d at 1179, n. 5.

business openly operating as a state-authorized medical marijuana dispensary, then the principal and interest payments earned by the bank on that loan could be subject to forfeiture, if the bank knew that those payments derived from the sale of marijuana in violation of federal law.[98]

In addition to the risk of asset forfeiture, federal anti-money laundering laws (i.e., Sections 1956 and 1957 of the criminal code) criminalize the handling of proceeds that are known to be derived from certain unlawful activities,[99] including the sale and distribution of marijuana.[100] Violators of these anti-money laundering laws may be subject to fines and imprisonment,[101] and any real or personal property involved in or traceable to prohibited transactions is subject to criminal or civil forfeiture.[102] For example, a bank employee could be subject to a 20-year prison sentence and criminal money penalties under Section 1956 for knowingly engaging in a financial transaction involving marijuana-related proceeds that is conducted with the intent to promote a further offense (e.g., withdrawing marijuana-generated funds in order to pay the salaries of medical marijuana dispensary employees).[103] Similarly, a bank officer could face a 10-year prison term and criminal money penalties under Section 1957 for knowingly depositing or withdrawing $10,000 or more in cash that is derived from the distribution and sale of marijuana.[104]

Furthermore, Congress has crafted laws that affirmatively enlist financial institutions[105] to aid in the investigation and prosecution of those who violate federal laws, including the CSA.[106] For example, financial institutions generally must file suspicious activity reports (SARs)[107] with the

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[98] See, for example, United States v. Funds Held ex rel. Wetterer, 210 F.3d 96, 104 (2d Cir. 2000) ("In this Circuit, the government's burden is to show a nexus between the illegal conduct and the seized property. Once the government establishes that there is probable cause to believe that a nexus exists between the seized property and the predicate illegal activity, the burden shifts to the claimant to show by a preponderance of the evidence (1) that the defendant property was not in fact used unlawfully, or (2) that the predicate illegal activity was committed without the knowledge of the owner-claimant, 18 U.S.C. § 981(a)(2), that is, that the claimant is an 'innocent owner.'") (internal citations and quotations omitted).

[99] 18 U.S.C. §§1956(c)(7), 1957(f)(3). For a full list of predicate offenses, see the "Specified Unlawful Activities" section of CRS Report RL33315, *Money Laundering: An Overview of 18 U.S.C. 1956 and Related Federal Criminal Law*, by Charles Doyle.

[100] 18 U.S.C. §§1956, 1957. For a detailed analysis of federal anti-money laundering laws, see CRS Report RL33315, *Money Laundering: An Overview of 18 U.S.C. 1956 and Related Federal Criminal Law*, by Charles Doyle.

[101] Section 1956 violations are punishable by imprisonment for not more than 20 years and fines of up to $500,000 or twice the value of the property involved, whichever is greater. 18 U.S.C. §1956(a)(1). Section 1957 violations are punishable by imprisonment for not more than 10 years and fines of up $250,000 (or $500,000 for organizations) or twice the value of the property involved in the transaction, whichever is greater. Ibid. §§1957(b), 1957(h), 3571, 3559. Conspiracy to violate either section carries the same maximum penalties, as does aiding and abetting the commission of either offense. Ibid. §§2, 1956(h). See, for example, United States v. Lyons, 740 F.3d 702, 715 (1st Cir. 2014). For a detailed description of the penalties for violating these laws, see CRS Report RL30722, *Drug Offenses: Maximum Fines and Terms of Imprisonment for Violation of the Federal Controlled Substances Act and Related Laws*, by Brian T. Yeh.

[102] 18 U.S.C. §§981(a)(1)(A), 982(a)(1).

[103] Ibid. §1956(a)(1)(A)(i). See for example, Department of Justice, "Man Sentenced to 35 Months Imprisonment for Bank Fraud and Money Laundering," Press Release, July 19, 2013, available at https://www.justice.gov/usao-edwi/pr/man-sentenced-35-months-imprisonment-bank-fraud-and-money-laundering (announcing the sentence of an individual who pled guilty to violating 18 U.S.C. §1956 and other criminal laws while working as a bank officer).

[104] Ibid. §1957(a), (d).

[105] For the purposes of the Bank Secrecy Act and anti-money laundering laws, the term "financial institution" is defined broadly to include banks, savings associations, credit unions, broker dealers, insurance companies, pawnbrokers, automobile dealers, casinos, cash checkers, travel agencies, and precious metal dealers, among others. 31 U.S.C. §5312(a)(2).

[106] See, for example, 12 U.S.C. §§1951-59; 31 U.S.C. §§5311-32.

[107] Filing SARs are mandatory under certain circumstances, but financial institutions may file SARs even when not

Treasury Department's Financial Crimes Enforcement Network (FinCEN) regarding financial transactions[108] suspected to be derived from specified illegal activities,[109] including the sale of marijuana.[110] Depository institutions[111] and certain other financial institutions[112] also must establish and maintain anti-money laundering programs, designed to ensure that the institutions' officers and employees will have sufficient knowledge of their customers and of the businesses of those customers to identify the circumstances under which filing SARs is appropriate.[113] Even in the absence of suspicion, financial institutions must file currency transaction reports (CTRs) with FinCEN relating to transactions involving $10,000 or more in cash or other "currency."[114] The failure to comply with these reporting requirements can result in fines and imprisonment.[115]

Additionally, financial institutions, their employees, and certain other affiliated parties could be subject to administrative enforcement actions by federal regulators for violating the Bank Secrecy Act or anti-money laundering laws.[116] For example, the federal banking regulators[117] may utilize

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mandated by law. See, for example, 12 C.F.R. §§1020.320(a) (banks); 1022.320(a) (money services businesses).

[108] "Transaction":

> means a purchase, sale, loan, pledge, gift, transfer, delivery, or other disposition, and with respect to a financial institution includes a deposit, withdrawal, transfer between accounts, exchange of currency, loan, extension of credit, purchase or sale of any stock, bond, certificate of deposit, or other monetary instrument, security, contract of sale of a commodity for future delivery, option on any contract of sale of a commodity for future delivery, option on a commodity, purchase or redemption of any money order, payment or order for any money remittance or transfer, purchase or redemption of casino chips or tokens, or other gaming instruments or any other payment, transfer, or delivery by, through, or to a financial institution, by whatever means effected.

31 C.F.R. §1010.100(bbb).

[109] 18 U.S.C. §§1956(c)(7), 1957(f)(3). For a full list of predicate offenses, see the "Specified Unlawful Activities" section of CRS Report RL33315, *Money Laundering: An Overview of 18 U.S.C. 1956 and Related Federal Criminal Law*, by Charles Doyle.

[110] 21 U.S.C. §§841-890; 31 U.S.C. §5318(g); 31 C.F.R. §1020.320.

[111] There are several different types of depository institutions, including banks, savings associations, and credit unions. A depository charter can be issued by either a state or federal chartering authority.

[112] Some financial institutions are exempt from establishing anti-money laundering programs. 31 U.S.C. §5318(h)(2); 31 C.F.R. §1010.205.

[113] See generally 31 U.S.C. §5318(h)(1); 31 C.F.R. §§1020.200-1020.220. See also 12 U.S.C. §1786(q)(1) (credit unions); 12 U.S.C. §1818(s) (banks and savings associations). See also CRS Legal Sidebar WSLG1515, *Wake Up Call for Financial Institution Management: Anti-Money Laundering Program Is Your Personal Responsibility*, by M. Maureen Murphy.

[114] 31 U.S.C. §5313; 31 C.F.R. subpt.1020C; 31 C.F.R. subpt.1010C. "Currency" is defined as:

> The coin and paper money of the United States or of any other country that is designated as legal tender and that circulates and is customarily used and accepted as a medium of exchange in the country of issuance. Currency includes U.S. silver certificates, U.S. notes and Federal Reserve notes. Currency also includes official foreign bank notes that are customarily used and accepted as a medium of exchange in a foreign country.

31 C.F.R. §1010.100(m).

[115] 31 U.S.C. §5322. The willful failure to file SARs and CTRs is punishable by imprisonment for not more than five years or not more than 10 years in cases of a substantial pattern of violations or transactions involving other illegal activity. Ibid. Structuring a transaction to avoid the reporting requirement exposes the offender to the same maximum terms of imprisonment. Ibid. §5324(d). For a detailed description of penalties for violations of Bank Secrecy Act reporting and monitoring requirements, see CRS Report RL33315, *Money Laundering: An Overview of 18 U.S.C. 1956 and Related Federal Criminal Law*, by Charles Doyle.

[116] See, for example, 12 U.S.C. §§1786, 1818, 1831o.

[117] For these purposes, the federal banking regulators are: the Office of the Comptroller of the Currency (OCC) for national banks and federal savings associations; the Board of Governors of the Federal Reserve System for domestic operations of foreign banks and state-chartered banks that are members of the Federal Reserve System; the Federal

administrative enforcement powers against depository institutions and their directors, officers, controlling shareholders, employees, agents, and affiliates that engage in unlawful, marijuana-related activities.[118] The banking regulators have the legal authority, for instance, to issue cease and desist orders, impose civil money penalties, and issue removal and prohibition orders that temporarily or permanently ban individuals from working for any depository institution.[119] The banking regulators also have the authority, under certain circumstances, to revoke an institution's federal deposit insurance coverage and to take control of and liquidate a depository institution.[120] In fact, a criminal conviction for violating the Bank Secrecy Act or anti-money laundering laws is an explicit ground for the appointment of the Federal Deposit Insurance Corporation "as receiver [to] place the insured depository institution in liquidation."[121]

FinCEN and DOJ Guidance to Financial Institutions

In response to state marijuana legalization efforts, FinCEN issued guidance with respect to marijuana-related financial crimes on February 14, 2014.[122] This guidance appears to provide a roadmap for financial institutions seeking to comply with suspicious activity reporting requirements when providing financial services to state-authorized marijuana businesses, while also alerting FinCEN to transactions that might trigger federal enforcement priorities.[123]

The guidance notes that:

> [b]ecause federal law prohibits the distribution and sale of marijuana, financial transactions involving a marijuana-related business would generally involve funds derived from illegal activity. Therefore, a financial institution is required to file a SAR on activity involving a marijuana-related business (including those duly licensed under state law) in accordance with this guidance and [FinCEN regulations].[124]

FinCEN advised financial institutions that, in providing services to a marijuana business, they must file one of three types of special SARs:

1. A marijuana limited SAR: The marijuana limited SAR is seen to be appropriate when the bank determines, after the exercise of due diligence, that a customer is not engaged in any activities that violate state law or implicate the investigation

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Deposit Insurance Corporation (FDIC) for state savings associations and state-chartered banks that are not members of the Federal Reserve System; and the National Credit Union Administration (NCUA) for federally insured credit unions. Ibid. §§1766, 1813(q).

[118] See, for example, ibid. §1786 (credit unions); ibid. §§1818, 1831o (banks and savings associations). See also Office of the Comptroller of the Currency, "OCC Assesses $2.5 Million Civil Money Penalty Against Gibraltar Private Bank and Trust Company for Bank Secrecy Act Violations, Press Release, February 25, 2016, available at https://www.occ.gov/news-issuances/news-releases/2016/nr-occ-2016-20.html (ordering the payment of a civil money penalty and remedial actions for allegedly "fail[ing] to maintain an effective Bank Secrecy Act/Anti-Money Laundering (BSA/AML) compliance program.").

[119] Ibid.

[120] See, for example, ibid. §§1786, 1787 (credit unions); ibid. §§1818, 1821, 1831o (banks and savings associations).

[121] 12 U.S.C. §1821(c)(5)(M), (d)(2)(E).

[122] Department of the Treasury, *Financial Crimes Enforcement Network, BSA Expectations Regarding Marijuana-Related Business*, FIN-2014-G001, February 14, 2014, available at https://www.fincen.gov/resources/statutes-regulations/guidance/bsa-expectations-regarding-marijuana-related-businesses. The Administration could reverse or otherwise make significant changes to its enforcement priorities and policies. See generally CRS Report R43708, *The Take Care Clause and Executive Discretion in the Enforcement of Law*, by Todd Garvey.

[123] Ibid.

[124] Ibid., p. 3.

and prosecution priorities in the 2014 Cole Memorandum (see "Department of Justice Guidance Memos for U.S. Attorneys");[125]

2. A marijuana priority SAR: A marijuana priority SAR must be filed when the financial institution believes a customer is engaged in activities that implicate DOJ's investigation and prosecution priorities;[126] and
3. A marijuana termination SAR: A financial institution is instructed to file a marijuana termination SAR when it finds it necessary to sever its relationship with a customer to maintain an effective anti-money laundering program.[127]

FinCEN also provides examples of "red flags" that may indicate that a marijuana priority SAR is appropriate.[128] The FinCEN guidance does not impact financial institutions' obligations to file currency transaction reports.[129]

Select Implications of State Marijuana Legalization

While the majority of the American public supports marijuana legalization, some have voiced concern over possible negative implications, particularly with respect to *recreational* legalization. Some concerns were outlined as enforcement priorities by DOJ in monitoring state legalization.[130] These implications include, but are not limited to, the potential impact of legalization on (1) use of marijuana, particularly among youth; (2) traffic-related incidents involving marijuana-impaired drivers; (3) trafficking of marijuana from states that have legalized it into neighboring states that have not; and (4) U.S. compliance with international treaties. On the other hand, some have been encouraged by the potential outcomes from marijuana legalization, including new tax revenue for states and a potential decrease in marijuana-related arrests.

Not all potential implications are discussed in this report, and some are yet to be fully measured. Of note, data on potential effects of marijuana legalization should be interpreted with caution, as they are fairly limited, and not all factors are presented when reporting changes in statistics since state legalization. Further, conclusions about the impact of marijuana legalization would be premature without broader inclusion of both historical data and additional years of post-legalization data, as well as consideration of other factors aside from legalization.

U.S. Demand for Marijuana

As discussed, marijuana is the most commonly used illicit drug in the United States. In 2015, an estimated 22.2 million individuals aged 12 or older were current (past month) users of marijuana. The percentage of users has gradually increased over the last several years—from 6.9% in 2010

[125] Ibid., pp. 3-4.

[126] Ibid., p. 4.

[127] Ibid., pp. 4-5.

[128] Ibid., pp. 5-7. Some examples of "red flags" noted in the guidance are: "[t]he business is unable to produce satisfactory documentation or evidence to demonstrate that it is duly licensed and operating consistently with state law"; and "[a] customer seeks to conceal or disguise involvement in marijuana-related business activity." Ibid.

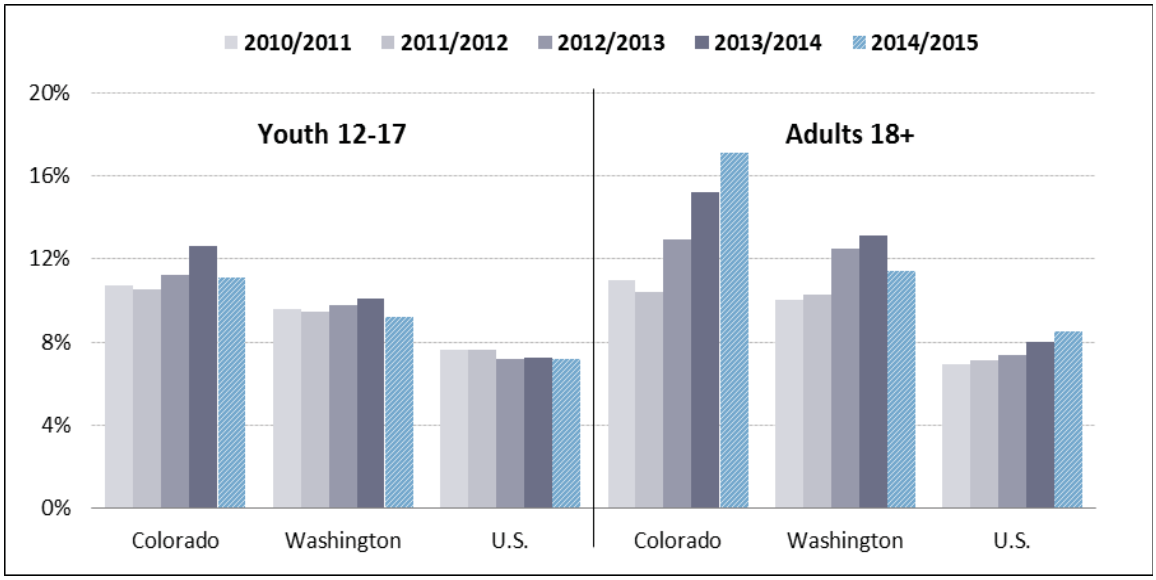
[129] Ibid., p. 7. For a discussion of currency transaction reporting requirements, see *supra* notes 114-115 and surrounding text.

[130] See James M. Cole, *Memorandum for all United States Attorneys*, U.S. Department of Justice, Guidance Regarding Marijuana Enforcement, Washington, DC, August 29, 2013, pp. 1-2.

to 8.3% in 2015.[131] The rate of past-month marijuana use among youth (aged 12 to 17), however, has remained fairly unchanged over this period (7.0%).[132]

Figure 3. Estimates of Current Marijuana Use in Colorado, Washington, and the United States, 2010-2015

Percentages Among Youth (Ages 12-17) and Adults (18 and Older)



Source: Created by the Congressional Research Service (CRS) based on available population data from the Substance Abuse and Mental Health Services Administration (SAMHSA), *National Survey on Drug Use and Health (NSDUH)*, State Data, 2010/2011, 2011/2012, 2012/2013, 2013/2014, and 2014/2015, http://www.samhsa.gov/data/.

Notes: This figure presents yearly estimates of marijuana use in Colorado, Washington, and the United States and does not show statistical changes in these data. To review year-to-year, statistically significant changes, if any, see the NSDUH state data reports. The 2015/2016 state data are not yet available from SAMHSA. Annual state-level estimates are based on 2 calendar years of pooled NSDUH data, so two consecutive sets of estimates have a one-year overlap. For more information on the NSDUH methodology, see 2014-2015 National Survey on Drug Use and Health: Guide to State Tables and Summary of Small Area Estimation Methodology. Current use of marijuana is defined as use in the past 30 days.

In the states that legalized recreational marijuana in November 2012 (Washington and Colorado), the percentages of youth (aged 12-17) and adults (aged 18 and older) who are current users have changed in various ways over the 2010-2015 period according to survey data. For adults, the changes generally match national trends over the same time period (see **Figure 3**). Colorado and Washington have higher percentages of use for adults and youth compared to national estimates—both before and after recreational legalization began. Of note, the 2014/2015 percentages of marijuana use among youth are fairly similar to the percentages reported in 2010/2011, while adult percentages are higher than those reported in 2010/2011.[133] Rates of drug use may be

[131] *Results from 2015 NSDUH*, Tables 1.1A and 1.1B.

[132] Results from *2015 NSDUH*, Table 1.2B and *Results from the 2014 National Survey on Drug Use and Health: Summary of National Findings*.

[133] Substance Abuse and Mental Health Services Administration (SAMHSA), *National Survey on Drug Use and Health (NSDUH)*, State Data, 2010/2011, 2011/2012, 2012/2013, 2013/2014, and 2014/2015, http://www.samhsa.gov/data/. The observed differences between estimates were not evaluated in terms of statistical significance—the probability that an observed difference in the population estimates would occur due to random variability if there was no difference in

influenced by many possible factors including availability of the drug, family, peers, school, economic status, and community variables.[134]

Of note, some state government officials in states that have legalized marijuana have monitored changes in drug use patterns and emerging research on the health effects of marijuana. For example, the Colorado Department of Public Health and Environment (CDPHE) was given the responsibility to "monitor changes in drug use patterns, broken down by county and race and ethnicity, and the emerging science and medical information relevant to the health effects associated with marijuana use."[135]

Marijuana-Related Traffic Incidents

The recent use of marijuana has been shown to impair driving ability.[136] According to the National Highway Traffic Safety Administration (NHTSA), "[l]ow doses of THC moderately impair cognitive and psychomotor tasks associated with driving, while severe driving impairment is observed with high doses, chronic use and in combination with low doses of alcohol."[137] Some may be concerned that recreational marijuana legalization could be associated with an increase in marijuana-related traffic incidents. In Colorado, despite limited traffic data, the Department of Public Safety reports the following:

> [T]he number of summons issued for Driving Under the Influence [DUI] in which marijuana or marijuana-in-combination[[138]] with other drugs [was recorded] decreased 1% between 2014 and 2015 (674 to 665).
>
> The prevalence of marijuana or marijuana-in-combination identified by CSP [Colorado State Patrol] as the impairing substance increased from 12% of all DUIs in 2014 to 15% in 2015.
>
> The Denver Police Department found summons where marijuana or marijuana-in-combination was recorded increased from 33 to 73 between 2013 and 2015. Citations for marijuana or marijuana-in-combination account for about 3% of all DUIs in Denver. Toxicology results from Chematox Laboratory showed an increase in positive cannabinoid screens for drivers, from 57% in 2012 to 65% in 2014. Of those that tested positive on the initial screen, the percent testing positive for delta-9 Tetrahydrocannabinol (THC) at 2 nanograms/millileter rose from 52% in 2012 to 67% in 2014.
>
> Fatalities with THC-only or THC-in-combination positive drivers increased 44%, from 55 in 2013 to 79 in 2014. Note that the detection of any THC in [the] blood is not an indicator

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the estimates being compared. To review year-to-year, statistically significant changes, see the NSDUH state data reports.

[134] National Institute on Drug Abuse, *Preventing Drug Use among Children and Adolescents (In Brief)*, October 2003, https://www.drugabuse.gov/publications/preventing-drug-abuse-among-children-adolescents/chapter-1-risk-factors-protective-factors/what-are-risk-factors.

[135] See Colorado Revised Statutes, Title 25, §1.5-110. See the most recent report, CDPHE, Retail Marijuana Public Health Advisory Committee, *Monitoring Health Concerns Related to Marijuana in Colorado: 2016*, 2016.

[136] Blood THC concentrations drop quickly after individuals smoke marijuana. See Rebecca L. Hartman and Marilyn A. Huestis, "Cannabis effects on driving skills," *Clinical Chemistry*, vol. 59, no. 3 (March 2013), pp. 478-492; and Rebecca L. Hartman, Timothy L. Brown, and Gary Milavetz, et al., "Cannabis effects on driving lateral control with and without alcohol," *Drug and Alcohol Dependence*, vol. 154 (September 1, 2015), pp. 25-37.

[137] National Highway Traffic Safety Administration, *Drug and Human Performance Fact Sheets: Cannabis/Marijuana (Δ 9 -Tetrahydrocannabinol, THC)*, https://one.nhtsa.gov/people/injury/research/job185drugs/cannabis.htm.

[138] In this report, the concept of marijuana "in combination" references marijuana in combination with other drugs.

> of impairment but only indicates presence in the system. Detection of delta-9 THC, one of the psychoactive properties of marijuana, may be an indicator of impairment.[139]

In monitoring the impacts of recreational marijuana legalization in Washington State, government researchers report that there was no trend identified in the percentage of drivers testing positive for marijuana (either marijuana only or marijuana in combination with other drugs/alcohol) for those involved in traffic fatalities and who were tested for drugs or alcohol.[140] They also report that "marijuana incidents"[141] on the highways and roads decreased from 2,462 in 2012 to 625 in 2014. Changes in these data may be influenced by many possible factors including changes in enforcement practices and priorities. It is possible that the sharp drop in marijuana incidents may be explained by the legalization of marijuana possession[142] after 2012. For example, many traffic stops involving the smell of marijuana would no longer require further law enforcement investigation unless the individual in question is under the age of 21, there is suspicion of drug trafficking, or other reasons.

Marijuana Arrests

After the legalization of the possession, sale, manufacturing, and distribution of certain quantities of marijuana for recreational purposes, one might expect the number of marijuana arrests to go down in jurisdictions that have done so. Indeed, Washington State reports that "all criminal activities involving marijuana decreased between 2012 and 2014."[143] Possession was cited as the most common criminal activity, and the number of marijuana possession arrests decreased from 5,133 in 2012 to 2,091 in 2013, and then to 1,918 in 2014.[144] Additionally, the number of marijuana incidents decreased from 6,336 in 2012 to 2,326 in 2014.[145]

In Colorado, the number of marijuana arrests decreased by nearly half from 12,894 in 2012 to 6,502 in 2013, and then increased to 7,004 in 2014. Of note, the number of marijuana arrests for youth (aged 10-17) increased by 6%, from 3,235 in 2012 to 3,400 in 2014, after a slight decline in 2013.[146]

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[139] Jack Reed, *Marijuana Legalization in Colorado: Early Findings: A Report Pursuant to Senate Bill 13-283*, Colorado Department of Public Safety, March 2016, p. 6, (hereinafter, *Marijuana Legalization in Colorado: Early Findings: A Report Pursuant to Senate Bill 13-283*).

[140] Washington State Office of Financial Management, Forecasting and Research Division, *Monitoring the Impacts of Recreational Marijuana Legalization*, 2015 Update Report, January 2016, p. 3, (hereinafter, *Monitoring the Impacts of Recreational Marijuana Legalization*).

[141] OFM relies on the FBI's definition of the term "incident" and states the following: "an 'incident' occurs when any law enforcement officer investigates a scene or situation, whether that investigation results in an arrest or not. Incidents involving multiple illicit drugs or other criminal activities are counted only once, and are included in whichever category is listed first by the local law enforcement agency." Ibid., p. 4.

[142] Washington State legalized the possession of marijuana in limited amounts by adults.

[143] *Monitoring the Impacts of Recreational Marijuana Legalization*, pp. 3 and 17.

[144] Ibid, p. 17.

[145] Of note, over this same period, the number of incidents increased each year for amphetamines/methamphetamines and heroin, and decreased each year for incident data in which no drug type was provided and drug type was unknown. See *Monitoring the Impacts of Recreational Marijuana Legalization*, p. 14.

[146] *Marijuana Legalization in Colorado: Early Findings: A Report Pursuant to Senate Bill 13-283*, p. 22.

Marijuana Trafficking

Transnational Trafficking

Mexican transnational criminal organizations have historically been the primary foreign suppliers of marijuana to the United States, with small amounts also coming from Canada and the Caribbean. While anecdotal reports about the impact of domestic legalization initiatives on the domestic marijuana black market exist, officials have noted that there is an "intelligence gap" with respect to data on exactly how domestic legalization has impacted the amount of Mexican-produced marijuana entering the United States.[147] For one, estimates on domestic marijuana consumption cannot speak to the source of this marijuana. In addition, drug seizure data from the various federal, state, and local law enforcement agencies do not give a sense of the origin of the marijuana. Further, there is no marijuana "signature program," like there is for cocaine and heroin, that can help determine the geographic origin of cannabis plants used to produce the seized marijuana.[148]

Marijuana cultivation in Mexico has decreased, though it is unclear precisely how this affects or is driven by U.S. demand for Mexican marijuana. One of the tradeoffs has been an increase in production of other drugs. Reportedly, the trafficking organizations have shifted production to more profitable drugs such as heroin and methamphetamine.[149] Consistent with a decline in Mexican marijuana cultivation, there has been a general decline in marijuana seizures along the Southwest border between 2010 and 2015. However, the DEA's outlook on marijuana trafficking is that "Mexico-produced marijuana will continue to be trafficked into the United States in bulk quantities and will likely increase in quality to compete with domestically-produced marijuana."[150]

One notable statistic is that since the first states began legalizing marijuana for recreational use in 2012, there has been a "sharp decline" in the number of individuals prosecuted and sentenced for federal marijuana trafficking offenses.[151] As experts have noted, however, this decline could be driven by a number, or combination, of factors such as federal efforts to prosecute marijuana-related drug offenders, efforts by drug traffickers to conceal their illegal contraband entering the United States, and the amount of illegal marijuana being shipped into the United States.[152]

Trafficking from States that Have Legalized into Other States

Some states have alleged that there has been increased marijuana trafficking from nearby states that have legalized marijuana possession or sale for medical or recreational purposes. For instance, according to DEA testimony, there has been increased marijuana trafficking in states surrounding Colorado since the state legalized recreational use.[153] The Rocky Mountain High

[147] U.S. Drug Enforcement Administration, *2015 National Drug Threat Assessment Summary,* DEA-DCT-DIR-008-16, October 2015, p. 71 (hereinafter, *2015 National Drug Threat Assessment Summary*).

[148] *National Drug Threat Assessment Summary 2016*, p. 116.

[149] Nick Miroff, "Losing Marijuana Business, Mexican Cartels Push Heroin and Meth," *The Washington Post*, January 11, 2015.

[150] *National Drug Threat Assessment Summary 2016*, p. 125.

[151] U.S. Sentencing Commission, *Quick Facts: Drug Trafficking Offenses*, May 2016.

[152] Christopher Ingraham, "Federal Marijuana Smuggling is Declining in the Era of Legal Weed," *The Washington Post*, May 26, 2016, referencing statements by Beau Kilmer, a drug policy researcher at RAND Corp.

[153] U.S. Congress, Senate Committee on the Judiciary, *Hearing on Oversight of the Drug Enforcement Administration*, Testimony of Administrator Michele M. Leonhart [transcript], 113th Cong., 2nd sess., April 30, 2014. Administrator

Intensity Drug Trafficking Area (HIDTA) reported 394 instances of interdiction of Colorado marijuana destined for 36 other states in 2015.[154] Additionally, the HIDTA's report indicates that interdiction experts estimate these seizures represent about 10% or less of the total amount that is moved across the border undetected.[155]

In December 2014, Nebraska and Oklahoma filed a lawsuit in the U.S. Supreme Court[156] against Colorado claiming that their law enforcement and criminal justice systems had been adversely impacted by Colorado's laws legalizing marijuana.[157] The complaint included claims that Colorado's "statutes and regulations are devoid of safeguards to ensure marijuana cultivated and sold in Colorado is not trafficked to other states."[158] In March 2016, however, the Supreme Court declined to hear the case challenging Colorado's marijuana law.[159]

The Changing Domestic Black Market

There have been reports of changes in the domestic black market for marijuana as states have moved to legalize it for medical and recreational purposes. For instance, the market in Denver, CO, has been described as smaller and less violent than it previously was. In addition, buyers there are said to be purchasing more from "mom-and-pop operations" rather than from entities affiliated with larger cartels.[160] Most of the domestically produced marijuana (other than that which is produced in accordance with various state laws) is cultivated in California.[161] This cultivation is carried out not only by U.S. persons, but also by foreign criminal networks. For instance, Mexican traffickers run large outdoor grow sites in California, which are sometimes established on public lands.

The DEA has indicated that marijuana concentrates—such as hashish, hash oil, and keif—are a growing concern for federal law enforcement. These substances have "potency levels far exceeding those of leaf marijuana."[162] The DEA has also stated that one effect of state marijuana legalization initiatives has been an increase in seizures of marijuana concentrates and an increase in the number of THC extraction laboratories in the United States.[163]

Broadly, there has been a shifting demand for higher-quality marijuana. The marijuana produced in the United States and Canada is generally thought to be of superior quality to the marijuana produced in Mexico. To be responsive to the U.S. demand for high-quality marijuana, Mexican

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Leonhart further stated, "Take for instance, Kansas, and we've talked to our partners in Kansas and they've already been seeing a 61 percent increase in marijuana seizures coming from Colorado."

[154] Rocky Mountain High Intensity Drug Trafficking Area, *The Legalization of Marijuana in Colorado: The Impact*, September 2016, p. 4.

[155] Ibid., p. 110.

[156] The Constitution provides the Supreme Court with original jurisdiction over "Controversies between two or more States," meaning such claims can be filed directly with the Supreme Court without first being litigated in the lower federal courts. U.S. CONST., art. III, §2. cl. 1.

[157] Jack Healy, "Nebraska and Oklahoma Sue Colorado Over Marijuana Law," *The New York Times,* December 18, 2014.

[158] States of Nebraska and Oklahoma v. State of Colorado, S. Ct., Complaint, p. 3.

[159] Nebraska, et al. v. Colorado, 577 U.S. ___, 136 S. Ct. 1034 (2016); *see also* David G. Savage, "Supreme Court Rejects Challenge to Colorado Marijuana Law From Other States," *The Los Angeles Times,* March 21, 2016.

[160] Tom James, "The Failed Promise of Legal Pot," *The Atlantic*, May 9, 2016.

[161] *National Drug Threat Assessment Summary 2015*, p. 72.

[162] *National Drug Threat Assessment Summary 2015*, p. v.

[163] *National Drug Threat Assessment Summary 2016*, p. 105.

drug traffickers have tried to improve their product.[164] However, it is not just U.S. consumers who demand higher-quality marijuana. The demand exists in Mexico as well; there have even been anecdotal reports of traffickers moving high-quality marijuana produced in the United States across the Southwest border for sale and distribution in Mexico.[165] U.S. officials have not yet reported data on the quantity or frequency of this southbound smuggling.

The Marijuana Gray Market

In Colorado, state law allows the cultivation of up to 99 marijuana plants for patients and caregivers and up to 6 plants per individual for recreational purposes. In what has been dubbed "the gray market," marijuana is sometimes being grown legally *but then sold illegally.*[166] In addition to federal and local enforcement actions against gray market actors, Colorado Governor Hickenlooper reportedly is seeking to establish new limits on residential plants and give law enforcement additional resources to combat unlicensed marijuana growers.[167]

Legalization Impact on Criminal Networks

A number of criminal networks rely on profits generated from the sale of illegal drugs—including marijuana—in the United States. Mexican drug trafficking organizations control more of the wholesale distribution of marijuana than other major drug trafficking organizations in the United States.[168] One estimate has placed the proportion of U.S.-consumed marijuana that was imported from Mexico at somewhere between 40% and 67%.[169] While the Mexican criminal networks control the wholesale distribution of illicit drugs in the United States, they "are not generally directly involved in retail distribution of illicit drugs."[170] In order to facilitate the retail distribution and sale of drugs in the United States, Mexican drug traffickers have formed relationships with U.S. street, prison, and outlaw motorcycle gangs.[171] Although these gangs have historically been involved with retail-level drug distribution, their ties to the Mexican criminal networks have allowed them to become increasingly involved at the wholesale level as well. Trafficking and distribution of illicit drugs is a primary source of revenue for these gangs.[172]

A number of organizations have assessed the potential profits generated from illicit drug sales, both worldwide and in the United States, but "[e]stimates of marijuana ... revenues suffer particularly high rates of uncertainty."[173] The former National Drug Intelligence Center (NDIC),

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[164] Ibid., p. 116.

[165] John Burnett, "Legal Pot In the U.S. May Be Undercutting Mexican Marijuana," *NPR All Things Considered*, December 1, 2014.

[166] John Frank, "Colorado governor calls marijuana gray market 'a clear and present danger'," *The Denver Post*, November 15, 2016.

[167] Brian Eason "The top 10 issues facing Colorado lawmakers Eason and John Frank, in the 2017 session," *The Denver Post*, January 9, 2017.

[168] *National Drug Threat Assessment Summary 2016*.

[169] Beau Kilmer, Jonathan P. Caulkins, and Brittany M. Bond, et al., *Reducing Drug Trafficking Revenues and Violence in Mexico: Would Legalizing Marijuana in California Help?*, RAND International Programs and Drug Policy Research Center, 2010.

[170] Organization of American States, *The Drug Problem in the Americas: Studies: The Economics of Drug Trafficking*, p. 18.

[171] *National Drug Threat Assessment Summary 2016*.

[172] Ibid. See also *National Drug Threat Assessment Summary 2015*.

[173] Organization of American States, *The Drug Problem in the Americas: Studies: The Economics of Drug Trafficking*, 2013, p. 7.

for instance, estimated that the sale of illicit drugs in the United States generates between $18 billion and $39 billion in U.S. wholesale drug proceeds for the Colombian and Mexican drug trafficking organizations annually.[174] The proportion that is attributable to marijuana sales, however, is unknown.[175] Without a clear understanding of (1) actual proceeds generated by the sale of illicit drugs in the United States, (2) the proportion of total proceeds attributable to the sale of marijuana, and (3) the proportion of marijuana sales controlled by criminal organizations and affiliated gangs, any estimates of how marijuana legalization might impact the drug trafficking organizations are purely speculative.

Marijuana proceeds are generated at many points along the supply chain, including production, transportation, and distribution. Experts have debated which aspects of this chain—and the related proceeds—would be most heavily impacted by marijuana legalization. In addition, the potential impact of marijuana legalization in some subset of the states (complicated by varying legal frameworks and regulatory regimes) may be more difficult to model than the impact of federal marijuana legalization. For instance, in evaluating the potential fiscal impact from the 2012 Washington and Colorado legalization initiatives on the profits of Mexican drug trafficking organizations, the Organization of American States (OAS) hypothesized that "[a]t the extreme, Mexican drug trafficking organizations could lose some 20 to 25 percent of their drug export income, and a smaller, though difficult to estimate, percentage of their total revenues."[176]

Other scholars have based their estimates on a hypothetical federal legalization of marijuana when estimating the potential financial impact of marijuana legalization. Under this scenario, small-scale growers at the start of the marijuana production-to-consumption chain might be put out of business by professional farmers, a few dozen of which "could produce enough marijuana to meet U.S. consumption at prices small-scale producers couldn't possibly match."[177] Large drug trafficking organizations generate a majority of their marijuana-related income (which some estimates place at between $1.1 billion to $2.0 billion) from exporting the drug to the United States and selling it to wholesalers on the U.S. side of the border.[178] This revenue could be jeopardized if the United States were to legalize the production and consumption of recreational marijuana. Of note, the Tax Foundation has estimated that the annual U.S. marijuana market is $45 billion—0.28% of GDP.[179] Under a legalization regime, some portion of the

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[174] U.S. Department of Justice, National Drug Intelligence Center, *National Drug Threat Assessment 2009,* December 2008, p. 49.

[175] A 2006 Office of National Drug Control Policy figure estimated that over 60% of Mexican drug trafficking organizations' revenue could be attributed to marijuana sales. However, a number of researchers and experts have questioned the accuracy of this number and provided other estimates of marijuana proceeds. See, for example, Beau Kilmer, *Debunking the Mythical Numbers about Marijuana Production in Mexico and the United States*, RAND Drug Policy Research Center. See also U.S. Government Accountability Office, *Drug Control: U.S. Assistance has Helped Mexican Counternarcotics Efforts, but Tons of Illicit Drugs Continue to Flow into the United States*, GAO-07-1018, August 2007. Another estimate has placed the proportion of Mexican DTO export revenues attributable to marijuana at between 15% and 26% of total drug revenues. See Beau Kilmer, Jonathan P. Caulkins, and Brittany M. Bond, et al., *Reducing Drug Trafficking Revenues and Violence in Mexico: Would Legalizing Marijuana in California Help?*, RAND International Programs and Drug Policy Research Center, 2010.

[176] Organization of American States, *The Drug Problem in the Americas: Studies: The Economics of Drug Trafficking*, p. 41.

[177] Jonathan P. Caulkins, Angela Howken, and Beau Kilmer, "How Would Marijuana Legalization Affect Me Personally?" in *Marijuana Legalization: What Everyone Needs to Know* (Oxford University Press, 2012).

[178] Beau Kilmer, Jonathan P. Caulkins, and Brittany M. Bond, et al., *Reducing Drug Trafficking Revenues and Violence in Mexico: Would Legalizing Marijuana in California Help?*, RAND International Programs and Drug Policy Research Center, 2010.

[179] Gavin Ekins and Joseph Henchman, *Marijuana Legalization and Taxes: Federal Revenue Impact*, Tax Foundation,

revenue that might have previously been generated by traffickers could be lost to authorized sellers (in the form of profits) and governments (in the form of taxes).

International Response[180]

Developments in state marijuana laws and policies, particularly those that relate to recreational marijuana activities, have raised some concerns about the United States' compliance with three United Nations (U.N.) drug control treaties that impose certain international obligations relating to marijuana. These treaties generally seek to curb the use of controlled substances while carving out exceptions for medicinal and scientific uses. The United States is a party to the following drug treaties:

- The Single Convention on Narcotic Drugs (Single Convention)[181] requires parties to the convention to "take such legislative and administrative measures as may be necessary ... to limit exclusively to medical and scientific purposes" the manufacture, distribution, trade, use, and possession of "cannabis."[182]
- The 1971 Convention on Psychotropic Substances requires that specific controls be placed upon THC.[183]
- The 1988 U.N. Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances requires parties to establish criminal penalties for the possession, purchase, or cultivation of marijuana for nonmedicinal consumption, but only to the extent that such action is consistent with the "constitutional principles and basic concepts of [the country's] legal system."[184]

The International Narcotics Control Board (INCB or Board) and the Commission on Narcotic Drugs of the Economic and Social Council (Commission) are responsible for monitoring parties' compliance with these treaties,[185] though they appear to have limited ability to enforce such compliance. For example, the Single Convention provides that the Commission may "call the attention of the Board to any matters which may be relevant to the functions of the Board,"[186] while the Board may take measures that are "most consistent with the intent to further the co-operation of Governments with the Board and to provide the mechanism for a continuing dialogue between Governments and the Board which will lend assistance to and facilitate effective national action to attain the aims of this Convention."[187]

May 12, 2016.

[180] This section was authored by Brian T. Yeh, Legislative Attorney, Congressional Research Service.

[181] Single Convention on Narcotic Drugs, March 30, 1961, 18 U.S.T. 1407, https://www.unodc.org/unodc/en/treaties/single-convention.html (last visited January 6, 2017). The Single Convention was amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs.

[182] Ibid. at art. 2, 4, 21, 28.

[183] Convention on Psychotropic Substances, February 21, 1971, 32 U.S.T. 543. The convention directs parties to "prohibit all use except for scientific and very limited medical purposes by duly authorized persons, in medical or scientific establishments which are directly under the control of their Governments or specifically approved by them."

[184] December 20, 1988, S. Treaty Doc. No. 101-4 (1989).

[185] Single Convention on Narcotic Drugs, art. 5, March 30, 1961, 18 U.S.T. 1407; Convention on Psychotropic Substances, art. 17, 19, February 21, 1971, 32 U.S.T. 543; Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, art. 21, 22, December 20, 1988, S. Treaty Doc. No. 101-4 (1989).

[186] Single Convention on Narcotic Drugs, art. 8.

[187] Ibid, at art. 9(5).

It is unclear whether, or to what extent, the enactment of state laws authorizing the use of marijuana for recreational purposes affects the United States' compliance with the drug treaties. Some assert that state-level recreational marijuana legalization (and the federal government response to those state laws) does not conform with the international obligations regarding marijuana, while others disagree with this interpretation. For example, the then-President of the INCB stated in 2013 that recreational marijuana legalization in states is inconsistent with the Single Convention's requirement that parties limit lawful uses of cannabis to medical and scientific purposes.[188] On the other hand, in 2014, the then-Assistant Secretary of State for International Narcotics and Law Enforcement Affairs appeared to express a contrary view when he urged the international community to "accept flexible interpretation of" the U.N. Drug Control Conventions.[189] He appealed to countries "to tolerate different national drug policies, to accept the fact that some countries will have very strict drug approaches; other countries will legalize entire categories of drugs."[190] A Stanford University professor has also opined that the United States is not in violation of the drug control conventions on account of state-level laws,[191] although a Brookings Institution fellow has argued otherwise.[192]

Some observers have raised doubts about claims that the drug treaties contain the "flexibilities" that can accommodate state recreational marijuana laws; they have instead argued for reforms of the treaties to expressly permit them.[193] Yet in September 2014, President Obama disagreed that the international drug control regime needs revision in light of marijuana policy developments.[194] The Trump Administration's stance on this issue has not yet been articulated.

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[188] Raymond Yans, INCB President, *Report of the International Narcotics Control Board*, March 11-15, 2013, at 7, https://www.incb.org/documents/Speeches/Speeches2013/CND_2013_Speech_FINAL_ENGLISH_120313_cl.pdf; "INCB has to underline, it is our mandate, the central role of the 1961 Convention which needs to be implemented worldwide, on the national level, but also on the sub-national level."

[189] U.S. Department of State, William R. Brownfield, *Trends in Global Drug Policy,* New York Foreign Press Center Briefing, October 9, 2014.

[190] Ibid.

[191] Keith Humphreys, "Can the United Nations Block U.S. Marijuana Legalization?*," Huffington Post*, September 25, 2013 (updated November 25, 2013); "Countries with federated systems of government like the U.S. and Germany can only make international commitments regarding their national-level policies. Constitutionally, U.S. states are simply not required to make marijuana illegal as it is in federal law. Hence, the U.S. made no such commitment on behalf of the 50 states in signing the UN drug control treaties."

[192] Jonathan Rauch, "Marijuana Legalization Poses a Dilemma for International Drug Treaties," *Brookings,* October 14, 2014; quoting Brookings fellow Wells Bennett as saying that "if 10, 15, 20 states enact and operate responsible regimes for the regulation of marijuana—we will be enforcing the Controlled Substances Act less and less in jurisdictions that have regulated, legal marijuana markets. And that will create more and more tension with our international commitments to suppress marijuana. At that point, it will be extraordinarily difficult for the U.S. to maintain that it complies with its obligations."

[193] See, for example, Wells Bennett and John Walsh, "Marijuana Legalization Is an Opportunity to Modernize International Drug Treaties," October 2014, *Brookings*.

[194] The White House, *Presidential Determination—Major Drug Transit or Major Illicit Drug Producing Countries for Fiscal Year 2015,* September 15, 2014. "The U.N. drug conventions ... allow sovereign nations the flexibility to develop and adapt new policies and programs in keeping with their own national circumstances while retaining their focus on achieving the conventions' aim of ensuring the availability of controlled substances for medical and scientific purposes, preventing abuse and addiction, and suppressing drug trafficking and related criminal activities.... [R]evising the U.N. drug conventions is not a prerequisite to advancing the common and shared responsibility of international cooperation designed to enhance the positive goals we have set to counter illegal drugs and crime."

Tax Revenue

All eight of the states that have legalized marijuana for recreational purposes levy some combination of taxes and business licensing fees at the level of marijuana cultivation or retail sales (in addition to general state sales taxes).[195] Tax rates on the cultivation and retail sales are more commonly levied on an *ad valorem* basis, or as a percentage of price.[196] The tax treatment of medical marijuana varies by state. In some states, medical marijuana is indirectly taxed further back the distribution chain at the cultivator level. In addition, states tax the retail sales of medical marijuana differently. In Colorado, for example, medical marijuana sales are exempt from a 10% special excise tax that applies to recreational marijuana sales, but they are still subject to the 2.9% general state sales tax.[197] In Washington, medical marijuana sales are subject to the same 37% excise tax that applies to recreational sales, but they are exempt from the state's 6.5% general sales tax.[198]

While some states utilize marijuana-related revenue streams for general spending purposes, others have approved measures to dedicate a portion of this revenue for spending on education (Colorado and Oregon), criminal justice programs (Alaska), or public health and substance abuse programs (Washington).[199]

Overall, though, these tax and spending regimes have been subject to change, as government officials and voters respond to changes in revenue collections and budget priorities.

Selected Issues Before Congress—The Path Forward

Given the current federal marijuana policy gap with certain states, there are a number of issues that Congress may address. These include, but are not limited to, issues surrounding financial services for marijuana businesses, federal tax issues for these businesses, oversight of federal law enforcement, allowance of states to implement medical marijuana laws and involvement of federal health care workers, and consideration of marijuana's designation as a Schedule I drug.

Provision of Financial Services to the Marijuana Industry

In spite of the guidance issued by FinCEN and DOJ, many financial institutions remain reluctant to openly enter relationships with state-authorized marijuana businesses.[200] Some marijuana businesses and marijuana industry proponents have complained that even when marijuana

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[195] As mentioned in the "Recreational Legalization" section of this report, Washington, DC, has not legalized the commercial sale of recreational marijuana.

[196] Alaska is the only state that imposes a flat dollar tax rate on marijuana: $50 per ounce is imposed when marijuana is sold or transferred from a marijuana cultivation facility to a retail marijuana store or marijuana product manufacturing facility. See Alaska Department of Revenue, "Marijuana Tax," accessed January 11, 2017, http://www.tax.alaska.gov/programs/programs/index.aspx?60000.

[197] See Colorado Department of Revenue, "Marijuana Taxes," accessed January 11, 2017, https://www.colorado.gov/pacific/tax/marijuana-taxes-quick-answers.

[198] See Washington Department of Revenue, "Taxes Due on Marijuana," accessed January 11, 2017, http://dor.wa.gov/Content/FindTaxesAndRates/marijuana/Default.aspx.

[199] See Office of Governor Bill Walker, "Governor Walker Signs Historic Criminal Justice Reform Bill," press release, July 11, 2016, at; Laurel Andrews, "Here's Where Half of the Revenue from Alaska's Legal Pot Will Go," *Alaska Dispatch News*, July 14, 2016.

[200] Sophie Quinton, *Why Marijuana Businesses Still Can't Get Bank Accounts*, The PEW Charitable Trusts, March 22, 2016.

businesses are able to open bank accounts or secure other financial services, those customer relationships are frequently terminated in relatively short order, especially when the existence of the relationship between the financial institution and the marijuana business becomes public.[201]

Over the years, several legislative proposals have been designed to jump-start financial relationships with state-authorized marijuana businesses. Some of these proposals would attempt to alleviate BSA reporting burdens beyond the measures detailed in the 2014 FinCEN guidance.[202] These proposals also would amend banking laws to prevent banking regulators from "prohibit[ing], penaliz[ing], or otherwise discourag[ing] a depository institution from providing financial services to a marijuana-related legitimate business" (i.e., one that is in compliance with a state or local marijuana regulatory regime).[203]

While such measures, if enacted, might help around the edges, many financial institutions and their federal regulators may remain apprehensive about ties to the marijuana industry while marijuana is listed as a Schedule I controlled substance under the CSA. In the absence of legislative change to the CSA, financial institutions must proceed with the knowledge that the Administration could reverse or otherwise make significant changes to its enforcement priorities and policies.[204] In other words, while these financial institutions may not be the subject of law enforcement investigations currently, the option remains.

Other legislative proposals[205] would reclassify marijuana as a Schedule II substance—this would legalize marijuana for medical purposes. This would likely do more to ease bank concerns with providing financial services to *medical* marijuana businesses but would not *entirely* eliminate a financial institution's legal risks, particularly if it associates with medical marijuana businesses that operate in states or localities lacking strong regulatory oversight and enforcement standards. Additionally, the reclassification of marijuana to Schedule II probably would have little impact on the provision of financial services to *recreational* marijuana businesses because they would still be operating in violation of the CSA.

Federal Tax Treatment

Marijuana producers and retailers may not deduct the costs of selling their product (e.g., payroll, rent, or advertising) for the purposes of the federal income tax filings.[206] The Internal Revenue Code (IRC) Section 280E states that

> No deduction or credit shall be allowed for any amount paid or incurred during the taxable year in carrying on any trade or business if such trade or business (or the activities which comprise such trade or business) consists of trafficking in controlled substances (within the meaning of schedule I and II of the Controlled Substances Act) which is prohibited by Federal law or the law of any State in which such trade or business is conducted.

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[201] Ibid. See also David Migoya, "Oregon bank opens doors to Colorado marijuana businesses," *The Denver Post*, January 20, 2015,

[202] See, for example, S. 683, 114th Cong.; S. 1726, 114th Cong.; H.R. 1538, 114th Cong.; and H.R. 2076, 114th Cong.

[203] Ibid.

[204] See generally CRS Report R43708, *The Take Care Clause and Executive Discretion in the Enforcement of Law*, by Todd Garvey.

[205] See, for example, S. 683, 114th Cong.; H.R. 1538, 114th Cong.

[206] For more legal analysis, see CRS Report R44056, *Marijuana and Federal Tax Law: In Brief*, by Erika K. Lunder.

Media reports indicate that the Internal Revenue Service (IRS) has enforced Section 280E in audits of marijuana-related businesses by refusing to accept these businesses' deductions.[207] IRC Section 280E does not prohibit a marijuana business from deducting the costs of cultivating or acquiring marijuana as a "cost of goods sold," though.[208] Effectively this constitutes an implicit tax on marijuana-related businesses equal to the value of the tax benefit of such deductions if these firms had engaged in an industry that was legal under federal law. One such public case involves the Sacramento-based Canna Care marijuana dispensary. The IRS disallowed $2.6 million in deductions for employee salaries, rent, and other costs over a three-year period, which resulted in the business owing $875,000 in additional taxes. Canna Care challenged the IRS in U.S. Tax Court, but ultimately the court upheld the IRS ruling.[209]

The discrepancies between federal, state, and local tax treatments of marijuana-related businesses may create economic incentives to engage in the underground economy. In addition to the uncertainty of federal tax enforcement procedures (and costs of any related legal assistance), the inability of marijuana businesses to deduct their business expenses is effectively an implicit tax up to 39.6% (if organized as sole-proprietor or partnership) or 35% (if organized as a C corporation) of the cost of these expenses.[210] These implicit taxes are paid in addition to state and local sales and special excise taxes.[211] The status quo administration of federal tax laws creates an economic advantage for illicit marijuana sellers, who are not subject to direct taxation of their sales.

Past marijuana-related tax proposals have varied in scope.[212] Some would have exempted a business (that conducts marijuana sales in compliance with state law) from the Section 280E prohibition against allowing business-related tax credits or deductions for expenditures in connection with trafficking in controlled substances.[213] In contrast, one bill would have removed marijuana from all lists of controlled substances (and, indirectly, IRC §280E restrictions on marijuana),[214] and another would have imposed a federal excise tax on domestic recreational marijuana retail sales that would begin at 10% of the price and phase in a tax rate of 25% over four years.[215]

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[207] For example, see Jeff Daniels, "IRS Said to be Auditing Colorado Marijuana Businesses," *CNBC*, July 12, 2016, http://www.cnbc.com/2016/07/12/irs-said-to-be-auditing-colorado-marijuana-businesses.html; and Will Yankowicz, "Marijuana Companies' Biggest Battle Might Be Against the IRS," *Slate*, July 1, 2016, http://www.slate.com/blogs/moneybox/2016/07/01/legal_cannabis_businesses_pay_taxes_under_a_code_reserved_for_illegal_drug.html.

[208] See CRS Report R44056, *Marijuana and Federal Tax Law: In Brief*, by Erika K. Lunder.

[209] See Canna Care, Inc. v. Commissioner, T.C. Memo 2015-206, October 22, 2015, http://ustaxcourt.gov/UstcInOp/OpinionViewer.aspx?ID=10586.

[210] With 35% being the top, marginal tax bracket for corporations and 39.6% being the top, marginal tax bracket for individuals under the federal income tax code.

[211] Colorado imposes a sales tax of 10% and an excise tax of 15% on retail marijuana sales, in addition to a general 2.9% state sales tax and any local sales taxes. See State of Colorado Department of Revenue, "Retail Marijuana Return Filing Overview," January 29-31, 2014, http://www.colorado.gov/cms/forms/dor-tax/RetailMarijuanaReturnFilingOverviewJan2014.pdf. The state of Washington, which began allowing recreational marijuana sales in 2014, will impose an excise tax of 25% on the sales price of marijuana within an established, state-distribution system.

[212] For more general analysis of federal proposals to tax marijuana, see CRS Report R43785, *Federal Proposals to Tax Marijuana: An Economic Analysis*, by Jane G. Gravelle and Sean Lowry.

[213] See the Small Business Tax Equity Act of 2015 (H.R. 1855; S. 987) from the 114th Congress.

[214] See the Regulate Marijuana Like Alcohol Act (H.R. 1013) from the 114th Congress.

[215] See the Marijuana Tax Revenue Act of 2015 (H.R. 1014) from the 114th Congress.

Oversight of Federal Law Enforcement

Review of Agency Missions

In exercising its oversight authorities, Congress may choose to examine the extent to which (if at all) federal law enforcement missions—in particular the DEA's mission—are impacted by state legalization of marijuana. For instance, policymakers may elect to review the mission of each federal law enforcement agency involved in enforcing the CSA and examine how its drug-related investigations may be influenced by the varying state-level policies regarding marijuana. As noted, federal law enforcement has generally prioritized the investigation of drug traffickers and dealers over that of low-level drug users. Policymakers may question whether these policies and priorities are implemented consistently across states with different drug policies regarding marijuana.

Cooperation with State and Local Law Enforcement

One issue policymakers may debate is whether or how to incentivize task forces, fusion centers, and other coordinating bodies charged with combating drug-related crimes. Before determining whether to increase, decrease, or maintain funding for coordinated efforts such as task forces, policymakers may consider whether state and local counterparts are able to effectively achieve task force goals if the respective state marijuana policy is not in agreement with federal marijuana policy. Policymakers may choose to evaluate whether certain drug task forces are sustainable in states that have established policies that are either inconsistent—such as in states that have *decriminalized* small amounts of marijuana possession—or are in direct conflict—including states that have *legalized* either medical or recreational marijuana—with federal drug policy. For instance, might there be any internal conflicts that prevent task force partners from collaborating effectively to carry out their investigations?

Of note, the Arizona Court of Appeals ruled that patients who possess marijuana in compliance with the Arizona Medical Marijuana Act are entitled to the return of their marijuana that law enforcement may have seized during a traffic stop.[216] In states such as Colorado, media reports indicate that some local law enforcement officers avoid seizing marijuana in certain cases because they do not want to have to return the marijuana to its owner—an act that is tantamount to distribution of a Schedule I controlled substance, a violation of federal law.[217]

Oversight and Continuation of Federal Enforcement Priorities

As noted, in responding to states with recreational legalization initiatives, DOJ issued federal enforcement priorities for states with legal marijuana. According to DOJ, it monitors the effects of state legalization by

- collaborating with other DOJ components and other federal agencies in assessment of marijuana enforcement-related data;
- prosecuting cases that threaten federal enforcement priorities; and
- consulting with state officials about areas of federal concern.[218]

[216] State v. Okun, 231 Ariz. 462 (Ariz. Ct. App. 2013). The U.S. Supreme Court denied certiorari in 2014. Arizona v. Okun, 572 U.S. ___, 134 S. Ct. 1759 (2014).

[217] Jessica Maher, "Law enforcement conflicts still exist with legal pot," *Reporter-Herald*, January 2, 2014.

[218] U.S. Government Accountability Office, *DOJ Should Document Its Approach to Monitoring the Effects of*

As of December 2015, however, DOJ has not documented its efforts to monitor the effects of state legalization and ensure that these priorities are being emphasized. It is unclear how the metrics to evaluate these priorities will be used to determine whether federal intervention is needed in states that have legalized.[219] For example, one of the eight enforcement priorities listed by Deputy Attorney General Cole was to prevent the diversion of marijuana to other states. While it seems the DEA is aware of increased marijuana trafficking from Colorado to Kansas, it is unclear what level of increased trafficking might trigger action by the federal government against state marijuana laws. Congress may choose to exercise oversight over DOJ's enforcement priorities and metrics for tracking illicit activity in the states. Congress may also request research on or an investigation of this issue outside of actions by the Administration.

The Administration may alter or reverse its enforcement priorities at any time. As mentioned, in a February 2017 White House press statement, the Trump Administration indicated there may be increased enforcement against recreational marijuana, and stated that there is a "big difference" between medical and recreational marijuana.[220]

Medical Marijuana

State Medical Marijuana Laws and Federal Law Enforcement

State medical marijuana laws have raised questions for federal policymakers about enforcing federal law related to marijuana in situations where individuals or organizations are acting in compliance with state law. In previous Congresses, Members of both the House and the Senate have introduced legislation that would amend the CSA such that provisions relating to marijuana would not apply to a person who is acting in compliance with relevant state law.[221]

As discussed, in recent years, Congress has included policy riders in appropriations acts to prohibit DOJ from using funds to prevent states from implementing their medical marijuana laws.[222] Congress may decide to alter, maintain, or reverse this provision. Notably, in a February 2017 White House press statement, the Trump Administration signaled some acceptance of the medicinal use of marijuana: "[t]he President understands the pain and suffering that many people go through who are facing especially terminal diseases and the comfort that some of these drugs, including medical marijuana, can bring to them."[223]

Legalization, GAO-16-1, December 30, 2015.

[219] Ibid, pp. 30-31.

[220] The White House, Office of the Press Secretary, *Press Briefing by Press Secretary Sean Spicer, 2/23/2017, #15*, February 22, 2017, https://www.whitehouse.gov/the-press-office/2017/02/23/press-briefing-press-secretary-sean-spicer-2232017-15.

[221] See, for example, the Compassionate Access, Research Expansion, and Respect States (CARERS) Act of 2015 (H.R. 1538/S. 683 in the 114th Congress).

[222] See the Consolidated Appropriations Act, 2016 (P.L. 114-113), §542; and the Consolidated and Further Continuing Appropriations Act, 2015 (P.L. 113-235), §538 from the 114th Congress. Of note, the medical marijuana provision remains in effect during the FY2017 continuing resolution (The Further Continuing Appropriations Act, 2017 (P.L. 114-254).) that continues appropriations for the bureaus and agencies funded through the annual Commerce, Justice, Science, and Related Agencies appropriations until April 28, 2017

[223] The White House, Office of the Press Secretary, *Press Briefing by Press Secretary Sean Spicer, 2/23/2017, #15*, February 22, 2017, https://www.whitehouse.gov/the-press-office/2017/02/23/press-briefing-press-secretary-sean-spicer-2232017-15.

State Medical Marijuana Laws and Federal Health Care Providers

A topic of particular interest to federal policymakers has been how federal health care providers—especially those in the Department of Veterans Affairs (VA)—deal with state medical marijuana laws. VA policy does not deny health care services to veterans who participate in state marijuana programs; however, it does prohibit VA providers from completing the forms that effectively take the place of prescriptions in state medical marijuana programs.[224] Members in both chambers have introduced legislation that would allow VA providers to complete such forms.[225] Similar provisions passed the Senate as part of an FY2016 appropriations bill, and passed the Senate Committee on Appropriations as part of an FY2017 appropriations bill; however, neither were included in an enacted appropriations law.[226]

Consideration of Marijuana as a Schedule I Drug: Maintain or Minimize the Gap

As the gap between federal and state policies on marijuana widens each year, policymakers might decide to reevaluate federal marijuana policy. It has only been a few years since states began to legalize recreational marijuana, but over 20 years since they began to legalize medical marijuana. A large majority of states now have marijuana policies that contradict the CSA.

In addressing state-level legalization efforts, Congress could take one of several routes. It could elect to take no action, thereby upholding the federal government's current marijuana policy and enforcement priorities. It may also decide that the CSA must be enforced in states and direct federal law enforcement to strictly enforce the CSA, even when individuals may be in compliance with state laws. Alternatively, Congress could choose to reevaluate marijuana's placement as a Schedule I controlled substance. Given the history of its scheduling, Congress may consider establishing a committee of experts to evaluate the efficacy of marijuana laws in the United States and address other issues such as the medicinal value and harm of marijuana use.[227]

Upon reevaluation, should Congress determine that marijuana no longer meets the criteria to be a Schedule I substance, it could take legislative action to remove it from the list of substances on that schedule. In doing so, Congress may (1) place marijuana on one of the other schedules (II, III, IV, or V) of controlled substances or (2) remove marijuana as a controlled substance altogether. If Congress chooses to remove marijuana as a controlled substance, it could alternatively seek to regulate and tax commercial marijuana activities. If marijuana *remains* a controlled substance under the CSA under any schedule, this would not eliminate the existing conflict with states that have legalized recreational marijuana. If the conflict remains, Congress may choose to continue to allow states to carry on with implementation of recreational marijuana

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[224] Department of Veterans Affairs, Veterans Health Administration (VHA), *Access to Clinical Programs for Veterans Participating In State- Approved Marijuana Programs*, VHA Directive 2011-004, Washington, DC, January 31, 2011, http://www.va.gov/vhapublications/viewpublication.asp?pub_id=2362. This directive expired on January 31, 2016; however, it is cited in VHA Directive 1134 (published on November 28, 2016) and thus appears to remain in effect.

[225] See the Veterans Equal Access Act (H.R. 667 in the 114th Congress); and the Compassionate Access, Research Expansion, and Respect States (CARERS) Act of 2015 (H.R. 1538/S. 683 in the 114th Congress).

[226] See §246 of H.R. 2029 (in the 114th Congress) as engrossed in the Senate on November 10, 2015, and §249 of S. 2806 (in the 114th Congress) as reported to the Senate on April 18, 2016.

[227] These would be similar to the efforts of the National Commission on Marihuana and Drug Abuse, also known as the Shafer Commission, which was established under the CSA to study marijuana in the United States. See **Appendix B** for further discussion of the Shafer Commission.

laws, or it may choose to press for increased enforcement action against or within the states to attempt to stop state-sanctioned, recreational marijuana.

Appendix A. Medical Research on Marijuana

Approved Drugs and Ongoing Research

The Food and Drug Administration (FDA) has approved two drugs containing synthetic THC: nabilone and dronabinol. Nabilone is FDA-approved as an antiemetic (to reduce nausea or prevent vomiting) for patients receiving chemotherapy for cancer.[228] Dronabinol is FDA-approved as both an antiemetic for patients on chemotherapy and an appetite stimulant for patients with AIDS-related weight loss.[229] In addition, drugs containing plant-derived THC and/or cannabidiol (CBD, a nonpsychoactive chemical component of marijuana) are in the drug development and approval process.[230]

The UK-based GW Pharmaceuticals has plant-derived cannabinoid drug products in trials with the goal of FDA approval.[231] Its drug Sativex®, which is composed primarily of plant-derived THC and CBD, has already gained approval in 30 other countries for the treatment of spasticity[232] due to multiple sclerosis.[233] In 2014, the company announced that the FDA had granted "Fast Track" designation to Sativex as a potential pain reliever for patients with advanced cancer;[234] however, in 2015, three trials of Sativex failed to show superiority over a placebo.[235] The company continues to seek approval of Sativex and other plant-derived cannabinoid products for treatment of various conditions (e.g., childhood epilepsy).[236]

Scientific Evaluations of Marijuana

Recent evaluations conducted separately by the FDA and the National Academies of Sciences, Engineering, and Medicine (the National Academies) illustrate the challenge of meeting the required standard of evidence. While taking different approaches to their evaluations, both the FDA and the National Academies have found that the current evidence base falls short.

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[228] FDA first approved nabilone in 1985 under the trade name Cesamet®, which is registered to Meda Pharmaceuticals Inc. See http://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=018677.

[229] FDA first approved dronabinol in 1985 under the trade name Marinol®, which is registered to AbbVie Inc. See http://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=018651.

[230] Department of Health and Human Services, Food and Drug Administration, *FDA and Marijuana: Questions and Answers*, http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm#determinations. For an explanation of the FDA's drug development and approval process, see http://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm.

[231] GW Pharmaceuticals, "GW Pharmaceuticals plc Reports Fourth Quarter and Year-End 2016 Financial Results and Operational Progress," press release, December 5, 2016, http://ir.gwpharm.com/releasedetail.cfm?ReleaseID=1002545.

[232] Spasticity refers to problems with muscle control. It is a disorder often found in people with multiple sclerosis, cerebral palsy, and other conditions.

[233] Ibid.

[234] GW Pharmaceuticals, "GW Pharmaceuticals Announces that Sativex Receives Fast Track Designation from FDA in Cancer Pain," press release, April 28, 2014, http://ir.gwpharm.com/releasedetail.cfm?ReleaseID=842890. For an explanation of FDA's "Fast Track" designation, see http://www.fda.gov/forpatients/approvals/fast/ucm20041766.htm.

[235] GW Pharmaceuticals, "GW Pharmaceuticals and Otsuka Announce Results From Two Remaining Sativex(R) Phase 3 Cancer Pain Trials," press release, October 27, 2015.

[236] GW Pharmaceuticals, "GW Pharmaceuticals plc Reports Fourth Quarter and Year-End 2016 Financial Results and Operational Progress," press release, December 5, 2016. Of note, the FDA does not release this kind of information, which is proprietary; this information is publicly available because the company released it.

FDA Evaluation. The FDA evaluated only marijuana, not drugs containing a plant-derived chemical constituent of marijuana or drugs containing synthetic THC. Its analysis of marijuana's potential therapeutic effects is limited to 11 published studies that met criteria for inclusion in the review (e.g., that the study must be a randomized controlled trial).[237] The studies examined marijuana's use to treat neuropathic pain (five studies), stimulate appetite in patients with HIV (two studies), treat glaucoma (two studies), treat spasticity in multiple sclerosis (one study), and treat asthma (one study).[238] The evaluation also assessed potential risks of marijuana use (see text box, "Risks Associated with Marijuana Use"). The evaluation, called an eight-factor analysis, was conducted by the FDA pursuant to a request by the DEA.[239] The DEA requests such scientific and medical evaluations from the Secretary of Health and Human Services (HHS) in response to petitions asking the DEA to reschedule marijuana administratively.[240]

National Academies Evaluation. The National Academies evaluated cannabis, its constituents, and drugs containing synthetic THC. For each of 11 health topics, the report assessed "fair- and good-quality" research, relying on systematic reviews published since 2011 (where available) and primary research published after the systematic review (or since 1999, if no systematic review exists).[241] The 11 health topics are (1) therapeutic effects; (2) cancer; (3) cardiometabolic risk; (4) respiratory disease; (5) immunity; (6) injury and death; (7) prenatal, perinatal, and postnatal exposure to cannabis; (8) psychosocial effects; (9) mental health; (10) problem cannabis use; and (11) cannabis use and abuse of other substances.[242] The report presents nearly 100 conclusions, including some related to the challenges in conducting research with cannabis and cannabinoids.

Federal Research Requirements for Marijuana

Many federal research requirements are standard across all schedules of controlled substances; however, some requirements vary according to the assigned schedule of the particular substance. Federal regulations are more stringent for Schedule I substances—including marijuana. Examples of this include the following:

- For Schedule I substances, such as marijuana, even if practitioners have a DEA registration for a substance in Schedules II-V, they must obtain a *separate* DEA registration for Schedule I substances.
- Individuals who seek to register to manufacture a controlled substance in Schedule I or II are subject to production quota limitations as determined by the DEA,[243] but registrants for substances in Schedules III-V are not subject to such quotas.

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[237] Department of Justice, Drug Enforcement Administration, "Denial of Petition to Initiate Proceedings to Reschedule Marijuana," 81 *Federal Register* 53687-53766 and 53767-53845, August 12, 2016.

[238] Ibid.

[239] The term "eight-factor analysis" refers to the eight factors to be included pursuant to 21 U.S.C. §811(c).

[240] The request for a scientific and medical evaluation is required by 21 U.S.C. §811(b). The results of the most recent eight-factor analysis prior to August 2016 are available at Department of Justice, Drug Enforcement Administration, "Denial of Petition to Initiate Proceedings to Reschedule Marijuana," 76 *Federal Register* 40551-40589, July 8, 2011.

[241] National Academies of Sciences, Engineering, and Medicine, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*, Washington, DC, 2017, p. S-3, doi: 10.17226/24625.

[242] Ibid.

[243] See 21 U.S.C. §826.

- Researchers are required to store Schedule I and II substances in electronically monitored safes, steel cabinets, or vaults that meet or exceed certain specifications.[244] They are required to store Schedule III-V substances by secure standards but the requirements are less stringent than those required for Schedule I and II substances.
- When researchers apply for a DEA registration to conduct research involving Schedule I controlled substances, they must comply with federal regulations specifying the form and content of the research protocols.[245] The DEA Administrator must forward a copy of the application and research protocol to HHS, which is responsible for determining "the qualifications and competency of the applicant, as well as the merits of the protocol."[246] The HHS Secretary delegates that responsibility to the FDA. *No equivalent process is required for Schedule II-V controlled substances.*

Marijuana Supply for Researchers

Under the CSA, the Attorney General is required to register an applicant to manufacture Schedule I or II controlled substances "if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971."[247] In the case of marijuana, the National Center for Natural Products Research at the University of Mississippi has been the only registered manufacturer, operating under a contract administered by the National Institute on Drug Abuse (NIDA) within HHS's National Institutes of Health. For nearly 50 years, it has been the only official source through which researchers may obtain marijuana for research purposes—and which some have referred to as a "federal research monopoly."[248] Some have contended that marijuana provided by NIDA to researchers is "both qualitatively and quantitatively inadequate."[249] Marijuana's status as a Schedule I drug has reportedly created difficulty for researchers who seek to study the substance but are potentially unable to meet the strict requirements of the CSA, or perhaps they seek to utilize a different quality of marijuana than what is available through NIDA.

In August 2016, the DEA announced a policy change "designed to foster research by expanding the number of DEA-registered marijuana manufacturers."[250] Under the new policy, the DEA is willing to license additional growers to "operate independently, provided the grower agrees (through a written memorandum of agreement with DEA) that it will only distribute marijuana

[244] 21 C.F.R. §§1301.72(a)(1)(i)-(iii) (specifications required for safes and steel cabinets storing Schedule I and II drugs or substances); see also 21 C.F.R. §§1301.72(a)(2) and 1301.72(a)(3)(i)-(vi) (specifications required for vaults storing Schedule I and II drugs or substances).

[245] 21 C.F.R. §1301.18(a).

[246] 21 U.S.C. §823(f); 21 C.F.R. §1301.32(a).

[247] 21 USC §823(a).

[248] See *NIDA's Role in Providing Marijuana for Research*, available at http://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research; and Marc Kaufman, "Federal Marijuana Monopoly Challenged," *Washington Post*, December 12, 2005.

[249] Marc Kaufman, "Federal Marijuana Monopoly Challenged," *Washington Post*, December 12, 2005; and Department of Justice, Drug Enforcement Administration, "Lyle E. Craker; Denial of Application," 74 *Federal Register* 2101, January 14, 2009.

[250] Department of Justice, Drug Enforcement Administration, *DEA Announces Actions Related to Marijuana and Industrial Hemp*, August 11, 2016.

with prior, written approval from DEA."[251] In addition, under the new policy, these growers will only be permitted to supply marijuana to DEA-registered researchers whose "protocols have been determined by [HHS] to be scientifically meritorious." This new approach, DEA states, will allow individuals to obtain a DEA cultivation registration "not only to supply federally funded or other academic researchers, but also for strictly commercial endeavors funded by the private sector and aimed at drug product development." Given that both the FDA and the DEA identified the lack of research as a significant factor in denying the rescheduling petitions in 2016, and to the extent that this policy may increase the amount of marijuana research conducted, the change *could* contribute to future debate on rescheduling.

[251] Department of Justice, Drug Enforcement Administration, "Applications To Become Registered Under the Controlled Substances Act To Manufacture Marijuana To Supply Researchers in the United States," 81 *Federal Register* 53846-53848, August 12, 2016.

Appendix B. Background on Federal Marijuana Policy

Early 20th Century

Prior to 1937, the growth and use of marijuana was legal under federal law.[255] During the course of promoting federal legislation to control marijuana, Henry Anslinger, the first commissioner of the Federal Bureau of Narcotics (FBN),[256] and others submitted testimony to Congress regarding the evils of marijuana use, claiming that it incited violent and insane behavior.[257] Of note, Commissioner Anslinger had informed Congress that "the major criminal in the United States is the drug addict; that of all the offenses committed against the laws of this country, the narcotic addict is the most frequent offender."[258] The federal government *unofficially* banned marijuana under the Marihuana Tax Act of 1937 (MTA; P.L. 75-238).[259] The MTA imposed a strict regulation requiring a high-cost transfer tax stamp on marijuana sales, and these stamps were rarely issued by the federal government.[260] Shortly after passage of the MTA, all states made the possession of marijuana illegal.[261]

Anti-marijuana Propaganda

In the early 20th century, enforcement of drug laws was primarily the responsibility of local police, and the FBN occasionally assisted.[252] Due to limited and reduced appropriations during the Great Depression, the FBN budget and the number of narcotic agents declined and remained low for years. Publicity and warnings of the dangers of narcotics, in particular marijuana, became methods of drug control for the FBN.[253] In seeking federal control of marijuana and uniform narcotic laws, Commissioner Anslinger made personal appeals to civic groups and legislators and pushed for, and received, editorial support in newspapers; many newspapers maintained a steady stream of anti-marijuana propaganda in the 1930s.[254]

Mid-20th Century

In the decades after enactment of the MTA, Congress continued to pass drug control legislation and further criminalized drug abuse. For example, the Boggs Act (P.L. 82-255), passed in 1951,

[252] David F. Musto, *The American Disease: Origins of Narcotic Control*, 3rd ed. (New York: Oxford University Press, 1999), pp. 183-200, p. 228.

[253] Ibid., p. 214.

[254] Richard J. Bonnie and Charles H. Whitebread II, *The Marijuana Conviction: A History of Marijuana Conviction in the United States* (New York: The Lindesmith Center, 1999), pp. 94-95.

[255] States regulated marijuana but did not begin to ban it until after 1937.

[256] In 1930, the Federal Bureau of Narcotics (FBN) was established within the Treasury to handle narcotic enforcement.

[257] See statements by H. J. Anslinger, Commissioner of Narcotics, Bureau of Narcotics, Department of the Treasury and Dr. James C. Munch, before the U.S. Congress, House Committee on Ways and Means, *Taxation of Marihuana*, 75th Cong., 1st sess., April 27-30, May 4, 1937, HRG-1837-WAM-0002.

[258] U.S. Congress, House Committee on Ways and Means, *Taxation of Marihuana*, 75th Cong., 1st sess., April 27-30, May 4, 1937, HRG-1837-WAM-0002, p. 7.

[259] Congressional testimony indicated that marijuana, while it was a problem in the Southwest United States starting in the mid-1920s, became a "national menace" in the mid-1930s (1935-1937). See statement by H. J. Anslinger, Commissioner of Narcotics, Bureau of Narcotics, Department of the Treasury, before the U.S. Congress, House Committee on Ways and Means, *Taxation of Marihuana*, 75th Cong., 1st sess., April 27, 1937.

[260] Charles F. Levinthal, *Drugs, Society, and Criminal Justice*, 3rd ed. (New York: Prentice Hall, 2012), p. 58.

[261] In Leary v. United States (395 U.S. 6 (1968)), the MTA was overturned by the U.S. Supreme Court as a violation of the Fifth Amendment's privilege against compelled self-incrimination.

established mandatory prison sentences for some drug offenses, while the 1956 Narcotic Control Act (P.L. 84-728) further increased penalties for drug offenses. In conjunction with growing support for a medical approach to addressing drug abuse, there was a strong emphasis on law enforcement control of narcotics. Congress shifted the constitutional basis for drug control from its taxing authority to its power to regulate interstate commerce,[262] and in 1968 the FBN merged with the Bureau of Drug Abuse Control and was transferred from Treasury to the Department of Justice.[263] Several years later, President Nixon would declare a war on drugs.[264]

Congress and President Nixon enhanced federal control of drugs in the enactment of comprehensive federal drug laws—including the Controlled Substances Act (CSA), enacted as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (P.L. 91-513). The CSA placed the control of marijuana and other plant, drug, and chemical substances under federal jurisdiction regardless of state regulations and laws. In designating marijuana as a Schedule I controlled substance, this legislation *officially* prohibited the manufacture, distribution, dispensation, and possession of marijuana.[265]

The Shafer Commission

As part of the CSA, the National Commission on Marihuana and Drug Abuse, also known as the Shafer Commission, was established to study marijuana in the United States.[266] Specifically, this commission was charged with examining issues such as

> (A) the extent of use of marihuana in the United States to include its various sources of users, number of arrests, number of convictions, amount of marihuana seized, type of user, nature of use;
>
> (B) an evaluation of the efficacy of existing marihuana laws;
>
> (C) a study of the pharmacology of marihuana and its immediate and long-term effects, both physiological and psychological;
>
> (D) the relationship of marihuana use to aggressive behavior and crime;
>
> (E) the relationship between marihuana and the use of other drugs; and
>
> (F) the international control of marihuana.[267]

The Shafer Commission, in concluding its review, produced two reports: (1) *Marihuana: A Signal of Misunderstanding*, and (2) *Drug Use in America: Problem in Perspective*.[268]

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[262] As stated in Article I, §8, cl. 3 of the U.S. Constitution, "Congress shall have the Power ... To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes." For more information about the commerce clause, see CRS Report R43023, *Congressional Authority to Enact Criminal Law: An Examination of Selected Recent Cases*, by Charles Doyle.

[263] David F. Musto, *The American Disease: Origins of Narcotic Control*, 3rd ed. (New York: Oxford University Press, 1999), p. 239. The shift in constitutional authority was part of the Drug Abuse Control Amendments of 1965 (P.L. 89-74).

[264] For a broader discussion of the federal government's drug enforcement history, see CRS Report R43749, *Drug Enforcement in the United States: History, Policy, and Trends*, by Lisa N. Sacco.

[265] 21 U.S.C. §812 and §841. Of note, growing a marijuana plant is considered *manufacturing* marijuana.

[266] The commission was composed of two Members of the Senate, two Members of the House, and nine members appointed by the President of the United States. President Nixon appointed Raymond Shafer as the commissioner.

[267] P.L. 91-513, §601(d).

[268] National Commission on Marihuana and Drug Abuse, *Marihuana: A Signal of Misunderstanding*, First Report of the National Commission on Marihuana and Drug Abuse, Washington, DC, March 1972 (hereinafter, First Report of

In its first report, the Shafer Commission discussed the perception of marijuana as a major social problem and how it came to be viewed as such.[269] It made a number of recommendations, including the development of a "social control policy seeking to discourage marihuana use, while concentrating primarily on the prevention of heavy and very heavy use."[270] In this first report, the commission also called the application of criminal law in cases of personal use of marijuana "constitutionally suspect" and declared that "total prohibition is functionally inappropriate."[271] Of note, federal criminalization and prohibition of marijuana was never altered, either administratively or legislatively, to comply with the recommendations of the Shafer Commission.

In its second report, the Shafer Commission reviewed the use of all drugs in the United States, not solely marijuana. It examined the origins of the country's drug problem, including the social costs of drug use, and once again made specific recommendations regarding social policy. Among other conclusions regarding marijuana, the commission indicated that aggressive behavior generally cannot be attributed to its use.[272] The commission also reaffirmed its previous findings and recommendations regarding marijuana and added the following statement:

> The risk potential of marihuana is quite low compared to the potent psychoactive substances, and even its widespread consumption does not involve social cost now associated with most of the stimulants and depressants (Jones, 1973; Tinklenberg, 1971). Nonetheless, the Commission remains persuaded that availability of this drug should not be institutionalized at this time.[273]

At the conclusion of the second report, the Shafer Commission recommended that Congress launch a subsequent commission to reexamine the broad issues surrounding drug use and societal response.[274] While a number of congressionally directed commissions regarding drugs have since been established,[275] no such commission has been directed to review the comprehensive issues of drug use, abuse, and response in the United States.

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the Shafer Commission); and National Commission on Marihuana and Drug Abuse, *Drug Use in America: Problem in Perspective*, Second Report of the National Commission on Marihuana and Drug Abuse, Washington, DC, March 1973 (hereinafter, Second Report of the Shafer Commission).

[269] The commission stated that three factors contributed to the perception of marijuana as a major national problem, including "[1] the illegal behavior is highly visible to all segments of our society, [2] use of the drug is perceived to threaten the health and morality not only of the individual but of society itself, and [3] most important, the drug has evolved in the late sixties and early seventies as a symbol of wider social conflicts and public issues." First Report of the Shafer Commission, p. 6.

[270] First Report of the Shafer Commission, p. 134.

[271] Ibid., pp. 142-143.

[272] Second Report of the Shafer Commission, p. 158.

[273] Ibid, p. 224. In this statement, the Shafer Commission cites the following studies: R.T. Jones, *Mental Illness and Drugs: Pre-Existing Psychopathology and Response to Psychoactive Drugs*, Paper Prepared for the National Commission on Marihuana and Drug Abuse, 1973; and J.R. Tinklenberg, *Marihuana and Crime*, Paper Prepared for the National Commission on Marihuana and Drug Abuse, Unpublished, October 1971.

[274] Second Report of the Shafer Commission, pp. 410-411.

[275] See, for example, the President's Media Commission on Alcohol and Drug Abuse Prevention and the National Commission on Drug-Free Schools.

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INSIGHT

The Schedule I Status of Marijuana

Updated September 11, 2020

The Controlled Substances Act (CSA) places various substances in one of five schedules based on their medical use, potential for abuse, and safety or risk for dependence. The five schedules are progressively ordered with Schedule V substances regarded as the least dangerous and addictive and Schedule I substances considered the most dangerous and addictive. Schedule I substances are considered to have a "high potential for abuse" with "no currently accepted medical use in treatment in the United States." The CSA prohibits the manufacture, distribution, dispensation, and possession of Schedule I substances except for federal government-approved research studies.

Marijuana is listed as a Schedule I controlled substance under the CSA, and has been on Schedule I since the CSA was enacted in 1970 (P.L. 91-513). For background on how marijuana came to be placed on Schedule I, see Appendix B of CRS report, *The Marijuana Policy Gap and the Path Forward*.

The Schedule I status of marijuana means that the substance is strictly regulated by federal authorities. Yet, over the last several decades, most states and territories have deviated from across-the-board prohibition of marijuana, and now have laws and policies allowing for some cultivation, sale, distribution, and possession of marijuana.

Select Issues Surrounding the Schedule I Status of Marijuana and the Policy Gap with States

Select key issues related to the Schedule I status of marijuana and the gap between federal and state marijuana policies are highlighted below.

- **Institutions of Higher Education (IHEs).** It has been reported that IHEs may decline to permit research on marijuana on their campuses, because doing so may put them at risk of losing federal funds. An IHE's policy prohibiting marijuana on campus may also affect students for whom their states have authorized the use of medical marijuana. Under the Higher Education Act of 1965, each IHE must adopt a program to prevent the use of illicit drugs and alcohol and annually distribute standards of conduct that prohibit the unlawful possession, use, or distribution of illicit drugs and alcohol on the institution's property or as part of any of its activities and that describe applicable legal sanctions.
- **Financial Services for Marijuana-Related Businesses.** Despite the guidance issued by the Treasury Department's Financial Crimes Enforcement Network (FinCEN) on how financial

institutions may provide banking services to marijuana-related businesses, many financial institutions remain reluctant to openly enter into relationships with state-authorized marijuana businesses due to the Schedule I status of marijuana.

- **Research on Marijuana.** The Schedule I status has reportedly created difficulty for researchers who seek to study marijuana, but are potentially unable to meet the strict requirements of the CSA, or seek a different strain, potency, or quality of marijuana for their research than what is lawfully available.
- **Legal Consequences for Individuals.** Violations of federal marijuana laws, even in instances where individuals are using marijuana consistent with state laws, give rise to a range of other issues including eligibility for student financial aid, housing and food assistance, gun ownership, visas, and employment.

Drug Enforcement Administration (DEA) Rejection of Petitions to Reschedule

Over the years, several entities have submitted petitions to the DEA to reschedule marijuana. In August 2016, after a five-year evaluation process done in conjunction with the Food and Drug Administration (FDA), the DEA rejected two petitions—one submitted by two state governors and the other submitted by a New Mexico health provider—to move marijuana to a less-restrictive schedule under the CSA. Consistent with past practice, the rejections were based on a conclusion by both the FDA and DEA that marijuana continues to meet the criteria for inclusion on Schedule I—namely that it has a high potential for abuse, has no currently accepted medical use, and lacks an accepted level of safety for use under medical supervision.

Authority to Alter the Schedule I Status of Marijuana

Both Congress and the Administration have the ability to alter marijuana's status as a Schedule I substance. The Administration could make such changes on its own, though it is bound by the CSA to consider factors including a substance's medical utility and risk of abuse and dependence prior to altering its scheduling status. Congress could also alter marijuana's status by amending the CSA, but without such confines. Of note, in congressional hearings and other forums, some Members of Congress in both major parties have questioned the Schedule I status of marijuana while other Members have maintained that marijuana should remain illegal. Those questioning its status have expressed support for, at minimum, moving it to a lower schedule. Some have gone further and supported its removal from the CSA altogether. Those continuing to support its Schedule I status express concern over the negative implications of its widespread use.

Options for Congress

Congress could choose to maintain the federal prohibition on marijuana, but if it wanted to address the Schedule I status, it could do a number of things: (1) amend the CSA to move marijuana to a less restrictive schedule; (2) create an entirely new schedule or other category for marijuana; or (3) remove it entirely from the CSA. If marijuana remains a controlled substance under the CSA *under any schedule*, that would maintain the existing conflict between the federal government and states that have legalized *recreational* marijuana, though moving marijuana to a less restrictive schedule could help mitigate conflicts between federal law and state *medical* marijuana laws. The creation of a new schedule solely for marijuana would give Congress an opportunity to modify the criminality of marijuana under the CSA. If Congress chose to remove marijuana from the CSA entirely, it could seek to regulate and tax commercial marijuana activities.

In 2019, the House Judiciary Committee marked up and ordered to be reported H.R. 3884, the Marijuana Opportunity Reinvestment and Expungement Act of 2019 (the MORE Act). Among other things, the bill (see also S. 2227) would remove marijuana from the CSA. Other bills introduced in the House in the 116th Congress, including H.R. 4323 and H.R. 171, would move marijuana to a lower schedule of the CSA.

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NATURAL PRODUCTS

Cannabis research stalled by federal inaction

US scientists face numerous barriers to studying health effects of cannabis

by ***Britt E. Erickson***

JUNE 29, 2020 | APPEARED IN **VOLUME 98, ISSUE 25**

Credit: Shutterstock

Clinical researchers in the US are unable to study the safety and efficacy of cannabis products purchased from legal, state-authorized dispensaries because cannabis is illegal under federal law.

Researchers in the US who want to investigate the medical benefits and risks of cannabis are frustrated. They would like to evaluate the wide array of cannabis products sold in states where cannabis is legal, but federal law prohibits them from doing so because cannabis is still illegal at the federal level.

Most studies on the therapeutic effects of cannabis have relied on synthetic formulations of specific chemicals made by cannabis plants, such as the cannabinoids tetrahydrocannabinol (THC)—the psychoactive component of cannabis—and cannabidiol (CBD). A few researchers have looked at the efficacy of whole cannabis plants to treat chronic pain, but no clinical studies have been conducted on cannabis products purchased from state-authorized dispensaries. US researchers can only study the effects of cannabis using plant material grown by the University of Mississippi under contract with the National Institute on Drug Abuse (NIDA).

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Cannabis industry gets crafty with terpenes

In March, the US Drug Enforcement Administration released a new rule intended to allow more organizations to grow more varieties of cannabis, but the cannabis research community says the proposal is still too restrictive. Additionally, cannabis researchers face the need to get approval from three federal agencies, and funding is limited. All these obstacles hinder cannabis research, the community says, leaving medical providers and consumers in the dark about the benefits and risks of cannabis products.

MISSISSIPPI MONOPOLY

The University of Mississippi typically harvests about 10 kg of cannabis grown indoors and about 500 kg grown outdoors—enough material to supply researchers for several years. The cannabis is ground into small particles of uniform size to be standardized for clinical research.

Credit: University of Mississippi (both)

Researchers have complained for years about the quality and potency of the cannabis grown by the University of Mississippi. In general, it has lower levels of THC than products that are available in legal state markets, says Morgan Fox, media relations director of the National Cannabis Industry Association (NCIA), a trade group for the cannabis industry. Researchers have reported that the cannabis is moldy. Additionally, the material is "basically like powder," Fox says. "So it is not really representative of what people are actually consuming," he says.

The cannabis grown by the University of Mississippi has the appearance of being poor quality because it is highly processed. It is dried immediately after harvesting and stored for long periods of time, sometimes years, in a walk-in freezer at −20 °C. It is also irradiated to kill off any yeasts and molds, following complaints about mold received by the US Food and Drug Administration, says Mahmoud ElSohly, a research professor who oversees the **marijuana research facility** at the University of Mississippi. Before it is shipped out to researchers, the cannabis is typically ground up into particles of uniform size.

ElSohly claims that the cannabinoids in the plant material are stable over time. "We have the appropriate stability studies" to show that, he says. But the flavor compounds in cannabis, known as terpenes, are destroyed during the drying process. Terpenes may have beneficial health effects and enhance the effects of THC and CBD. It is hard to study such effects, however, when cannabis provided for medical research doesn't contain terpenes.

Terpenes aside, there is a good reason why cannabis grown at the University of Mississippi contains much less THC than that of cannabis sold in state dispensaries, ElSohly says. Cannabis cigarettes made for research all have to be the same size and shape, he says. When experienced cannabis users were asked to smoke a cigarette with 8% THC, they could not finish it, he says. So the highest THC content in cannabis cigarettes provided for clinical research is 6%, he notes. For comparison, cannabis sold in state dispensaries often contains as much as 30% THC.

"Our charge is not to make material similar to what is out there on the illicit market or in the state-authorized medical marijuana programs," ElSohly says. "We are here to prepare standardized material for research that is given to all investigators so the outcome for one study can be easily compared with the outcome of another study."

EXPANDING SOURCES, THE DEA'S WAY

The DEA acknowledges that the quality and potency of the cannabis supplied by the University of Mississippi is not representative of the cannabis that people are actually consuming in the real world. But the agency has yet to approve any of the dozens of applications from organizations who want to provide more realistic cannabis products to researchers for medical studies.

Many of those applications have been pending **since 2016**, when the DEA announced that it would adopt a new approach to increase the number of entities registered to grow cannabis for legitimate US researchers.

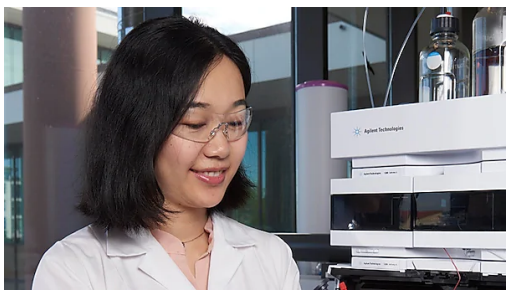
In **August 2019**, the DEA released the names of 33 applicants who requested to grow cannabis as bulk manufacturers for research. Many of the applicants requested approval to supply cannabis extract, which can be used in vaping products, edibles, and oral tinctures. Since then, the DEA has received a few additional applications.

The agency claims, however, that because "the size of the applicant pool is unprecedented," it does not plan to make decisions about the applications until it changes the policies and practices that govern the bulk marijuana growers program.

The DEA provided details about those changes in the **proposed rule** released on March 23. The agency did not respond to a request from C&EN asking about the timeline for the regulation, but the process is likely to take several more months, if not years.

Under the proposed rule, potential growers of cannabis for research have to satisfy a list of public interest criteria spelled out in the US Controlled Substances Act (CSA).

The criteria include having effective controls against diversion of cannabis from research to illicit uses. The DEA interprets that to mean restricting the amount grown by limiting the number of registered manufacturers "to that which can produce an adequate and uninterrupted supply of marihuana under adequately competitive conditions." It is unclear whether the DEA will cap the number of registered manufacturers to satisfy the diversion control criteria.



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In addition, growers must have a supply agreement with a researcher who has the appropriate DEA license to study cannabis. Alternatively, growers who plan to supply cannabis for their own research purposes must register with the DEA to study cannabis and can only grow the amount authorized in their research protocol.

Potential growers also must be able to consistently produce and supply cannabis "of a high quality and defined chemical composition." The DEA has yet to define exactly what that means. Moreover, applicants have to show "prior compliance with the CSA and DEA regulations." It is possible that companies that have grown cannabis for state-authorized programs would be excluded from consideration because such activities are illegal under the CSA.

Besides meeting the criteria under the CSA, applicants also have to be in compliance with US obligations under an international treaty, the Single Convention on Narcotic Drugs. To meet that requirement, the DEA would take physical possession of the cannabis within 4 months of harvest

and be responsible for selling the product to researchers. Growers would have to notify the DEA at least 15 days before harvest. The DEA would also have the "exclusive right of importing, exporting, wholesale trading, and maintaining stocks of cannabis and cannabis resin," excluding cannabis-derived drugs and cannabis preparations that are regulated by the FDA, according to the proposed rule. Presumably the DEA would honor the supply contracts between growers and researchers.

> **"As more states allow cannabis, the federal government still strictly controls and prohibits it, even restricting legitimate medical research.**
>
> — ***Anna G. Eshoo,*** *chair of health subcommittee, Committee on Energy and Commerce, House of Representatives*

CANNABIS COMMUNITY CONCERNS

In general, the cannabis industry claims that the rule would further hinder cannabis research in the US and make it harder for organizations other than the University of Mississippi to provide cannabis to legitimate researchers.

"The DEA is not a public health or a scientific organization and has much different priorities and expertise than those organizations," the NCIA's Fox says. The DEA doesn't have expertise related to facilitating research and is not in a good position to judge what research is necessary and appropriate, he notes. "So overall, we feel that they are not the appropriate agency to be charged with being the gatekeeper for research production," he says.

The NCIA suggests that the National Institutes of Health or some other agency within the Department of Health and Human Services would be better suited to oversee cannabis produced for research.

In addition, to improve the diversity of cannabis products available to researchers, a great place to start "would be approving applications for production, particularly ones that have been sitting in the application process for up to 4 years," Fox says. Regulators should also find "some way to allow researchers to be able to legally do research on products that are available in legal regulated cannabis markets."

Some lawmakers agree. In comments submitted to the DEA, **Sen. Brian Schatz (D-HI)** urges the US Attorney General to waive the requirement that cannabis growers register with the DEA. Such a waiver would allow researchers with appropriate DEA licenses to obtain cannabis products from state dispensaries for research purposes.

Researchers point to the recent outbreak of severe lung disease linked to vaping cannabis-based products to emphasize why it is important to study products that people are actually consuming. The outbreak "is extremely frightening, yet the issue cannot be effectively studied because researchers cannot work directly with cannabis products that are in actual use," says **Theresa A. Maldonado**, vice president for research and innovation for the University of California system, in

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comments submitted to the DEA. She asks the DEA to allow university researchers to study cannabis products that are legally purchased from state dispensaries "without being subject to prosecution, withdrawal of federal funds, or other sanctions."

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The University of Mississippi's ElSohly isn't worried about increasing the pool of growers who supply cannabis for research. "I have no problem with that," he says. The University of Mississippi has been the sole provider of cannabis for research for more than 50 years. "It doesn't really take away from what we are doing. It is not a competition per se, it just adds to the variety of products that are out there to be tested." But he questions how realistic it is to test cannabis purchased from various dispensaries across the US. "Every product is going to be different," he says.

CHANGING CRITERIA FOR GROWING CANNABIS

Growers must meet the following requirements under the Drug Enforcement Administration's March 23 proposed rule:

- have a supply agreement with a DEA Schedule I licensed researcher or have their own license to conduct cannabis research and an authorized research protocol
- be able to consistently produce and supply high-quality cannabis
- show prior compliance with the Controlled Substances Act and DEA regulations
- notify the DEA at least 15 days before harvest and allow the DEA to take physical possession of the cannabis within 4 months of harvest
- give the DEA exclusive rights to distribute the cannabis, including importing and exporting.

RESEARCHERS TURN ELSEWHERE

As the DEA drags its feet in approving new cannabis sources for research, some university researchers have resorted to studying cannabis-based drugs imported from countries such as Canada. For example, a research group at the University of California San Diego is studying a cannabis-derived drug imported from the Canadian company Tilray to treat a movement disorder called essential tremor.

Tilray has also provided researchers at Columbia University with a cannabis-based product to test for efficacy in treating breast cancer patients suffering from taxane-induced nerve damage, a side effect of treatment with the chemotherapy drugs paclitaxel and docetaxel.

"Sourcing materials from other countries is currently pursued by NIDA in an attempt to provide more products," says Heike Newman, a senior regulatory manager at the University of Colorado Denver who provides regulatory guidance to clinical researchers at the university who are interested in studying cannabis. "We know it is an option," she says. "But working with these companies directly to get their products is costly and our researchers with approved funding don't have the financial means to continue with that approach."

> "Not everyone who is willing to participate in a clinical

trial wants to smoke cannabis.

— ***Heike Newman,*** *senior regulatory manager, University of Colorado Denver*

In addition to wanting a more varied cannabis supply, “what researchers really need are more and different formulations,” such as oral solutions or dermal products rather than rolled cigarettes, Newman says. “Not everyone who is willing to participate in a clinical trial wants to smoke cannabis,” she says. The University of Mississippi does supply two cannabis extracts, one that is high in THC and low in CBD and another that is high in CBD and low in THC, ElSohly says. Because of the growing interest in CBD oil, “we had an option to prepare 50 kg of extract,” he notes.

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Even so, the chorus of lawmakers calling for change is growing. Several members of Congress grilled regulators in January about the barriers to cannabis research during the first-ever cannabis **hearing** of the health subcommittee of the Committee on Energy and Commerce in the US House of Representatives.

The bulk of the hearing centered on how to resolve a dilemma that has plagued cannabis policy for decades. The DEA classifies cannabis as a Schedule I drug—a category for substances that have no medical value and high potential for abuse. Other Schedule I drugs include heroin, LSD, and ecstasy. The Schedule I classification means that researchers must jump through all sorts of hoops, including seeking approval from three federal agencies, to study cannabis. The DEA can change how cannabis is categorized or take it off controlled substance schedules entirely if it has sufficient scientific evidence to justify the change, but researchers are impeded from doing the work that might provide such evidence because of the drug’s Schedule I status.

House lawmakers are considering several bills that would reschedule or deschedule cannabis. There does not appear to be broad support in Congress or within the federal government, however, to legalize cannabis at the federal level.

One possible solution to expedite medical research on cannabis is to create a subcategory of Schedule I, NIDA director Nora Volkow testified at the January hearing. NIDA has been working with the FDA and the DEA to create such a pathway, not just for marijuana but for S**chedule I substances in general**, “so that researchers don’t have to go through all of the obstacles and the delayed process,” she said.

Another obstacle that researchers face is extremely competitive funding for cannabis research. In fiscal 2018, the NIH funded about $148 million on cannabinoid research, of which about $38 million was devoted to cannabis therapeutics. The NIH prioritizes funding for cannabis therapeutic studies focused on treating pain, addiction, and inflammatory disorders, as well as for studies examining the adverse health effects of cannabis on prenatal and adolescent development.

Related: Boom or bust ahead for cannabidiol in the US?

As the number of states legalizing cannabis for medical and adult use grows, nearly everyone agrees that more research is needed to better understand the benefits and risks.

“Thirty-three states now allow the medicinal use of cannabis and 11 states and the District of Columbia have legalized cannabis for adult use,” subcommittee chair Anna G. Eshoo (D-CA) noted during the hearing. “As more states allow cannabis, the federal government still strictly controls and prohibits it, even restricting legitimate medical research.”

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COMMENTS

Shuki Greer
(June 30, 2020 10:39 AM)
This seems like an absurd number of requirements in order to be qualified as a cultivator for researchers. If the DEA is so intent on abiding by this 60 year old Single Convention, they should start with the MASSIVE LEGAL MARKETS AROUND THE COUNTRY!

The UN isn't going to say "The US isn't following the treaty because they allow cannabis cultivation for research purposes without giving the DEA custody of the plants in time". They are going to say "The US isn't following the treaty because its freakin legal and available in 11 states across the country." This is a clear pretext on the hands of the DEA to inhibit the development of a scientific body of research that would support full cannabis legalization.

This is exactly what John Elias just testified about to the House Judiciary Committee. Both Sessions and Barr are hell-bent against marijuana like they have been watching Reefer Madness on repeat. Its a shame that our leaders aren't listening to the people. Cannabis legalization is happening already, and will not be stopped. It just might take a few baby boomers to retire before we get there.
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New Angina Drugs

Two calcium channel blockers, nifedipine and verapamil, have been approved for treatment of vasospastic and classical effort-associated angina. These drugs are also referred to as "calcium entry blockers" or "calcium antagonists."

Drugs of this pharmacologic class have some common properties but also have important differences in clinical use.

Both agents inhibit transmembrane influx of extracellular calcium into cardiac and vascular smooth muscle, and produce, in isolated tissues, negative inotropic effects, depressed sino-atrial (SA) and atrio-ventricular (AV) node function, and vasodilation. At clinical doses in humans, however, the vascular effects are usually predominant, causing reduced peripheral vascular resistance and lower blood pressure and preventing or reversing coronary spasm. The effects on cardiac tissues are usually less prominent, probably because of afterload reduction and reflex sympathetic responses to vasodilation. In patients with normal cardiac function not on other negatively inotropic drugs, the negative inotropic effects of the drugs are not usually manifested.

In some cases, however, heart failure can be induced or worsened, and particular care must be paid to concomitant use of calcium channel blockers with beta blockers and to use in patients with aortic stenosis, where vasodilation would not be expected to produce significant afterload reduction.

Effects on AV and SA node function are also not prominent *in vivo* with nifedipine, although they can occur with verapamil.

Effectiveness

Verapamil, but not nifedipine, is an effective agent intravenously in interrupting supraventricular tachycardia and slowing the heart rate in atrial fibrillation.

Both drugs are effective in angina due to vasospasm and in chronic stable angina. Current labeling for nifedipine recommends it for use in stable angina only in patients "who remain symptomatic despite adequate doses of beta blockers and/or organic nitrates or who cannot tolerate those agents." This reservation is based on the limited long-term evidence of safety and effective-

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ness in people with stable angina.

Although the effectiveness of these agents in angina is documented, many aspects of their effectiveness remain to be defined. Uncontrolled reports[1] and studies in which these agents have been added to, or substituted for, organic nitrates that had proved insufficiently effective [2,3] in vasospastic angina seem to indicate a special ability of the calcium antagonists to prevent vasospastic angina. In two well-controlled studies comparing nifedipine with isosorbide dinitrate, however, [4,5] there was little difference between the two treatments. There are no similar direct comparisons of verapamil and organic nitrates.

Safety

The side-effect profile of these agents overlaps but is by no means identical. In general, nifedipine appears to have a somewhat greater tendency to decrease peripheral resistance and lower blood pressure than verapamil, and does not tend to inhibit SA or AV nodal conduction. There is often a small increase in heart rate, and typical symptoms and signs of vasodilation (dizziness, flushing, numbness and tingling of extremities, peripheral edema, or palpitations) are common but usually tolerable.

More serious reactions can also occur. Excessive hypotension occurs occasionally with the use of nifedipine, usually during the initial titration or at the time of upward dosage adjustment. It may be more likely in patients taking beta blockers concomitantly.

A few patients have developed increased frequency, duration, or severity of angina upon starting nifedipine or at the time of dosage increases.[6]

Nifedipine dosage should be titrated over a 7 to 14 day period, if possible, to enable the physician to assess response at each dose level and monitor blood pressure before proceeding to higher doses.

There are isolated reports of patients recently withdrawn from beta blockers who have developed marked worsening of angina and even infarction.[7]

If possible, it is advisable to taper beta blockers before stopping them and beginning nifedipine. It does not appear that nifedipine can treat the increased angina sometimes associated with beta blocker withdrawal.

Concomitant use of nifedipine and beta blockers is usually well tolerated. However, there is little controlled experience with the combination, which is known to increase the likelihood of congestive heart failure and severe hypotension.

In rare instances, patients have developed heart failure after beginning nifedipine, usually when the drug was added to a beta blocker.[8] Patients with tight aortic stenosis may also be at greater risk of developing heart failure with nifedipine.[9]

Nifedipine may be given concomitantly with nitrates, but there have been no controlled studies to assess the antianginal effectiveness of this combination.

Nifedipine has been reported to increase serum digoxin concentrations by about 50 percent and must be used with great caution with concomitant digoxin.[10]

Blood pressure falls with oral verapamil, but marked decreases appear unusual. There is usually a slight decrease in heart rate. Symptoms of vasodilation are not common. On the other hand, verapamil can inhibit SA node function and AV conduction, and cause sinus bradycardia, nodal escape rhythm, and/or AV block. It is, therefore, contraindicated in patients with pre-existing AV conduction abnormalities or sick sinus syndrome.

Verapamil has generally been avoided in patients with pre-existing

heart failure and is contraindicated in patients with severe left ventricular dysfunction because it can worsen heart failure.

There are few studies of verapamil given in combination with beta blockers, but it is clear that the combination can impair cardiac function in some patients,[11] even when cardiac function was initially good.[12]

Verapamil can cause constipation, which is usually mild.

In studies carried out in the United States, there were two reported instances of rechallenge-confirmed liver injury among the first 1,000 patients treated.[13] The patients had a picture of predominantly hepatocellular injury (transaminases in the 1,000 unit range), although there were no liver biopsies to confirm this; there was prompt resolution on discontinuation of the drug. In nearly 4,000 patients treated since that time, only isolated instances of enzyme abnormalities have been reported. The world literature does not include any reports of liver injury similar to the one previously cited.[13]

Patients on verapamil should have periodic liver function tests. The drug should be stopped if abnormalities are seen. Physicians can help define the frequency and severity of this adverse reaction by reporting observed cases promptly to FDA.

In patients with impaired liver or kidney function, verapamil should be administered only with great caution. (Verapamil is highly metabolized by the liver and 70 percent of an administered dose is excreted as metabolites in the urine.)

Verapamil increases serum digoxin levels in patients on chronic digoxin therapy and must be used with caution in such patients. Maintenance digoxin doses should be reduced and the patient should be carefully monitored to avoid over- or under-digitalization when verapamil is administered.

Disopyramide should not be given within 48 hours before or 24 hours after verapamil due to the combined negative inotropic effects of the two drugs.

Until further data are available, verapamil and quinidine should be used together cautiously, especially in patients with hypertrophic cardiomyopathy, because there have been a few reports of pulmonary edema in patients given the combination.[14]

As with nifedipine, verapamil may be given concomitantly with nitrates, although the effectiveness of the combination has not been evaluated.

More complete information for prescribing these drugs is available in the package inserts.

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13. Brodsky SJ, et al.: Hepatotoxicity due to treatment with verapamil. *Annals of Int Med* 1981; 94(4):490-491.
14. Epstein S, Rosing D: Verapamil: its potential for causing serious complications in patients with hypertrophic cardiomyopathy. *Circ* 1981; 64:437-441.

Sucralfate Approved for Duodenal Ulcer

Sucralfate (Carafate), a basic aluminum salt of polysulfated sucrose, has been approved for short-term (up to 8 weeks) treatment of duodenal ulcer. The drug is chemically unlike any other drug used for treatment of duodenal ulcer.

Sucralfate exerts its effect through local rather than systemic action, and there is little systemic absorption. Although the mechanism of sucralfate's anti-ulcer activity has not been fully defined, studies suggest that, with extracellular protein, it forms an ulcer-adherent complex that covers the ulcer site and protects it against further attack by acid, pepsin, and bile salts. The medication has negligible acid-neutralizing capacity and its anti-ulcer effects cannot be attributed to neutralization of gastric acid.

In two U.S. multicenter, placebo-controlled studies with endoscopic evaluation at 2 and 4 weeks, sucralfate was more effective than placebo in promoting complete healing, and statistically significantly better at 4 weeks. In the first study, the ulcer healing rate at 4 weeks was 75.2 percent for sucralfate and 63.6 percent for placebo. In the second study the 4-week ulcer healing rate was 92 percent for sucralfate and 58 percent for placebo.

The better result in the second study may be attributable to the dosage schedule used. In the first trial, sucralfate was given 2 hours after meals and at bedtime rather than as now recommended, 1 hour before meals and at bedtime. The latter regimen was used in several foreign studies and in the second U.S. study.

There are no known contraindications to the use of sucralfate. Adverse reactions in clinical trials involving more than 2,400 patients were minor and only rarely led to the discontinuation of the drug. The most frequent complaint was constipation, which was reported by 2.2 percent of patients. Other adverse effects reported in no

more than 1 of every 350 patients were diarrhea, nausea, gastric discomfort, indigestion, dry mouth, rash, pruritus, back pain, dizziness, sleepiness, and vertigo.

No long-term studies have been carried out and there is no recognized reason for long-term use of sucralfate. Specifically, it is not known whether sucralfate can prevent ulcer recurrence. Long-term studies will be needed to assess the possibility of adverse effects associated with long-term use, e.g., effects on absorption of fat-soluble vitamins.

The recommended adult dosage is 1 g four times a day on an empty stomach. Antacids may be prescribed as needed for relief of pain but should not be taken within 30 minutes before or after administration of sucralfate.

While healing with sucralfate may occur during the first week or two, treatment should be continued for 4 to 8 weeks unless healing has been confirmed by X-ray or endoscopy.

Ritodrine Update

Since the approval of ritodrine (Yutopar) for use in premature labor (see November 1980 and July 1981 *Drug Bulletins*), FDA has been monitoring several areas of concern about the drug's known cardiovascular effects. In light of a number of adverse reaction reports, the labeling of ritodrine has been updated to warn about:

- the need to monitor the patient's state of hydration;
- the possibility of pulmonary edema with or without the concomitant use of corticosteroids, many cases of which seem to be related to overhydration;
- the possible unmasking of occult cardiac disease, the first sign of which may be chest pain.

Ritodrine, a beta$_2$-sympathomimetic drug, may be useful in preterm labor in pregnancies of at least 20 weeks gestation when contraindications have been ruled out.

However, in pregnancies of more than 32 weeks, physicians should carefully weigh the risks and benefits before administering the drug.

When gestational age is in doubt, intrauterine growth retardation should be considered in the differential diagnosis of preterm labor. Among low birth weight infants, about 9 percent may be growth retarded for gestational age. Prolongation of labor beyond term will not correct the growth retardation of these babies.

Initial administration of ritodrine is intravenous. To minimize the risk of hypotension, the patient should be maintained in the left lateral position during infusion and careful attention should be given to her state of hydration. The amount of i.v. fluids administered should be monitored to avoid either circulatory fluid overload (overhydration) or inadequate hydration. An excess sodium load should be avoided in hydrating the patient.[1]

The boxed warning for ritodrine has been amended to read:

> Maternal pulmonary edema has been reported in patients treated with Yutopar, sometimes after delivery. While occurring infrequently, it has occurred more often when patients were treated concomitantly with corticosteroids. Maternal death from this condition has been reported with or without corticosteroids given concomitantly with drugs of this class.
>
> Patients so treated must be closely monitored in the hospital. The patient's state of hydration should be carefully monitored. (See Dosage and Administration.) If pulmonary edema develops during administration, the drug should be discontinued. Edema should be managed by conventional means.
>
> Because cardiovascular responses are common and more pronounced during intravenous administration of Yutopar, cardiovascular effects, including maternal pulse rate and blood pressure and fetal heart rate, should be closely monitored. Observe for premonitory or actual maternal signs and symptoms of pulmonary edema. A persistent high tachycardia (over 140 beats per minute) and/or persistent tachypnea (respiratory rate over 20 per minute) may be signs of impending pulmonary edema with drugs of this class.
>
> Occult cardiac disease may be unmasked with the use of Yutopar. If the patient complains of chest pain or tightness of chest, the drug should be temporarily discontinued and an ECG should be done as soon as possible.
>
> The drug should not be administered to patients with mild to moderate preeclampsia, hypertension, or diabetes unless the attending physician considers that the benefits clearly outweigh the risks.

Reference:

1. Philipsen T, et al.: Pulmonary edema following ritodrine-saline infusion in premature labor. *Ob Gyn* 1981; 58(3): 304-7.

Use of Approved Drugs for Unlabeled Indications

The appropriateness or the legality of prescribing approved drugs for uses not included in their official labeling is sometimes a cause of concern and confusion among practitioners.

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, a drug approved for marketing may be labeled, promoted, and advertised by the manufacturer only for those uses for which the drug's safety and effectiveness have been established and which FDA has approved. These are commonly referred to as "approved uses." This means that adequate and well-controlled clinical trials have documented these uses, and the results of the trials have been reviewed and approved by FDA.

The FD&C Act does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such "unapproved" or, more precisely, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.

The term "unapproved uses" is, to some extent, misleading. It includes a variety of situations ranging from unstudied to thoroughly investigated drug uses. Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigations. Before such advances can be added to the approved labeling, however, data substantiating the effectiveness of a new use or regimen must be submitted by the manufacturer to FDA for evaluation. This may take time and, without the initiative of the drug manufacturer whose product is involved, may never occur. For that reason, accepted medical practice often includes drug use that is not reflected in approved drug labeling.

With respect to its role in medical practice, the package insert is informational only. FDA tries to assure that prescription drug information in the package insert accurately and fully reflects the data on safety and effectiveness on which drug approval is based.

Hepatitis B Vaccine for Use in Selected Populations

An inactivated hepatitis B vaccine (Heptavax-B) has been licensed for use in the United States. It is intended for selected populations at high risk of acquiring hepatitis B, one of three known forms of viral hepatitis. (The others are hepatitis A and non-A non-B hepatitis.)

The vaccine is the first to be made from human blood. Noninfectious antigen is purified from the plasma of asymptomatic human carriers of hepatitis B. After a series of chemical treatments, followed by the addition of alum adjuvant, the vaccine is administered in three intramuscular injections over a 6-month period.

Vaccination is not intended for the general population, but is recommended for persons older than 3 months of age who are at increased risk of hepatitis B virus infection. These persons will include health care workers, institutionalized patients, laboratory workers, hemodialysis staff and patients, family contacts of carriers, some military personnel, and persons with numerous sexual partners.

There continues to be a dialogue among government agencies, industry, and the medical community about use of the vaccine in selected high-risk groups. The Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control (CDC), with assistance from representatives of FDA, the National Institutes of Health, and the medical community, has met several times to discuss specifically which population groups should receive this vaccine. The ACIP will meet once more in May of this year to draft final guidelines for use of this vaccine.

Efficacy

In clinical trials, 85 to 96 percent of persons receiving three doses of either 20 mg or 40 mg of vaccine were immune to infection. The duration of protection is presently unknown. However, in clinical trials, vaccine-induced antibodies, shown to provide protection against infection, persisted for at least 24 months in those receiving all three doses and will probably last for at least 5 years. After this time, a booster may be necessary to maintain immunity.

Side effects have been mainly local, mild, and transitory.

Availability

Due to the complexity of the methods used for producing the vaccine, it will be summer or fall of 1982 before the product is generally available from Merck, Sharp & Dohme. This manufacturer can supply complete physician information.

Advice on Limiting Intake of Bonemeal

Due to the unknown but often substantial lead content of individual samples of bonemeal and dolomite, FDA advises practitioners that these substances should be used as little as possible in infants, young children, and pregnant or lactating women.

Bonemeal is used primarily as calcium and/or phosphorus supplements. Bonemeal supplements are usually composed of finely crushed, processed bone and are packaged in powder, capsule, tablet, or wafer form. The source of bone is usually cattle but sometimes also horses. Bone marrow may also be added to this product. All bonemeal products contain lead which originates primarily from the diet of the animals from which the bone is taken. Bone serves as a repository for lead in the body and, in general, the older the animal the more lead in its bones.

Dolomite is a mineral deposit, consisting of calcium-magnesium carbonate with traces of other elements, including lead. Dolomite is used as a calcium and magnesium supplement and, like bonemeal, may be purchased in powder, capsule, tablet, or wafer form.

While a large portion of the small amounts of dietary lead ingested by humans is excreted, some is deposited in the mineral fabric of bone and some goes into soft tissue. Infants and children tend to absorb lead more efficiently than adults. When it is consumed in excess, lead may produce toxic reactions including central nervous system damage, anemia, and abdominal pain. As in animals, the accumulation of lead in human bone increases with age. Additionally, studies with

adult volunteers have shown that over a long time, the accumulation of lead in the body is proportional to the level of intake.

FDA Surveys

FDA has undertaken limited surveys to identify the extent of lead contamination of bonemeal and to determine whether the problem is limited or industry-wide.

One survey by FDA's Division of Consumer Studies of approximately 3,000 persons, 16 years of age and older, determined that about 1 percent of the population surveyed consumed bonemeal as a calcium source. More than 90 percent of the individuals consuming bonemeal were women, 50 years of age or older. The available information suggests that the average intake of bonemeal does not usually exceed 10 g/day.

No reliable information is available on the use of bonemeal as a calcium source for young children or infants. However, it is possible that bonemeal has been used as a calcium supplement for infants who have an intolerance for milk.

Although levels are usually lower, FDA scientists have found some samples of bonemeal containing lead at concentrations as high as 17 to 20 parts per million (ppm). Comparably high levels of lead have also been detected in some samples of dolomite.

It is known that the consumption of bonemeal containing 5 to 10 ppm lead by infants and children may result in lead intakes that clearly exceed the FDA recommended tolerable or maximal daily intake from all sources. For the infant, lead intake should be as low as possible and less than 100 micrograms/day, and for children between 6 months and 2 years the intake of lead should be no more than 150 micrograms/day.

Special Risk

Individuals at special risk of lead toxicity from the consumption of bonemeal or dolomite include infants, children, women of childbearing age, and possibly the elderly. Others who ingest bonemeal at the recommended doses (usually not more than 5 to 10 grams/person/day) would not ordinarily exceed the WHO/FAO (World Health Organization/Food and Agriculture Organization) guideline for a tolerable daily adult intake of 430 micrograms of lead. However, individuals who consume more than two to three times the recommended dose would be at greater risk if the lead content of the bonemeal is high.

Pregnant or lactating women taking bonemeal or dolomite to meet increased calcium needs may have sufficient increased lead intake and absorption to present a health hazard to the developing fetus, via placental transfer of lead, or to the nursing infant from its mother's milk.

Bendectin PPI Available

A patient package insert (PPI) for Bendectin, an antiemetic combination of doxylamine and vitamin B_6 used in pregnancy, has been issued by the manufacturer, Merrell Dow Pharmaceuticals.

Pads of the PPIs are being distributed to retail pharmacies and physicians who are high prescribers of the drug, and are available to other health professionals from the manufacturer, upon request.

A Spanish language version of the PPI will be available upon request from the manufacturer.

In its summary section, the PPI explains: "Bendectin is used to treat the nausea and vomiting that may occur during the first few weeks of pregnancy. You should take this drug only if nausea and vomiting interfere with your eating or daily activities and if other treatments prescribed by your doctor do not relieve your symptoms. These other treatments include eating soda crackers or dry toast, or drinking hot or cold liquids as soon as you wake up in the morning.

"There is no way to prove that any substance taken by pregnant women does not cause birth defects on rare occasions. For this reason, no drug, including Bendectin, should be taken during pregnancy unless it is clearly necessary."

As was discussed in the March 1981 issue of the *Drug Bulletin*, the revised physician labeling for Bendectin cautions physicians that the drug should be used only when more conservative treatment for nausea and vomiting in pregnancy has failed and when symptoms are sufficiently distressing to require drug intervention.

Class I Recalls

As a special service to health professionals, the *Drug Bulletin* is publishing information on recent Class I recalls. The following products have been withdrawn voluntarily in firm-initiate Class I recalls because they pose serious health hazards:

Infant Formula

Nursoy Concentrated Liquid, 13-ounce cans, coded A26M, B2M, and B9M, and Nursoy Ready-to-Feed 32-ounce cans coded A28M and B11M. Codes may be preceded by a number such as 1,2, or 3, which can be ignored. Example: 2A26M. Formula lacks vitamin B_6, which can result in serious health effects ranging from irritability to convulsions. Cans may be returned to the retailer for refund or replacement. Recall date: March 3, 1982.

SMA powder and liquid with code numbers A25M through A31M, and B1M through B15M. Code numbers may be preceded by a number such as 1,2, or 3, which can be ignored. Example: 2A25M. Formula is deficient in vitamin B_6, which can result in serious health effects ranging from irritability to convulsions. Cans may be returned to the retailer for refund or replacement. Recall date: March 12, 1982.

Defibrillator

Safeguard 3, serial numbers 290, 374, 379, 380, 1001, 1002, 1006. The storage capacitor may fail, resulting in low discharge energy and consequent failure to defibrillate. The manufacturer, Safeguard Medical Systems, Inc., Beltsville, Md., will replace faulty condensors. Recall date: Dec. 14, 1981.

Congress of the United States
Washington, DC 20515

December 6, 2019

The Honorable William P. Barr
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

Dear Attorney General Barr:

We write to ask for clarification in the Justice Department's current and proposed policies regarding the access to research-grade cannabis, including forthcoming new regulations governing schedule I licenses to manufacture cannabis for research.[1]

In response to a congressional inquiry, both the National Institutes of Health (NIH) and the U.S. Food and Drug Administration (FDA) discussed how federal restrictions inhibit marijuana research in a variety of ways, including limitations on the diversity and quality of research-grade cannabis.[2] The agencies stated that "[a] larger body of rigorous research, including on cannabis and cannabinoid products that are already in use or that could be developed into FDA-approved medications, is key to furthering our understanding of their potential medical benefits and risks."

One barrier to research is that the Drug Enforcement Administration (DEA) has registered one entity to produce research-grade marijuana—the University of Mississippi. Both NIH and FDA note that having one source producing the marijuana necessary for research limits "the diversity of products and formulations available to researchers" and slows "the development of cannabis-based medication." Due to the limitations associated with cultivating all research-grade marijuana at a single facility, the agencies "support licensing additional entities to supply cannabis, including extracts and derivatives, to legitimate researchers and drug product developers in the United States."

As recently as 2016, DEA has acknowledged the need for increased diversity and quality of research-grade cannabis.[3] However, both DEA and the Justice Department have delayed the approval of licenses to manufacture marijuana for over three years. Furthermore, the Justice Department is now considering a new regulatory scheme to govern how additional manufacturers for research will operate.

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[1] Drug Enforcement Administration, "Bulk Manufacturer of Controlled Substances Applications: Bulk Manufacturers of Marihuana," 84 FR 44920, 28 Oct. 2019, https://www.federalregister.gov/documents/2019/08/27/2019-18456/bulk-manufacturer-of-controlled-substances-applications-bulk-manufacturers-of-marihuana.
[2] "FDA and NIH on Marijuana," https://www.scribd.com/document/425284413/FDA-And-NIH-On-Marijuana#from_embed.
[3] Drug Enforcement Agency, "Applications To Become Registered Under the Controlled Substances Act to Manufacture Marijuana To Supply Researchers in the United States," 81 FR 53846 12 Aug. 2016, https://www.federalregister.gov/documents/2016/08/12/2016-17955/applications-to-become-registered-under-the-controlled-substances-act-to-manufacture-marijuana-to.

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At the same time, the status quo does not address a barrier to research raised by both NIH and FDA: "under federal law, researchers are unable to purchase strains of marijuana or products containing marijuana from state dispensaries (even with non-federal funds), resulting in a significant gap in our understanding of these products and their impact on health." Both agencies recommended that researchers should be able to obtain cannabis from state-legal sources.

Additionally, NIH and FDA jointly recognized the problems in industry development of licensed drugs with data from products obtained from third-parties, such as the University of Mississippi. In many states, cannabis law and regulations already provide for licensing of industrial manufacturing activities, and products are available for medical use in those states, but not for research leading to FDA licensure.

There is a need for a greater diversity of cannabis products so that research on benefits and risks reflects the realities of what consumers and patients are using. NIH and FDA have strongly recommended streamlining the process for conducting research and product development activities with cannabis and other Schedule I substances, and that the DEA take action to assure that interpretations of processes and policies are universally applied in local DEA jurisdictions.

We request the following:

1) That the DEA amend, in light of the strong statements of continued research needs by both NIH and FDA and without need for further legislative action, its current policies so as to allow researchers with Schedule I licenses to obtain cannabis-derived products from state authorized dispensaries for research purposes.[4]

2) That the DEA issue in the near future a public clarification of its interpretation of the hemp provision in the *Agricultural Improvement Act of 2018*—which removes "hemp" from the definition of "marihuana" under the *Controlled Substances Act*. Cannabis preparations that conform to the hemp definition should not require a Schedule I research registration, regardless of the classification of the cannabis source ingredients used in the final preparation.[5]

Please respond in writing by December 20, 2019. Thank you for your attention to this matter.

Sincerely,

BRIAN SCHATZ
United States Senator

HARLEY ROUDA
Member of Congress

[4] Under 21 U.S.C. § 822(d), "The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety."
[5] Under P.L. 115-334, hemp 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 delta9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."

KAMALA D. HARRIS
United States Senator

CORY GARDNER
United States Senator

MATT GAETZ
Member of Congress

EARL BLUMENAUER
Member of Congress

TONY CÁRDENAS
Member of Congress

JIMMY PANETTA
Member of Congress

ANGIE CRAIG
Member of Congress

BILL FOSTER
Member of Congress

RASHIDA TLAIB
Member of Congress

KATIE PORTER
Member of Congress

CINDY AXNE
Member of Congress

SCOTT H. PETERS
Member of Congress

JOSEPH P. KENNEDY, III
Member of Congress

BARBARA LEE
Member of Congress

PETER A. DEFAZIO
Member of Congress

DAVID TRONE
Member of Congress

MIKE LEVIN
Member of Congress

JOE NEGUSE
Member of Congress

DAVID E. PRICE
Member of Congress

cc: Uttam Dhillon
Acting Administrator
Drug Enforcement Administration

91st Congress, 2d Session - - - House Report No. 91-1444 (Part 1)

COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970

REPORT

OF THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

HOUSE OF REPRESENTATIVES

TOGETHER WITH

INDIVIDUAL VIEWS

TO ACCOMPANY

H.R. 18583

A BILL TO AMEND THE PUBLIC HEALTH SERVICE ACT AND OTHER LAWS TO PROVIDE INCREASED RESEARCH INTO, AND PREVENTION OF, DRUG ABUSE AND DRUG DEPENDENCE; TO PROVIDE FOR TREATMENT AND REHABILITATION OF DRUG ABUSERS AND DRUG DEPENDENT PERSONS; AND TO STRENGTHEN EXISTING LAW ENFORCEMENT AUTHORITY IN THE FIELD OF DRUG ABUSE

SEPTEMBER 10, 1970.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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U.S. GOVERNMENT PRINTING OFFICE
48-707 WASHINGTON : 1970

91ST CONGRESS } HOUSE OF REPRESENTATIVES { REPT. 91–1444
2d Session } { (Part 1)

COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970

SEPTEMBER 10, 1970.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. STAGGERS, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 18583]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 18583) to amend the Public Health Service Act and other laws to provide increased research into, and prevention of, drug abuse and drug dependence; to provide for treatment and rehabilitation of drug abusers and drug dependent persons; and to strengthen existing law enforcement authority in the field of drug abuse, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment strikes out all after the enacting clause and inserts a new text, which is set forth in italic in the reported bill.

PRINCIPAL PURPOSE OF THE BILL

This legislation is designed to deal in a comprehensive fashion with the growing menace of drug abuse in the United States (1) through providing authority for increased efforts in drug abuse prevention and rehabilitation of users, (2) through providing more effective means for law enforcement aspects of drug abuse prevention and control, and (3) by providing for an overall balanced scheme of criminal penalties for offenses involving drugs.

BACKGROUND

Titles I and II of the reported bill were the subject of hearings before the Subcommittee on Public Health and Welfare on February 3, 4, 17, 18, 19, 20, 25, 26, and 27, and on March 2 and 3, 1970. Following the hearings, the subcommittee considered the legislative proposals

before it during a total of 37 executive sessions, as a result of which a clean bill (H.R. 18583) was introduced incorporating revisions in the legislation before the subcommittee.

The legislation was further considered in executive sessions before the full Interstate and Foreign Commerce Committee on 8 occasions, and titles I and II were ordered reported to the House unanimously on August 14, 1970, together with title III incorporated in the bill pursuant to action of the Ways and Means Committee (as indicated below).

Legislation providing increased law enforcement authority in the field of drug abuse was transmitted to the Congress by the President on July 14, 1969. Because the proposed legislation repeals the tax laws and other laws under the jurisdiction of the Committee on Ways and Means used to control narcotic drugs, the President's message was at first referred to the Committee on Ways and Means. However, because the proposed legislation also deals with drugs regulated under the Federal Food, Drug, and Cosmetic Act, the proposed legislation was divided into two bills, H.R. 13742 (referred to the Committee on Ways and Means) and H.R. 13743 (referred to the Committee on Interstate and Foreign Commerce). The two bills were, in general, identical, except with respect to the drugs covered by their provisions, with H.R. 13742 being limited to narcotic drugs and marihuana (regulated today under the Internal Revenue Code of 1954 and other Acts), and H.R. 13743 being limited to drugs today regulated under the Federal Food, Drug, and Cosmetic Act.

Hearings were held on H.R. 13742 and H.R. 17463 (a bill combining the provisions of H.R. 13742 and H.R. 13743) on July 20, 21, 22, 23, and 27. Thereafter the Committee on Ways and Means decided to consider only the provisions relating to imports and exports of narcotic drugs, marihuana, and depressant and stimulant drugs and recommended to the Interstate and Foreign Commerce Committee an amendment to H.R. 18583 which is incorporated in the bill as title III thereof. The reported bill is based upon the provisions of the legislation heretofore discussed, with the form in which the bill is reported being designed to preserve the jurisdiction of the Ways and Means Committee over future amendments to this legislation relating to imports and exports of drugs covered by the bill.

By agreement between the Interstate and Foreign Commerce Committee and the Ways and Means Committee, the former committee will handle and have jurisdiction over titles I and II of the reported bill, and the latter will handle and have jurisdiction over title III of the bill, as set forth in the following letter from Chairman Mills to Chairman Staggers:

COMMITTEE ON WAYS AND MEANS,
HOUSE OF REPRESENTATIVES,
Washington, D.C., August 12, 1970.

HON. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives.

DEAR MR. CHAIRMAN: In accordance with our prior understanding relative to committee jurisdiction over the subject of narcotic and dangerous drug legislation, this letter is to advise you that the Committee

on Ways and Means has completed action on its portion of the legislation to be reported to the House by the Committee on Interstate and Foreign Commerce.

I am authorized and directed by the Committee on Ways and Means to formally forward to you under cover of this letter the legislative language which is to be contained in title III of the comprehensive drug bill which will be reported by the Committee on Interstate and Foreign Commerce. This title III contains the matters over which the Committee on Ways and Means will have jurisdiction and is related to the subject of importation and exportation, and amendments and repeals of revenue laws. The short title for title III is the "Controlled Substances Import and Export Act."

There will also be forwarded to you appropriate report language relating to title III for you to include in the committee report which your committee will file on this legislation, in accordance with our understanding.[1]

Further, the Committee on Ways and Means will handle matters related to title III of the legislation before the Committee on Rules, and on the floor of the House of Representatives when the bill is considered by the House.

Sincerely yours,

WILBUR D. MILLS, *Chairman.*

SUMMARY OF THE BILL

H.R. 18583, as reported, consists of three titles. Title I establishes rehabilitation programs relating to drug abuse; title II provides authority for the Justice Department with respect to law enforcement aspects of control of drug abuse; and title III, as recommended by the Committee on Ways and Means, covers provisions relating to importation and exportation of drugs subject to abuse.

Title I: Rehabilitation.—The bill provides authority for the Department of Health, Education, and Welfare to increase its efforts in the rehabilitation, treatment, and prevention of drug abuse, through community mental health centers and through public health service hospitals and facilities. Over a 3-year period $75 million in increased authorizations are provided for community mental health center facilities to deal with narcotic addicts and drug dependent persons, $29 million is authorized for drug abuse education activities, and $60 million is authorized for special facilities in areas having percentages of narcotic addicts and drug dependent persons.

Increased research and training activities are authorized through the National Institute of Mental Health out of appropriations otherwise authorized for that institute. Section 4 of the bill would encourage treatment of narcotic addicts by individual physicians.

Title II: Control and Enforcement.—The bill provides for control by the Justice Department of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal.

[1] Repot language referred to in this paragraph may be found on pages 71 through 80 of this report.

The drugs with respect to which these controls are enforced initially are those listed in the bill. These drugs are those which by law or regulation have been placed under control under existing law. This includes all hard narcotics and opiates, marihuana, all hallucinogens (such as LSD), amphetamines, barbiturates, and tranquilizers subject to abuse.

A procedure is established for classification of future drugs which create abuse problems. Under this procedure, if the Attorney General feels that a drug should be controlled, he will gather data, and request a scientific and medical evaluation by the Secretary of HEW. If the Secretary of HEW determines, on the basis of these and any other data, that the drug should not be controlled, the Attorney General may not control the drug; otherwise, the Attorney General may publish notice in the Federal Register and proceed in accordance with rulemaking procedures, which provide notice and opportunity for a hearing, to list the drug for control.

An exception is made in the case of treaty obligations of the United States. If a drug is required to be controlled pursuant to an international treaty, convention, or protocol in effect on the enactment of the bill, the drug will be controlled in conformity with the treaty or other international agreement obligations.

In the case of drugs providing serious addiction or abuse problems (those listed in schedules I and II) tighter controls are provided. These controls include the establishment of quotas for imports and for domestic manufacture. Transfers of these drugs may only be made through the use of officially prescribed order forms, with a copy furnished the Attorney General.

All persons in the distribution chain are required to be registered, and, with certain exceptions, must keep records with respect to all transfers of controlled drugs. Practicing physicians are required to keep records of schedule I substances; keep records of narcotic drugs in other schedules which they dispense (as distinguished from prescribing or administering) to patients; and if they charge for other controlled drugs regularly, keep records of these transactions. Researchers are not required to keep records with respect to controlled substances used by them at registered establishments that keep records.

Criminal Penalties.—The bill revises the entire structure of criminal penalties involving controlled drugs by providing a consistent method of treatment of all persons accused of violations. With one exception involving continuing criminal enterprises, hereafter discussed, all mandatory minimum sentences are eliminated.

Possession of controlled drugs is made a misdemeanor, except where the possession is for the purpose of distribution to others. In the case of a first offense of simple possession, the court may place the offender on probation for not more than 1 year. If at the end of the period of probation the offender has not violated the conditions of probation, the proceedings against him may be dismissed without a court adjudication of guilt.

If the offender is below the age of 21 when the offense occurs, he may obtain a court order expunging from all official records all recordation relating to his arrest, indictment, trial, and finding of guilt. The procedure described above for first offenders may only be utilized once by an individual, and a second offense of possession thereafter will be treated as a first offense.

Manufacture or distribution of illicit drugs is punishable by up to 15 years in prison in the case of schedule I or II narcotic drugs, and by up to 5 years in the case of non-narcotic schedule I or II drugs or any other controlled drugs in schedule III. Illegal sales or manufacture of schedule IV drugs (generally minor tranquilizers) would carry a 3-year sentence for a first offense and of schedule V drugs would carry a 1-year sentence.

Second offenses carry double the penalty for first offenses.

Where a person over 18 sells drugs to a person below 21, the first offense punishment is twice that otherwise prescribed.

Where an individual engages in a continuing criminal enterprise involving a continuing series of violations undertaken by him in concert with five or more other persons and from which he derives substantial income, he is punished by a mandatory minimum sentence of not less than 10 years and up to life imprisonment, together with a fine of up to $100,000 and forfeiture to the United States of all profits derived from the enterprise.

Administration.—The bill specifies a number of administrative authorities for the Attorney General, authorizing research and education programs relating to law enforcement aspects of drug abuse, cooperation with State and local law enforcement authorities, administrative inspections, forfeitures, and execution of search warrants, including authority to enter premises without giving notice of authority and purpose if a judge or U.S. magistrate has authorized such entry in the warrant after determining that there is probable cause to believe that—

(1) property sought may and, if notice is given, will be easily and quickly destroyed or disposed of, or

(2) the giving of such notice will immediately endanger the life or safety of the executing officer or another person.

Commission on Marihuana and Drug Abuse.—The bill establishes a Presidential commission on marhuana and drug abuse which will study and report to the Congress within 1 year on problems involved in marihuana use, and within 2 years on the causes of drug abuse and their relative significance.

Title III: Imports and exports.—Title III of the bill as recommended by the Committee on Ways and Means provides for control of imports and exports of drugs subject to abuse through a system of registration of importers and exporters, and permits for or notification to the Attorney General of transactions, with criminal penalties for transactions outside the legitimate chain.

Total Authorization

The bill authorizes $403 million in additional appropriations as follows:

(1) Increased authorization for community mental health centers: 1971, $10 million; 1972, $25 million; 1973, $40 million.

(2) Drug abuse education: 1971, $7 million; 1972, $10 million; 1973, $12 million.

(3) Special projects: 1971, $20 million; 1972, $20 million; 1973, $20 million.

(4) Commission on marihuana and drug abuse: $1 million.

(5) Department of Justice: 1972, $60 million; 1973, $70 million; 1974, $90 million, plus an additional amount for increased enforcement personnel of $6 million per fiscal year.

Control Provisions

The bill is designed to meet problems that have arisen under existing narcotic and dangerous drug laws due to recent governmental reorganization, court rulings, and the changing posture of the drug problem facing this country.

Since 1914 the Congress has enacted more than 50 pieces of legislation relating to control and diversion, from legitimate channels, of those drugs referred to as narcotics and dangerous drugs. This plethora of legislation has necessarily given rise to a confusing and often duplicative approach to control of the legitimate industry and to enforcement against the illicit drug traffic. This bill collects and conforms these diverse laws in one piece of legislation based upon new scientific information, the restructured Federal law enforcement efforts under Reorganization Plan No. 1 of 1968, and greater information concerning the scope of the problem. The bill classifies substances subject to control in five schedules according to their abuse potential, and psychological and physical effects. It sets forth penalties which are designed to correspond to violations involving substances contained in the respective schedules.

The bill is designed to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a "closed" system of drug distribution for legitimate handlers of such drugs. Such a closed system should significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.

The bill also specifically recognizes our international obligations under the Single Convention of 1961 and will allow the United States to immediately control under the schedules of the bill drugs hereafter included under schedules of the Single Convention upon the recommendation of the World Health Organization.

Extent of the Problem

Drug abuse in the United States is a problem of ever-increasing concern, and appears to be approaching epidemic proportions. One indication of the upsurge in drug abuse in the last few years can be found in arrest statistics, although for every individual apprehended, countless others go undetected. For 1968, uniform crime reports indicate that 162,177 persons were arrested by State and local authorities for drug violations, constituting a 322-percent increase over the number of drug arrests made in 1960. Of the total number arrested in 1968, 43,200 were under the age of 18 and 6,243 were under the age of 15. Another indication of the growing seriousness of the problem is that, according to testimony presented to the committee, a leading cause of death among teenagers in the United States today in many major metropolitan areas is overdosage of heroin.

Since drug abuse involves illegal activities under both State and Federal law, reliable statistics cannot be obtained on the actual extent of drug abuse in the United States; however, it is apparent that the extent of drug abuse, particularly among the young, is increasing greatly. Estimates are that between 8 and 12 million persons have tried marihuana. Studies involving some colleges and graduate schools indicate that 50 percent or more of the students have abused drugs at one time or another; and testimony before the committee in hearings on this and other legislation has indicated that substantial numbers of high school students and in some cases grammar school students are involved in the abuse of drugs.

With regard to the stimulant and depressant drugs, now regulated under the Federal Food, Drug, and Cosmetic Act as amended by the Drug Abuse Control Amendments of 1965 and in 1968, it should be noted that as estimated in a report by this committee in March of 1965 on the Drug Abuse Control Amendments of 1965, almost 50 percent of the 9 billion amphetamines and barbiturates produced legitimately in this country were diverted into illicit channels. As of late 1969, when that diversion figure was rechecked, it was still accurate.

Testimony further indicated that hallucinogenics accounted for the greatest single increase in drug offenses in the United States. Probably the most widely abused drug in this class was marihuana, which accounted for most of the 64-percent increase in total narcotic and marihuana arrests between 1967 and 1968. The recent Federal Bureau of Investigation Uniform Crime Reports indicated that instances of marihuana violations had risen 200 percent between 1967 and 1969. It was also estimated that in certain high school and college environments, over 50 percent of all the students had had some experience with marihuana.

Consequences of Drug Abuse

The consequences of drug abuse are varied, depending upon the type of drug abused. In addition to the ever-present danger of arrest and imprisonment, the consensus among the medical profession is to the effect that the abuse of drugs by individuals has adverse effects upon the physical or mental health of the abusers.

Abuse of drugs can create in the abuser a dependency upon the drug itself. The dependence may be physical, in which case the abuser suffers pronounced discomfort in the absence of the drug upon which he has become dependent, with consequences ranging from illness through grand mal convulsions and death.

In addition to the dangers associated with the creation of physical dependence occurring in the case of abuse of certain of the drugs proposed to be controlled under the bill, all of the drugs covered can create psychological dependence in the abuser. In general, a person is considered as psychologically dependent upon drugs when the physical sensation or psychological state brought about through the use of the drug is of such a nature that he desires the repetition of the sensation or state, and feels more or less psychological disturbance or distress during periods of abstinence from the drug.

With respect to psychological dependence, the extent of dependence varies in accordance with the personality of the abuser. Some persons, having a drug-dependent personality, are extremely prone to the use

of drugs, and are likely to use a wide variety of them, in search of a psychic state different from their normal state because of their inherent dissatisfaction with themselves. In general, these persons appear to lack initiative and self-reliance, and are passive, inadequate, and immature.[1]

The extent of psychological dependence created also varies with the characteristics of the drugs themselves. In addition, the extent of psychological dependence created in the individual abuser depends upon the motivations underlying his abuse of drugs in the first instance. As was pointed out in the report of the President's Advisory Commission on Narcotic and Drug Abuse, known as the Prettyman Commission:

> Some use drugs to seek relief from the tedium of their jobs and their lives. Some talented, even brilliant, individuals take to drugs to escape the fear of failure, or the knowledge that they have not fulfilled their potential. Some become hooked accidentally when they find themselves unable to give up the drug after undergoing medical treatment with one or more of these drugs to relieve pain. A larger number take to certain drugs to offset fatigue, and this group includes truckdrivers, theatrical people, and even doctors and nurses facing the letdown that follows long hours of tension. A very much larger group try psychotoxic drugs for kicks, out of curiosity or bravado. They are usually juveniles who frequently find themselves unable to shake off the drug habit.
>
> There is great ignorance of the patterns of drug abuse. The practice of drug addiction appears to be spread by the users themselves. The immediate physiological craving associated with withdrawal from narcotic drugs can now be alleviated by medical treatment. Because the original underlying psychological causes persist, however, the relapse rate following withdrawal from drugs is very high.

Alternative Approaches to Drug Abuse

The reported bill combines both the punitive and rehabilitive approaches to the problem of drug abuse. It seeks, through appropriate regulation of the manufacture and distribution of drugs, to reduce the availability of drugs subject to abuse except through legitimate channels of trade and for legitimate uses. The bill provides criminal penalties, with sentencing provisions generally left to the discretion of the courts, for offenses involving the distribution, sale, and use of drugs subject to abuse, and provides for a greatly increased Federal effort in the fields of prevention and rehabilitation.

In discussing the underlying philosophy involved in this dual approach to the problem, the Prettyman Commission report stated as follows:

> The abuse of drugs has aroused two extreme attitudes—the punitive and the permissive.
>
> Some people are concerned primarily with the effects of drug abuse on the community. They know that it can debilitate and destroy the inner fabric of a man, and that if it leads to addiction, the abuser becomes obsessed with his drug, living for nothing else. They also know that drug abusers usu-

[1] Meyer, A. S., "Social and Pyschological Factors in Opiate Addiction," Board of Applied Research, Columbia University, New York, 1952.

ally commit crimes against property because of their habit. They know that drug abuse is primarily spread by the drug abuser who persuades others to try the drug. Though they may not always consider drug abuse a crime, this school takes an essentially punitive approach. Because most serious drug abusers return to drugs if left to themselves; these people would shut the drug abuser away from society for as long as possible.

In contrast to this attitude, others hold that serious drug abuse is usually symptomatic of a mental disturbance and that the drug abuser is a sick person. They attribute his crimes to an inner compulsion for which he should not be held responsible under our code of criminal justice. They feel that the drug abuser must be treated for his sickness rather than punished. Some feel his disease is incurable and that he should be maintained on the drug.

This Commission does not accept either of these extreme attitudes, but it subscribes to certain aspects of each. Rehabilitation is the humanitarian ideal, to be sought wherever possible. But rehabilitation is not simple. It requires the skills of many disciplines and the efforts of many agencies. The drug abuser who steals or who sells drugs to finance his habit is guilty of a crime. Like any other citizen, he should face the consequences. Whether he can be held criminally responsible can only be decided in the courts, case by case. The Commission cannot assert a general rule that every confirmed drug abuser is so impelled by his habit that he is not accountable for his acts under criminal law.

If the abuser is to be penalized, he should not be penalized in the spirit of retribution. The modern concept of criminology should apply—that penalties fit offenders as well as offenses. Penalties should be designed to permit the offender's rehabilitation wherever possible. Although society must often be protected from the offender for a time, penalties in specific cases should recognize the need for reformation.

The deterrent effect of long sentences is vigorously debated. Some evidence indicates that the threat of long sentences may deter nonusing traffickers, but it does not necessarily deter the drug abuser. Deterrence is essentially an appeal to a normal sense of reason which the drug abuser has lost. The persistence of narcotic abuse, despite severe penalties for the possession of narcotics, is persuasive evidence that the abuser will risk a long sentence for his drug.

The general philosophy of this Commission can be stated in three parts:

(1) The illegal traffic in drugs should be attacked with the full power of the Federal Government. The price for participation in this traffic should be prohibitive. It should be made too dangerous to be attractive.

(2) The individual abuser should be rehabilitated. Every possible effort should be exerted by all governments—Federal, State, and local—and by every community toward this end. Where necessary to protect society, this may have to be done at times against the abuser's will. Pertinent to all, the causes of drug abuse must be found and eradicated.

(3) Drug users who violate the law by small purchases or sales should be made to recognize what society demands of them. In these instances, penalties should be applied according to the principles of our present code of justice. When the penalties involve imprisonment, however, the rehabilitation of the individual, rather than retributive punishment, should be the major objective.

Approach of the Bill

CRIMINAL PENALTIES

The reported bill provides severe criminal penalties for persons engaged in illicit manufacture or sale of controlled drugs primarily for the profits to be derived therefrom. Section 408 of the bill provides that persons engaged in continuing criminal enterprises involving violations of the bill, from which substantial profits are derived, shall, upon conviction, be sentenced to not less than 10 years in prison, and may be imprisoned up to life, with a fine of up to $100,000, plus forfeiture of all profits obtained in that enterprise. A second conviction under this section will lead to a mandatory sentence of not less than 20 years and up to life imprisonment, a fine up to $200,000, and forfeiture of all such profits.

This section 408 is the only provision of the bill providing minimum mandatory sentences, and is intended to serve as a strong deterrent to those who otherwise might wish to engage in the illicit traffic, while also providing a means for keeping those found guilty of violations out of circulation.

The penalties for other violations of the bill are, in general, less severe, depending upon whether the offense involves distribution to minors, other illicit transactions involving "pushing" or incidental thereto, more or less technical violations, or possession for personal use, which involves the least severe penalties of all.

Except when continuing criminal enterprises serve as the basis for an indictment, manufacture, sale, or other distribution of controlled drugs will carry penalties which vary, depending upon the danger of the drugs involved. If the drugs are narcotic drugs listed in schedules I or II, which have the highest probability of creating severe physical as well as psychological dependence, the penalties which may be imposed are up to 15 years imprisonment and a fine of up to $25,000 for a first offense. If the drug involves nonnarcotic substances listed in schedules I or II, or any substance (whether or not a narcotic) included in schedule III, the penalties for a first offense are up to 5 years imprisonment, plus a fine of not more than $15,000. If the drug is a schedule IV substance, the penalty is up to 3 years imprisonment and a fine of $10,000, and if a schedule V substance is involved, the penalty is up to 1 year imprisonment, plus a fine of not more than $5,000.

Where a violation of the bill involves distribution to a person below the age of 21 by a person who is 18 or more years of age, the penalty authorized is twice the penalty otherwise authorized for a first offense, with substantially increased penalties for second and subsequent violations.

More or less technical violations set forth in section 402 of the bill are punishable by less severe penalties. In case of knowing and in-

tentional violations of this provision, imprisonment up to 1 year for a first offense is provided for.

The foregoing sentencing procedures give maximum flexibility to judges, permitting them to tailor the period of imprisonment, as well as the fine, to the circumstances involved in the individual case.

The severity of existing penalties, involving in many instances minimum mandatory sentences, have led in many instances to reluctance on the part of prosecutors to prosecute some violations, where the penalties seem to be out of line with the seriousness of the offense. In addition, severe penalties, which do not take into account individual circumstances, and which treat casual violators as severely as they treat hardened criminals, tend to make convictions somewhat more difficult to obtain. The committee feels, therefore, that making the penalty structure in the law more flexible can actually serve to have a more deterrent effect than existing penalties, through eliminating some of the difficulties prosecutors and courts have had in the past arising out of minimum mandatory sentences.

ILLEGAL POSSESSION FOR PERSONAL USE

The bill also provides that illegal possession of controlled drugs by an individual for his own use is a misdemeanor, with a sentence of up to 1 year imprisonment and a fine of not more than $5,000 or both. The possession involved here is possession for one's own use; possession with intent to manufacture, distribute, or dispense controlled substances is subject to the penalties prescribed for the act of manufacture, distribution, or dispensing itself. The quantity of a drug found in the possession of a person, of course, bears upon the question of whether or not his possession is for his own use, or is for the purpose of illicit transactions involving others, for which much more severe penalties are provided.

In the case of a first prosecution for the offense of possession, the bill provides that if the defendant is found guilty or pleads guilty, the judge may, in lieu of entering a judgment of guilty place the accused person upon probation. The period of probation may not exceed 1 year and shall be subject to such conditions as the court may prescribe. After the defendant has completed his probation, the court shall discharge the defendant and dismiss the proceedings against him without entering a judgment of guilty. This procedure is only available to a defendant one time, and a nonpublic record is to be retained by the Department of Justice of this discharge or dismissal for the purpose of insuring that this lenient treatment is provided only once to a defendant.

The bill further provides that in the case of a person below the age of 21 years who is found guilty, or pleads guilty, to a charge of simple possession, the court may, after dismissal or discharge and upon application, issue an order expunging from all official records all recordation relating to the arrest, indictment, or information, trial, finding of guilty, and dismissal or discharge (except for the nonpublic record retained by the Department of Justice). This expunging of all records restores the defendant to the status he occupied before his arrest and he may not thereafter be held guilty of perjury or giving a false statement for failure to reveal or acknowledge his arrest, indictment, or trial in response to any inquiry made to him for any purpose.

MARIHUANA

The extent to which marihuana should be controlled is a subject upon which opinions diverge widely. There are some who not only advocate its legalization but would encourage its use; at the other extreme there are some States which have established the death penalty for distribution of marihuana to minors. During the hearings, Dr. Stanley F. Yolles, who was the Director of the National Institute of Mental Health, submitted a chart of fable and fact concerning marihuana. That chart is as follows:

MARIHUANA

FABLE	FACT
1. Marihuana is a narcotic.	1. Marihuana is not a narcotic except by statute. Narcotics are opium or its derivations (like some synthetic chemicals with opium-like activity).
2. Marihuana is addictive.	2. Marihuana does not cause physical addiction, since tolerance to its effects and symptoms on sudden withdrawals does not occur. It can produce habituation (psychological dependence).
3. Marihuana causes violence and crime.	3. Persons under the influence of marihuana tend to be passive. It is true that sometimes a crime may be committed by a person while under the influence of marihuana. However, any drug which loosens one's self-control is likely to do the same and relates primarily to the personality of the user.
4. Marihuana leads to increase in sexual activity.	4. Marihuana has no aphrodisiac property.
5. Marihuana is harmless.	5. Instances, of acute panic, depression, and psychotic states are known, although they are infrequent. Certain kinds of individuals can also become over-involved in marihuana use and can lose their drive. We do not know the effects of long-term use.
6. Occasional use of marihuana is less harmful than occasional use of alcohol.	6. We do not know. Research on the effects of various amounts of each drug for various periods is underway.
7. Marihuana use leads to heroin.	7. We know of nothing in the nature of marihuana that predisposes to heroin abuse. It is estimated that less than 5% of chronic users of marihuana go on to heroin use.

FABLE	FACT
8. Marihuana enhances creativity.	8. Marihuana might bring *fantasies* of enhanced creativity but they are illusory, as are "instant insights" reported by marihuana users.
9. More severe penalties will solve the marihuana problem.	9. Marihuana use has increased enormously in spite of the most severely punitive laws.
10. It is safe to drive while under the influence of marihuana.	10. Driving under the influence of any intoxicant is hazardous.

In the bill as recommended by the administration and as reported by the committee, marihuana is listed under schedule I, as subject to the most stringent controls under the bill, except that criminal penalties applicable to marihuana offenses are those for offenses involving nonnarcotic controlled substances.

The committee requested recommendations from the Department of Health, Education, and Welfare concerning the appropriate location of marihuana in the schedules of the bill, and by letter of August 14, 1970 (printed in this report under the heading "Agency Reports"), the Assistant Secretary for Health and Scientific Affairs recommended "that marihuana be retained within schedule I at least until the completion of certain studies now underway."

In addition, section 601 of the bill provides for establishment of a Presidential Commission on Marihuana and Drug Abuse. The recommendations of this Commission will be of aid in determining the appropriate disposition of this question in the future.

Rehabilitation

The reported bill would provide increased authority for Federal agencies dealing with problems of drug abuse. Title I would provide increased research, training, education, and rehabilitation authority for the Secretary of Health, Education, and Welfare. That title would also provide increased authority for rehabilitation efforts through community mental health centers and through special projects in areas having more serious drug abuse problems for rehabilitation efforts directed to narcotic addicts and drug dependent persons. A total of $164 million in additional appropriations over a 3-year period is authorized in this title for these increased rehabilitation efforts and activities.

Community Mental Health Centers Amendments and Special Provisions for Narcotic Addicts

In 1963 the Congress enacted the Community Mental Health Centers Act, authorizing Federal matching grants for the construction of community mental health centers, designed to provide for the treatment of the mentally ill in facilities close to their homes, where through intensive care they could be returned to their families and jobs at an earlier date than generally is the case where patients are cared for in State institutions. In 1965 this legislation was amended to authorize Federal grants to pay a portion of the costs of staffing of these facilities.

In 1968, this legislation was further amended to authorize specially earmarked funds for the construction and staffing of facilities affiliated with community mental health centers for the treatment of alcoholics or narcotic addicts.

The reported bill would further expand the authority contained in the 1968 amendments to provide funds for construction or staffing of facilities for the treatment and rehabilitation of drug dependent persons, in addition to narcotic addicts. There are approximately 350 community mental health centers in operation in the United States today, and the purpose of the amendments made by the reported bill is to provide increased activities at these centers to provide for persons within the centers' catchment areas suffering from drug problems.

In 1966 the Congress enacted the Narcotic Addict Rehabilitation Act of 1966, providing increased Federal efforts in the rehabilitation of narcotic addicts through civil commitment procedures and increased efforts at rehabilitation. Some areas of the country, such as New York, Chicago, Detroit, Los Angeles, and other areas, have substantially greater percentages of narcotic addicts than do other areas of the United States. The reported bill, therefore, authorizes special assistance, through matching grants for the construction and staffing of facilities, for the treatment and rehabilitation of narcotic addicts in those areas.

Medical Treatment of Narcotic Addiction

Section 4 of the reported bill provides that the Secretary of Health, Education, and Welfare, after consultation with national organizations, shall determine appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts, and report thereon from time to time to the Congress. The purpose of this provision is to clarify for the medical profession in the United States the extent to which they may safely go in treating narcotic addicts as patients. There are relatively few practicing physicians in the United States today who treat narcotic addicts because of uncertainty as to the extent to which they may prescribe narcotic drugs for addict patients. This problem was discussed in the report of the Prettyman Commission (pp. 56 and 57) as follows:

> Since the passage of the Harrison Act of 1914, the Federal narcotics laws have expressly permitted a physician to prescribe narcotic drugs for a patient in the course of "professional practice only" and for "legitimate medical uses" and "legitimate medical purposes." Under this statutory language there is no doubt that a physician may prescribe narcotic drugs for a patient suffering acute pain or from a painful and incurable disease. But a controversy has existed for 50 years over the extent to which narcotic drugs may be administered to an addict solely because he is an addict.
>
> During the first 10 years following enactment of the Harrison Act, the Supreme Court affirmed several convictions under the act involving the indiscriminate prescribing of narcotic drugs for addicts. In 1925, however, in *Linder* v. *United States*, 268 U.S. 5, the Court indicated that the dispensing of

narcotic drugs by a physician for the purpose of relieving conditions incident to addiction was not in every instance a violation of the act. The case concerned a doctor who had given one tablet of morphine and three tablets of cocaine to an addict. The Harrison Act, said the Court, "says nothing of 'addicts' and does not undertake to prescribe methods for their medical treatment. They are diseased and proper subjects for such treatment, and we cannot possibly conclude that a physician acted improperly or unwisely or for other than medical purpose solely because he has dispensed to one of them, in the ordinary course and in good faith, four small tablets of morphine or cocaine for relief of conditions incident to addiction."

The regulations of the Bureau of Narcotics, however, do not seem to be in accord with that language. The current regulations state: "An order purporting to be a prescription issued to an addict or habitual user of narcotics, not in the course of professional treatment but for the purpose of providing the user with narcotics sufficient to keep him comfortable by maintaining his customary use, is not a prescription within the meaning and intent of the [Harrison] Act; and the person filling such an order, as well as the person issuing it, may be charged with violation of the law." [1]

The practicing physician has thus been confused as to when he may prescribe narcotic drugs for an addict. Out of a fear of prosecution many physicians refuse to use narcotics in the treatment of addicts except occasionally in a withdrawal regimen lasting no longer than a few weeks. In most instances they shun addicts as patients.

Drug abuse is not a uniform problem throughout the country, and even in the areas of highest incidence few medical practitioners come into contact with the afflicted. It is estimated that most medical practitioners never see a habitual drug abuser. Nevertheless, spokesmen for the profession have a responsibility to speak for the physicians who are concerned.

The committee expects that the determinations made by the Secretary of Health, Education, and Welfare will clarify for the medical profession the conditions under which narcotic drugs may be prescribed for the medical treatment of narcotic addicts. Although the committee is concerned about the appropriateness of having Federal officials determine the appropriate method of the practice of medicine, it is necessary to recognize that for the last 50 years this is precisely what has happened, through criminal prosecution of physicians whose methods of prescribing narcotic drugs have not conformed to the opinions of Federal prosecutors of what constitutes appropriate methods of professional practice. In view of this situation, this section will provide guidelines, determined by the principal health agency of the Federal Government, after consultation with appropriate national professional organizations. Those physicians who comply with the recommendations made by the Secretary will no longer jeopardize their professional careers by accepting narcotic addicts as patients.

[1] Code of Federal Regulations, title 26, sec. 151.392.

Presidential Commission Recommendations

On January 15, 1963, by Executive order President Kennedy established the President's Advisory Commission on Narcotic and Drug Abuse, which submitted its final report to the President in November of 1963. The membership of that Commission consisted of Judge E. Barrett Prettyman, Chairman, Dr. James Dixon, Harry M. Kimball, Dr. Roger Egeberg, Austin MacCormick, Dr. Raphael Sanchez-Ubeda, and James Dumpson. That Commission's final report made 25 recommendations, discussed hereafter in this report.

In 1966, President Johnson established the President's Commission on Law Enforcement and Administration of Justice, which submitted a general report "The Challenge of Crime in a Free Society" in February of 1967. Chapter 8 of that report made findings and recommendations with respect to narcotics and drug abuse. The members of that Commission were as follows:

Nicholas deB. Katzenbach, *Chairman*

Genevieve Blatt	James B. Parsons
Charles D. Breitel*	Lewis F. Powell, Jr.
Kingman Brewster	William P. Rogers
Garrett H. Byrne	Robert G. Storey
Thomas J. Cahill	Julia D. Stuart
Otis Chandler	Robert F. Wagner*
Leon Jaworski	Herbert Wechsler
Thomas C. Lynch*	Whitney M. Young, Jr.
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The Katzenbach Commission made a number of additional recommendations with respect to drug abuse and its control, discussed hereafter.

With the enactment of this bill, virtually all of these recommendations of the Prettyman Commission and the Katzenbach Commission will have been implemented in whole or in part through legislation, reorganization plans, or administrative action, although certain of them have been modified. This report sets forth below the action taken on each of these recommendations.

Action on Prettyman Commission Recommendations

The 25 recommendations of the Prettyman Commission, and actions taken to carry them out, are as follows:

1. The Commission recommends that the President issue a directive to all Federal executives who can play a part in combating the problem of narcotic and drug abuse to initiate immediately more aggressive action in the national interest. This recommendation is basic to all that follow.

Action. Both Presidents Johnson and Nixon have issued directives to Federal executives in this area.

2. The Commission recommends that the President appoint a Special Assistant for Narcotic and Drug Abuse from the White House staff to provide continuous advice and assistance in launching a coordinated attack. The Special Assistant will have general coordinating

authority and the organizational responsibility to follow through on the evaluation and the implementation of the Commission's recommendations.

Action. An Interdepartmental Commission on Drug Abuse has been appointed on the staff of the White House in compliance with this recommendation.

3. The Commission recommends that a citizens' advisory committee be created for service from time to time. This committee should be composed of authorities from all facets of drug abuse and be drawn from all relevant disciplines and professions. It should critically review progress made toward the development and execution of a Federal policy and program. The Special Assistant would serve as liaison between the President and the advisory committee.

Action. The reported bill authorizes establishment of advisory committees with respect to the prevention and control of drug abuse.

4. The Commission recommends that a core of information and educational materials be prepared by the Secretary of Health, Education, and Welfare to provide the public and all professions involved with accurate knowledge on narcotic and drug abuse to combat the misinformation that is so prevalent today.

Action. Both the National Institute of Mental Health and the Bureau of Narcotics and Dangerous Drugs have prepared and are distributing such information. The National Institute of Mental Health also maintains the National Clearinghouse for mental health information, the world's largest computerized repository of mental health and related research findings.

5. The Commission recommends that the Federal Council for Science Technology, with the advice of an ad hoc committee of experts, design a comprehensive research plan covering all aspects of narcotic and drug abuse and that the National Institute of Mental Health earmark for narcotic and drug abuse research a specific amount from its extramural research budget for each fiscal year to finance the operation of the plan.

Action. The National Institute of Mental Health is responsible for the conduct of such a comprehensive research plan, and is in the process of carrying it out.

6. The Commission recommends that the Secretary of Health, Education, and Welfare establish a national reporting system to collect, collate, and analyze data on all forms of narcotic and drug abuse so as to obtain an accurate assessment of the problem. This should be set up on a cooperative basis with Federal, State, municipal, and private agencies participating.

Action. Both the National Institute of Mental Health and the Bureau of Narcotics and Dangerous Drugs are involved in conducting services regarding known or suspected drug abuse. In addition, section 503(a)(4) of the bill provides for maintenance in the Department of Justice of a unit to compile information and statistics, in cooperation with state and local agencies to aid in combatting drug abuse.

7. The Commission recommends that the functions of the Bureau of Narcotics relating to the investigation of the illicit manufacture, sale, or other distribution, or possession of narcotic drugs and marihuana be transferred from the Department of the Treasury to the Department of Justice.

Action. This recommendation was carried out by Reorganization Plan No. 1 of 1968.

8. The Commission recommends that the responsibility for the investigation of the illicit traffic in dangerous drugs be transferred from the Department of Health, Education, and Welfare to the Department of Justice.

Action. This recommendation was carried out pursuant to Reorganization Plan No. 1 of 1968.

9. The Commission recommends that the functions of the Bureau of Narcotics relating to the regulation of the legitimate importation, exportation, manufacture, sale, and other transfer of narcotic drugs and marihuana be transferred from the Department of the Treasury to the Department of Health, Education, and Welfare. Narcotic drugs would be regulated under the power to regulate interstate and foreign commerce, not under the tax power; and the importation, production, sale, or other transfer of marihuana would be prohibited except where expressly licensed for legitimate scientific purposes or for the emergency production of hemp.

Action. This bill provides for regulation of all drugs under the interstate and foreign commerce power. The regulation of legitimate manufacture of drugs subject to abuse will be carried out under this bill by the Department of Justice, except that the functions of the Food and Drug Administration are not superseded by the authority of the Department of Justice.

10. The Commission recommends that a unit be established within the Department of Health, Education, and Welfare to determine the safety and efficacy of and to regulate all narcotic and dangerous drugs capable of producing severe psychotoxic effects which can lead to criminal or lawless behavior when abused. This unit would also regulate the legitimate importation, exportation, manufacture, sale and other transfer of narcotic and dangerous drugs.

Action. Under Reorganization Plan No. 1 of 1968, a Bureau of Narcotics and Dangerous Drugs has been established in the Department of Justice to regulate all these drugs (including legitimate importation, exportation, manufacture, and distribution) to prevent diversion from legitimate channels. Safety and efficacy will continue to be regulated under the Federal Food, Drug, and Cosmetic Act by the Department of Health, Education, and Welfare.

11. The Commission recommends a substantial increase in the number of Federal enforcement personnel assigned to the investigation of the illicit importation of and trafficking in narcotic drugs, marihuana, and dangerous drugs.

Action. At the end of June, 1968, the Bureau of Narcotics and Dangerous Drugs had 615 agents. By June, 1970, this number had increased to over 900. In addition, section 103 of the bill authorizes the addition of at least 300 more agents during fiscal 1971.

12. The Commission recommends that the penalty provisions of the Federal narcotics and marihuana laws which now prescribe mandatory minimum sentences and prohibit probation or parole be amended to fit the gravity of the particular offense so as to provide a greater incentive for rehabilitation.

Action. As discussed earlier in this report, elimination of almost all mandatory minimum sentences, as well as elimination of the prohibition against probation and parole of narcotic offenders, is accomplished by this bill.

13. The Commission recommends that all non-narcotic drugs capable of producing serious psychotoxic effects when abused be brought under strict control by Federal statute.

Action. This recommendation was accomplished by the enactment of the Drug Abuse Control Amendments of 1965.

14. The Commission recommends that the training school now conducted by the Bureau of Narcotics be more fully publicized among State and local law enforcement agencies, that in-service training sessions, workshops and seminars be conducted in the areas where drug abuse is most prevalent, and that the Federal Government provide field training courses for the dissemination of current Federal information on narcotics control to State and local law enforcement officers.

Action. Approximately twenty thousand state and local officers were provided training by the Bureau of Narcotics and Dangerous Drugs during fiscal year 1970, and the reported bill (section 503(a)(3)) authorizes continuation of this program.

15. The Commission recommends the enactment of legislation authorizing the use of wiretapping by Federal law enforcement officials in limited circumstances and under strict controls to detect and prevent the international smuggling of narcotics.

Action. The Omnibus Crime Control and Safe Streets Act of 1968 provides this authority.

16. The Commission recommends that the United States request the United Nations to establish a system of international control of the distribution of dangerous drugs. The Commission does not see the necessity of new Federal legislation to supplement the general smuggling law by expressly prohibiting the illegal importation of dangerous drugs into the United States.

Action. The Single Convention on Narcotic Drugs, 1961, ratified by the United States in 1967, and the Psychotropic Protocol, presently nearing final draft form, respond to this recommendation.

17. The Commission recommends that the United States invite the Mexican Government to assist in the establishment of a Joint United States-Mexico Commission for consultation on the development of better methods to curb the illegal flow of narcotics, marihuana, and dangerous drugs between Mexico and the United States.

Action. Negotiations are underway with the Mexican government to deal with problem areas of mutual concern in this area.

18. The Commission recommends that the United States oppose, in its present form, ratification of the Single Convention on Narcotic Drugs, 1961, until there is a correction of those sections which weaken the control and limitation of world opium cultivation and production as established in the Protocol of 1953.

Action. A five-ton limit per country on the production of crude opium was approved in 1967, and assurances have been given with regard to the enforcement of these provisions.

19. The Commission recommends that the Federal Government encourage and increase assistance to State and municipalities to develop

and strengthen their own treatment programs and confine its activities in the immediate future to research instead of maintaining extensive public treatment programs.

Action. Provisions carrying out this recommendation have been established under Title IV of the Narcotic Addict Rehabilitation Act of 1966. In addition, the Community Mental Health Centers Act was amended in 1968 to provide Federal assistance for treatment programs, and this authority is expanded by amendments made in section 1 of the reported bill.

20. The Commission recommends that Federal regulations be amended to reflect the general principle that the definition of legitimate medical use of narcotic drugs and legitimate medical treatment of a narcotic addict are primarily to be determined by the medical profession.

Action. Section 4 of the reported bill, providing for determinations by the Secretary of Health, Education, and Welfare of appropriate methods of professional practice in the medical treatment of narcotic addicts, responds to this recommendation.

21. The Commission recommends that legislation be designed to provide authority for the Federal Government to render direct financial and technical assistance to State governments (singly or acting together on a regional basis), to local governments, and to private nonprofit organizations for the establishment, maintenance, and expansion of broad treatment and rehabilitation programs and the training of staff and personnel to staff and operate the programs.

Action. Such authority is contained in the Community Mental Health Centers Act, as amended by section 1 of the bill. In addition, the Narcotic Addict Rehabilitation Act of 1966 specifically recognizes and encourages State participation in such programs.

22. The Commission recommends Federal assistance to State governments, acting singly or on a regional basis, and to local governments for the construction of nonhospital treatment centers for narcotic and dangerous drug abusers and for new treatment units in existing State and local hospitals.

Action. The 1968 amendments to the Community Mental Health Centers Act and the further amendments made to that Act by the reported bill respond to this recommendation.

23. The Commission recommends that the Public Health Service hospitals in Lexington, Ky., and Fort Worth, Tex., accept voluntary patients only for purposes of research study in the future.

Action. Section 2 of the reported bill provides broader treatment authority in all Public Health Service hospitals for persons with drug abuse and other drug dependent problems. Until adequate numbers of community based facilities are available, this broadened authority will continue to be necessary.

24. The Commission recommends that the Bureau of Prisons establish a special treatment program for confirmed narcotic and drug abusers within the Federal prison system.

Action. Title II of the Narcotic Addict Rehabilitation Act of 1966 provides for special treatment of convicted narcotic addicts.

25. The Commission recommends that a Federal civil commitment statute be enacted to provide an alternative method of handling the federally convicted offender who is a confirmed narcotic or marihuana abuser.

Action. Title II of the Narcotic Addict Rehabilitation Act of 1966 provides such treatment for narcotic addicts but not for marihuana users. Persons with drug abuse problems may be treated in Federal facilities under amendments made by the reported bill, and additional facilities under the Community Mental Health Centers Act are also provided for under the bill.

ACTION ON KATZENBACH COMMISSION RECOMMENDATIONS

The Katzenbach Commission made the following recommendations, in addition to those already made by the Prettyman Commission. These recommendations, and action to carry them out are set forth below:

(1) *Recommendation.* Research should be undertaken devoted to early action on the further development of a sound and effective framework of regulatory and criminal laws with respect to dangerous drugs. In addition, research and educational programs concerning the effects of such drugs should be undertaken.

Action. The reported bill responds to this recommendation of development of regulatory and criminal laws. The legislation also authorizes substantial research and educational programs.

(2) *Recommendation.* The enforcement and related staff of the Bureau of Customs should be materially increased.

Action. The 1971 Appropriation Act for the Treasury Department, as passed by the House, contains funds for a substantial increase in the enforcement and related staff of the Bureau of Customs.

(3) *Recommendation.* State and Federal drug laws should give a large enough measure of discretion to the courts and correctional authorities to enable them to deal flexibly with violators, taking account of the nature and seriousness of the offense, the prior record of the offender and other relevant circumstances.

Action. The penalty structure set forth in the reported bill provides a flexible system of penalties for Federal offenses, in accordance with both this recommendation and recommendation No. 12 of the Prettyman Commission. The recommended Model State law also contains similar provisions.

(4) *Recommendation.* The National Institute of Mental Health should devise and execute a plan of research, to be carried on both on an intramural and extramural basis, covering all aspects of marihuana use.

Action. In addition to recent research activities of the Institute, public law 91–296 provides for the conduct of such research by the Secretary of Health, Education, and Welfare and section 601 of the reported bill provides for the establishment of a Commission on Marihuana and Drug Abuse.

(5) *Recommendation.* The enforcement staff of the Bureau of Narcotics should be materially increased. Some part of the added personnel should be used to design and execute a long-range intelligence effort aimed at the upper echelons of the illicit drug traffic.

Action. As was pointed out with respect to recommendation No. 11 of the Prettyman Commission, the enforcement staff of the Bureau of Narcotics and Dangerous Drugs has been substantially increased, and section 103 of the reported bill provides for a further increase in personnel. In addition, mobile strike forces have been established by the Bureau to concentrate on upper echelons of the illicit drug traffic.

(6) *Recommendation.* Those States which do not already have adequate legislation should adopt a model State drug abuse control act similar to the Federal Drug Abuse Control Amendments of 1965.

Action. A model State Drug Abuse Act has been developed and recommended to the States. Revisions will, of course, be necessary to conform that model act to this act, since the reported bill and State laws are designed to be mutually supporting.

(7) *Recommendation.* The recordkeeping provisions of the 1965 amendments should be amended to require that records must be segregated or kept in some other manner that enables them to be promptly identified and inspected.

Action. The recordkeeping provisions of the reported bill will provide more ready accessibility of records with respect to controlled substances, under section 307 of the reported bill.

(8) *Recommendation.* A core of educational and informational materials should be developed by the National Institute of Mental Health.

Action. Much information has been prepared both by the National Institute of Mental Health and the Bureau of Narcotics and Dangerous Drugs. In addition, the proposed section 253 of the Community Mental Health Centers Act contained in section 1(c) of the reported bill provides specific authority for preparation of educational and informational materials, and for training of professional and other personnel to work in the area of drug abuse education.

Law Enforcement

Titles II and III of the bill deal with law enforcement aspects of drug abuse, and provide authority for the Department of Justice to keep track of all drugs subject to abuse manufactured or distributed in the United States in order to prevent diversion of these drugs from legitimate channels of commerce. The legislation would accomplish this result through a variety of approaches depending upon the type of activities engaged in which are proposed to be regulated.

Control Determinations

Part B of the bill (sections 201 and 202) lists the drugs initially subject to control under the legislation, and establishes a procedure for future determinations as to drugs to be subject to the controls of the bill.

Considerable controversy arose during the hearings over this provision of the bill, with respect to the proper role of the Attorney General and the Secretary of Health, Education, and Welfare in making determinations concerning which drugs should be controlled. The reported bill strikes a balance between the extent to which control decisions should be based upon law enforcement criteria, and the extent to which such decisions should be based on medical and scientific determinations. The bill provides that the ultimate authority for decision as to whether or not drugs should be controlled, and the schedule in which they are to be placed, shall rest with the Attorney General, based upon all the evidence, with all scientific and medical

determinations being made by the Secretary of Health, Education, and Welfare, and these determinations being made binding upon the Attorney General.

The procedure which the Attorney General must then follow to control a drug involves rulemaking proceedings on the record after opportunity for a hearing. This provides opportunity for consideration of the views of persons who would be adversely affected by control of a drug, with judicial review available thereafter; however, this administrative proceeding is more streamlined in its operation than the existing procedures under section 701(e) of the Federal Food, Drug, and Cosmetic Act, so that controls may be established expeditiously where necessary, with full consideration of all factors involved in the decision—law enforcement problems, medical, and scientific determinations, and the interests of parties affected by the decision to control.

Registration Requirements

The legislation provides that all persons engaged in the legitimate distribution chain involving drugs included in one of the schedules under the bill must be registered with the Attorney General. Registration requirements vary according to the type of activity engaged in, with registration being permitted for the manufacture of more dangerous drugs only where the Attorney General determines that such registration is *consistent* with the public interest and with United States obligations under treaties existing on the effective date of this part of the bill, and where he determines that adequate safeguards against diversions exist. Registration of distributors of such drugs and of manufacturers and distributors of less dangerous drugs would be permitted unless the Attorney General determines that registration would be *inconsistent* with the public interest. Practitioners (including pharmacies and hospitals) engaged in the distribution chain would be required to be registered, but registration would be as a matter of right where the individual or firm is engaged in activities involving these drugs which are authorized or permitted under State law, except that in the case of registration for research with Schedule I substances (i.e., substances that have no accepted medical use in treatment in the United States), registration is conditioned on certification of the qualifications of the researcher (after review of the project) by the Secretary of HEW to the Attorney General.

Quotas

Existing law relating to the regulation of narcotics provides a closed system, with limitations upon quantities of basic ingredients such as opium and coca leaves, which may be imported with quotas thereafter established for the total domestic production of basic classes of narcotic drugs.

Through control of the quantities of the basic ingredients needed for the manufacture of narcotics, and the requirement of order forms for all transfers of these drugs, it has been possible to keep diversions of narcotic drugs from legitimate channels of trade to an almost irreducible minimum.

The bill continues this system for controlled substances in Schedules I and II, extending the coverage of the existing quota provisions to include the hallucinogens and other drugs included in Schedule I of the bill.

RECORDS AND REPORTS

Existing law provides for inventories and recordkeeping with respect to all drugs subject to control under the Drug Abuse Control Amendments of 1965 and under the laws regulating narcotic drugs. The bill continues, and strengthens these requirements, as recommended by both the Prettyman Commission and the Katzenbach Commission, and requires that records be maintained either separately of all other records of the registrant or alternatively, in the case of nonnarcotic substances, be in such form that information required is readily retrievable from the ordinary business records of the registrant. As pointed out in a letter to the committee from the Office of the Deputy Attorney General, set forth hereafter in this report under the heading "agency reports", ordinary business records will frequently serve the purposes of this section, so long as the information required is readily retrievable through the use of red-line, asterisk, or other types of identification of items on invoices or other records.

Practicing physicians will be required to continue the recordkeeping required under existing laws, under which a physician is required to keep records of all narcotic drugs which are dispensed to a patient (except by prescribing or administration) and, in case the physician is regularly engaged in charging his patients for nonnarcotic controlled substances he must keep records of all such substances dispense to them.

Researchers engaged in clinical investigations, or in preclinical research or in teaching, at an institution which maintains required records, will not be required to keep records in addition to those kept by the institution.

ADMINISTRATIVE PROVISIONS

Part E of title II of the bill (sections 501 through 516) sets forth a number of administrative provisions necessary to carry out the legislation, such as authority for cooperative arrangements with State and local governments, advisory committees, administrative hearings, subpenas, standards for judicial review, arrest and other powers of enforcement personnel, administrative inspections, forfeitures, injunctions, enforcement proceedings, grants of immunity from prosecution, burden of proof, and payments and advances.

The Attorney General is authorized under this part to engage in education and research programs in the area of enforcement of the laws under his jurisdiction concerning drugs or other substances which are or may be subject to control under this legislation. The Attorney General is granted authority under section 502(c) which is the same as that granted to the Secretary of Health, Education, and Welfare under section 3 of title I. The Attorney General or the Secretary may authorize persons engaged in research to withhold the names and other identifying characteristics of persons who are the subjects of such research. In addition, the Attorney General is authorized to permit persons engaged in research to possess, distribute, and dispense controlled substances, and he may exempt such persons from State or

Federal prosecution for such possession, distribution, and dispensing. The purpose is to encourage further research involving controlled substances, with restrictions designed to prevent the occurrence under this authorization of illicit activities masquerading as research.

"No-Knock" Search Warrants

One of the more controversial provisions of the bill is subsection (b) of section 509 which would permit an officer executing a warrant relating to controlled dangerous substances to enter without giving notice of his authority and purpose if so authorized in the warrant. The warrant could authorize such entry on a finding of probable cause to believe the property sought may, and, if such notice is given, will, be easily and quickly destroyed or disposed of, or that danger to the life or limb of the officer or another will result from announcement.

The purpose of this provision, as explained in the hearings, is to provide law enforcement officials with a tool to aid in combatting the illicit traffic in drugs which has proved helpful in all of the 29 States where this authority exists either by statute or common law.

General "no-knock" provisions, not limited to narcotics, have been previously considered by the Department of Justice and the view has been expressed that they are constitutional in concept even though constitutional challenge as to their application to specific fact situations is likely.

The conclusion that "no-knock" legislation even broader than subsection (b) is constitutional is based on the decision in *Ker* v. *California*, 374 U.S. 23 (1963). That case upheld unannounced entry and seizure of narcotics without a warrant primarily on the basis of the officer's need to prevent destruction of the evidence. The judgment of the exigency of the circumstances was that of the police officers, not an independent judicial officer, and yet the court upheld the search as coming within one of the permissible exceptions of the announcement of authority and purpose requirements. Among the objections of the four dissenters was reliance on the subjective judgment of the police officers.

While decided by a closely divided court 6 years ago, *Ker* has not been overruled or limited with respect to unannounced entry in subsequent cases. In *La Peluso* v. *California*, 385 U.S. 829 (1966), the Supreme Court refused to reconsider it. *Sabbath* v. *United States*, 391 U.S. 585 (1968), while holding unannounced entry by Federal officers invalid on the basis of 18 U.S.C. 3109, did not disturb the constitutional holdings in *Ker*. (See footnote 8, 391 U.S. at 591).

In a somewhat related area, the Court has very recently recognized the valid governmental interest in preventing harm to the officer or destruction or concealment of evidence. *Chimel* v. *California*, 395 U.S. 752 (1969), involved the permissible scope of searches incident to the execution of an arrest warrant. It held that such "contemporaneous searches" must be limited to the person of the arrested individual and the immediate area under his control. The holding is premised on the concept that warrantless searches are permissible under the Fourth Amendment only for certain limited purposes. As in unannounced entry cases, one of these purposes is the prevention of the destruction of evidence. (See 395 U.S. at 763.)

Ker is still controlling law with respect to the constitutionality of unannounced entry and is reinforced by the rationale of *Chimel*. On the basis of *Ker*, it is the view that subsection (b) is constitutional.

Section-by-Section Analysis of H.R. 18583

The bill, to be known as the "Comprehensive Drug Abuse Prevention and Control Act of 1970", is in three titles, title I relating to rehabilitation (including prevention and treatment) of drug abusers and of drug dependent persons, and titles II and III dealing with law enforcement aspects of drug abuse.

Provisions of the Bill

Title I—Rehabilitation

Section 1 of title I broadens the provisions of the Community Mental Health Centers Act relating to grants for construction and staffing of facilities for treatment of narcotic addiction and for special projects in the field of narcotic addiction, so as to cover other problems of drug abuse and drug dependence, and accordingly increases the existing combined appropriation authorizations under that Act in the drug and alcoholism fields from the present $30 million for fiscal year 1971, $35 million for fiscal year 1972, and $40 million for fiscal year 1973 by $10 million, $25 million, and $40 million, respectively. It likewise broadens present authority for special staffing grants for consultation services.

This section of the bill further adds two new sections to part D of the Community Mental Health Centers Act: A section (sec. 253) on drug abuse education and a section (sec. 256) on special projects for narcotic addicts and drug dependent persons. (Present sections 253 and 254 are redesignated as sections 254 and 255, respectively.)

The new section 256 of the Community Mental Health Centers Act authorizes annual appropriations of $20 million each for the fiscal years 1971, 1972, and 1973 for grants by the Secretary of Health, Education, and Welfare to public or nonprofit private agencies and organizations for projects for the treatment and rehabilitation of narcotic addicts or other drug dependent persons, which include detoxification services, institutional services (including medical, psychological, educational, and counseling services), and community-based aftercare services. The duration of Federal support, and the cost-percentage of Federal support (including higher Federal percentages in urban or rural poverty areas), for any such project follow the pattern set for staffing grants by the Community Mental Health Centers Amendments of 1970 (P.L. 91–211). Priority is to be given to projects in States, and areas within States, having the higher percentages of narcotic addicts or other drug dependent persons. Applications for grants under this section from applicants in any State must be forwarded through the State agency responsible for administering the State's mental health center plan submitted under section 204 of the act or, where there is a separate State agency designated by the Governor as responsible for planning, coordinating, and executing the State's efforts in the treatment and rehabilitation of narcotic addicts and drug dependent persons, then through that agency.

The new section 253 of the Community Mental Health Centers Act proposed by the bill authorizes grants and contracts by the Secretary of Health, Education, and Welfare (1) for the collection, preparation, and dissemination of educational materials on drug use and abuse and the prevention of such abuse, and (2) for the development and evaluation of programs of drug abuse education directed at the general public, schoolage children, and special high-risk groups. This section further directs the Secretary, acting through the National Institute of Mental Health, to (1) serve as a focal point for collection and dissemination of information related to drug abuse; (2) collect, prepare, and disseminate materials (including films and other educational devices) dealing with drug abuse and its prevention; (3) provide for preparation, production, and conduct of programs of public education (including those using films and other educational devices) in this field; (4) train persons to organize and participate in programs of public drug abuse education; (5) coordinate activities with respect to health education aspects of drug abuse carried on by Federal departments and agencies designated by the Secretary; (6) provide technical assistance to State and local health and educational agencies with respect to the establishment and implementation of programs and procedures for public education on drug abuse; and (7) undertake other activities essential to a national program for drug abuse education. Finally, this section authorizes the Secretary, acting through the National Institute of Mental Health, to develop and conduct workshops, institutes, and other activities for the training of professional and other personnel to work in the area of drug abuse education. For carrying out this section 253, the bill authorizes appropriations of $7 million for fiscal year 1971, $10 million for fiscal year 1972, and $12 million for fiscal year 1973.

The committee is aware that nonspecific authority for drug abuse education and training, and grants therefor, can be found in, and is utilized under, existing broad authority in the Public Health Service Act and other statutes administered by the Department of Health, Education, and Welfare, and it is by no means intended by the present bill to negate or narrow such authority by implication. There are, however, reasons why the committee recommends the more specific authority above outlined. It gives statutory emphasis to the overriding importance of these activities. It makes the National Institute of Mental Health a focal point for drug abuse information; it sets forth those educational, training, and informational activities which the Secretary is to conduct through the National Institute of Mental Health; and it authorizes the Secretary to coordinate, through the Institute, activities with respect to the health education aspects of drug abuse carried on by Federal agencies.

Drug abuse and narcotic addiction and other drug dependence are clearly health, as well as social, problems and require health and medical approaches to provide a single base of knowledge on which to mount the multiple preventive-educational programs needed. The National Institute of Mental Health, as a health agency closely allied with the scientific community in medical and social science areas, is particularly well-suited to provide such a base.

Section 2(a) of this title expands significantly the direct patient care authorities of the Department of Health, Education, and Welfare under part E of title III of the Public Health Service Act to include,

in addition to narcotic addicts, other persons with "drug abuse and drug dependence problems." This reflects the committee's concern that the Federal direct patient care activities be broadened to include not only those physically addicted but those who have psychological problems related to their repetitive use or desire to use drugs of abuse. This does not, however, expand authority under other laws to commit persons for treatment.

Section 2(b) adds to the Public Health Service Act a definition of "drug dependent person". The term is defined (in a way similar to the World Health Organization's definition) as a person who is using a controlled substance (as defined in title II of the bill) and is in a state of psychic or physical dependence, or both, resulting from such use on a continuous basis. Drug dependence, the bill states, is characterized by behaviorial and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or avoid the discomfort caused by its absence.

Section 3(a) of this title grants the Secretary of Health, Education, and Welfare a much needed authority to protect the privacy of drug research subjects by nondisclosure of identification data of such individuals. It enables the researcher, when authorized by the Secretary, to assure research subjects complete anonymity, with immunity from prosecution for withholding this identifying information. This authority is not limited to research conducted or supported by the Federal Government.

Subsection (b) of this section amends section 507 of the Public Health Service Act to permit funds that are available (1) under the Public Health Service Act or (2) under the Community Mental Health Centers Act, for programs relating to drug dependence, drug abuse, and alcoholism, to be used for 100 percent grants to Veterans' Administration hospitals, Saint Elizabeths Hospital, and hospitals of the Public Health Service and the Bureau of Prisons, for such purposes.

Section 4. Existing narcotic laws permit the administration of narcotics in the professional practice of medicine but relatively few physicians treat narcotic addiction as such because of uncertainties as to the possibility of prosecution. Section 4 authorizes the Secretary of Health, Education, and Welfare, after consultation with the Attorney General and organizations representative of persons who are knowledgeable and experienced in the treatment of narcotic addicts, to determine and report to Congress on appropriate methods of professional practice in the medical treatment of narcotic addicts. The section does not supersede the existing procedures of the Federal Food, Drug, and Cosmetic Act for investigation and approval of new drugs.

TITLE II—CONTROL AND ENFORCEMENT

This title is divided into 7 parts as follows:

Part A—Short Title; Findings and Declaration; Definitions.

Part B—Authority to Control; Standards and Schedules.

Part C—Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances.

Part D—Offenses and Penalties.

Part E—Administrative and Enforcement Provisions.
Part F—Advisory Commission.
Part G—Conforming, Transitional and Effective Date, and General Provisions.

Part A—Short Title, etc.—This part contains the short title, findings, definitions, and provision for increased numbers of personnel of the Bureau of Narcotics and Dangerous Drugs.

Section 100—Short title

This section provides that title II of this legislation may be cited as the "Controlled Substances Act".

Section 101—Findings and declarations

This section states the principal reasons why it is necessary to make the controls of title II applicable to all controlled substances regardless of whether they or their components have ever been outside the State in which they are found. It is not intended, however, to preempt the field to the exclusion of the States. See section 708, below.

This section thus contains a finding and declaration by Congress that—

(1) Many of the drugs included within this title have a presently accepted medical purpose.

(2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial detrimental effect on the public's health and general welfare.

(3) Controlled substances either flow through interstate or foreign commerce or they have a substantial and direct effect upon interstate commerce; because they have moved in such commerce after manufacture or when distributed locally have usually been transported in such commerce immediately before distribution or they are substances which commonly flow through interstate commerce prior to possession.

(4) Those substances manufactured or distributed on a purely intrastate basis cannot be differentiated from those manufactured or distributed for interstate commerce, so that it is not feasible to distinguish controls over each type.

(5) Federal control over intrastate traffic in controlled substances is essential to control over incidents of interstate traffic.

(6) The United States is a party to the Single Convention on Narcotic Drugs, 1961, and other international conventions designed to establish effective controls over international and domestic traffic in controlled substances.

Section 102—Definitions

These definitions apply for the purposes of title II of the bill.

Paragraph (1) defines "addict" to mean any individual who habitually uses any narcotic drug as defined by this act so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of such narcotic drugs as to have lost the power of self-control with reference to his addiction.

Paragraph (2) defines "administer" to mean the direct application of a controlled substance to the body of a patient or research subject by a practitioner, or in his presence by his authorized agent, or by the

patient or research subject's own application in the presence of a practitioner. This paragraph further defines application to include application by injection, inhalation, ingestion, or any other means. The definition of "administer" is intended to include administration to an animal, and the term "patient" is to be read as including an animal patient.

Paragraph (3) defines "agent" to mean an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. The term does not include a common or contract carrier, public warehouseman, or employee thereof, when acting in the usual course of the carrier's or warehouseman's business.

Paragraph (4) defines "Bureau of Narcotics and Dangerous Drugs" to mean the Bureau of Narcotics and Dangerous Drugs, Department of Justice.

Paragraph (5) defines the term "control" to mean the addition of a drug or other substance or immediate precursor to a schedule under part B of title II either directly or by rescheduling such substance.

Paragraph (6) defines "controlled substance" to mean a drug, other susbtance, or immediate precursor in schedules I through V under part B of title II of this Act. Distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in the Internal Revenue Code of 1954 may not be included in any schedule.

Paragraph (7) defines "counterfeit substance" to mean a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance, and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.

Paragraph (8) defines "deliver" or "delivery" to mean the actual, constructive, or attempted transfer of a controlled substance, whether or not there exists an agency relationship.

Paragraph (9) defines "depressant or stimulant substance" to mean (1) a drug which contains any quantity of (A) barbituric acid or any of the salts of barbituric acid, or (B) any derivative of barbituric acid which has been designated by the Secretary of Health, Education, and Welfare as habit forming under section 502(d) of the Federal Food, Drug, and Cosmetic Act; (2) a drug which contains any quantity of (A) amphetamine or any of its optical isomers, (B) any salt of amphetamine or any salt of an optical isomer of amphetamine, or (C) any substance which the Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system; (3) lysergic acid diethylamide; or (4) any drug which contains any quantity of a substance which the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

Paragraph (10) defines "dispense" to mean to deliver a controlled substance to the ultimate user or human research subject by or pursuant to the lawful order of a practitioner, including the labeling,

prescribing, or administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery. "Dispenser" is a practitioner who so delivers a controlled substance to the ultimate user or human research subject.

Paragraph (11) defines "distribute" to mean to deliver a controlled substance other than by administering or dispensing. "Distributor" means a person who so distributes.

Paragraph (12) defines "drug" as having the same meaning given to it by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act which reads as follows:

"(g)(1) Articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3) of this paragraph; but does not include devices or their components, parts, or accessories."

Paragraph (13) defines "felony" to mean any Federal or State offense classified by applicable Federal or State law as a felony.

Paragraph (14) defines "manufacture" to mean the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis. The term also includes the packaging, repackaging, or labeling of any container of any controlled substance, except when done by practitioners who prepare, compound, package, or label prescription orders as an incident to their administration or dispensing of such drug or substance in the course of their professional practice. "Manufacturer" is defined as a person who manufactures a drug or other substance.

Paragraph (15) defines "marihuana" to mean all parts of the plant Cannabis sativa L., whether growing or not, including its seeds. It also includes the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or resin. The term does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the extracted resin), fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination.

Paragraph (16) defines "narcotic drug" to mean any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (1) opium, coca leaves, and opiates; (2) a compound, manufacture, salt, derivative, or preparation of opium, coca leaves, or opiates; and (3) a substance (and any compound, manufacture, salt, derivative, or preparation thereof) which is chemically identical with any of the substances referred to in clause (1) or (2), except that the term "narcotic drug" shall not include decocainized coca leaves or extracts of coca leaves, which extracts do not contain cocaine or ecgonine.

Paragraph (17) defines "opiate" to mean any drug or other substance having an addiction forming or addiction sustaining liability similar to morphine or being capable of conversion into a drug having such addiction forming or addiction sustaining liability.

Paragraph (18) defines the term "opium poppy" to mean the plant of the species *Papaver somniferum L.*, but not its seeds.

Paragraph (19) defines "poppy straw" to mean all parts, except the seeds, of the opium poppy, after mowing.

Paragraph (20) defines "practitioner" to mean a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

Paragraph (21) defines "production" to include the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

Paragraph (22) defines "immediate precursor" to mean a substance which the Attorney General has found to be and by regulation designated as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used, in the manufacture of a controlled substance, and the control of which is necessary to prevent, curtail, or limit such manufacture.

Paragraph (23) defines "Secretary" to mean the Secretary of Health, Education, and Welfare unless the context otherwise indicates.

Paragraph (24) defines "State" to mean any State, territory, or possession of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the Canal Zone.

Paragraph (25) defines "ultimate user" to mean a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for administration to an animal owned by him or by a member of his household.

Paragraph (26) defines "United States," when used in a geographic sense, to mean all places and waters, continental or insular, subject to the jurisdiction of the United States, and is intended to include the Canal Zone and the Trust Territory of the Pacific Islands.

Section 103. Increased number of enforcement personnel

This section authorizes the Bureau of Narcotics and Dangerous Drugs to add at least 300 agents, together with necessary supporting personnel, to its present number and for that purpose authorizes an annual appropriation of $6,000,000 beginning with the fiscal year 1971.

(See also, the authorizations in section 709, in addition to these sums, for other purposes.)

PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

Section 201. Authority and criteria for classification of substances

Subsection (a) of this section authorizes the Attorney General, pursuant to the rulemaking provisions of the Administrative Procedure Act (now subchapter II of 5 U.S.C.), to by rule add a substance to a schedule or transfer a substance between schedules. This

subsection further permits the Attorney General to remove a substance entirely from the schedules by rule if he finds that the substance no longer meets the requirements for inclusion in any of the schedules. Except as noted below, such rules are to be made on the record after opportunity for hearing. The Attorney General may initiate proceedings to control a substance on his own motion, or he may initiate proceedings at the request of the Secretary of Health, Education, and Welfare or on the petition of an interested party.

Subsection (b) requires that, before initiating proceedings to add a drug or other substance to one of the schedules of the bill, or to reschedule it or remove it entirely from the schedules, and "after gathering the necessary data", the Attorney General shall request from the Secretary of Health, Education, and Welfare a scientific and medical evaluation and his recommendation as to whether or not the substance should be added, deleted, or rescheduled as a controlled substance. The phrase "after gathering the necessary data" is not intended to authorize the Attorney General to undertake or support medical and scientific research for that purpose, which is within the competence of the Department of Health, Education, and Welfare, or to limit the Secretary's evaluation to data submitted to him by the Attorney General but rather to defer submission of a request to the Secretary until the Attorney General, on the basis of all the information available to him—particularly any information developed by him as to the scope, pattern, and significance of abuse of a drug or substance in this country—has reason to believe that there may be ground for controlling or decontrolling a drug or other substance. The phrase "after gathering the necessary data" does, however, envision the utilization of Bureau of Narcotics and Dangerous Drugs laboratory facilities for chemical analysis, especially in the case of substances being abused in the street which require identification.

In making his recommendation and evaluation, the Secretary must consider certain factors listed in subsection (c) and more specifically described under that subsection, as to the substances' pharmacological effect, the state of current knowledge regarding the substance, the risk to the public health posed by the substance, the substance's psychic or physiological dependence liability, and whether or not the substance is an immediate precursor of a substance already controlled. The Secretary must also consider any medical and scientific considerations involved in the substance's potential for abuse, its history and current pattern of abuse, and the scope of its abuse. Subsection (a) further provides that the Secretary's evaluations and recommendations shall be in writing and shall be binding on the Attorney General as to medical and scientific matters. The subsection also specifies that a recommendation by the Secretary that a substance should not be controlled is binding on the Attorney General. After receiving the recommendation of the Secretary, the Attorney General shall consider it and all other relevant data to ascertain whether there is substantial evidence of a potential of abuse such as to warrant the initiation of a control proceeding. In making this determination, the Attorney General is to consider the same criteria as the Secretary considers in making his evaluations and recommendations, subject, of course, to the above-mentioned requirements as to the effect to be given the Secretary's recommendations. If the Attorney General finds that all

the relevant data constitutes substantial evidence of a potential for abuse, he may proceed under the rulemaking procedures of the Administrative Procedure Act to control the substance.

Subsection (c) of this section sets out a number of factors which the Attorney General must consider in making his findings under subsection (a) of this section and subsection (b) of section 202. These factors include: (1) a substance's actual or relative potential for abuse; (2) scientific evidence of the substance's pharmacological effect, if known; (3) the state of current scientific knowledge regarding the substance; (4) the substance's history and current pattern of abuse; (5) the scope, duration, and significance of abuse of the substance; (6) the risk to the public health posed by the substance; and (7) the psychic or physiological dependence liability of the substance. It should also be noted that these factors must be considered by the Secretary of Health, Education, and Welfare in making his evaluations and recommendations to the Attorney General under subsection (b) of this section.

A key criterion for controlling a substance, and the one which will be used most often, is the substance's potential for abuse. If the Attorney General determines that the data gathered and the evaluations and recommendations of the Secretary constitute substantial evidence of potential for abuse, he may initiate control proceedings under this section. Final control by the Attorney General will also be based on his findings as to the substance's potential for abuse.

The term "potential for abuse" is found in the definition of a "depressant or stimulant drug" contained in section 201(v) of the Federal Food, Drug, and Cosmetic Act and is characterized further in the regulations (21 CFR 166.2(c)) promulgated under that section as follows:

> The Director may determine that a substance has a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect if:
>
> (1) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community; or
>
> (2) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or
>
> (3) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or
>
> (4) The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

These regulations follow and extend the suggestions contained in the report of this committee accompanying H.R. 2, 89th Congress, which became the Drug Abuse Control Amendments of 1965 (House Report No. 130, 89th Congress, first session, page 7 (1965)).

The report went further in its discussion of the "potential" aspect of the term. It stated that it did not intend that potential for abuse be determined on the basis of "isolated or occasional nontherapeutic purposes." The committee felt that there must exist "a substantial potential for the occurrence of significant diversions from legitimate channels, significant use by individuals contrary to professional advice, or substantial capability of creating hazards to the health of the user or the safety of the community" (at page 7).

With respect to the question of the extent to which actual, as distinguished from potential, abuse was required to be established, that report stated that "the Secretary of Health, Education, and Welfare should not be required to wait until a number of lives have been destroyed or substantial problems have already arisen before designating a drug as subject to controls of the bill" (at page 7).

In speaking of "substantial" potential the term "substantial" means more than a mere scintilla of isolated abuse, but less than a preponderance. Therefore, documentation that, say, several hundred thousand dosage units of a drug have been diverted would be "substantial" evidence of abuse despite the fact that tens of millions of dosage units of that drug are legitimately used in the same time period. The normal way in which such diversion is shown is by accountability audits of the legitimate sources of distribution, such as manufacturers, wholesalers, pharmacies, and doctors.

Misuse of a drug in suicides and attempted suicides, as well as injuries resulting from unsupervised use are regarded as indicative of a drug's potential for abuse.

Aside from the criterion of actual or relative potential for abuse, subsection (c) of section 201 lists seven other criteria, already referred to above, which must be considered in determining whether a substance meets the specific requirements specified in section 202(b) for inclusion in particular schedules and accordingly should be designated a controlled substance under a given schedule (including transfer from any other schedule) or removed entirely from the schedules. A brief discussion of each of these criteria follows.

(1) *Scientific evidence of its pharmacological effects.*—The state of knowledge with respect to the effects of uses of a specific drug is, of course, a major consideration, e.g., it is vital to know whether or not a drug has an hallucinogenic effect if it is to be controlled because of that effect. The best available knowledge of the pharmacological properties of a drug should be considered.

(2) *The state of current scientific knowledge regarding the substance.*—Criteria (1) and (2) are closely related. However, (1) is primarily concerned with pharmacological effects and (2) deals with all scientific knowledge with respect to the substance.

(3) *Its history and current pattern of abuse.*—To determine whether or not a drug should be controlled, it is important to know the pattern of abuse of that substance, including the social, economic, and ecological characteristics of the segments of the population involved in such abuse.

(4) *The scope, duration, and significance of abuse.*—In evaluating existing abuse, not only must the Attorney General know the pattern of abuse, but he must know whether the abuse is widespread. He must also know whether it is a passing fad, or whether it is a significant chronic abuse problem like heroin addiction. In reaching his decision, the Attorney General should consider the economics of regulation and enforcement attendant to such a decision. In addition, he should be aware of the social significance and impact of such a decision upon those people, especially the young, that would be affected by it.

(5) *What, if any, risk there is to the public health.*—If a drug creates no danger to the public health, it would be inappropriate to control the drug under this bill.

(6) *Its psychic or physiological dependence liability.*—There must be an assessment of the extent to which a drug is physically addictive or psychologically habit forming, if such information is known.

(7) *Whether the substance is an immediate precursor of a substance already controlled.*—The bill allows inclusion of immediate precursors on this basis alone into the appropriate schedule and thus safeguards against possibilities of clandestine manufacture.

It should be noted that the above-mentioned factors do not require specific findings to be made with respect to control under or removal from, schedules, but rather are factors to be considered in making the special findings required under section 202(b) for control under such schedules.

Under subsection (d), where control of a drug or other substance by the United States is required by reason of its obligations under an international treaty, convention, or protocol which is in effect on the effective date of part B of the bill (i.e., the date of its enactment), the bill does not require that the Attorney General seek an evaluation and recommendation by the Secretary of Health, Education, and Welfare, or pursue the procedures for control prescribed by the bill but he may include the drug or other substance under any of the five schedules of the bill which he considers most appropriate to carry out the obligations of the United States under the international instrument, and he may do so without making the specific findings otherwise required for inclusion of a drug or other substance in that schedule. The reference to treaties, conventions, or protocols in effect upon enactment of the bill is intended to refer to the Single Convention on Narcotic Drugs, 1961, and to those predecessor conventions or protocols as to which the United States may still have an obligation. This would include any obligations of the United States that might arise after enactment of the bill by reason of changes in the schedules of the Single Convention by the international organs specified in the convention under the authority of the provisions of the convention in effect as to the United States on the date of enactment of the bill.

Subsection (e) of this section provides that if the Attorney General designates a substance as an immediate precursor, he may place it in the same schedule in which the controlled substance of which it is an immediate precursor is placed, or in a schedule with a higher numerical designation, whichever the Attorney General deems appropriate. For example, under section 202, lysergic acid, which is the immediate precursor of lysergic acid diethylamide (LSD–25), is contained in schedule III, while lysergic acid diethylamide is contained in schedule I.

In determining in which schedule to place an immediate precursor, the Attorney General need not follow the procedures prescribed by section 201 (a) and (b), or make the findings required by sections 201(a) and 202(b), for placement of a controlled substance in a schedule.

Subsection (f) provides that if at the time a new-drug application is submitted to the Secretary of Health, Education, and Welfare for a drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, it appears that such drug has an abuse potential, such information is to be forwarded by the Secretary to the Attorney General.

Subsection (g)(1) requires the Attorney General to exclude any nonnarcotic substance from a schedule if the substance may be sold over the counter without a prescription under the Federal Food, Drug, and Cosmetic Act.

Subsection (g)(2) provides that the drug dextromethorphan is not to be deemed included in any of the schedules contained in section 202 unless subsequently controlled after the date of enactment of part B pursuant to the provisions of section 201. This section is merely designed to insure that dextromethorphan, which is used in a number of cough syrups sold over the counter without a prescription, will not be controlled by virtue of its relationship to drugs already listed in the schedules on the date of enactment. However, this subsection is not intended to prevent control of the drug in the future should an abuse potential be found.

Section 202

Subsection 202(a) establishes five schedules and provides that these schedules shall *initially* consist of the substances listed in section 202. The subsection further provides for a semiannual updating and republishing of the schedules during the 2-year period beginning 1 year after the date of enactment of title II of the act. After the expiration of this 2-year period, the schedules are to be updated and republished on an annual basis.

Subsection (b) sets out the criteria for each schedule of controlled drugs. However, findings with respect to these criteria are not required for placement of a substance in a schedule to carry out a U.S. obligation under a treaty, convention, or protocol in effect on the date of controlled substance in a schedule.

The criteria for those substances listed in schedule I are: a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

The criteria for substances listed in schedule II are: a high potential for abuse, a currently accepted medical use in treatment in the United States, or a currently accepted medical use with severe restrictions, and that abuse may lead to severe psychological or physical dependence.

The criteria for substances listed in schedule III are: a potential for abuse less than that for substances in schedules I and II, a currently accepted medical use in treatment in the United States, and that abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

The criteria for substances listed in schedule IV are: a low potential for abuse relative to the substances listed in schedule III, a currently accepted medical use in treatment in the United States, and that abuse of the substance may lead to limited physical or psychological dependence relative to the substances in schedule III.

The criteria for the substances listed in schedule V are: a low potential for abuse relative to the substances in schedule IV, a currently accepted medical use in treatment in the United States, and that abuse may lead to limited physical or psychological dependence relative to the substances listed in schedule IV.

Subsection (c) sets out the various narcotics, marihuana, stimulants, depressants, hallucinogens, and immediate precursors controlled under existing law and lists them in one of the five schedules. The listing of a drug by the bill under one schedule or another is not intended to affect the extent to which it is regulated under other laws. Methadone, listed in schedule II, for example, is used today in a number of programs for treatment of narcotic addicts and the adoption of this bill will not, of itself, lead to any change in the extent to which such use is permitted today.

Subsection (d) authorizes the Attorney General to except any compound, mixture, or preparation containing any stimulant or depressant substance contained in paragraph (a) or (b) of schedule III or in schedule IV or V from the application of all or any part of title II, if the substance contains one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system, provided that such admixtures shall not be included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a stimulant or depressant effect on the central nervous system.

Part C—Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

Section 301

Section 301 authorizes the Attorney General to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of substances covered by the act.

Section 302. Persons required to register

Subsection (a) of section 302 requires every person who engages in the manufacture, distribution, or dispensing of controlled substances or who proposes to engage therein to register annually with the Attorney General.

Under subsection (b) of section 302, persons registered by the Attorney General to manufacture, distribute, or dispense controlled substances are authorized to possess, manufacture, distribute, or dispense such substances (including any such activity in the conduct of research) to the extent that they are authorized to do so by their registration. The committee inserted this subsection to make it clear that persons registered under this title are authorized to deal in or handle controlled substances.

Subsection (c) of this section exempts from registration an agent or employee of a manufacturer, distributor, or dispenser of controlled substances when he is acting in the course of his business or employ-

ment; a common or contract carrier or warehouseman, or employee thereof, whose possession of controlled substances is in the usual course of his business or employment; and an "ultimate user" who possesses a controlled substance for a purpose specified in section 102(25), which defines the term "ultimate user." This subsection also specifically authorizes possession of such substances by persons described in the subsection. In the case of an ultimate user who lawfully obtains a drug and whose possession is for his own use or for a member of his household or an animal owned by him, his possession is that authorized by the bill, as referred to in section 404(a) (relating to the offense of possession).

Subsection (d) of this section authorizes the Attorney General to waive the registration requirement of subsection (a) if he finds that such waiver is consistent with the public health and safety.

Subsection (e) of this section requires a separate registration at each principal place of business of the person required to register.

Subsection (f) of this section authorizes the Attorney General to inspect the establishment of a registrant or an applicant for registration in accordance with the rules and regulations promulgated by him.

Section 303. Registration requirements

Subsection (a) of section 303 requires the Attorney General to register an applicant to manufacture controlled substances included in schedule I or II of title II if he determines that such registration is consistent with the public interest and with U.S. obligations under international treaties, conventions, or protocols in effect on the effective date of this part. In determining what constitutes the public interest, the Attorney General must consider the following factors: (1) Maintenance of effective controls against diversion of particular controlled substances and any schedule I or II substance compounded therefrom into other than legitimate medical, scientific, or industrial channels, by limiting the importation and 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 such purposes; (2) compliance with applicable State and local law; (3) promotion of technical advances in the art of manufacturing these substances and the development of new substances; (4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances; (5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective controls against diversion; and (6) such other factors as may be relevant to and consistent with the public health and safety.

Subsection (b) of section 303 requires the Attorney General to register an applicant to distribute a controlled substance included in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest the Attorney General shall consider the following factors: (1) Maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels; (2) compliance with applicable State and local law; (3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such

substances; (4) past experience in the distribution of controlled substances; and (5) such other factors as may be relevant to and consistent with the public health and safety.

Subsection (c) of this section provides that a registration granted under subsections (a) and (b) of the section shall not entitle a registrant to manufacture and distribute controlled substances in schedules I and II other than those specified in the registration, or any quantity of those controlled substances in excess of the quota assigned pursuant to section 306.

Subsection (d) of this section requires the Attorney General to register an applicant to manufacture controlled substances in schedule III, IV, or V unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest the Attorney General shall consider the following factors: (1) Maintenance of effective controls against diversion of particular controlled substances and any schedules III, IV, and V substance compounded therefrom into other than legitimate medical, scientific, or industrial channels; (2) compliance with applicable State and local law; (3) promotion of technical advances in the art of manufacturing these substances and the development of new substances; (4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances; (5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and (6) such other factors as may be relevant to and consistent with the public health and safety.

Subsection (e) of this section requires the Attorney General to register an applicant to distribute controlled substances included in schedule III, IV, or V unless he determines that the issuance of the registration is inconsistent with the public interest. In determining the public interest the Attorney General must consider the following factors: (1) Maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels; (2) compliance with applicable State and local law; (3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances; (4) past experience in the distribution of controlled substances; and (5) such other factors as may be relevant to and consistent with the public health and safety.

The criteria for registration set out in subsections (a), (b), (d), and (e) are to be considered by the Attorney General when passing on an application for initial registration under this title and when passing on an application for annual renewal of registration which is required by subsection 302(a). The criteria set out in subsection 304(a), relating to revocation and suspension of registration, are not the criteria to be considered by the Attorney General when granting or denying a renewal of registration under section 303.

Subsection (f) of this section provides that practitioners shall be registered under this title to dispense or conduct research in substances listed in schedules II through V if they are authorized to dispense or conduct research under the law of the State in which they practice. Practitioners engaging in research with nonnarcotic substances in schedules II through V, who are already registered in another capacity under part C, will not be required to obtain a separate registration to

conduct such research. However, practitioners conducting research in narcotic substances listed in schedules II through V may be required to obtain a separate registration even though they are already registered under this title in another capacity.

Pharmacies, as distinguished from pharmacists, when engaged in commercial activities, will be registered under subsection (f) if they are authorized to dispense under the law of the State in which they regularly conduct business. The committee inserted this language to make clear that only pharmacies and not pharmacists employed by them will be required to register. However, this provision is not intended to apply to a pharmacist who is using controlled substances in teaching or research and is not doing so as an employee or agent of a registered establishment. In that case, he will have to be personally registered.

Registration applications under subsection (f) by practitioners wishing to conduct research on schedule I substances are to be referred to the Secretary of Health, Education, and Welfare who shall determine the qualifications and competency of each applicant, as well as the merits of each research protocol. In determining the merits of the research protocol, the Secretary is required to consult with the Attorney General as to whether or not there are effective procedures to adequately safeguard against diversion of the controlled substances to be used in the proposed research. If the Secretary deems a researcher qualified, the Attorney General may only deny him registration if he finds that the applicant has materially falsified his application, has had his State license or registration revoked or denied, or has been convicted of a felony under Federal or State law relating to controlled substances.

Section 304. Denial, revocation, or suspension of registration

Subsection (a) of this section empowers the Attorney General to revoke or suspend any registration issued under this title if it is found that the holder has falsified his application, lost his State license, or has been convicted of a felony violation relating to any controlled substance.

Subsection (b) of this section authorizes the Attorney General to limit the revocation or suspension to the particular controlled substance with which the action is concerned.

Subsection (c) of this section requires that the Attorney General serve notice upon the applicant or registrant of the intended action prior thereto and give him an opportunity to show cause why the proceeding should not commence. Proceedings under this subsection shall be in accordance with subchapter II of chapter 5, of title 5, of the United States Code, and they shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this act or any law of the United States.

Subsection (d) of this section permits the Attorney General, at his discretion, to suspend a registration simultaneously with the institution of the proceedings under this section, where he finds that there is an imminent danger to the public health or safety.

Subsection (e) of this section provides that a suspension or revocation under this section shall operate to suspend or revoke any quota applicable under section 306.

Subsection (f) of this section empowers the Attorney General to place under seal controlled substances within the control of the person whose registration is suspended or revoked until court action has been completed thereon. Upon a revocation order becoming final, all controlled substances subject to the order shall be forfeited to the Federal Government, and shall be disposed of in accordance with section 511(e).

Section 305. Labeling and packaging requirements

Subsection (a) of this section makes it unlawful to distribute a controlled substance in a commercial container unless the container, when and as required by the Attorney General, bears a label, as defined in section 201(k) of the Federal Food, Drug, and Cosmetic Act, containing an identifying symbol in accordance with regulations promulgated by the Attorney General. A different symbol is to be required for each schedule of controlled substances.

Subsection (b) of this section makes it unlawful for the manufacturer of a controlled substance to distribute the substance unless the labeling, as defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act, of the substance contains the identifying symbol required by subsection (a), when and as required by the regulations of the Attorney General.

Subsection (c) of this section requires the Secretary of Health, Education, and Welfare to prescribe regulations under section 503(b)(2) of the Federal Food, Drug, and Cosmetic Act to provide that the labels of drugs listed in schedules II, III, and IV shall, when dispensed to or for a patient, contain a warning that it is a crime to transfer the drug to any person other than a patient.

Subsection (d) prohibits the distribution of controlled substances listed in schedules I and II and narcotic substances listed in schedules III and IV unless the bottle or other container, stopper, covering, or wrapper in which it is packaged is securely sealed in a manner prescribed by the Attorney General.

Section 306. Quotas applicable to certain substances

Subsection (a) of this section requires the Attorney General to determine total quantity and to establish quotas for the production of each basic class of controlled substances included in schedules I and II for every calendar year in order to provide for the estimated medical, scientific, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.

Subsection (b) of this section requires the Attorney General to limit or reduce individual production quotas so as not to exceed the amount determined necessary each year under subsection (a). The quota of each registered manufacturer for each controlled substance in schedule I or II shall be revised in the same proportion as the limitation or reduction of the aggregate of the quotas. Provision is also made to subtract from a manufacturer's following year's quota that produced in excess of quota revision before such revision.

Subsection (c) of this section provides that on or before July 1 of each year, upon application by a registered manufacturer, the Attorney General shall fix a manufacturing quota for the controlled substances in schedules I and II that the manufacturer seeks to produce.

The Attorney General, in fixing quotas, determines the manufacturer's estimated disposal, inventory, and other requirements for the calendar year, and in making the determination, the Attorney General considers the manufacturer's current rate of disposal, the trend of the national disposal rate during the preceding calendar year, the manufacturer's production cycle and inventory position, the economic availability of raw materials, yield and stability problems, emergencies such as strikes and fires, and other factors.

Subsection (d) of this section provides for the fixing of quotas for schedule I and II substances for those registrants who have not manufactured that substance during one or more previous years. In fixing these quotas the Attorney General is to consider generally those factors applicable in subsection (c) of this section.

Subsection (e) of this section provides for application for increased quotas by a registered manufacturer to meet his needs during the year. In processing such an application, the Attorney General is to consider those factors which may have a bearing on the need for such an increase.

Subsection (f) of this section provides that no quota shall be required for incidentally produced substances resulting from the manufacturing process used in the manufacture of a controlled substance with respect to which its manufacturer is registered under this title. The Attorney General may, by regulation, restrict the retention and disposal of such incidentally produced substances.

Section 307—Records and reports of registrants

Subsection (a)(1) of this section provides that every registrant, except those specifically excluded under subsection (c) of this section, must on the effective date of the section and every second year thereafter, make a complete and accurate record of all stocks of controlled substances on hand. Regulations prescribed by the Attorney General under this section must permit the biennial inventory to be prepared on the registrant's regular general physical inventory date which is nearest to and does not vary by more than 6 months from the biennial date that would otherwise apply.

Subsection (a)(2) provides that at the time a substance is first designated as a controlled substance, all registrants under title II manufacturing, distributing, or dispensing the substance must make complete and accurate records of all stocks on hand.

Subsection (a)(3) requires that on the effective date of section 305 and thereafter, every registrant manufacturing, distributing, or dispensing controlled substances must maintain on a current basis a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of. However, this paragraph specifically does not require a registrant to maintain a perpetual inventory.

Subsection (b) of this section provides that required records shall be in accordance with and contain the information required by the Attorney General pursuant to regulations. In addition, records are to be maintained separately from all other records of the registrant or, in the alternative, in the case of nonnarcotic substances, be in such form that the information required by the Attorney General is readily retrievable from the ordinary business records of the registrant. All

records required to be kept under this section must be maintained and made available, for at least 2 years, for inspection and copying by officers of the United States authorized by the Attorney General.

Under this subsection, records of narcotic drugs must be maintained separate and apart from all other records kept by a registrant. However, in the case of nonnarcotic substances, a registrant has the option of maintaining them either separately or in a manner such that they can readily and easily be separated or retrieved. In the case of the wholesale druggist, this may mean that he asterisk or "redline" all controlled substance items on a shipping invoice. The wholesale druggist will not be required to prepare and keep two invoices—one containing controlled substance items and the other containing noncontrolled substance items—so long as he asterisks, redlines, or in some manner identifies those items on an invoice which relate to controlled substances.

Subsection (c)(1)(A) excepts from the recordkeeping requirements the prescribing or administering of narcotic controlled substances listed in schedules II through V by a practitioner in the lawful course of his professional practice. However, practitioners who dispense these narcotic drugs (*other than* by prescribing or administering them) are subject to the recordkeeping requirements of this section with respect to the narcotic drugs so dispensed.

Subsection (c)(1)(B) of this section exempts from the recordkeeping requirements practitioners who dispense (*including* prescribing or administering) nonnarcotic controlled substances listed in schedules II through V to their patients, unless the practitioner is regularly engaged in charging the patients for such substances, either separately or together with charges for other professional services. In that case, the practitioner will be subject to the recordkeeping requirements of this section with respect to the drugs dispensed.

Subsection (c)(2)(A) of this section provides that the recordkeeping requirements do not apply to the use of controlled substances, at establishments registered under title II which keep records with respect to such substances, in research conducted in conformity with an exemption granted under section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act. The intent of this subsection is to exclude from the requirements of this section registrants using controlled substances in animal or human research under the investigational new drug procedures of the Federal Food, Drug, and Cosmetic Act, but only if the establishments at which they are conducting research are registered and keeping records of the controlled substances used in the research.

Subsection (c)(2)(B) of this section provides that the recordkeeping requirements do not apply to the use of controlled substances, at establishments registered under title II which keep records with respect to such substances, in preclinical research or in teaching. Here again, if the establishment at which the research is being conducted is registered and keeps records with respect to the controlled substances used in the research, the individual researcher-registrant will not be required to keep records.

Subsection (c)(2)(C) provides that the recordkeeping requirements will not apply to the extent of any exemption granted by the Attorney General.

Subsection (d) of this section requires manufacturers registered under title II to make reports, when and as required by the Attorney General, of every sale, delivery, or other disposal of any controlled substance. This subsection further requires all distributors registered under title II to make such reports with respect to narcotic controlled substances as may be required by the Attorney General. Reports under this subsection are to identify by registration number the person or establishment to whom sale, delivery, or other disposal was made, unless such person is exempt from registration.

Subsection (e) of this section provides that regulations promulgated under sections 505(i) and 512(j) of the Federal Food, Drug, and Cosmetic Act, relating to investigational use of drugs, are to include such procedures as the Secretary of Health, Education, and Welfare, after consultation with the Attorney General, determines are necessary to insure the security and accountability of controlled substances used in research.

Section 308. Order forms

Subsection (a) of this section makes it unlawful for any person to distribute a controlled substance in schedule I or II unless the substance is distributed pursuant to a written order of the person to whom the substance is distributed, made on a form issued by the Attorney General in blank in accordance with subsection (d) and regulations.

Subsection (b) of this section provides that the order form requirements of subsection (a) do not apply to the exportation of schedules I and II substances from the United States in conformity with the provisions of title III. Subsection (b) further provides that the order form requirements do not apply to a common or contract carrier or warehouseman whose delivery or storage of a controlled substance is in the lawful and usual course of business.

Subsection (c)(1) of this section requires persons distributing schedule I or II controlled substances to preserve the order form for 2 years and make it available for inspection and copying by officers of the United States authorized by the Attorney General and by State or local enforcement officers who under their laws are authorized to inspect such orders.

Subsection (c)(2) of this section requires that the person who gives an order form required under subsection (a) must make a duplicate of it and preserve it for a period of 2 years and make it available for inspection and copying.

Subsection (d)(1) provides that the Attorney General may only issue order forms to persons registered as manufacturers, distributors, or dispensers under section 303 or persons exempted from registration under subsection 302(d). This subsection also makes it unlawful for any person other than the one to whom an order form is issued to use the form for the purpose of obtaining controlled substances or to furnish the form to anyone with intent thereby to procure the distribution of such substances.

Subsection (d)(2) provides that the Attorney General may charge reasonable fees relating to the issuance of order forms.

Subsection (e) makes it unlawful for a person to obtain by means of order forms schedule I and II controlled substances for any purpose other than their use, distribution, dispensing, or administration in the conduct of a lawful business or in the course of professional practice.

Section 309. Prescriptions

Subsection (a) provides that, except when dispensed by a practitioner, other than a pharmacist, to an ultimate user, no schedule II substance which is a prescription drug under the Federal Food, Drug, and Cosmetic Act may be dispensed without a written prescription of a practitioner. Provision is made, however, for the dispensing of schedule II substances on oral prescriptions in emergency situations, as prescribed by the Secretary of Health, Education, and Welfare after consultation with the Attorney General. The subsection further provides that a prescription for a schedule II drug may not be refilled.

Subsection (b) provides that, except when dispensed by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance listed in schedule III or IV which is a prescription drug under the Federal Food, Drug, and Cosmetic Act may be dispensed without a written or oral prescription in conformity with the provisions of that act. Such prescriptions may not be filled or refilled more than 6 months after their date and they may not be refilled more than five times after their date unless renewed by the practitioner.

Subsection (c) provides that no controlled substance listed in schedule V which is a drug may be distributed or dispensed for a nonmedical purpose.

Subsection (d) of this section provides that when it appears to the Attorney General that a drug not considered to be a prescription drug under the Federal Food, Drug, and Cosmetic Act should be considered a prescription item because of its abuse potential, the Attorney General shall so advise the Secretary of Health, Education, and Welfare, and furnish him all relevant available data.

PART D--OFFENSES AND PENALTIES

Section 401. Prohibited acts A—Penalties

Section 401(a). This section makes it unlawful for a person to knowingly or intentionally (1) manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance, except as authorized by this title; or (2) create, distribute, dispense, or possess with intent to distribute or dispense, a counterfeit substance.

Except in the case of violations punishable under section 405 (relating to distribution to persons under 21), section 401(b) establishes the following penalties for anyone who violates section 401(a):

(1)(a) In the case of a narcotic drug in schedule I or II, up to 15 years in prison and/or a fine of not more than $25,000 may be imposed, except that if the person has one or more prior convictions for an offense punishable under this subsection, or for a felony under another provision of this title or of title III or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, such person shall be sentenced to not more than 30 years and/or a fine of not more than $50,000. A special parole term of 3 years is imposed in addition to any prison term under this paragraph, and if there exists a prior conviction, the special parole term is for 6 years.

(b) In the case of a schedule I or II nonnarcotic substance or a schedule III substance, a violator shall be imprisoned for not more than 5 years and/or fined not more than $15,000, except that in the case

of prior convictions as above described, the punishment is not more than 10 years and/or a fine of not more than $30,000. A special parole term of 2 years is added to the prison term unless there was a prior conviction, in which case it would be for 4 years.

(2) In the case of a schedule IV substance, the sentence is to be for not more than 3 years and/or a fine of not more than $10,000. If there is a prior conviction as above described, the sentence shall be for not more than 6 years and/or a fine of not more than $20,000. A special parole term of 1 year is imposed except in the case where there is a prior conviction, in which case it would be for 2 years.

(3) In the case of a schedule V substance, sentence is to be for a prison term of not more than 1 year and/or a fine of not more than $5,000. If there is a prior conviction, the punishment shall be for not more than 2 years and/or a fine of not more than $10,000.

Section 401(c) provides that the special parole term imposed under this section or section 405 may be revoked if its conditions are violated, and in such a case the original term of imprisonment is increased by the period of the special parole term. The prisoner may be required to serve part or all of the new prison term. The special parole term is in addition to and not in lieu of any other parole provided by law.

Section 402. Prohibited acts B—Penalties

Section 402(a) makes it unlawful (1) to distribute or dispense a controlled substance, which is a prescription drug without a lawful prescription in violation of section 309; (2) for a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration; (3) for a registrant to distribute a controlled substance without the required identifying symbol or without its container being securely sealed where required; (4) to remove, alter, or obliterate a required symbol or label; (5) to refuse or fail to make, keep or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required by this title or title III; (6) to refuse entry into any premises or inspection authorized by this title; (7) to remove, break, injure, or deface a seal placed upon controlled substances pursuant to this act or to remove or dispose of substances so placed under seal; or (8) to use for his own advantage or reveal, other than to duly authorized officers or employees of the United States or to the courts (including disclosure pursuant to discovery process), any information acquired in the course of an inspection authorized by this title concerning any method of process which as a trade secret is entitled to protection.

Section 402(b) prohibits a person who is registered to manufacture any schedule I or II controlled substance which is (1) not expressly authorized by his registration and by a properly assigned quota; or (2) in excess of a quota assigned to him.

Section 402(c)(1) subjects a violator of this section to a civil penalty of not more than $25,000, except as 402(c)(2) provides otherwise. The U.S. district court or otherwise proper U.S. court having jurisdiction of matters of this nature shall have jurisdiction to enforce this paragraph. Section 402(c)(2)(A) provides that in the event of prosecution by information or indictment alleging that the violation was

committed knowingly, and if the trier of fact so finds, such person shall, except as provided by section 402(c)(2)(B), be imprisoned for not more than 1 year and/or fined not more than $25,000. Section 402(c)(2)(B) provides that for a violation referred to in subparagraph (A) committed after one or more prior convictions, the violator shall be sentenced to a term of imprisonment of not more than two years and/or fined not more than $50,000. Section 402(c)(3) provides that except under the conditions specified in 402(c)(2), a violation of this section does not constitute a crime, and a judgment and the imposition of a civil penalty shall not give rise to any disability or legal disadvantage based on conviction for a criminal offense.

Section 403. Prohibited acts C—Penalties

Section 403(a) makes it unlawful for any person to knowingly or intentionally (1) in the case of a registrant, distribute controlled substances in schedule I or II, in the course of his legitimate business, except pursuant to an order on an order form issued by the Attorney General; (2) use fictitious, revoked, or suspended registration numbers, or a number issued to another person, in connection with manufacture or distribution of controlled substances; (3) acquire a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge; (4) furnish false, fraudulent, or incomplete material information in any application, report, record, or other document required under this law; or (5) make, distribute, or possess an instrument designed to print or reproduce the trademark or other identifying mark of another upon any drug or container or its labeling so as to render such drug a counterfeit substance.

Section 403(b) makes it unlawful for any person to knowingly or intentionally use any communication facility in committing or facilitating the commission of a felony under this title or title III. Each separate use of a communication facility is deemed a separate offense, and the term "communication facility" is defined as any instrumentality for the transmission of writing, signs, signals, pictures, or sounds.

Section 403(c) provides that any person who violates this section shall be imprisoned for not more than 5 years and/or fined $30,000. If there is a prior conviction, the person shall be imprisoned for not more than 10 and/or fined not more than $10,000.

Section 404. Penalty for simple possession; conditional discharge and expunging of records for first offense

Section 404(a) makes it unlawful for any person knowingly or intentionally to possess a controlled substance unless it was obtained from a practitioner directly or pursuant to a valid prescription or order, except as otherwise authorized by this title or title III. Any person who violates this section shall be imprisoned for not more than 1 year and/or fined not more than $5,000. If there is a prior conviction under this subsection, he shall be sentenced to not more than 2 years and/or fined not more than $10,000.

Section 404(b)(1) provides that if a person, who has not previously been convicted of violating subsection (a) of this section, any other provision of this title, or any other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, is found guilty of violating section 404(a), after a trial or a plea of guilty, the court may, without entering a judgment of guilty, and with

the consent of such person, defer further proceedings and place the person on probation upon such reasonable conditions as it may require and for such a period, not to exceed 1 year, as the court may prescribe. Upon a violation of a condition of probation, the court may enter an adjudication of guilt and proceed as otherwise provided. The court may dismiss the proceedings against such person and discharge him from probation before the expiration of the probation period. If the person does not violate the conditions of probation, the court may discharge the person and dismiss the charges against him at the end of his term of probation. Such discharge and dismissal shall be without a court adjudication of guilt, but a nonpublic record shall be retained by the Department of Justice solely to be used by the courts in determining whether or not, in subsequent proceedings, such person qualifies under this subsection. A discharge and dismissal shall not be deemed a conviction of a crime, but may occur only once with respect to any person. Section 404(b)(2) provides that after a dismissal and discharge under the above subsection, if the person was not over 21 years of age at the time of the offense, he may apply to the court for an order to expunge from all official records (other than the nonpublic records retained by the Department of Justice) all recordation of his arrest, indictment or information, trial, finding of guilty, and dismissal and discharge pursuant to this section. The court shall make such an order if the person fits the qualifications and the order shall restore such person, in the contemplation of the law, to the status he occupied before such arrest, indictment or information. No person as to whom such order has been entered shall thereafter be held guilty of perjury or giving a false statement by reason of his failure to recite or acknowledge such arrest, indictment, information, or trial in response to any inquiry.

The committee is confident that judges, in administering the provisions of this section, will recognize that many defendants coming before them will be in need of medical treatment and that the judges will require that these persons undergo some form of prescribed treatment as a condition of their probation.

Section 405. Distribution to persons under age 21

Section 405(a) provides that anyone at least 18 years of age who violates section 401(a)(1) by distributing a controlled substance to a person under the age of 21 may be punished by twice the amount of imprisonment and/or fine, and twice the special parole term, authorized in section 401(b) for that substance. Thus, in the case of a first offense under this section, imprisonment of up to 30 years, or a fine of up to $50,000, could be imposed, plus at least 6 years' special parole, if a schedule I or II narcotic is involved; 10 years' imprisonment, $30,000 fine, or both, plus 4 years' special parole, if a nonnarcotic schedule I or II substance or any schedule III substance is involved; 6 years' imprisonment, a $20,000 fine, plus a 2 years' special parole in the case of a schedule IV substance; and 2 years' imprisonment, a $10,000 fine, or both, in the case of a schedule V substance.

Section 405(b) provides that if a person commits a violation of section 405(a) after a prior conviction under this section (or of section 303(b)(2) of the Federal Food, Drug, and Cosmetic Act as in effect prior to enactment of this bill, which relates to distribution to minors), the prison term and/or fine will be up to three times the corresponding

penalty and special parole term under section 401(b). Thus in the case of a second or subsequent offense under this section, these sentences could range from up to 45 years' imprisonment or $75,000, plus 9 years' special parole, for a narcotic schedule I or II substance; to 15 years' imprisonment or $45,000, plus 6 years' special parole, for a nonnarcotic schedule I or II substance or any schedule III substance; to 9 years' imprisonment or $30,000 plus 3 years' special parole, in the case of a schedule IV substance; and to 3 years' imprisonment or $15,000, or both, in the case of schedule V substances.

Section 406. Attempt and conspiracy

Section 406 provides that any person who attempts or conspires to commit any offense defined in this title may be punished by imprisonment and/or fine which may not exceed the maximum amount set for the offense, the commission of which was the object of the attempt or conspiracy.

Section 407. Additional penalties

Section 407 provides that any penalty imposed for violation of this title shall be in addition to, and not in lieu of, any civil or administrative penalty or sanctions authorized by law.

Section 408. Continuing criminal enterprise

Section 408(a) provides that any person who engages in a continuing criminal enterprise shall upon conviction for that offense be sentenced to a term of imprisonment for not less than 10 years and up to life, to a fine of not more than $100,000, and to the forfeiture prescribed in paragraph (2) of this section. If the person engages in this activity subsequent to one or more prior convictions under this section, he shall receive a penalty of not less than 20 years' imprisonment and up to life, a fine of not more than $200,000, and the forfeiture prescribed. Section 408(a)(2) provides that a person convicted under paragraph (1) shall forfeit to the United States (A) the profits obtained by him in such enterprise, and (B) any of his interest in, claim against, or property or contractual rights of any kind affording a source of influence over, such enterprise.

Section 408(b) provides that a person is engaged in a continuing criminal enterprise if (1) he violates any provision of title II or title III which is punishable as a felony, and (2) such violation is part of a continuing series of violations of title II or III which are undertaken by such person in concert with five or more other persons with respect to whom he occupies a position of organizer, supervisor, or manager; and from which he obtains substantial income or resources.

Section 408(c) states that any sentence which is imposed under this section shall not be suspended, that probation shall not be granted, and that section 4202 of title 18 of the United States Code and the act of July 15, 1932 (D.C. Code, sec. 24–203–24–207), relating to parole, shall not apply.

Section 408(d) determines that the district courts of the United States (including courts in the territories or possessions of the United States having jurisdiction under subsection (a)) shall have jurisdiction to enter restraining orders or prohibitions, or take such other actions, including the acceptance of satisfactory performance bonds, in connection with any property or other interest subject to forfeiture under this section as they deem proper.

Section 409. Proceedings to establish previous convictions.

Sec. 409. This section prescribes the procedure for establishing prior convictions so as to authorize imposition of an increased penalty upon a subsequent conviction.

PART E. ADMINISTRATIVE AND ENFORCEMENT PROVISIONS

Section 501. Procedures

Section 501 serves three purposes. First, it authorizes the Attorney General to delegate his functions under title II to other officials in the Department of Justice. Second, it authorizes him to promulgate rules and regulations for the efficient execution of his functions under title II. Third, it allows him to accept gifts and bequests on behalf of the Department where the donor intends that such items are to be used to control the abuse of dangerous substances.

Section 502. Education and research programs of the Attorney General

Subsection (a) of this section authorizes the Attorney General to carry out educational and research programs directly related to enforcement of laws relating to drugs or other substances which are or may be subject to control under this title. Such programs may include any of the items in paragraphs (1) through (6).

Paragraph (1) of subsection (a) specifies educational and training programs on drug abuse or on controlled substances law enforcement for local, State, and Federal personnel and is intended to include training of college deans and security personnel in relation to such enforcement, and forensic chemists. It is also intended to include speeches and lectures by personnel of the Bureau of Narcotics and Dangerous Drugs on drug abuse or controlled substances law enforcement. Paragraph (2) of subsection (a) specifies studies or special projects designed to compare effects of various enforcement strategies on drug use and abuse. Paragraph (3) of subsection (a) specifies studies or special projects designed to assess and detect accurately the presence in the human body of drugs or other substances which are or may be subject to control under this title, including the development of rapid field identification methods which would enable agents to detect microquantities of these drugs or other substances. Paragraph (4) of subsection (a) specifies studies or special projects designed to evaluate the nature and sources of the supply of illegal drugs throughout the country. Paragraph (5) of subsection (a) specifies studies or special projects to develop more effective methods to prevent diversion of controlled substances into illegal channels. Paragraph (6) of subsection (a) specifies studies or special projects to develop information necessary to carry out the Attorney General's functions under section 201 of this title.

The provision of section 502(a)(6), authorizing the Attorney General to carry out studies or special projects to develop information necessary to carry out his functions under section 201, is intended to authorize him to develop relevant information, particularly information as to the scope, pattern, and significance of abuse of a drug or substance in this country, but is not intended to authorize him to conduct or support medical or scientific research of the kinds authorized to be conducted or supported by the Department of Health, Education, and Welfare under its own authority.

Subsection (b) of this section authorizes the Attorney General to enter into contracts for educational and research activities without performance bonds.

Subsection (c) of this section permits the Attorney General to authorize researchers to withhold the names of persons who are subjects of research. A person so authorized cannot be compelled to identify his research subjects in any civil, criminal, legislative, or administrative proceeding either State or Federal.

Subsection (d) of this section permits the Attorney General on his own motion or at the request of the Secretary of Health, Education, and Welfare to authorize researchers to possess, distribute, and dispense controlled substances. While they are already authorized to do so for the purpose of such research by virtue of being registered under part C, the Attorney General's action under subsection (d) immunizes the researcher from prosecution under other laws, particularly State or local law. However, this does not excuse compliance with applicable requirements of the Federal Food, Drug, and Cosmetic Act. See section 707 of this bill.

Section 503. Cooperative arrangements

Subsection (a) of this section provides for cooperation between all of the Federal enforcement authorities and the State and local enforcement authorities. The Attorney General is authorized to exchange information, cooperate in prosecution, conduct training, maintain files on addicts and other controlled substance offenders, maintain statistics on violations, and conduct programs to eradicate the growth of the plant species from which controlled substances may be extracted.

Subsection (b) of this section provides for the furnishing of technical and other assistance to the Attorney General by other agencies of the Federal Government but allows those agencies to withhold the names or other identifying characteristics of patients or research subjects which they have undertaken to keep confidential.

Section 504. Advisory committees

Section 504 provides for appointment of committees by the Attorney General to advise him with respect to preventing and controlling the abuse of controlled substances.

The committee deleted from this section the original language which provided for continuation of the Scientific Advisory Committee whose function is to advise on whether a particular substance should be controlled. Instead, it assumes that under section 201 the Secretary of Health, Education, and Welfare will perform the functions of the Scientific Advisory Committee under present statutory authority.

Section 505. Administrative hearings

Subsection (a) of this section authorizes the Attorney General in carrying out his functions under title II to conduct administrative hearings, sign and issue subpenas, administer oaths, examine witnesses, and receive evidence at any place in the United States.

Subsection (b) of this section requires that all hearings held under this act be conducted in accordance with the Administrative Procedure Act.

Section 506. Subpenas

Subsection (a) of this section authorizes the Attorney General to subpena witnesses and compel their attendance and testimony in investigations relating to his functions under title II. He is also authorized to compel production of records or other tangible things which constitute or contain evidence and upon which he has made a finding as to materiality or relevancy.

Subsection (b) of this section provides that the Attorney General may designate the person to serve the subpena, that service upon a natural person is by personal delivery, that service may be made upon a corporation by delivery to an officer of that corporation, and that the affidavit of the person serving the subpena or a copy thereof constitutes proof of delivery of the subpena.

Subsection (c) of this section provides that refusal to respond to a subpena allows the Attorney General to invoke court aid, and refusal to obey a court order compelling participation in an administrative proceeding is punishable as contempt.

Section 507. Judicial review

Section 507 makes all determinations of the Attorney General final and conclusive, except that a person aggrieved by a decision may have this decision reviewed by the U.S. Court of Appeals for the District of Columbia or by the court of appeals of the circuit in which his principal place of business is located, upon petition filed within 30 days after notice of the decision. Findings of the Attorney General supported by substantial evidence would be conclusive. It is intended that support by substantial evidence or its absence should be determined on the record considered as a whole.

Section 508. Powers of enforcement personnel

Subsection (a) of this section incorporates and expands upon section 702(e) of the Food and Drug Act (21 U.S.C. 372(e)) and 26 U.S.C. 7607. Section 702(e) contains the authority granted to agents of the former Bureau of Drug Abuse Control by the Drug Abuse Control Amendments of 1965. Section 7607 contains the authority granted to agents of the former Bureau of Narcotics.

The authorities in each of the above sections have been carried over by section 508. These authorities confer the right to carry firearms and execute and serve search-and-arrest warrants, subpenas, and summonses. This authority is expanded to include the execution and service of judicially issued administrative inspection warrants.

Section 702(e)(4) of the Food and Drug Act and 26 U.S.C. 7607(2) granted agents the authority to make arrests for dangerous-drug and narcotic drug or marihuana offenses, respectively, committed in the agent's presence or, in the case of felonies, when the agent has probable cause.

Paragraph (3) of section 508 of the bill broadens this arrest authority to include any offenses against the United States. Paragraph (4) contains the authority to seize property which is in violation of the narcotic and dangerous drug laws. Paragraph (5) grants the agents authority to perform other law enforcement duties as the Attorney General may designate. This section is not aimed at any particular

function, but provides the Attorney General with flexibility in the utilization of enforcement personnel wherever and whenever the need arises.

Section 509. Search warrants

Subsection (a) of this section incorporates 18 U.S.C. 1405 and authorizes service of a search warrant at any time of the day or night if probable cause has been established to the satisfaction of the judge or U.S. magistrate issuing the warrant.

Subsection (b) of this section authorizes an agent, in cases where the violation carries a penalty of more than 1 year, to execute a search warrant without announcing his authority and purpose and, in the process, break into the premises to be searched, if the judge or U.S. magistrate issuing the warrant is satisfied that there is probable cause to believe that the property sought may, and, if such notice is given, will be quickly and easily destroyed or disposed of, or that immediate danger to the agent will result if notice is given. A statement that notice is not required must be included in the warrant. Officers acting under such warrants are required to give identification, reasons, and authority for their entrance as soon as it is practicable after entrance. This section incorportaes current case law and procedures adopted by many States.

Section 510. Administrative inspections and warrants

Subsection (a) of this section defines "controlled premises", for purposes of this section, to mean (1) places where records or documents required under title II are kept or required to be kept, and (2) places, including conveyances, where persons registered or exempted from registration are permitted to handle controlled substances.

Subsection (b) of this section authorizes the Attorney General to conduct administrative inspections of controlled premises.

Paragraph (1) of this subsection confers this authority upon the Attorney General for the purpose of inspecting, copying, and verifying the correctness of records, reports, or documents required to be kept under title II and for the purpose of otherwise facilitating the carry out of his functions under these titles. Paragraph (2) of this subsection allows the Attorney General to designate "inspectors" to carry out the inspection functions. The inspector has the right to enter upon stating his purpose to the owner, operator, or agent in charge, after presenting that person with his credentials and a written notice of his inspection authority. If an administrative inspection warrant is required or has in fact been issued, written notice shall consist of the warrant. Paragraph (3) of this subsection authorizes the inspector, unless restricted by an administrative inspection warrant, to inspect and copy records required to be kept or made and to inspect the premises, equipment, raw materials, finished and unfinished drugs, containers, labeling, etc., appropriate for verification of such records or otherwise bearing on the provisions of title II, and to inventory controlled substances and take samples thereof. Paragraph (4) of this subsection states that unless consent in writing is obtained, no inspection may be extended to financial data, sales data, or pricing data.

Subsection (c) of this section provides that subsection (b) shall not preclude inspection without a warrant of books and records pursuant to an administrative subpena issued in accordance with section 506 of this title, or inspections without a warrant which are conducted under the following circumstances: (1) with the consent of the owner of the premises; (2) in situations presenting imminent danger to health or safety; (3) where mobility of a conveyance to be inspected makes it impractical to obtain a warrant; (4) in emergency situations where time or opportunity to apply for a warrant is lacking; (5) where a warrant is not constitutionally required.

Subsection (d) of this section authorizes the issuance and execution of administrative-inspection warrants. Paragraph (1) of this subsection authorizes issuance of such warrants by Federal judges, judges of a State court of record, and U.S. magistrates. These warrants may be issued only within the territorial jurisdiction of these officials and upon a sworn application showing probable cause and only for the purpose of conducting inspections of controlled premises authorized by this act or regulations promulgated under it and for seizing property appropriate to such inspection. The subsection defines probable cause as "a valid public interest in the enforcement of this title or regulations sufficient to justify inspection * * * in the circumstances specified in the application."

The provisions authorizing the issuance of judicial warrants for administrative inspections under the bill have been inserted because of the Supreme Court's decisions in *Camara* v. *Municipal Court*, 387 U.S. 53, and *See* v. *Seattle*, 387 U.S. 541, both decided on June 5, 1967. The first case involved a criminal prosecution for violating a municipal housing code by refusing to permit inspection, without warrant, of a dwelling unit in a building; the second case involved a conviction for refusing to permit a city fire department inspector to enter and inspect, without a warrant, a locked commercial warehouse. The Court held that in both instances a warrant was constitutionally required, but that probable cause for a warrant should be determined in the light of a "flexible standard of reasonableness that takes into account the public need for effective enforcement of the particular regulation involved". The Court expressly reserved opinion as to the constitutionality of such accepted regulatory techniques as licensing programs which require inspections prior to operating a business or marketing a product (cf sec. 302 of this bill). In deference to these decisions a provision for issuance of judicial warrants for administrative inspections has been inserted in the bill as above described.

Section 511. Forfeitures

Subsection (a) of this section sets forth the conditions for forfeiture and the property to be forfeited. These include all controlled substances produced or obtained in violation of the act, all raw materials, products, and equipment used, or intended for use, in manufacturing, handling, or conveying controlled substances in violation of the act and any container for property previously described. Also subject to forfeiture are all conveyances used, or intended for use, to transport or conceal such violative property. Exempted from this last provision are conveyances belonging to common carriers where the owner or person in charge of the conveyance was not a consenting party nor privy to a violation of

title II, and conveyances where the owner did not have knowledge of activities in which the conveyance was used or where the conveyance was unlawfully in possession of the person who so used it. Also subject to forfeiture are books, records, formulas, and other documents or instruments which are used or intended for use in violation of the act.

Subsection (b) of this section states that any property subject to forfeiture under the act may be seized by process issued pursuant to the supplemental rules for certain admiralty and maritime claims. Further, seizure may be made without such process when incident to an arrest or under the authority of a search warrant or administrative inspection warrant; when the property seized has been the basis of a prior judgment in favor of the United States in a criminal injunction or forfeiture proceeding under title II; when the Attorney General has probable cause to believe that the property is directly or indirectly dangerous to health or safety; or when the Attorney General has probable cause to believe that the property has been used or is intended to be used in violation of title II.

Subsections (c) and (e) of this section state, respectively, various means by which the Attorney General may store or dispose of the seized property.

Subsection (d) of this section provides that forfeiture proceedings shall be in accord with the provisions of existing U.S. customs law.

Subsection (f) of this section provides that all substances listed in schedule I which are illegally possessed, sold, transferred, or the owner of which is unknown, are contraband and are subject to seizure and forfeiture.

Subsection (g) of this section provides for the seizure and forfeiture of all plants from which substances in schedules I and II may be derived where such plants have unknown owners, are wild or are grown in violation of title II. The failure to produce appropriate license to grow the subject plants constitutes authority for their seizure and forfeiture. Additionally, authority is granted to enter upon lands, or into dwellings pursuant to a search warrant, to seize such plants.

Section 512. Injunctions

Subsection (a) of this section authorizes U.S. courts to issue injunctions against violators of title II in accordance with the Federal rules of civil procedure. Subsection (b) of this section provides for jury trial of violators of injunctions in accordance with the Federal rules of civil procedure.

Section 513. Enforcement proceedings

This section incorporates section 305 of the Food and Drug Act (21 U.S.C. 335) and authorizes the Director of the Bureau of Narcotics and Dangerous Drugs, to allow a person against whom criminal action is contemplated under title II an opportunity to present his views or show cause as to why he should not be prosecuted. This proceeding is generally intended to cover technical violations by registrants and allows for administrative compliance, if possible, before court action is initiated.

Section 514. Immunity and privilege

This section authorizes the U.S. attorney, with the approval of the Attorney General, to make application to the court to order any wit-

nesses in a case brought under the provisions of title II, to testify or produce evidence within his possession. No such witnesses shall be prosecuted or subjected to any penalty or forfeiture because of this compelled testimony or production of evidence, if such witness has claimed his privilege against self-incrimination. This exemption does not preclude prosecution for perjury or contempt committed during the trial at hand.

Section 515. Burden of proof; liabilities

Subsection (a)(1) provides that it shall not be necessary for the Government to negate any exemption or exception set forth in title II, but that the burden of going forward with the evidence with respect to such exemption or exception shall be on the person claiming its benefits.

Subsection (a)(2) provides that, in prosecutions for possession of a controlled substance under section 404(a), a prescription label identifying the substance for purposes of section 503(b)(2) of the Federal Food, Drug, and Cosmetic Act shall be prima facie evidence that the substance was obtained pursuant to a valid prescription.

Subsection (b) of this section provides that in the absence of proof that a person is a registrant or holder of an order form issued under title II, the presumption shall be that he is not and the burden of going forward with the evidence as to the registration or order form is upon him.

Subsection (c) of this section provides that the burden of going forward with the evidence to establish that a vehicle, vessel, or aircraft used in connection with the substances listed in schedule I was used lawfully is upon the person engaged in that use.

Subsection (d) of this section exempts Federal officers from liability when lawfully engaged in enforcing title II and further exempts State and local officers when lawfully engaged in enforcing any law relating to controlled substances.

Section 516. Payments and advances

Subsection (a) of this section authorizes the payments of moneys from appropriated funds to persons who furnish information concerning violations of title II.

Subsection (b) of this section provides that moneys expended and subsequently recovered shall be reimbursed to the current appropriation of the Bureau.

Subsection (c) authorizes the Attorney General to direct the advance of funds by the Treasury Department in connection with the enforcement of title II.

Part F—Advisory Commission

Section 601—Establishment of Commission on Marihuana and Drug Abuse

This section provides for the appointment of a Commission on Marihuana and Drug Abuse, composed of two members from each House, and nine members appointed by the President.

The Commission is directed to conduct a study of marihuana, including but not limited to—

(1) the extent of marihuana use in the United States;

(2) the efficiency of existing marihuana laws;

(3) the pharmacology of the drug and its immediate and long-term effects, both physiological and psychological;

(4) the relationship of marihuana use to aggressive behavior and crime;

(5) the relationship between marihuana and the use of other drugs; and

(6) the international control of marihuana.

The Commission is directed to submit, within 1 year after the date funds first become available to carry out the study, to the President and Congress a comprehensive report on this study, including its recommendations and proposals for legislative and administrative action.

The Commission is further directed to conduct a comprehensive study of the causes of drug abuse (not limited to marihuana use) and their relative significance, to make such interim reports as it deems advisable, and within 2 years after the date funds first become available to carry out the study to submit to the President and Congress a final report, including such legislative and administrative recommendations as it deems appropriate. It is the intent of the committee that the Commission should include in its study an examination of such subjects as the relationship, if any, to drug abuse by the young of individual personality with reference to personality traits which may make an individual prone to drug abuse; peer group relationships; patterns of family relations which appear to provide greater susceptibility than others to drug abuse; the degree to which societal tensions within the immediate community and Nation relate to drug abuse, including consideration of poverty, urban decay, war, and social permissiveness; availability and exposure to hard drugs; leisure activity; personal and family use of alcoholic beverages and drugs; movies, lyrics of rock music; advertising; underground newspapers; and other influences in the general social environment.

This section provides that the Commission's total expenditures shall not exceed $1 million.

Part G—Conforming, Transitional and Effective Date, and General Provisions

Section 701—Repeals and conforming amendments

Section 701 deletes from the Federal Food, Drug, and Cosmetic Act the provisions relating to depressant or stimulant drugs inserted by the Drug Abuse Control Amendments of 1965, and the 1968 penalty amendments, and makes conforming amendments to the Federal Food, Drug, and Cosmetic Act, section 302(a) of the Public Health Service Act, and sections 1114 and 1952 of title 18 of the U.S. Code. Section 302(a) of the Public Health Service Act, which now requires the Service to investigate the use and misuse of narcotic drugs and advise the Attorney General on the quantities of narcotic drugs necessary to supply U.S. medicinal and scientific requirements, is also broadened so as to require research into drug abuse and drug dependence for all controlled substances and to require the Service to advise the Attorney General on domestic requirements for all such substances.

See, also, sections 1101 and 1102 of the bill with respect to repeals of, and conforming amendments to, laws within the jurisdiction of the Ways and Means Committee.

Section 702—Pending proceedings

Subsection (a) of this section provides that prosecutions for a violation of law occurring prior to the effective date of section 701 shall not be affected by the repealers or amendments contained in that section.

Subsection (b) of this section provides that civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of section 701 shall not be affected by the repealers or amendments contained in that section.

Subsection (c) provides that all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs on the date of enactment of the act are to be continued and brought to a final determination in accord with the laws and regulations in effect prior to the date of enactment. The subsection further provides that where a drug is finally determined under such proceedings to be a depressant or stimulant drug, as defined in section 201(v) of the Federal Food, Drug, and Cosmetic Act, the drug shall automatically be controlled under title II of this bill by the Attorney General without any further proceedings and listed in the appropriate schedule of section 202 after obtaining the recommendation of the Secretary of Health, Education, and Welfare as to the scheduling.

This provision will require that the administrative hearings relating to the control of the drugs chlordiazepoxide and diazepam under section 201(v) of the Federal Food, Drug, and Cosmetic Act, if they are pending on the date of enactment, must be continued and brought to a close under the provisions of the Federal Food, Drug, and Cosmetic Act rather than terminated and reinstituted under the control provisions of this bill. If controlled under the provisions of the Federal Food, Drug, and Cosmetic Act, this provision authorizes the Attorney General to control the two drugs under the provisions of title II of this act and list them in the appropriate schedule after obtaining the recommendation of the Secretary, without regard to the procedures and findings required for control in section 201. In this instance, control will be automatic.

Subsection (c) further provides that for any drug not already listed in section 202, with respect to which a final control determination has been made prior to the date of enactment of the bill, the Attorney General is authorized to control it without further proceedings and list it in the appropriate schedule after obtaining the recommendation of the Secretary of Health, Education, and Welfare.

Section 703—Provisional registration

Subsection (a) of this section provides that persons engaged in the manufacture, distribution, or dispensing of controlled substances on the day before the effective date of section 302 and who are registered on that day under section 510 of the Federal Food, Drug, and Cosmetic Act or under section 4722 of the Internal Revenue Code of 1954, are to be deemed to have a provisional registration for the manufacture, distribution, or dispensing of controlled substances. The committee inserted this language to insure against any possibility that legitimate manufacturers, distributors, or dispensors could be held in technical violation of regulatory and penalty provisions of title II for nonregistration during the transitional period in which these persons will be registering under title II.

Subsection (b) provides that the revocation and suspension provisions of section 304 are applicable to provisional registrations.

Subsection (c) provides that unless revoked or suspended, a provisional registration shall continue in effect until the date on which the provisional registrant is registered under section 303 or has his registration denied under that section, or until such date as may be prescribed by the Attorney General for the registration of manufacturers, distributors, or dispensers, as the case may be.

Section 704—Effective dates and other transitional provisions

Subsection (a) of this section provides that, except as otherwise provided, title II shall become effective on the first day of the seventh calendar month that begins after the day immediately preceding the date of enactment.

Subsection (b) provides that parts A (relating to definitions), B (relating to control and classification), E (relating to administrative and enforcement provisions), and F (relating to the advisory commission) and sections 702, 704, and 705 through 709 are to become effective upon enactment.

Subsection (c) provides that sections 305 (relating to labels and labeling) and 306 (relating to manufacturing quotas), are to become effective on the date specified in subsection (a), unless the Attorney General postpones the effective date by an order published in the Federal Register. The Attorney General may postpone the effective dates for these sections for such a period as he deems necessary for the efficient administration of title II.

Section 705—Continuation of regulations

This section provides for the continuation of existing administrative regulations which are in effect on the day preceding enactment of title II unless modified, superseded, or repealed by the Attorney General.

Section 706—Severability

This section provides that if a provision of the Act is held invalid, all valid provisions that are severable shall remain in effect.

Section 707—Saving provision

This section provides that nothing in the Act, except this part and (to the extent of any inconsistency) sections 307(e) and 309, shall in any way affect the provisions of the Federal Food, Drug, and Cosmetic Act.

Section 708—Application of State law

This section provides that title II of the bill is not intended to occupy the field (including criminal penalties) to the exclusion of any otherwise valid State law unless there is a direct and positive conflict between the latter and a provision of this title, so that the two cannot consistently stand together.

Section 709—Appropriations authorization

This section provides the appropriation authorization for the expenses of the Department of Justice in carrying out its functions under title II, except for section 103 which contains a specific appropriation authorization. Appropriations of $60 million for the fiscal year

ending June 30, 1972; $70 million for the fiscal year ending June 30, 1973; and $90 million for the fiscal year ending June 30, 1974, are authorized.

TITLE III

Title III of the bill is explained hereafter in this report, in the portion prepared by the Committee on Ways and Means.

AGENCY REPORTS

H.R. 18583, was introduced as a clean bill on July 22, 1970, after the conclusions of hearings and executive sessions before the Subcommittee on Public Health and Welfare. No agency reports have been received on this bill; however, reports received on H.R. 13743 and other bills on which hearings were held before the subcommittee are relevant, and are included below.

In addition, a letter from the Department of Health, Education, and Welfare with respect to the scheduling of marihuana, and a letter from the Department of Justice concerning certain recordkeeping requirements in the bill, are also set forth below.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
August 14, 1970.

HON. HARLEY O. STAGGERS
Chairman Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: In a prior communication, comments requested by your committee on the scientific aspects of the drug classification scheme incorporated in H.R. 18583 were provided. This communication is concerned with the proposed classification of marihuana.

It is presently classed in schedule I(C) along with its active constituents, the tetrahydrocannabinols and other psychotropic drugs.

Some question has been raised whether the use of the plant itself produces "severe psychological or physical dependence" as required by a schedule I or even schedule II criterion. Since there is still a considerable void in our knowledge of the plant and effects of the active drug contained in it, our recommendation is that marihuana be retained within schedule I at least until the completion of certain studies now underway to resolve this issue. If those studies make it appropriate for the Attorney General to change the placement of marihuana to a different schedule, he may do so in accordance with the authority provided under section 201 of the bill.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the administration's program.

Sincerely yours,

ROGER O. EGEBERG, M.D.,
Assistant Secetary for Health and Scientific Affairs.

OFFICE OF THE DEPUTY ATTORNEY GENERAL,
Washington, D.C., August 28, 1970.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives,
Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request for the views of the Department of Justice on an amendment to subsection 307(b) of H.R. 18583, which was agreed to by the Committee on Interstate and Foreign Commerce in executive session. This amendment is designed to afford persons registered under the bill the option of maintaining required records either separately or in such a manner that they are readily retrievable from their ordinary business records.

In order to comply with U.S. obligations under international treaties, protocols, and conventions, existing Federal law requires separate records to be kept for all narcotic drugs manufactured or distributed. However, there is no such requirement for stimulant and depressant drugs, which are presently regulated under the Drug Abuse Control Amendments of 1965 (P.L. 89–74, 79 Stat. 226). The Department agrees with the committee that there is no need at this time to require manufacturers and distributors of stimulant and depressant drugs to keep separate records, so long as the required records are kept in such a manner that they can be easily identified and separated out from the registrant's ordinary business records.

Subsequent to the committee's amendment, representatives of the Department of Justice met with committee staff to work out appropriate alternative language which would require the maintenance of separate records for narcotic drugs while at the same time insuring that records for nonnarcotic controlled substances will not have to be kept separate and apart from all other records. The agreed upon language reads as follows:

"or, alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant,"

The Department interprets the phase "readily retrievable" to mean that a distributor need only red-line, asterisk, or in some other manner identify all nonnarcotic controlled substance items on an invoice or other record he maintains. This is the present practice among many manufacturers and distributors, and is acceptable to the Department of Justice.

We appreciate your having afforded us the opportunity to express our views on the committee's amendment to this extremely significant legislation.

Sincerely,

RICHARD G. KLEINDIENST,
Deputy Attorney General.

EXECUTIVE OFFICE OF THE PRESIDENT,
BUREAU OF THE BUDGET,
Washington, D.C., March 6, 1970.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in reply to your request for the views of the Bureau of the Budget on H.R. 13743, a bill to protect the public health and safety by amending the depressant, stimulant, and hallucinogenic drug laws, and for other purposes.

For the reasons expressed by the Attorney General in his testimony on February 3, 1970, before your Subcommittee on Public Health and Welfare, the Bureau of the Budget recommends the enactment of S. 3246 as passed by the Senate on January 28, 1970.

Sincerely yours,

WILFRED H. ROMMEL,
Assistant Director for Legislative Reference.

DEPARTMENT OF THE TREASURY,
OFFICE OF THE GENERAL COUNSEL,
Washington, D.C., February 4, 1970.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Reference is made to your request for the views of this Department on H.R. 13743, to protect the public health and safety by amending the depressant, stimulant, and hallucinogenic drug laws, and for other purposes.

The Attorney General, on July 15, 1969, forwarded to the House of Representatives the administration's comprehensive legislative proposal to control narcotic and dangerous drugs. The proposed legislation incorporates the provisions of the administration's proposal except those relating to the control of narcotic drugs derived from opium and coca and the cannabis-based drugs. Those provisions are incorporated in H.R. 13742 which is pending before the Committee on Ways and Means.

The Department recommends the enactment of the administration's proposal.

The Department has been advised by the Bureau of the Budget that there is no objection from the standpoint of the administration's program to the submission of this report to your committee.

Sincerely yours,

ROY T. ENGLERT,
Acting General Counsel.

GENERAL SERVICES ADMINISTRATION,
Washington, D.C., March 10, 1970.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Your letter of September 15, 1969, requested the views of the General Services Administration on H.R. 13743, 91st Congress, a bill to protect the public health and safety by amending the depressant, stimulant, and hallucinogenic drug laws, and for other purposes.

GSA's interest in the bill arises from section 704, under which certain property may be seized by the Attorney General and subject to forfeiture to the United States.

Subsection 704(c) provides that, in the case of seized property, the Attorney General may either place the property under seal; remove it to a place designated by him; or require that the General Services Administration take custody and remove it to an appropriate location for disposition in accordance with law.

Subsection 704(e) provides that, in the case of forfeited property, the Attorney General may either retain it for official use; sell such property which is not required to be destroyed by law and which is not harmful to the public, with the additional provision that the proceeds may be disposed of for payment of certain expenses; require the General Services Administration to take custody and remove it for disposition in accordance with law; or forward it to the Bureau of Narcotics and Dangerous Drugs for disposition, which disposition may include delivery for medical or scientific use to any Federal or State agency, under regulations of the Attorney General.

Disposition of seized property could not be effected under the bill until after its forfeiture has occurred either by court action or by operation of law. Since GSA therefore would be unable to dispose of property merely seized, it would serve no useful purpose to require GSA to take custody of such property prior to forfeiture. Accordingly, it is recommended that the following changes be made on page 61 of the bill: add the word "or" after the semicolon on line 18; change the semicolon to a period and delete the word "or" on line 20; and delete paragraph (3), lines 21 through 24.

With respect to forfeited property, we feel that (a) it also should be made available to other Federal agencies for official use, if not required by the Attorney General, particularly when it may involve property such as aircraft, vehicles, or vessels; (b) there appears to be no need for additional authority to sell such property, since there is already adequate sales authority provided in title 40 United States Code 304f through 304m; and (c) such property forwarded to the Bureau of Narcotics and Dangerous Drugs for disposition should be limited to controlled dangerous substances. Therefore, in view of the above, we recommend that section 704(e) be replaced by the following new subsection:

"(e) Whenever property is forfeited under this act, the provisions of title 40 United States Code 304f through 304m shall apply: *Provided*, That the Attorney General may forward any controlled dangerous substances to the Bureau of Narcotics and Dangerous Drugs for disposition, which disposition may include delivery for medical or scientific use to any Federal or State agency, under regulations of the Attorney

General; and *Provided further*, That the proceeds of sale of any forfeited property may be used for payment of all proper expenses of the proceedings for forfeiture and sale, including expenses of seizure, maintenance of custody, advertising and court costs."

Subject to the above recommended changes, GSA has no objection to the enactment of H.R. 13743.

The Bureau of the Budget has advised that, from the standpoint of the administration's program, there is no objection to the submission of this report to your committee.

Sincerely,

ROD KREGER,
Assistant Administrator.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
OFFICE OF THE SECRETARY,
Washington, D.C., April 14, 1970.

HON. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This letter is in response to your request of September 15, 1969, for a report on H.R. 13743, a bill entitled the "Controlled Depressant and Stimulant Drugs Act of 1969."

Title I of the bill contains the findings of Congress with regard to the necessity of controlling dangerous substances and the definition of the bill's principal terms.

Title II designates the substances to be controlled and lists criteria to be considered by the Attorney General in deciding whether to add, delete, or reschedule substances as controlled dangerous substances. Before making this decision, the Attorney General must request the advice in writing of the Secretary of Health, Education, and Welfare and of the Scientific Advisory Committee established by the act, both of which must render such advice within a reasonable time. Each controlled substance is listed in one of four hierarchal schedules depending on its relative abuse potential, medical usefulness, and dependence-producing liability.

Title III provides for the regulation of the manufacture, distribution, and dispensing of controlled substances. All persons must obtain an annual registration from the Attorney General before engaging in the manufacture, distribution, or dispensing of any controlled substance. The Attorney General must establish quotas for the production of schedule I and II substances sufficient to provide for the country's estimated medical, scientific, and industrial needs for lawful export and for maintenance of reserve stocks.

Title IV provides for the monitoring and control of the import and export of controlled substances. The controls are patterned after the presently existing Narcotic Drugs Import and Export Act with alterations sufficient to extend them to other dangerous substances.

Title V sets out the bill's offenses and penalties. In general the bill's penalty structure is modeled after existing law, although with respect to some of the specific substances listed in the bill, its penalties are more severe than under existing law. A novel provision of the bill which stems generally from a provision of the 1968 penalty amendments to the Federal Food, Drug, and Cosmetic Act, gives the court discretion,

without entering a judgment of guilt and without the defendant's consent, to place on probation anyone who is found guilty of possession of a controlled dangerous substance and who has never previously been convicted under the bill or any other Federal or State law relating to stimulant, depressant, or hallucinogenic drugs. If the conditions of probation are fulfilled, the court must dismiss the proceedings, which in that event are not to count as a conviction, but if the probation terms are violated the court may enter a guilty verdict and impose the allowed penalty. This procedure may be used only once with respect to any person.

The final titles contain various administrative provisions, including authority for the Attorney General to carry out educational or research programs necessary for the effective enforcement of the act and the requirement that he appoint a committee of experts of diversified professional backgrounds, selected from a list drawn by the National Academy of Sciences, to advise him with respect to dangerous substances which may be subject to control. The bill would repeal the Food and Drug Act's special provisions relating to depressant or stimulant drugs.

Expressly excluded from the scope of H.R. 13743 are the substances covered by present tax laws (narcotics and marihuana) and for that reason covered by a separate bill, H.R. 13742, which was referred to the Ways and Means Committee. The latter bill excludes depressant or stimulant drugs, which are covered by H.R. 13743. Taken together, the two bills are the equivalent of the original administration bill (S. 2637) submitted to Congress by the Attorney General on this subject. Since the framework of the two bills is the same and their drug coverage provisions are complementary, and since the division is based on committee jurisdiction, we recommend that the legislation as finally enacted be a single comprehensive law for all dangerous controlled substances, with appropriate distinctions within the comprehensive law.

In addition to this unification, we strongly support the present version of the administration proposal contained in S. 3246 as passed unanimously by the Senate on January 28, 1970. Especially important are the provisions of S. 3246 to make penalties more flexible and more appropriately adapted to various offenses. We note, further, that under S. 3246 selection of the members of the Scientific Advisory Committee (from a list drawn by the National Academy of Sciences) is to be made by the Attorney General after consultation with this Department. We also invite favorable attention to the provisions of section 801 of the Senate bill requiring this Department and the Department of Justice to appoint jointly a committee to study all available information concerning marihuana and make recommendations with respect to the degree of control to be exercised over marihuana use.

Specific comments on the provisions of S. 3246 as well as H.R. 13743 have been presented by administration witnesses, including representatives of this Department, to the Public Health and Welfare Subcommittee in its hearings of February 3 and 4, 1970. These are strongly in support of the enactment of comprehensive legislation in the version of S. 3246 as passed by the Senate.

We are advised by the Bureau of the Budget that there is no objection to the presentation of this report from the standpoint of the administration's program.

Sincerely,

ROBERT H. FINCH, *Secretary.*

DEPARTMENT OF THE TREASURY,
OFFICE OF THE GENERAL COUNSEL,
Washington, D.C., November 17, 1969.

Hon. HARLEY O. STAGGERS,
Chairman, Interstate and Foreign Commerce Committee,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Reference is made to your request for the views of this Department on H.R. 10342, to authorize the Secretary of Health, Education, and Welfare to make grants for treatment and rehabilitation centers for drug addicts and drug abusers, and to carry out drug abuse education curriculum programs, and to strengthen the coordination of drug abuse control programs by establishing the National Council on Drug Abuse Control.

The proposed legislation would (1) authorize the Secretary of Health, Education, and Welfare to make grants to assist States and nonprofit private organizations in establishing, developing, equipping, and operating drug addict prevention, treatment, and rehabilitation centers, including the training and salaries of personnel necessary to operate such centers; (2) authorize the Secretary to make grants to assist medical schools and institutions of higher learning in developing and carrying out curriculum programs on drug abuse education; and (3) establish in the Executive Office of the President the National Council on Drug Abuse Control to advise and assist the President on drug control education programs and on drug abuse law enforcement activities. It would authorize to be appropriated over the 5 fiscal years 1970–74 $350 million to carry out (1) above, and $100 million to carry out (2) above.

The Department has no independent knowledge as to the necessity or desirability of the programs proposed by the bill and accordingly has no comment to make with respect to its general merits.

The Department has been advised by the Bureau of the Budget that there is no objection from the standpoint of the administration's program to the submission of this report to your committee.

Sincerely yours,

PAUL W. EGGERS, *General Counsel.*

DEPARTMENT OF THE TREASURY,
OFFICE OF THE GENERAL COUNSEL,
Washington, D.C., February 4, 1970.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Reference is made to your requests for the views of this Department on H.R. 11701, H.R. 12882, and H.R. 12894, bills relating to narcotic and drug abuse care and control, and H.R. 11697, a bill relating to marihuana.

On July 15, 1969, the Attorney General transmitted to the Congress a draft bill, to protect the public's health and safety by amending the narcotic, depressant, stimulant and hallucinogenic drug laws, and for other purposes.

The Department recommends favorable consideration of the Department of Justice proposed legislation in lieu of further action on H.R. 11701, H.R. 12882, H.R. 12894 and H.R. 11697.

The Department has been advised by the Bureau of the Budget that there is no objection from the standpoint of the administration's program to the submission of this report to your committee.

Sincerely yours,

ROY T. ENGLERT,
Acting General Counsel.

VETERANS' ADMINISTRATION,
OFFICE OF THE ADMINISTRATOR OF VETERANS, AFFAIRS,
Washington, D.C., October 30, 1969.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: We are pleased to furnish the following comments in response to your request for a report by the Veterans' Administration on H.R. 10408, 91st Congress, a bill to amend the Public Health Service Act to authorize the Secretary of Health, Education, and Welfare to provide financial assistance for education and information programs relating to drugs and their abuse, and for other purposes.

The bill would authorize the Secretary of Health, Education, and Welfare to assist projects designed to educate the public on problems of drug abuse by making grants to or entering into contracts with public or private nonprofit institutions of higher education or other public or private nonprofit agencies, institutions, or organizations. Such projects would include the development of curriculums on the use and abuse of drugs, the demonstration and testing of the effectiveness of such curriculums, and the dissemination of curricular materials and other information regarding the use and abuse of drugs.

Additionally, the bill provides for the establishment of an Advisory Committee on Drug Abuse Education to advise the Secretary concerning the administration and operation of the programs contemplated by the bill, to review and evaluate the implementing programs and projects and to make recommendations with respect thereto.

We are, of course, vitally concerned with the problem of drug addiction in connection with our extensive medical programs. While we are in agreement with the purposes and objectives of H.R. 10408, we defer to the views of the Department of Health, Education, and Welfare, which would have overall administrative responsibility for the proposed program, as to whether the approaches employed in this bill are the most effective methods for achieving its aims.

We are advised by the Bureau of the Budget that there is no objection to the presentation of this report from the standpoint of the administration's program.

Sincerely,

DONALD E. JOHNSON, *Administrator.*

DEPARTMENT OF DEFENSE,
OFFICE OF THE GENERAL COUNSEL,
Washington, D.C., January 20, 1970.

Hon. HARLEY O. STAGGERS,
Chairman, Interstate and Foreign Commerce Committee,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Reference is made to your request for the views of the Department of Defense with respect to H.R. 10408, 91st Congress, a bill to amend the Public Health Service Act to authorize the Secretary of Health, Education, and Welfare to provide financial assistance for education and information programs relating to drugs and their abuse, and for other purposes.

The purpose is as stated in the title. The bill also provides for the establishment of an Advisory Committee on Drug Abuse Education to assist the Secretary, and in addition the functions, powers, and duties of the Attorney General under Reorganization Plan No. 1 of 1968 to designate a drug as a depressant or stimulant or to find that a drug or other substance is an opiate are transferred to the Secretary of Health, Education, and Welfare. The attendant positions, personnel assets, property and unexpended balances of authorizations, allocations and funds are likewise transferred to that Secretary.

Inasmuch as the bill pertains to the personnel, functions, duties and authorizations of the Departments of Justice and Health, Education, and Welfare, the Department of Defense defers to the views of those agencies as to the merits of the bill.

The Bureau of the Budget advises that, from the standpoint of the administration's program, there is no objection to the presentation of this report for the consideration of the committee.

Sincerely,

L. NIEDERLEHNER,
Acting General Counsel.

VETERANS' ADMINISTRATION,
OFFICE OF THE ADMINISTRATION OF VETERANS AFFAIRS,
Washington, D.C., December 12, 1969.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: We are pleased to furnish the following comments in response to your request for a report by the Veterans' Administration on H.R. 10342, 91st Congress, a bill to authorize the Secretary of Health, Education, and Welfare to make grants for treatment and rehabilitation centers for drug addicts and drug abusers, and to carry out drug abuse education curriculum programs, and to strengthen the coordination of drug abuse control programs by establishing the National Council on Drug Abuse Control.

The bill is designed to deal with the problems of drug abuse and addiction in several ways. It would provide for grants to assist States and nonprofit private organizations in the establishment, development, and maintenance of prevention, treatment, and rehabilitation centers. It would also provide financial assistance to medical schools and other institutions of higher learning in the development and

implementation of drug abuse education curriculum programs. Finally, it would provide for the establishment of a National Council on Drug Abuse Control to coordinate programs conducted by Federal, State, and local public agencies or private organizations.

We are, of course, vitally concerned with the problems of drug addiction in connection with our extensive medical programs, and we note that the Administrator is designated as a member of the proposed National Council. The bill does not otherwise appear to impose additional administrative responsibilities upon the Veterans' Administration.

While we are in sympathy with the objectives of H.R. 10342, we defer to the view of the Department of Health, Education, and Welfare, which would have overall administrative responsibility, as to whether the approaches employed in this bill are the most effective methods for achieving its aims.

We are advised by the Bureau of the Budget that there is no objection to the presentation of this report from the standpoint of the administration's program.

Sincerely,

DONALD E. JOHNSON, *Administrator.*

TITLE III—IMPORTATION AND EXPORTATION; AMENDMENTS AND REPEALS OF REVENUE LAWS

I. Purpose

Title III, which is the result of work by the Committee on Ways and Means, has two major purposes. First, it would unify and integrate statutory controls over importation and exportation of narcotics and other dangerous drugs, reformulating the provisions of existing law so as to bring them into conformity with the proposed new system established by Title II. Second, it is designed to improve such controls by making the changes which are voted in the general discussion below. The changes providing for stricter supervision of the importation and exportation of depressant and stimulant drugs are intended to prevent the diversion of these substances into illicit channels, a problem which present statutory requirements have proven insufficient to meet. Through the changes in the penalty provisions of existing law, particularly through elimination of mandatory minimum sentences, the Committee has sought to arrive at a more realistic, more flexible, and thus more effective system of punishment and deterrence of violations of the Federal narcotic and dangerous drug laws.

II. General Discussion

Title III was developed by the Committee on Ways and Means after consideration of Administration proposals as contained in H.R. 13742 and H.R. 17463. It pertains primarily to the regulation of importation and exportation of the substances controlled under the provisions of Title II. In addition, since the bill provides for a comprehensive system of regulation of narcotics and dangerous drugs, title III contains the necessary repeals of existing narcotics and marihuana laws, along with conforming amendments. Its short title is the "Controlled Substances Import and Export Act."

Title III is designed to replace all present law (except the smuggling law, 18 U.S.C. 545) relating specifically to the importation and exportation of narcotic drugs and marihuana and to strengthen the present controls over the importation and exportation of depressant and stimulant drugs. As in the case of Title II, a number of provisions of Title III derive directly from the substance of existing statutes.

The basic law now controlling the importation and exportation of narcotics and marihuana is the Narcotic Drugs Import and Export Act (21 U.S.C. 171, 173, 174–184, 185). Existing law governing the importation and exportation of depressant and stimulant drugs is Section 801 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 381).

Through the provisions of Title III, the importation and exportation of *all* controlled substances—narcotics, marihuana, depressants, stimulants, and any other dangerous substances which may be brought under the controls provided by Title II—would be covered by a single statute, except that the safeguards of the Federal Food, Drug and Cosmetic Act against adulterated or misbranded drugs and

unapproved new drugs would continue to apply. These provisions of title III are based upon the schedules established by Title II, with the requirements for legal import or export of each drug or other substance varying according to its assigned schedule. Penalities for illegal import or export are to an extent also dependent upon the schedule of the substance involved.

Specifically, the title makes it unlawful to import into the United States any schedule I or II substance or any narcotic drug contained in schedule III, IV, or V except with the special consent of the Attorney General. Any other controlled substance could be imported only for medical, scientific, or other legitimate uses, and only in accordance with whatever notification or declaration requirements might be prescribed by the Attorney General. No controlled substance could be exported except in compliance with specified procedures, which would vary according to the schedule of the substance. Controls are provided for the transshipment of controlled substances through the United States to other countries and for their in-transit shipment within the United States for immediate export, and for the possession of controlled substances on board any vessel or aircraft or other vehicle arriving in or departing from the United States.

The title would specifically authorize the Attorney General to issue regulations exempting an individual from the above-mentioned restrictions if he is merely carrying a legitimate drug for his own personal medical use, or for administration to an animal accompanying him, and if he has lawfully obtained it and conforms with whatever notification procedures the Attorney General may require. It is the Committee's intent, in including this provision, that the Attorney General will exercise this authority so as to allow the exemption in all appropriate cases. In the case of exportation, the regulations would be consistent with the obligations of the United States under the Single Convention on Narcotic Drugs, 1961. The Attorney General is expected to give reasonable notice to travelers of the requirements of title III and his regulations thereunder, and to provide under these regulations a reasonably convenient declaration system for travelers.

Title III also requires yearly registration with the Attorney General of all persons importing any controlled substance and all persons exporting controlled substances in schedules I, II, III, or IV. The requirements are similar and supplementary to those created by Title II.

The title establishes penalties, for violation of the provisions therein, separate and apart from those provided under Title II.

Changes from existing law

Basic changes contemplated by Title III in the substance of existing law are as follows:

(1) Depressant or stimulant drugs classified in schedule I or II (which would initially include only the hallucinogens) would be subject to import controls similar to those provided by existing law for narcotic drugs and marihuana.

(2) In the case of stimulant and depressant drugs not classified in schedule I or II (under the present schedule this would include all such drugs except for the hallucinogens), the Attorney General could prescribe notification or declaration requirements for importation.

(3) The Attorney General would be given authority to permit the importation of finished narcotics in an emergency or because of inadequate competition among domestic manufacturers.

(4) With regard to exportation, hallucinogens would be subject to the following new controls:

(*a*) the country of destination must have a system, deemed adequate by the Attorney General, for the control of imports of such substances;

(*b*) the export must be consigned to a properly licensed receiver;

(*c*) evidence must be furnished the Attorney General that the substance is to be used in the receiving country for a legitimate need and purpose; and

(*d*) a permit to export the substance must be issued.

(5) In the case of depressant and stimulant drugs other than the hallucinogens, it would be required for legal export that:

(*a*) the Attorney General be furnished documentary proof that importation is not contrary to the laws or regulations of the country of destination;

(*b*) special invoices with such information as the Attorney General may prescribe, accompany the shipment, and that additional copies of the invoice be forwarded to the Attorney General before the substances are exported.

(6) Registration of importers and exporters of any substances classified in schedule I or II would be based on the Attorney General's determination that this would be consistent with the public interest and with certain treaty obligations. In other cases, registration would be based on his determination that it would not be inconsistent with the public interest. Registration would not be a matter of right, as under existing law. Registration criteria for schedule I or II substances as required by both this title and Title II would approximate to the licensing provisions of existing law for manufacturers of narcotics.

(7) Penalties for illegal import or export would be revised as indicated in the following table:

	Offense	Maximum fine	Sentence	Special parole term	Probation or suspended sentence permitted	Parole permitted
1st offense	Present law:					
	Narcotics	$20,000	5 to 20 yrs	No	No	No.
	Marihuana	20,000	5 to 20 yrs	No	No	Yes.
	Dangerous Drugs	10,000	Up to 5 yrs	No	Yes	Yes.
	H.R. 18583:					
	I & II narcotics	25,000	Up to 15 yrs	At least 3 years.	Yes	Yes.
	I & II non-narc. & III substances.	15,000	Up to 5 yrs	At least 2 years.	Yes	Yes.
	IV substances	15,000	Up to 5 yrs	At least 1 year.	Yes	Yes.
	V substances	15,000	Up to 5 yrs	No	Yes	Yes.
2d offense	Present law:					
	Narcotics	20,000	10 to 40 years	No	No	No.
	Marihuana	20,000	10 to 40 years	No	No	Yes.
	Dangerous Drugs	20,000	Up to 5 years	No	Yes	Yes.
	H.R. 18583:					
	I & II narcotics	50,000	Up to 30 years.	At least 6 years.	Yes	Yes.
	I & II non-narc. & III substances.	30,000	Up to 10 years.	At least 4 years.	Yes	Yes.
	IV substances	30,000	Up to 10 years.	At least 2 years.	Yes	Yes.
	V substances	30,000	Up to 10 years.	No	Yes	Yes.

(8) A separate penalty would be provided for importation of a schedule I, II, III, or IV substance for transshipment to another country, or for the in-transit shipment of such a substance, unless certain requirements were met. The penalty would be a civil penalty of up to $25,000 unless the violation were committed knowingly or intentionally and criminally prosecuted in which case it would be imprisonment for up to 1 year and/or a fine of up to $25,000.

III. Section-by-Section Analysis of Title III

Section 1000. Short Title

This section designates title III of the bill as the "Controlled Substances Import and Export Act".

Part A. Importation and Exportation

Section 1001. Definitions

Subsection (a)(1) of this section defines the term "import" to mean, with respect to any article, any bringing in or introduction of such article into any area, regardless of whether or not the bringing in or introduction constitutes an importation within the meaning of the tariff laws within the United States.

Subsection (a)(2) provides that the term "customs territory of the United States" has the meaning assigned to such term by general headnote 2 to the Tariff Schedules of the United States (19 U.S.C. 1202). Headnote 2 of the Tariff Schedules defines "customs territory of the United States" to mean "only the States, the District of Columbia, and Puerto Rico".

Subsection (b) provides that for purposes of title III the terms "controlled substance", "distribute", "manufacture", "narcotic drug", "ultimate user", and "United States" have the meanings assigned to such terms by section 102 of the bill.

Section 1002. Importation of controlled substances

Subsection (a) of this section provides that it is unlawful to import into the customs territory of the United States from any place outside thereof but within the United States, or to import into the United States from any place outside thereof, any controlled substance in schedule I or II of title II, or any narcotic drug listed in schedule III, IV or V of such title. (Section 102(26) of the bill defines United States, when used in a geographic sense, as including all places and waters, continental or insular, subject to the jurisdiction of the United States.)

Paragraphs (1) and (2) of this subsection provide for specific exceptions to the prohibition against the importation of controlled substances contained in subsection (a). Paragraph (1) permits the importation of those amounts of crude opium and coca leaves which the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes.

Paragraph (a)(2) continues the present policy of restricting imports of narcotic substances other than opium. The only exceptions are to meet an emergency supply situation in the United States, or an inadequately competitive situation which cannot be corrected by increasing the number of registered domestic manufacturers.

Paragraph (2) permits the importation of those amounts of any schedule I or II substances or any narcotic drugs listed in schedule III, IV, or V, which the Attorney General finds to be necessary to provide for the medical, scientific, or other legitimate needs of the United States, but only (a) during an emergency situation in which domestic supplies of such substances or drugs are found to be inadequate by the Attorney General, or (b) if the Attorney General finds that competition among domestic manufacturers of such substances is inadequate and will not be rendered adequate by registration of additional manufacturers under section 303 of title II.

Subsection (b) makes unlawful the importation into the customs territory of the United States from any place outside thereof (but within the United States), and the importation into the United States from any place outside thereof, of any nonnarcotic controlled substance in schedule III, IV, or V, unless the substance is imported for medical, scientific, or other legitimate uses, and pursuant to notification or declaration requirements prescribed by regulations of the Attorney General.

Subsection (c) authorizes the Attorney General to permit the importation of additional amounts of coca leaves, but requires all cocaine and ecgonine (and all salts, derivatives, and preparations from which cocaine or ecgonine may be synthesized or made) contained in such additional amounts of coca leaves to be destroyed under government supervision.

Section 1003. Exportation of controlled substances

Subsection (a) of this section makes unlawful the exportation from the United States of any narcotic drug in schedule I, II, III, or IV unless—

(1) it is exported to a country which is a party to one of four international conventions relating to control of narcotic drugs;

(2) the country has a system for the control of imports of narcotic drugs which is in conformity with the requirements of the conventions to which it is a party and which the Attorney General deems adequate;

(3) certain import permits (or licenses) are issued by the country of import;

(4) the exporter furnishes to the Attorney General evidence that (A) the narcotic drug is to be applied exclusively to medical or scientific uses within the country of import, and (B) there is an actual need for the narcotic drugs for medical or scientific uses within such country; and

(5) a permit to export the drug has been issued by the Attorney General.

Subsection (b) of this section permits the Attorney General to authorize (notwithstanding subsection (a)) the exportation of narcotic drugs for special scientific purposes in the country of destination, provided that the authorities of the country of destination will permit the importation of the drug for such purposes.

Subsection (c) prohibits the exportation from the United States of any nonnarcotic controlled substance in schedule I or II unless—

(1) it is exported to a country which has an adequate system for the control of imports of such substances;

(2) the substance is consigned to a holder of such permits or licenses as may be required under the laws of the country of import;

(3) evidence is furnished the Attorney General that (A) the substance is exclusively for medical, scientific, or other legitimate uses within the country of import, (B) it will not be exported from such country, and (C) there is an actual need for the substance for medical, scientific, or other legitimate uses within the country; and

(4) a permit to export the controlled substance has been issued by the Attorney General.

Subsection (d) contains authority to permit exports for special scientific purposes similar to that in subsection (b).

Subsection (e) prohibits the exportation from the United States to any other country of any nonnarcotic controlled substance in schedule III or IV or any controlled substance in schedule V unless—

(1) there is furnished (before export) to the Attorney General documentary proof that importation is not contrary to the laws or regulations of the country of destination; and

(2) certain requirements respecting invoices are met.

Section 1004. Transshipment and in-transit shipment of controlled substances

This section provides an exception to the rules of sections 1002 and 1003 (relating to imports and exports) for certain transshipments and in-transit shipments of controlled substances. Persons who comply with the requirements of this section would not be required to register as importers or exporters. Under paragraph (1), a controlled substance in schedule I may be imported into the United States for transshipment to another country, or be transferred or transshipped from one vessel, vehicle, or aircraft to another vessel, vehicle, or aircraft within the United States for immediate exportation, if and only if it is so imported, transferred, or transshiped for scientific, medical, or other legitimate purposes in the country of destination, and with the prior written approval of the Attorney General.

Under paragraph (2), a controlled substance in schedule II, III, or IV may be so imported, transferred, or transshipped if and only if advance notice is given to the Attorney General in accordance with regulations.

Section 1005. Possession on board vessels, etc., arriving in or departing from United States

This section makes it unlawful for any person to bring or possess on board any vessel or aircraft, or on board any vehicle of a carrier, arriving in or departing from the United States or the customs territory of the United States, a controlled substance in schedule I or II or a narcotic drug in schedule III or IV, unless such substance or drug is a part of the cargo entered in the manifest or part of the official supplies of the vessel, aircraft, or vehicle.

Section 1006. Exemption authority

Subsection (a) of this section authorizes the Attorney General, by regulation, to exempt from sections 1002 (a) and (b), 1003, 1004, and 1005 any individual who has a controlled substance (except a substance in schedule I) in his possession for his personal medical use, or for administration to an animal accompanying him, if he lawfully obtained such substance and he makes such declaration (or gives

such other notification) as the Attorney General may by regulation require. As noted above, it is anticipated the Attorney General will exercise his authority under this subsection.

Subsection (b) contains authority to exempt from this title particular compounds, etc., which is similar to the Attorney General's authority under section 202(d).

Section 1007. Persons required to register

Subsection (a) of this section prohibits any person from—

(1) importing into the customs territory of the United States from any place outside thereof (but within the United States), or importing into the United States from any place outside thereof, any controlled substance in schedule I, II, III, IV, or V of title II, or

(2) exporting from the United States any controlled substance in schedule I, II, III, or IV,

unless he is registered under section 1008, or is exempt from registration by reason of subsection (b).

Subsection (b) exempts from the registration requirements of subsection (a) (1) agents and employees of registrants, (2) carriers and warehousemen, (3) ultimate users, and, (4) importers and exporters for whom the Attorney General has waived the registration requirements. Section 102(25) of the bill defines an ultimate user as a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household. Persons exempted under this section may possess controlled substances for the purpose for which the exemption is available.

Section 1008. Registration Requirements

Subsection (a) of this subsection directs the Attorney General to register an applicant to import or export a controlled substance in schedule I or II if he determines that registration is consistent with the public interest and with United States obligation under international treaties, conventions, and protocol in effect on the effective date of section 1008. In determining the public interest, he is to consider the same factors which he is required to consider in registering manufacturers under section 303(a). Subsection (b) provides that registration under subsection (a) does not entitle a registrant to import or export controlled substances in schedule I or II other than those specified in the registration.

Subsection (c) directs the Attorney General to register an applicant to import a controlled substance in schedule III, IV, or V or to export a controlled substance in schedule III or IV, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest he is to consider the same factors that he considers in registering manufacturers under section 303(d).

Subsection (d) provides that no registration may be issued under part A of title III for a period in excess of one year, and that, unless the regulations of the Attorney General otherwise provide, sections 302(f), 304, 305, and 307 will apply to registrants under this section to the same extent such sections apply to registrants under section 303.

Subsection (e) authorizes the Attorney General to promulgate rules and regulations and to charge reasonable fees relating to the regis-

tration under this section. Subsection (f) provides that registrants under this section may import or export (and for purposes thereof, possess) controlled substances to the extent authorized by their registration and in conformity with the other provisions of this title and title II. Subsection (g) requires a separate registration at each principal place of business where the applicant imports or exports controlled substances.

Subsection (h) provides that, except in emergency situations described in section 1002(a)(2)(A), prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in schedule I or II, and prior to issuing a regulation under section 1002(a) authorizing the importation of such a substance, the Attorney General must give manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Section 1009. Manufacture or distribution for purposes of unlawful importation

This section makes it unlawful for any person to manufacture or distribute a controlled substance in schedule I or II knowing or intending that such substance be unlawfully imported into the United States. This section is intended to reach acts of manufacture or distribution committed outside the territorial jurisdiction of the United States.

Section 1010. Prohibited acts A—penalties

This section sets penalties for any person who contrary to section 1002, 1003, 1005, or 1007 knowingly or intentionally imports or exports a controlled substance, or brings or possesses on board a vessel, aircraft, or vehicle a controlled substance, or who contrary to section 1009 manufactures or distributes a controlled substance for purposes of unlawful importation.

Subsection (b)(1) provides that a violation with respect to a narcotic drug in schedule I or II will be punished by a fine of not more than $25,000, or by imprisonment of not more than 15 years, or both. If the sentence provides for imprisonment, it must include a special parole term of not less than 3 years in addition to the term of imprisonment.

Subsection (b)(2) provides that a violation with respect to a controlled substance other than a narcotic drug in schedule I or II will be punished by a fine of not more than $15,000, or by imprisonment of not more than 5 years, or both. If the sentence provides for imprisonment, it must, in addition to the term of imprisonment, include (A) a special parole term of not less than 2 years if such controlled substance is in schedule I, II or III, or (B) a special parole term of not less than 1 year if such controlled substance is in schedule IV.

Subsection (c) provides that a special parole term imposed under this section may be revoked if its terms and conditions are violated, and sets out the consequences of such a revocation.

Section 1011. Prohibited acts B—penalties

This section sets penalties for persons who violate section 1004.

Paragraph (1) provides that any such person shall, with respect to any such violation, be subject to a civil penalty of not more than

$25,000. Sections 402 (c)(1) and (c)(3) are applicable to civil penalties assessed under this paragraph. However, if such a violation is prosecuted by an information or indictment which alleges that the violation was committed knowingly or intentionally and the trier of fact specifically finds that the violation was so committed, then, under paragraph (2) such person may be sentenced to imprisonment for not more than 1 year or a fine of not more than $25,000 or both.

Section 1012. Second or subsequent offenses

This section provides that any person convicted of any offense under this part is, if the offense is a second or subsequent offense, punishable by a term of imprisonment twice that otherwise authorized, by twice the fine otherwise authorized, or by both. In addition, if the conviction is for an offense punishable under section 1010(b) and if it is the offender's second or subsequent offense, the court must impose twice the special parole term otherwise authorized.

Under subsection (b) a person is considered to be convicted of a second offense if, prior to the commission of such offense, prior convictions of him for a felony under any provision of this title or title II of the bill or under any other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant drugs, have become final. Section 409 applies with respect to any proceeding to sentence a person under this section.

Section 1013. Attempt and conspiracy

This section provides that any person who attempts or conspires to commit any offense defined in this title is punishable by imprisonment or fine or both which may not exceed the maximum punishment prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

Section 1014. Additional penalties

This section provides that any penalty imposed for violation of this title shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.

Section 1015. Applicability of part E of title II

This section provides that part E of title II applies with respect to functions of the Attorney General (and of officers and employees of the Bureau of Narcotics and Dangerous Drugs) under title III, to administrative and judicial proceedings under title III, and to violations of title III, to the same extent that such part applies to those functions, proceedings, and violations under title II.

Section 1016. Authority of Secretary of Treasury

This section provides that nothing in the bill shall derogate from the authority of the Secretary of the Treasury under the customs and related laws. This will assure the continuation of the responsibilities within the jurisdiction of the Treasury Department regarding the unlawful importation of narcotics and dangerous drugs. Your committee is informed that the words "customs and related laws" include over 40 separate existing statutes that Customs enforces or assists in enforcing.

PART B. AMENDMENTS AND REPEALS; TRANSITIONAL AND EFFECTIVE DATE PROVISIONS

Section 1101. Repeals

This section repeals the provisions of existing law which deal with narcotics and or marihuana and which are presently within the jurisdiction of the Ways and Means Committee. The principal laws repealed are the Harrison Narcotics Act (sections 4701–4736 of the Internal Revenue Code of 1954), the Marihuana Tax Act (sections 4741–4762 of the 1954 Code), the Narcotic Drugs Import and Export Act (21 U.S.C. 171, 173, 174, 176–184, 185), and the Narcotics Manufacturing Act of 1960 (21 U.S.C. 501–517).

Section 1102. Conforming amendments

This section makes conforming amendments to various provisions of law within the jurisdiction of the Ways and Means Committee to reflect the enactment of the bill and the repeals in section 1101.

Section 1103. Pending proceedings

Subsection (a) of this section provides that prosecutions for any violation of law occurring prior to the effective date of the repealer section (sec. 1101) will not be affected by, or abated by reason of, the repeals or the conforming amendments made by section 1101 or 1102.

Subsection (b) provides that civil seizures or forfeitures and injunctive proceedings commenced prior to such effective date will not be affected by, or abated by reason of, the repeals or conforming amendments.

Section 1104. Provisional registration

This section provides a provisional registration system for importers and exporters which is similar to that provided by section 703 for persons required to register under title II of the bill.

Section 1105. Effective dates and other transitional provisions

This section contains the effective date provisions for title III of the bill. These provisions parallel those for title II. In general, title III takes effect on the first day of the seventh calendar month that begins after the day immediately preceding the date of enactment; however, sections 1001, 1006, 1013, 1103, 1104, and 1105 take effect on the date of enactment. A special provision provides for postponing the effective date of the repeal of the licensing and quota provisions of the Narcotics Manufacturing Act of 1960 for any period for which the Attorney General postpones the effective date of the quota provisions of section 306 of title II of the Act. Subsection (d) contains a provision, similar to section 705, extending the applicability of regulations, etc., issued under existing law.

CHANGES IN EXISTING LAW

Changes in existing law made by the reported bill are set forth in part 2 of this report, printed as a separate document.

ADDITIONAL VIEWS

The main report of this committee accurately states that drug abuse in the United States is a problem of most serious concern. We feel that it is serious and complex enough to deserve precise congressional treatment, not the quick, rimfire legislative reflex action often set off by dramatic events and emotional responses. Initially, the evil involved here deserves accurate description. It is not "drug abuse"; it is abuse of people by misuse of drugs, and it is important that we not further abuse people by misuse of law and process in attempting to bring about reform.

It must be said, though, in behalf of the committee that its majority was not impervious to constitutional criticism and to suggestions going toward due—and fair—process. All of the presumptions of guilt contained in the language submitted by the Justice Department which appeared in the original bill have been omitted upon the suggestions offered by the signers of these additional views. It must be said, too, that the subcommittee and the full committee worked diligently to present a framework upon which to build solid legislation for control of narcotics, psychedelics, amphetamines, barbiturates, and tranquilizers in a single piece of legislation. We join in this endeavor, and each of us joined in the unanimous vote to bring this matter to the floor of the House.

Nevertheless, serious defects remain in the legislation as reported: defects which may cause unnecessary and unjust pain particularly to young people and their anxious parents, defects which may unnecessarily place serious constitutional impediments in the way of immediate enforcement, and defects which go against the grain of Anglo-American concepts of due process.

Since other provisions of the bill are in general wholesome we will pass at once to these defects. They fall in these categories:

I. Those provisions pertaining to the continuing criminal activity section, and

II. Those provisions pertaining to the no-knock section.

Let us consider them in order:

I. The Continuing Criminal Activity Provision

A. Origin of continuing criminal enterprise provision

Three variations of the "continuing criminal activity" concept appear in versions of legislation before Congress. The concept is contained in S. 30, relating to the control of organized crime, in a section called "Dangerous Special Offender Sentencing." The provision of that section most comparable to the provisions in this bill appears in the language of title X, section 1001 of S. 30. It would provide a new section in chapter 227, title 18, United States Code, Section 3575. Subsection (e) of that title would provide in part:

(e) A defendant is a special offender for purposes of this section if—

* * * * * * *

(2) The defendant committed such felony as part of a pattern of conduct which was criminal under applicable laws of any jurisdiction, which constituted a substantial source of his income, and in which he manifested special skill or expertise; * * *

This provision in the organized crime legislation deals with sentencing, as does the language of H.R. 18583 as originally introduced.

B. CONTINUING CRIMINAL ENTERPRISE PROVISIONS OF THIS BILL

The language in H.R. 18583 is somewhat different but is essentially to the same effect. It is, as it appears in its final form in the bill, as follows:

(b) For purposes of subsection (a), a person is engaged in a continuing criminal enterprise if—

(1) he violates any provision of this title or title III the punishment for which is a felony, and

(2) such violation is a part of a continuing series of violations of this title or title III—

(A) which are undertaken by such person in concert with five or more other persons with respect to whom such person occupies a position of organizer, a supervisory position, or any other position of management, and

(B) from which such person obtains substantial income or resources.

C. COMMON PROVISIONS OF BOTH BILLS

In both these bills, S. 30 and H.R. 18583 in its original form, the prosecuting attorney is called upon, in order to institute the special sentencing procedures, to file with the court an instrument specifying that the defendant falls in the category of a special offender, in which case special procedures are provided for sentencing.

Both bills provide for a hearing before sentencing wherein the defendant is permitted the ordinary representation and process, except that he is to be afforded only "the substance of such parts of the presentence report as the court intends to rely upon" and this only if there are not "placed in the record compelling reasons for withholding particular information."

D. ORIGINAL CONTINUING CRIMINAL ENTERPRISE PROVISIONS

Though the original provisions of the continuing criminal enterprise section are not contained in the bill as finally reported (the language quoted above *is* in the bill), it is important to discuss them for three reasons:

(1) They show the history, development, and rationale of the special offender concept which originated with the Justice Department;

(2) Some of the criticisms relating to them are also applicable to the amended provision in the reported bill; and

(3) There is substantial Justice Department sentiment to retain the language of the original bill, and members may be called upon to choose between the original language and the amended language.

Let us comment briefly on these three points:

First, there can be no doubt that the Justice Department in S. 30 and in H.R. 18583 and its precursors has shown little sensitivity either toward constitutional rights or toward modern concepts of penology and rehabilitation. Whatever bill is passed may be expected to be enforced by a department affected by those predilections reflected in its original recommendations. Therefore, it is necessary for Congress to speak clearly and unambiguously in opposition to peremptory sentencing practices if such are to be avoided.

Second, since some of the provisions are also applicable to the amended provision in the reported bill, testimony by the American Bar Association and the Association of the Bar of the City of New York on S. 30 are applicable to the reported bill.

Third, if an amendment is offered in behalf of the administration, it is important for members to know that the Dingell Amendment—though far from perfect—cures serious additional constitutional defects contained in the original bill. These are discussed below.

E. OBJECTIONS TO ORIGINAL PROVISIONS

The serious objections to the original language of H.R. 18583 which were eliminated by the Dingell amendment are as follows:

(1) Under the original language the court would have before him, in addition to the indictment, a statement that the defendant is a person who has been involved in a continuing criminal enterprise, which statement could contain material which neither the defendant nor his counsel would ever see. The court would have the entire presentence report before him and would determine what parts of such report he intends expressly to rely upon. Only these would be given to the defendant or his attorney and this would only be done at the time of the sentencing hearing. Furthermore, even this would not be available to the defendant or his attorney if the court found "compelling reasons for withholding particular information."

(2) "Information" of all kinds, not only hearsay and rumor but also, presumably, the fruits of unlawful searches or illegal wiretapping, could be used and the defendant sentenced to life without any of the real protections afforded by a jury trial. (See report of the Association of the Bar of the City of New York, on S. 30, p. 92.)

(3) The right to cross examination is an illusory one because, even if the probation officer who prepared the presentence report should be present at the hearing, cross examination of him would be no substitute for cross examination of the various people who provided the information in the presentence report. (See ibid, p. 93; "General Criticism of Title X" in the association's report further enlarges the points made here, pp. 89–94.)

(4) Under the original provisions of H.R. 18583 respecting one of the elements of a continuing criminal offense (that defendant had derived substantial "income or resources" from the enterprise) the burden of

proof would be on the defendant to show that *any* substantial income or resources in his name or under his control were not derived from lawful activities or interests. The Dingell amendment eliminated this provision which held the defendant guilty of this element of the offense unless he proved himself innocent.

Even the proponents of this special sentencing procedure had constitutional doubts about it. The Justice Department conceded: "The lack of direct precedent makes it virtually impossible to predict whether these procedures would survive constitutional challenges." Senate Hearings on S. 30, page 377. The report on the propoesd Organized Crime Control Act of 1969 (S. 30) by the Association of the Bar of the City of New York says: "We think that it is unlikely that the proposed procedures would pass constitutional muster" (see p. 91).

F. THE DINGELL AMENDMENT

The amendment offered by Mr. Dingell which was adopted by the full committee corrected these defects. Instead of providing a post-conviction-presentencing procedure, it made engagement in a continuing criminal enterprise a new and distinct offense with all its elements triable in court.

Thus, it is seen that the Dingell amendment improved the continuing criminal activity section. All of the signers of these additional views supported the Dingell amendment as preferable to the original language. However, candor requires that it be pointed out that this section still contains serious objections, objections which also apply to the original provisions in the continuing criminal offense portion of the bill. They are as follows:

(1) The definition of what is a continuing offense is indefinite in that—

(*a*) It is not at all clear what constitutes a "continuing series of violations of this title or title III * * *."

Suppose, for instance, that six young men attending a college reside together in a cooperative boarding house. All of them have engaged in the practice of smoking marihuana cigarettes and there has been, on a day or more, free exchange between them of such forbidden drug. Each incident of giving a cigarette to another constitutes a felony. How long must this practice continue in order to constitute a "continuing series of violations"? Would a single day's experiment with smoking "pot" constitute a "continuing series of violations," or would it require a week, a month, or a year of such activities to make the offenses "continuing"?

(*b*) *It is not at all clear what is meant by deriving "substantial income or resources" from the enterprise.*

Let us take the situation mentioned above. Suppose one of the young men is the house manager of the boarding house. As such he is in a general "supervisory position" or "other position of management" in the ordinary affairs of the house, but he has not ordinarily obtained any "income or resources" connected with the sale of marijuana. He has only been paid for his general house management. On one occasion he purchases $100 worth of marijuana and divides it with the other five members, selling it to them at cost. Has he then obtained "substantial income or resources" in connection with the enterprise?

Or what if such common purchase by one of the group is done each week? Also, does "substantial income or resources" relate to profits or, on the other hand, to mere receipt of money? Would "income or resources" include the advantage to the house manager of obtaining his own share of the marijuana at a cheaper rate because it was bought in bulk?

(2) The very severe penalty of the continuing criminal enterprise section (a minimum of ten years and a maximum of life imprisonment) is applicable to a broad range of criminal activities, some of which are very mild and some of which are very serious, without discrimination.

The American Bar Association in its "Standards Relating to Sentencing Alternatives and Procedures," approved August 1968, stated that the sentence imposed in special offender cases should not be disproportionately more severe than a maximum sentence generally provided by law for a given felony. Edward L. Wright, president of the American Bar Association, objected to the language of the special offender sentencing provisions of S. 30 because they violate such standard. (See his testimony before Subcommittee No. 5 of the House Judiciary Committee on July 23, 1970.)

The standard is even more flagrantly abused in the bill recommended by this committee. The student house manager described in the example above would have to receive at least a 10-year sentence if convicted at all. The same sentence might be received by a member of a ring of heroin peddlers operating wholly for profit. Indeed, it is conceivable in cases where long-haired students are particularly obnoxious that the student house manager—who is, say, also a black activist—would receive a life sentence. In another community a hard-working "straight" heroin peddler, with a large family and a good lawyer, might receive the 10-year sentence.

The point is that the range of penalty, running as it does up to the life sentence, is too wide to encompass offenses which range from hardly more than student peccadillos to hardened crime. The duty of the legislative body to bracket offenses and penalties is solely for the purpose of creating uniformity and fairness as between different judges, different juries, and different parts of the country in the application of the criminal law intended to be enforced fairly and uniformly.

Since there is no field of criminal law which is more subject to abuse—subject as it is to planting evidence, framing the accused or stirring up the prejudice of the community—than that involving drug abuse, it is extremely important that we not leave the range of risk and punishment to prosecutor's discretion. Unfortunately, prosecutor's discretion is sometimes like the discretion of the hound on the scent of the hare. It is our duty reasonably to constrain it.

(3) The mandating of a minimum penalty upon the Court presents the dilemma of—

(*a*) Holding a person guilty of a minor or moderate crime not guilty in order to avoid the inordinate sentence of 10 years, or

(*b*) Imposing a 10-year sentence upon one who is not guilty of a serious crime, not likely to be a repeater, and whose life may be ruined by the conviction.

II. The No-Knock Provision

The bill as reported from the committee contains a no-knock provision in the following language:

> (b) Any officer authorized to execute a search warrant relating to offenses involving controlled substances the penalty for which is imprisonment for more than 1 year may, without notice of his authority and purpose, break open an outer or inner door or window of a building, or any part of the building, or anything therein, if the judge or United States magistrate issuing the warrant (1) is satisfied that there is probable cause to believe that (A) the property sought may and, if such notice is given, will be easily and quickly destroyed or disposed of, or (B) the giving of such notice will immediately endanger the life or safety of the executing officer or another person, and (2) has included in the warrant a direction that the officer executing it shall not be required to give such notice. Any officer acting under such warrant, shall, as soon as practicable after entering the premises, identify himself and give the reasons and authority for his entrance upon the premises.

The no-knock provision of this bill is important because the no-knock approach is appearing in various pieces of special legislation apparently looking toward possible general adoption. It appeared in the District of Columbia crime bill which passed and became Public Law 91–358. It also appeared in the companion drug bill in the Senate, S. 3246. The provision bristles with constitutional questions.

A. THE BASIC CONSTITUTIONAL RIGHT

The fourth amendment protects "the right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures * * *." Upon the face of it, this language would appear to embrace the mandate that people shall not be broken in upon without a prior announcement of the purpose and authority of the intrusion unless there is no other reasonable way that law may be enforced.

There is a paucity of case authority, however, respecting whether or not an officer is constitutionally required to announce his purpose and authority when he forcibly enters premises to make an arrest. One reason for this is that the Supreme Court has not been called upon to answer the question in Federal cases upon a constitutional basis, because since at least 1917, the Federal officer has been required by statute to announce his purpose and authority. (See title 18, section 3109, United States Code.)

It is interesting to note that the language of section 3109 was originally adopted as a World War I measure. The impetus behind the action seems to have been to expedite search warrants seeking evidence of subversion or espionage. Thus, the act was to broaden authority to break in premises rather than to restrict. Obviously, even before the passage of section 3190 the breaking into premises without notice violated "the notions of justice of English-speaking peoples."

As early as *Semayne's* case (5 Co Rep 91a, 91b, 77 Eng. Rep.194, 195 (1603)), it was declared that:

> [i]n all cases when the King is party, the Sheriff (if the doors be not open) may break the party's house, either to arrest him, or to do other execution of the K[ing]'s process, if otherwise he cannot enter. But before he breaks it, he ought to signify the cause of his coming, and to make request to open doors * * *.

Thus, as to the qualification "after notice of his authority and purpose," the statute merely restated the common law and Constitutional law of the Nation.

There is no question but that the Constitution does not permit breaking and entering into premises for the purpose of search and seizure where the whole factual nexus shows action which offends "those canons of decency and fairness which express the notions of justice of English-speaking peoples even toward those charged with the most heinous offense." *Malinski* v. *New York*, 324 U.S. 401 at 416.

B. UNANNOUNCED ENTRY UNDER KER V. CALIFORNIA

The case of *Ker* v. *California* (374 U.S. 23), is the case which sheds the most light on the question. Its meaning is somewhat muddied by the fact that Justice Clark's opinion (joined by Justices Black, Stewart, and White) is the majority opinion only through its section I (though the results of the remainder are concurred in by the majority). Three Justices join Justice Brennan in his outright denunciation of unannounced instrusion, and Justice Harlan concurs in the result but would return to Justice Frankfurter's view in *Rochin* v. *California* (342 U.S. 165). Nevertheless, the opinion affords the following standards and guides: In the case of unannounced intrusion without warrant, as existed in Ker, the constitutional question of whether or not there was a reasonable search and seizure is clearly raised. Justice Clark and those who joined in the result of his opinion thought that it was. He wrote:

> Here justification for the officer's failure to give notice is uniquely present. In addition to the officer's belief that Ker was in possession of narcotics, which could be quickly and easily destroyed, Ker's furtive conduct in eluding them shortly before the arrest was ground for the belief that he might well have been expecting the police. We therefore hold that in the particular circumstances of this case the officer's method of entry, sanctioned by the law of California, was not unreasonable under the standards of the Fourth Amendment as applied to the States through the Fourteenth Amendment (at pp. 40, 41).

Justice Clark invoked chiefly the exception allowing unannounced entry when officers have reason to believe that someone within is attempting to destroy the evidence.

Justice Brennan, joined by the Chief Justice, Justice Douglas, and Justice Goldberg, would have overtunred the conviction on grounds that there was a lack of "evidence which shows that the occupants were in fact aware that the police were about to visit them." But,

except for this difference as to the evidentiary standard, the four judges who dissent seems to be in substantial accord with the four judges who support the opinion on the propositions—

(1) That the question involved in such unannounced entry is a constitutional one, and

(2) That search and seizure is unconstitutional unless there exists probable cause for the arrest, and probably cause in the case of an entry without notice is guarded within rather narrow standards.

It is the dissenting opinion that sets out exceptions to illegality of unannounced police intrusion into a private home as follows:

(1) Where the persons within already know of the officers' authority and purpose, or

(2) Where the officers are justified in the belief that persons within are in imminent peril of bodily harm, or

(3) Where those within, made aware of the presence of someone outside (because, for example, there has been a knock at the door) are then engaged in activity which justifies the officers in the belief that an escape or the destruction of evidence is being attempted.

THE FEDERAL EXCLUSIONARY RULE

It is recognized that "the Federal exclusionary rule is not a command of the fourth amendment but is a judicially created rule of evidence which Congress might negate." (See Justice Black's concurring opinion in *Mapp* v. *Ohio*, 367 U.S. 643, at p. 1094.) Also, it must be understood, as Justice Clark said in *Ker* v. *California*, *supra* at p. 33:

> And although the standard of reasonableness is the same under the fourth and fourteenth amendments, the demands of our Federal system compel us to distinguish between evidence held inadmissible because of our supervisory powers over Federal courts and that held inadmissible because prohibited by the U.S. Constitution.

Therefore, of course Congress could establish standards for applying the exclusionary rule so long as those standards did not trench upon "the right of the people to be secure in their persons, homes, papers, and effects, against unreasonable searches and seizures * * * ." Also, in making provisions respecting when evidence would be excluded, Congress would be bound by the fifth amendment's requirements of due process.

The close interrelationship between the fourth and fifth amendments, as they apply to this problem, has long been recognized. *Mapp* v. *Ohio*, 367 U.S. 643, at p. 662; *Boyd* v. *U.S.*, 116 U.S. 616. Indeed, the latter case considered the fourth and fifth amendments as running "almost into each other."

D. NO KNOCK PROVISION NOT CONSTITUTIONALLY DEFENSIBLE

The difficulty of Constitutional defense of the proposed no-knock provision of this bill is as much, if not more, involved with the fifth amendment as with the fourth. This provision provides a prior administrative-type determination upon ex parte testimony of law en-

forcement authorities that an exceptional situation permitting unannounced entry exists. The factors are stated in terms that "there exists probable cause to believe" that certain conditions exist. Such determination in advance of development of the facts could not possibly satisfy the standards enunciated by Justice Brennan and the Chief Justice in the *Ker* case, because they insist upon evidence which shows that the occupants were in fact aware that the police were about to visit them. The entire rationale of this opinion is based upon a demand that evidence exists, in fact, at the time of the entry, that would justify the unannounced entry.

But reliance need not be placed wholly on the opinion of these four judges who did not join in the majority opinion. The rationale of the other four judges who signed the majority opinion is likewise based upon the "circumstances within their [the officers'] knowledge" at the time of the act itself. The justification of the reasonableness of the arrest was based upon "Ker's furtive conduct in eluding [the officers] shortly before the arrest," not upon some general condition, or some usual practices of the suspect which might give reason to believe, under general policy, that it would be expedient to issue a warrant permitting no-knock entry.

It is our belief that there is a basic difference between the administrative-type process, related as it is to a legislative or administrative process or a determination in equity in injunctive processes, and a judicial-type process, relating to what the facts actually were at the time. The former, we think, does not satisfy due process in affording a means of determining whether or not the search or seizure was reasonable under the existing circumstances. The question is not one of condemning or exonerating officers for their acts, not one of judging the reasonableness of their motives. It is one of protecting people in their right to be secure in their persons, houses, papers, and effects against unreasonable searches and seizures. This is not a question of general policy as to the range of official authority to be determined in advance. It is a question of whether or not officers, when they invade the house of the accused and riffle through his papers and effects, are then and there, under the actual circumstances existing at the time, engaging in "unreasonable searches and seizures."

The no-knock provision of H.R. 18583 does not afford due process, because it follows the former course and not the latter. The process provided by this provision does not address the real question involved. It does not assure that, if it is followed, people will be "secure in their persons, houses, papers, and effects against unreasonable searches and seizures", but only that policemen will have to follow a certain form which proves to a magistrate, in an ex parte procedure, that they are at that time quite sincere in their beliefs that they should have a broad mandate to engage in searches and seizures upon more or less general policy grounds.

Conclusion

The signers of these additional veiws, although agreeing in general with the approach and terms of H.R. 18583, find that the two objectionable provisions of the bill discussed in I and II above very sharply

raise the warning expressed by Justice Brandeis in *United States ex. rel. Democratic Publishing Company* v. *Burleson* (255 U.S. 407):

> * * * In every extension of governmental functions lurks a new danger to civil liberty.
>
> Experience should teach us to be most on our guard to protect liberty when the government's purposes are beneficent.

The warning is particularly poignant when the two objectionable provisions of this bill are seen to be applications, in a narrow field, of rules which the Justice Department has espoused as far more general propositions.

In view of this, these objectionable provisions are seen to be the surveyor's slash through the majectic wilderness of privacy which may become the road that will despoil it.

JOHN E. MOSS.
JOHN D. DINGELL.
BROCK ADAMS
BOB ECKHARDT

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Part 1
DRUG ABUSE CONTROL AMENDMENTS—1970

HEARINGS
BEFORE THE
SUBCOMMITTEE ON
PUBLIC HEALTH AND WELFARE
OF THE
COMMITTEE ON
INTERSTATE AND FOREIGN COMMERCE
HOUSE OF REPRESENTATIVES
NINETY-FIRST CONGRESS
SECOND SESSION
ON

H.R. 11701 and H.R. 13743

BILLS TO PROVIDE FOR INCREASED RESEARCH AND TRAINING OF PERSONNEL TO DEAL WITH DRUG ABUSE PROBLEMS; INCREASED EDUCATIONAL AND INFORMATIONAL EFFORTS TO ATTEMPT TO PREVENT DRUG ABUSE; PROVIDING FACILITIES FOR THE CARE AND REHABILITATION OF DRUG ABUSERS; AND WITH REVISION OF EXISTING RESTRICTIONS ON DISTRIBUTION OF DRUGS SUBJECT TO ABUSE

(AND RELATED BILLS)

FEBRUARY 3, 4, 17, 18, 19, 20, 25, 26, 27; MARCH 2 AND 3, 1970

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STATEMENT OF HON. JOHN N. MITCHELL, ATTORNEY GENERAL, AS PRESENTED BY JOHN W. DEAN III, ASSOCIATE DEPUTY ATTORNEY GENERAL FOR LEGISLATION, DEPARTMENT OF JUSTICE; ACCOMPANIED BY JOHN E. INGERSOLL, DIRECTOR, BUREAU OF NARCOTICS AND DANGEROUS DRUGS; MICHAEL R. SONNENREICH, DEPUTY CHIEF COUNSEL; AND DR. EDWARD LEWIS, CHIEF MEDICAL OFFICER

Mr. DEAN. Mr. Chairman, I am accompanied this morning by Mr. John E. Ingersoll, Director of the Bureau of Narcotics and Dangerous Drugs, and also Mr. Michael Sonnereich, Deputy Chief Counsel, Bureau of Narcotics and Dangerous Drugs.

Mr. JARMAN. We appreciate your being with us to lead off in this important hearing on this seriously important subject.

Mr. DEAN. Before I commence the reading of the Attorney General's statement, I would like to again express as he did in a letter to you this morning, his regret that he is unable to appear personally this morning and his willingness to appear at a later date should the subcommittee desire his appearance.

Mr. JARMAN. Thank you very much.

Mr. DEAN. "Mr. Chairman, members of the subcommittee, it is a pleasure to appear before you today to discuss the need for effective new legislation to control and regulate narcotics and dangerous drugs. As you will recall, last July 14, the President sent a message to Congress outlining a 10-point program to combat the national problem of drug abuse. In that message the President called for:

"—A new Federal law to more effectively control the narcotics and dangerous drug problem from the Federal level.

"—Developing model State drug legislation to provide an interlocking trellis of laws to enable governments at all levels to more effectively deal with the problem.

"—Exploration of new avenues of cooperation with foreign governments to stop the production of illicit drugs at the source.

"—Initiating of a major new effort to guard the Nation's borders and ports against the illegal entry of narcotics and dangerous drugs from abroad.

"—New resources and men, and a redeployment of existing personnel, to focus a Federal crackdown on the major criminal enterprises engaged in drug trafficking.

"—A gathering of all authoritative information on the subject and a presentation of a balanced and objective educational program regarding the abuse of drugs for all Americans—especially the young people.

"—Expanding existing rsearch efforts to acquire new knowledge and a broader understanding in this entire area.

"—A concerted effort to develop promising programs in the field of the rehabilitation of those addicted to drugs.

"—A redoubling of special training programs in the field of narcotics and dangerous drug enforcement for State and local law enforcement officials.

"—A series of nationwide conferences with law enforcement officials of the various States and concerned Federal officials to obtain new firsthand information on the scope of the problem, to discuss areas where Federal assistance and aid can be most useful and to evaluate and exchange ideas on mutual policies.

"All of these areas dealt with in the President's message are vital in our Federal effort to deal with the problem. Today, however, I shall focus my comments principally on the law enforcement aspects of the problem, since this is the area of major concern to the Department of Justice.

"Education, research, and rehabilitation are the long-term answers to the drug abuse problem in the United States. But while we plan, prepare, and explore in detail each of these areas, it is important that we regulate the manufacture, importation and distribution of narcotics and dangerous drugs through a logical and enforceable control scheme.

"On July 15, 1969, the administration sent to Congress the proposed 'Controlled Dangerous Substances Act.' This is the proposal the President referred to in his message. This legislation, amended during consideration in the Senate, passed that body last Wednesday by a vote of 82 to nothing. This bill (S. 3246) is presently pending before the House. The administration supports it wholeheartedly and requests prompt and immediate action on it so that the law enforcement and regulatory tools it contains can be focused on the drug abuse problem.

"I would like to briefly highlight the major features of the Controlled Dangerous Substances Act and shall ask Mr. Ingersoll, Director of the Federal Bureau of Narcotics and Dangerous Drugs, to explain the details of this proposal with more specificity. The proposed legislation will, for the first time, bring about a unified approach to enforcing the narcotics and dangerous drug laws. It will vest—as does present law—the authority and responsibility with respect to the control of narcotics and dangerous drugs with the Attorney General. It will coordinate and codify the present diverse drug laws into one comprehensive law. It will improve drug law enforcement by giving Federal law enforcement officers the necessary tools to take effective, fast and fair action. Finally, the proposed new law will establish a realistic penalty structure for drug offenses.

"I would now like to mention some of the modifications and changes that the administration's proposal underwent while being acted upon in the Senate and point out that most of these changes were made with the full support and assistance of this administration.

"The hearings held before the Senate Juvenile Delinquency Subcommittee of the Senate Judiciary Committee were extensive and, I think, illuminating. Those hearings started September 15, 1969, and concluded October 20, 1969. Testifying before the subcommittee were members of the Department of Justice, the Department of Health, Education, and Welfare, members of the legitimate drug industry, city and State officials, and members of the medical professions. All segments of the bill were carefully analyzed and compared with

the other pending legislation. The discussions during the hearings, as well as those before the full Senate Judiciary Committee and on the floor of the Senate, shaped and refined the bill to where, I believe, it has become a meaningful new step toward combating drug abuse in this country.

"One provision that was inserted in the Senate, to which the administration subscribes, is title VIII, which provides for the establishment of a committee on marihuana. This committee will be jointly appointed by the Secretary of Health, Education, and Welfare and the Attorney General, and its study will review and analyze in depth the medical, legal, and law enforcement knowledge on marihuana and determine the effects and dangers. This new committee will, within 24 months of the effective date of the act, submit to the President and to the Congress, a comprehensive report on its findings and give its recommendations with respect to the degree of control to be exercised over marihuana. When appearing before the Senate Judiciary subcommittee on September 15, I supported such a committee and I support it now.

"Another major area that was discussed and analyzed in the Senate was with regard to the penalties to be placed on trafficking and use of these controlled dangerous substances. The Department of Justice submitted three alternative penalty schemes to the subcommittee for its consideration. One of those schemes is presently in the Senate-passed bill. Under this penalty structure, a clear differentiation is made between the trafficking offenses on one hand and simple possession offenses on the other. Federal penalties are scaled according to the type of offense involved; for example, trafficking in narcotic drugs listed in schedules I and II carries a penalty of up to 12 years' imprisonment, whereas trafficking in all other controlled dangerous substances, except those in schedule IV, carries a penalty of up to 5 years' imprisonment. Schedule IV, which covers the over-the-counter combination drugs and exempt narcotic preparations carries a penalty of up to 1 year for trafficking in these drugs. I should add that marihuana is no longer placed in the same posture as narcotic drugs and instead is treated as a hallucinogenic substance.

"With regard to simple possession offenses, the maximum term imposed is up to 1 year's imprisonment with a proviso, at the judge's discretion, allowing first offense treatment for those persons who have never been convicted of a prior offense. The thrust of this approach is to allow the judge to tailor the penalty to fit the particular defendant before him, based on the presence or absence of mitigating factors that the court considers to be meaningful.

"While possession offenses are not the major thrust of the Federal law enforcement efforts, the penalties must have enough 'teeth' in them to have a meaningful deterrent effect on those inclined toward illegal use of drugs. The greatest enforcement problem with the existing penalty structure is that it is too severe in relation to the culpability of the user and the dangers of the drugs. Also, the severity of the penalties, given the violation, are out of step with the rest of the Federal criminal sanctions in the U.S. Code. The result has been a reluctance on the part of prosecutors to prosecute and judges to sentence offenders under the existing penalty structure. The new

penalty structure will increase the credibility of the law and the resultant deterrent effect while at the same time providing sufficient flexibility to allow the punishment to fit the crime and the offender.

"In conclusion, the administration supports and recommends enactment of the Senate bill, S. 3246, which is presently pending before this House. Any proposed legislation which does not place together the narcotic, marihuana, and other dangerous drugs under one regulatory and penal scheme will not enable law enforcement to maximize its efficiency in this area and to handle the drug problem in the best way possible. To maximize effectiveness, the new Bureau of Narcotics and Dangerous Drugs was created out of two other agencies which had, in the past, divided Federal law enforcement responsibilities in this area. The same is now needed in the statutory tools this new Bureau must work with.

"I have left to Mr. John E. Ingersoll, Director of the Bureau of Narcotics and Dangerous Drugs, the task of explaining in more detail some of the provisions of the 'Controlled Dangerous Substances Act.' I only want to reassert that the 'Controlled Dangerous Substances Act' is a law enforcement measure and deals with research, education, and training only as they affect the needs of law enforcement in regulating the legitimate industry's commerce in controlled dangerous substances, and in maximizing the overall law enforcement capabilities of the Department of Justice. We need new tools to better meet the growing drug abuse problem. The 'Controlled Dangerous Substances Act' is the kind of tool we need."

Mr. Chairman, I believe that Mr. Ingersoll has a prepared statement at this time to follow.

Mr. JARMAN. Yes. We would be glad to hear from Mr. Ingersoll and then I am sure the subcommittee will have questions for you gentlemen.

STATEMENT OF JOHN E. INGERSOLL

Mr. INGERSOLL. Thank you, Mr. Chairman and members of the subcommittee.

In addition to the Bureau of Narcotics and Dangerous Drugs deputy chief counsel Michael Sonnenreich, who has been introduced to you, I have another member of my staff here, Dr. Edward Lewis, the bureau's chief medical officer, who is seated right back of me and will also be available to assist us in our testimony.

I, too, am pleased to have this opportunity to appear before you today. I would like to echo the Attorney General's feelings by reiterating the urgent need for modernization of present Federal narcotic, marihuana, and dangerous drug laws.

Recent arrest statistics are one indication of the upsurge in drug abuse over the last few years. For 1968, the uniform crime reports reveal that 162,177 persons were arrested by State and local authorities for narcotic and marihuana drug violations. This figure represents a 322-percent increase over the number of drug arrests made in 1960. Between 1967 and 1968 alone, the rate of increase in narcotic and marihuana drug violations was 64 percent. Part of this increase can be attributed to increased numbers of arrests for marihuana offenses alone, but the rise is still completely out of proportion with the arrest rates for other types of offenses.

Of the total number arrested in 1968, 43,200 were under the age of 18 and 6,243 were under the age of 15. Little explanation is necessary except to say that these figures do not truly reflect the total drug abuse picture. For every individual apprehended, countless scores go undetected.

Because it is a highly conspicuous topic these days, I am sure you have been convinced that the Nation is facing an ever-increasing drug abuse problem. So, in the interest of time I will not indulge in a further statistical exposition to prove the point. If you would like, I will be happy to provide any statistical data available to us. Suffice it to say for now that arrest statistics, death and injuries from drug abuse, increased fear and confusion all literally cry out for new innovations, new resolve and new legal tools to regain control.

While the primary interests of the Department of Justice in the drug abuse area stem from its law enforcement responsibilities, it is fully recognized that a law enforcement response alone would by no means provide the ultimate solution to the drug abuse dilemma. Its eradication as a sociopathic problem is going to require varied approaches utilizing education, research, and rehabilitation to help the victims of drug abuse as well as law enforcement to control the products of their abuse. Law enforcement at best can only push back, and, hopefully, eliminate the all-vital illicit distribution lines of the drug trafficker, perhaps the most sophisticated criminal of our times. This is by no means an easy task and for some time has required new legal tools and new objectives and investigative methods. But it is essential such an effort succeed so that the long-range educational, research, and rehabilitation programs have an opportunity to be successful, and so that they can operate, Mr. Chairman, in an atmosphere free of the proselytism of drug abuse. At least we must have the means to hold the line, while these other programs are moving to the total solution.

Mr. Chairman, while there are other bills pending before this subcommittee, such as H.R. 13473 and H.R. 11701, I would prefer to direct my comments tothe Controlled Dangerous Substances Act (S. 3246), which is the bill supported by the administration to cover all dangerous substances and which was just passed unanimously by the Senate and introduced into the House. To my way of thinking, this is the most comprehensive piece of enforcement legislation drafted to date in this narcotic and dangerous drug area and holds out great promises of being the most effective.

One of the underlying reasons necessitating revision of the Federal drug laws is that current law on the subject of narcotics, marihuana, and dangerous drugs is fragmented and often divergent. There are some seven separate major pieces of legislation covering the subject. Some of the reasons compelling change are as follows:

1. The penalties are inconsistent. They make an improper distinction between some substances and often little or no distinction between various criminal acts.
2. The regulatory controls over the manufacture and distribution of non-narcotic substances are inadequate to meet and deal with present problems of diversion.
3. Dangerous substances are not logically classified.
4. Many of the enforcement tools available to our agents need updating and refinement to meet current realities.

Any new legislation must be designed to coordinate and to unify the Federal approach, at least in the enforcement and regulatory areas. Bifurcated legislation will not suffice. Also, enforcement legislation must be enforceable to be effective. To be enforceable, it must be rational both in the intellectual and jurisdictional sense. To meet the test of rationality, therefore, such legislation must include all the narcotic and dangerous drugs within the framework of a unified law.

I am sure, Mr. Chairman, you are familiar with the recent floor debates concerning S. 3246 in the Senate. I would like at this time to discuss some of the issues raised in the Senate so they can be placed in better perspective.

You may recall an amendment introduced on the floor which would have permitted the Attorney General to bring any particular drug under control only upon a recommendation from the Secretary of Health, Education, and Welfare or the Scientific Advisory Committee established under title VI of the bill. This amendment failed to pass, and S. 3246, as presently written, allows the Attorney General upon his own motion or on the petition of an interested person to bring a drug under control. However, he is authorized to do so only after requesting the advice in writing of the Secretary of Health, Education, and Welfare and the advice in writing of the Scientific Advisory Committee.

The intent of the amendment was to insure that the scientific and medical information necessary for a determination of whether a substance should be brought under control was available. However, the legislation already insured that there would be sufficient medical and scientific input into any control decision by requiring that the Attorney General consider the advice of the Secretary of HEW and the Scientific Advisory Committee. Requiring the Attorney General to wait for a recommendation to control from sources outside of his direction would considerably slow down the control process without adding any more scientific or medical data. The Attorney General must have the ability to initiate the quest for the scientific information when there exists a potential or actual abuse problem. It is for this reason that he needs the authority to start the process on his own motion. The Attorney General has, and will continue to have, the facilities of the Bureau of Narcotics and Dangerous Drugs at his disposal. These presently include a chief medical officer—and I might add parenthetically that he will soon receive an assistant—a number of scientists, including pharmacologists, and a staff of chemists. In addition, the Bureau maintains five regional laboratories, scattered about the country in strategic cities. These laboratories daily process samples of drugs with abuse potential. So, the Department of Justice does have the scientific capability to detect abuse potential. In addition, its agents throughout the United States are in unique positions to recognize and document actual abuse. This, plus other sources of expertise available to him, qualify the Attorney General to make the best policy decision respecting the control of dangerous drugs.

I would like to now focus on some of the regulatory provisions governing the activities carried on by the legitimate drug industry. Unless specifically exempted, all individuals who manufacture, distribute, or dispense controlled dangerous substances must meet strict criteria for registration. Since the Federal Government's interest in

this area stems primarily from the need to protect against drug diversion it becomes absolutely essential to know who is dealing in these substances and how they are dealing in them. Registration is perhaps the most effective and least cumbersome way to insure this.

Incumbent on all registrants are the requirements for biennial inventories of all stocks of controlled dangerous substances on hand. To expedite matters and to lessen the burden, the bill requires that these inventories are to be conducted at the time of the registrant's regular fiscal inventory. Through advanced methods of conducting accountability audits, these provisions should serve as an effective deterrent against drug diversions since such diversion will be much more easily detected and pinpointed. Also, for the first time, the act will permit the screening of persons seeking registration and permit, under objective criteria, the Attorney General to suspend, revoke, or deny registration. This will insure the integrity of the system and will allow greater reliance to be placed on the legitimacy of those registered.

Tighter restrictions also are imposed on the importation and exportation of controlled dangerous substances than are found under existing Federal law. Finished narcotic drugs may be imported for the first time, but only in certain designated situations. The Attorney General must make a finding that either an emergency exists and domestic supplies of these drugs are inadequate to meet that circumstance, or that competition among domestic manufacturers is inadequate and cannot be remedied through registration of additional manufacturers. These provisions, of course, are intended to protect the interest of the consumer who has a legitimate need for these drugs.

Exportation of narcotic drugs can be carried out only pursuant to an export permit issued by the Attorney General. Several factors, such as the control system imposed by the country of destination and the ultimate use for a particular drug, must be considered before an export permit can be issued.

Before stimulant and depressant drugs can be exported, a triple invoice must be forwarded to the Attorney General identifying all parties to the shipment and the means of shipping. This is designed to allow the Attorney General, prior to actual exportation, to ascertain whether or not the drugs are being exported to a legitimate establishment. It will also enable him to ascertain the extent of any domestic manufacturer or distributor's export trade and thus pinpoint possible sources of diversion abroad. We feel that these controls will go a long way toward curtailing the illicit flow of these drugs at our borders and back and forth across them. Further, if the United States' position on illicit traffic of drugs like heroin and marihuana is to remain credible in the world community, it must take great care to assure that we do not become a source of illicit traffic in drugs manufactured here.

You may recall, Mr. Chairman, the recent Senate debate over the Attorney General's authority under S. 3246 to carry on educational and research programs. A proposed amendment, coupled with the floor debate which explained its intent, would have divested the Attorney General of his authority to establish methods for accurately assessing the effects of controlled dangerous substances and identifying those substances having a potential for abuse. He would have also been de-

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prived of his authority to enter into contracts with public and private institutions for research hearing on the abuse of controlled substances. It should be noted that these powers set out for the Attorney General are presently being exercised by him under existing law.

This amendment was opposed and failed to pass because the majority felt it necessary that the Attorney General have at his disposal the authority to gather the necessary information and data which go into making any decision to bring a drug under control. Depriving him of this ability would compel him to operate in the dark or else draw upon other sources, over which he has no control, for information.

I would like to turn now to some of the regulatory and enforcement provisions contained in S. 3246 to give you a better idea of why we consider this piece of legislation most effective from the law enforcement standpoint.

ORDER FORMS AND QUOTAS

The Controlled Dangerous Substances Act has two very important regulatory provisions which will allow, when necessary, very tight controls over the output and distribution of legitimately manufactured drugs which are subject to abuse. Section 306 of the bill allows for the establishment of quotas for all controlled dangerous substances in schedules I and II. This has the effect of allowing supply to be kept in line with legitimate needs, thereby avoiding overproduction and the consequent increased potential for diversion. Section 308 provides order forms for substances in schedules I and II. The existing order form requirements over narcotics have proven extremely effective in controlling against diversion of these drugs from legitimate channels.

Both of these provisions maximize Government control over legitimate production and distribution. Given the flexibility of the Controlled Dangerous Substances Act in shifting substances between schedules where the public interest dictates, substances meeting the criteria of schedules I and II could be placed in either of those schedules and trigger the quota and order form requirements of the act. This ability to tighten regulatory controls over substances deserving of such treatment is a necessary and useful diversion preventive measure.

"NO-KNOCK" AUTHORITY

Apparently the most controversial provision in the bill which was contested during the Senate floor debates concerned subsection 702(b), which would allow certain Federal officers, under defined circumstances, to execute a search warrant without first knocking and announcing their authority and purpose. Parenthetically let me add that we do not regard this as a controversial subject, but the debate in the Senate was lively and generated much public notice.

More commonly referred to as "no-knock," this provision has been misconstrued by a great number of people. The standards imposed for obtaining a no-knock warrant are quite stringent and, I think, deserving of special mention here. First, this authority is restricted to special agents of the Bureau of Narcotics and Dangerous Drugs.

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Secondly, the officers must first have grounds for obtaining a conventional search warrant, which requires meeting the constitutional standard of probable cause. Third, the search warrants must relate to offenses involving controlled dangerous substances, the penalty for which is imprisonment for more than 1 year. Fourth and last, a judge or magistrate must make a specific finding that there is probable cause to believe that if notice were given, either the evidence sought would be quickly and easily destroyed, or that the officers would be placed in danger of physical harm. An additional proviso, not commented on before, requires that officers executing a no-knock warrant identify themselves and their purpose as soon as practicable after gaining entry.

This provision is really only a codification of the common law rule. Under the common law, the officer could find, on the basis of probable cause, that if notice were given, it would lead to the quick destruction of the evidence sought or endanger his life. The Bureau of Narcotics and Dangerous Drugs feels that a neutral judge or magistrate should make such a finding before allowing an agent executing a search warrant to enter without announcing his authority and purpose when he believes that evidence may be quickly or easily destroyed. We also feel that this judicial review will protect the investigation and subsequent prosecution.

There is little doubt that this provision will prove to be a most effective law enforcement tool which will enable the arrest and successful prosecution of many major drug violators who, before, were virtually immune due to their ability to destroy evidence quickly. At the same time, however, I sincerely feel that adequate safeguards are incorporated, which prevent it from being abused or used indiscriminately. Based on existing case law, I share our legal counsel's conviction that the provision meets the test of reasonableness under the fourth amendment of the Constitution.

ADMINISTRATIVE INSPECTIONS AND WARRANTS

Succinctly stated, this provision is a codification of two recent United States Supreme Court decisions (*Camara* v. *Municipal Court of the City and County of San Francisco* and *See* v. *City of Seattle*) which held that, in the absence of consent or imminent danger to the public health and welfare, an administrative inspection must be conducted pursuant to a warrant, even though there may be a statute authorizing such an inspection. The provision sets out the standards and procedures which must be complied with for obtaining these warrants and the method by which they are to be executed.

As a point of clarification for those who have confused these warrants with conventional search warrants, administrative inspection warrants and conventional search warrants differ dramatically. As determined by the Supreme Court, the facts necessary for establishing probable cause in each case are different, and the procedures for their execution are different. While a conventional search warrant under S. 3246 may be executed at any time of the day or night, an administrative inspection warrant can only be executed during normal business

hours. While there may be instances where a conventional search warrant will authorize unannounced entries, an administrative inspection warrant can be executed only after the officers have shown the warrant and their credentials to the person in control of the premises. There is no instance that I can think of where a no-knock entry can be authorized for the purpose of executing an administrative inspection warrant. Such warrants are designed to permit the checking of controlled premises, which are defined as follows:

(a) places where persons registered or exempted from registration requirements under this Act are required to keep records; and
(b) places including factories, warehouses, establishments, and conveyances where persons registered or exempted from registration requirements under this Act are permitted to hold, manufacture, compound, process, sell, deliver, or otherwise dispose of any controlled dangerous substances.

Such warrants will be used when necessary in our routine and spot check accountability audits to insure proper recordkeeping, inventory control, and plant security of persons registered or exempted under this act. Such warrants are not intended for use in investigating clandestine operations. In those cases, regular search warrants will be sought.

IMMUNITY

The next topic I would like to discuss is the one of witness immunity. The immunity provisions found in S. 3246 generally conform to those found in S. 30, the Organized Crime Control Act, which was also recently passed by the Senate. The granting of immunity from certain types of prosecutions should be of great value and assistance to law enforcement since it will permit the compelling of testimony in any proceedings involving violations of the Federal drug laws. This will be most useful in allowing us to move into the hierarchy of organized criminal syndicates engaged in the illicit drug traffic, by immunizing the lesser luminaries and compelling information as to the larger criminal conspiracy.

FORFEITURES

The forfeiture provisions found in S. 3246 were essentially carried over from existing law with the exception that their scope of coverage has been expanded to include dangerous drugs as well as narcotics and marihuana. Effective law enforcement demands that there be a means of confiscating the vehicles and instrumentalities used by the drug trafficker in carrying on his trade. The trafficker must merchandise his product, and to do so, he needs mobility. Seizure and forfeiture of the vehicles he uses in carrying on his illicit trade will prevent their use in subsequent offenses and restrict mobility, which in many cases is vital to the illicit trafficker's success.

These, then, are some of the important regulatory and law enforcement tools within the Controlled Dangerous Substances Act. These are necessary tools if we are to make headway against the widespread drug abuse facing the country. Again, Mr. Chairman, I reiterate that this measure does not preempt the field nor does it pretend to encompass all that is needed in the total Federal effort against drug abuse

and misuse but, in order of priorities, it is needed now so that law enforcement can better perform its role within the context of this problem. Education, research, pre and postrehabilitative efforts all are hopes for the future. But, while postulating this future, we must live in and deal with the present.

Law enforcement is called upon to handle a problem. Drug abuse is a problem. To handle the problem effectively, fairly and flexibly, new legal tools are urgently needed. The Controlled Dangerous Substances Act is the tool we need. I, therefore, recommend prompt consideration and adoption of that measure by the House of Representatives.

Thank you, Mr. Chairman, for your patience in listening to this rather long statement.

Let me also add that our bureau is prepared to assist you and the subcommittee in any way possible during your consideration of new drug control legislation. My staff and I shall be pleased to try to answer any questions that you might have.

Mr. JARMAN. Thank you very much, gentlemen, for comprehensive testimony on this broad and complicated subject.

I think one question that I would ask at this point of Mr. Dean and any comment that any of you might have would be with reference to the provisions relating to criminal penalties, and I would refer, of course, to the House bill H.R. 13743, but also the Senate bill, S. 3246.

Does the Department recommend the penalties as set out in either bill or does the Department recommend any modification of them?

Mr. DEAN. As the Attorney General mentioned in his testimony that I read, we submitted three alternative penalty schemes to the Senate subcommitte that was considering the legislation, and the subcommittee and full committee adopted one of those schemes and it was ultimately adopted by the Senate on the floor.

I believe it would be the scheme that is now contained in the Senate-passed bill that the Department would recommend and suggest to the subcommittee.

Mr. JARMAN. Of the three proposals that you made to the Senate Committee, then, the one adopted would be the one that you would recommend to this committee?

Mr. DEAN. That is correct.

Mr. Chairman, it might be of interest to the subcommittee to see the alternatives we suggested to the subcommittee and the Senate so that you could look at the alternatives that were offered to them that we suggested as being viable penalty schedules for the proposed legislation. I would be happy to submit those for your consideration.

Mr. JARMAN. Yes. I think that would be helpful. Of course, the record in the other body will be available to us.

Mr. DEAN. Correct.

Mr. JARMAN. But we would like to have direct transmittal to this committee, if you will.

Mr. DEAN. Correct.

(The following information was received for the record:)

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Mr. ROGERS. Education, I think you covered.

Mr. INGERSOLL. Yes.

Mr. ROGERS. Do you feel that the basic education program should be in the Department of Education or National Institutes of Health?

Mr. INGERSOLL. I think the basic education program belongs in the Department of HEW and, as I have testified, our activities are intended to supplement those activities.

Mr. ROGERS. How are they coordinated?

Mr. INGERSOLL. Are you speaking of the interagency coordination?

Mr. ROGERS. I don't know how you coordinate it. That is what I want to know. How do you coordinate your education activities with those carried on by——

Mr. INGERSOLL. Through the White House, Mr. Chairman.

Mr. ROGERS. You make the White House coordinate that?

Mr. INGERSOLL. The White House has established an ad hoc committee to coordinate these programs, which are interagency in nature.

Mr. ROGERS. Including education as well as your scientific?

Mr. INGERSOLL. Yes, sir.

Mr. ROGERS. There was something in the bill Iwanted to check out. What about over-the-counter drugs. You classify them how?

Mr. INGERSOLL. Schedule IV. In the new bill these will be schedule IV.

Mr. ROGERS. How do you handle them presently?

Mr. INGERSOLL. Mr. Sonnenreich is the technician. I will refer it to him.

Mr. SONNENREICH. That is a proviso in the new law for the exemption of new admixtures. That doesn't mean we are going to cover all over-the-counter preparations. What we are going to do is probably continue the way we are under the existing Drug Abuse Control Amendments, and that is we will publish the list of exempt over-the-counter preparations. Then what we will do is any specific over-the-counter preparations that do cause abuse, have the abuse potential, if they are determined that way, then we would go through the administrative proceedings.

The major drugs that are covered in schedule IV right now are the over-the-counter exempt narcotic preparations—paragoric, some of your cough syrups, terpinhydrate, and so forth. These are covered under existing law and we have just recently passed on January 4 a new regulation to tighten up the controls at the pharmacy level in terms that you cannot—there must be a showing of proof of age. The person must be over 18 years of age. He is only limited to buy a certain quantity in a given 48-hour period.

We did this because of the fact that some of these substances are being heavily abused.

Mr. ROGERS. Well, now, it seems to me this would be very broad—you will simply find, say, that over-the-counter drugs are subject to abuse but anyone can basically come in and buy over-the-counter drugs, can they not?

Mr. SONNENREICH. No. What we wanted to do with this act was create maximum flexibility. The over-the-counter drugs will not be put under prescription, or anything of that nature. What we will do, and we are talking now about exempt narcotic preparations, the people must sign a log and we want to make certain that certain of these com-

Mr. ROGERS. Plus the language, "Such other factors as may be relevant to and consistent with public health and safety."

Mr. SONNENREICH. Correct.

Mr. ROGERS. And also in the beginning it says in determining the public interest, the following shall be considered, and he also in 28 says if he determines that such registration is consistent with the public interest, treating of international regulations. He sets forth the rules and regulations which I presume can give him pretty wide authority here.

Mr. SONNENREICH. Well, it certainly gives him authority. It gives him flexibility. These are the provisions that were set out. We are talking right now about schedules I and II and these were the provisions that are presently existing in the Manufacturing Act of 1960, which is the Narcotic Manufacturing Act.

One of the other factors that he must consider when he is talking about schedules I and II is the fact that you also have a problem of inadequate competition where there is a potential of inadequate competition, and this is a determination he must make in seeing whether or not the price to the consumer is fair and whether or not we don't have an antitrust problem.

Mr. ROGERS. You are putting antitrust in this, too.

Mr. SONNENREICH. Yes, sir.

Mr. ROGERS. Now, as I understand it in your categorizing 1, 2, 3, and 4—page 17—page 14—I notice on page 14, and I think this is true of schedule I and perhaps schedule II, in determining that a substance comes within this schedule, schedule I, the Attorney General shall find, (1), a high potential for abuse.

Mr. SONNENREICH. Yes, sir.

Mr. ROGERS. This may be a way for you to do it by having your agents report.

(2) No accepted medical use in the United States, and (3) a lack of accepted safety for use under medical supervision.

I would think those three determinations, which are two out of the three, would have such an orientation toward the science community and toward the medical community that it would be much easier for HEW to make that determination.

Mr. SONNENREICH. I would disagree with that, Congressman. No. 1 is clearly the street abuse problem or the abuse problem as found by agents of the Bureau of Narcotics and Dangerous Drugs. Two is a factual determination and normally where we get such information is through the AMA or WHO. You don't have to be a doctor to find out whether or not it has an accepted medical use in the United States or not. So the fact that you are asking whether it has got accepted medical use is something that a lawyer can find out as well as a doctor. I mean it is not something that you are going out to create research on.

Mr. ROGERS. Well, in turn, the HEW could simply get the reports on your activity sent over from your agents on what is being abused.

Mr. SONNENREICH. No. They would have to then start directing our agents.

Mr. ROGERS. No.

Mr. INGERSOLL. May I—that is a very practical consideration, Mr. Chairman.

Part 2
DRUG ABUSE CONTROL AMENDMENTS—1970

HEARINGS
BEFORE THE
SUBCOMMITTEE ON
PUBLIC HEALTH AND WELFARE
OF THE
COMMITTEE ON
INTERSTATE AND FOREIGN COMMERCE
HOUSE OF REPRESENTATIVES
NINETY-FIRST CONGRESS
SECOND SESSION
ON
H.R. 11701 and H.R. 13743
BILLS TO PROVIDE FOR INCREASED RESEARCH AND TRAINING OF PERSONNEL TO DEAL WITH DRUG ABUSE PROBLEMS; INCREASED EDUCATIONAL AND INFORMATIONAL EFFORTS TO ATTEMPT TO PREVENT DRUG ABUSE; PROVIDING FACILITIES FOR THE CARE AND REHABILITATION OF DRUG ABUSERS; AND WITH REVISION OF EXISTING RESTRICTIONS ON DISTRIBUTION OF DRUGS SUBJECT TO ABUSE

(AND RELATED BILLS)

FEBRUARY 3, 4, 17, 18, 19, 20, 25, 26, 27; MARCH 2 AND 3, 1970

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Mr. ROGERS. Now I would like for you to tell us on your schedules you determine what drugs fall within which schedule which is a legal or a medical determination. Start with schedule I on page 12. It is actual or relative potential for abuse.

Mr. SONNENREICH. Are we talking about the first criteria or the second one?

Mr. ROGERS. We might as well go to 14.

Mr. SONNENREICH. That is just a fact in Schedule I; it either is or isn't. We don't have to get any extra information. Heroin is not medically accepted now. They say it isn't and it isn't.

High potential for abuse would be considered pretty much as a law enforcement provision. We would have to go out and see what is happening. With heroin we would not.

Mr. ROGERS. What about the characteristics of the drugs? Would that be a consideration?

Mr. SONNENREICH. Almost all of the drugs you have in the narcotic category of schedule I are known already in terms of their addictive quality and things of this nature, but what we are talking about here is their high potential of abuse.

Mr. ROGERS. No, this is already determined because we are classifying these drugs as such. This is for new substances that you may classify.

Mr. SONNENREICH. But there are two criteria: One is potential and one is actual, the high potential for abuse. If it is a new drug and we want to classify it, the first question is does it have any potential for abuse and that is theoretical, that is a scientific determination. Then we have the second part of the determination, is there any actual abuse? If it is a known drug, we have to go out and find out whether or not there is actual abuse and that is a law enforcement determination.

Now if it is a theoretical drug that is not out on the streets, the answer is purely hypothetical and medical. If it is a known drug that is on the street, of course we have to collect the other information and point out diversion.

Mr. ROGERS. We hope that you categorize most of them that we know about on the street now, haven't you?

Mr. SONNENREICH. Yes, sir.

Mr. ROGERS. So mainly it would be scientific because it would be a new substance?

Mr. SONNENREICH. Mainly our feeling is that the trigger on your schedule I drugs which are really different from your II, III, and IV drugs. It is this basic determination that is not made by any part of the Federal Government. It is made by the medical communnity as to whether or not the drug has medical use or doesn't.

Mr. ROGERS. If it has medical use Food and Drug probably would have authorized it, wouldn't they?

Mr. SONNENREICH. I assume so, sir.

Mr. ROGERS. Now No. 2, no accepted medical use in the United States; 3, a lack of accepted safety for use under medical supervision, that is not legal.

Mr. SONNENREICH. No, sir.

Mr. ROGERS. On Schedule II on page 18, 1, a high potential for abuse. We have discussed that.

Mr. SONNENREICH. No, sir, it is different here. Now you are talking

ORAL ARGUMENT NOT YET SCHEDULED

No. 19-1120

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

IN RE SCOTTSDALE RESEARCH INSTITUTE, LLC,

Petitioner.

On Petition for a Writ of Mandamus to
William P. Barr, U.S. Attorney General, Uttam Dhillon, Acting Administrator of the U.S. Drug Enforcement Administration, and the U.S. Drug Enforcement Administration

---

RESPONSE TO MANDAMUS PETITION

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* Authorities on which we chiefly rely are marked with asterisks.

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GLOSSARY

The Act	Controlled Substances Act
DEA	U.S. Drug Enforcement Administration
Scottsdale	Scottsdale Research Institute, LLC

STATEMENT OF JURISDICTION

Petitioner "seeks a writ of mandamus directing the Attorney General, [the Drug Enforcement Administration (DEA)], or its Acting Administrator to issue a 'notice of application'" for petitioner's application to grow marijuana "by 90 days from the date of service of this amended petition or fifteen days after the writ issues, whichever is later." Am. Pet. 4. DEA published that notice of application on August 27, 2019. 84 Fed. Reg. 44920, 44923. Accordingly, as explained in the Argument section below, the petition for mandamus is now moot.

STATEMENT OF THE ISSUE

Whether the petition for a writ of mandamus is moot because the agency has granted the petition's request for relief.

STATEMENT OF THE CASE

I. STATUTORY AND REGULATORY FRAMEWORK

The Controlled Substances Act, 21 U.S.C. §§ 801-971, establishes a comprehensive federal scheme to regulate the manufacture and distribution of controlled substances. The Act divides controlled substances into five schedules, based on their potential for abuse, medical uses, and risk of physical or psychological dependence. *Id.* § 812(a)-(b). Generally speaking, a schedule I substance has no accepted medical use and a high risk for abuse, while schedule II-V substances have accepted medical uses and decreasing risk of abuse and dependence. *Id.* § 812(b).

Congress designated marijuana as a schedule I substance. *See* Pub. L. No. 91-513, title II § 202(c) (sched. I(c)), 84 Stat. 1242, 1249 (1970).[1]

As particularly relevant here, Congress granted the Attorney General authority to register applicants who seek to manufacture controlled substances under schedule I or schedule II of the Act. 21 U.S.C. § 823(a). The Attorney General, in turn, delegated this authority to the Administrator of DEA. 28 C.F.R. § 0.100. The Administrator will register an applicant to manufacture a controlled substance, like marijuana, "if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971." 21 U.S.C. § 823(a). In determining the public interest, the Administrator must consider how to maintain "effective controls against diversion" of controlled substances by limiting their "bulk manufacture" to "a number of establishments which can produce an adequate and uninterrupted supply * * * under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes." *Id.* § 823(a)(1). The Administrator must also consider compliance with state and local laws, the applicant's prior convictions relating to controlled substances, the promotion of technical advances and development of new substances, the applicant's manufacturing experience and

[1] The Controlled Substances Act uses the term "marihuana," but this brief uses the contemporary spelling except in direct quotations.

effective controls against diversion, and "such other factors as may be relevant to and consistent with the public health and safety." *Id.* § 823(a)(2)-(6).

If an applicant seeks to manufacture a schedule I or schedule II controlled substance "for use only in a clinical trial," the Administrator will "issue a notice of application not later than 90 days after the application is accepted for filing." 21 U.S.C. § 823(i)(2). The notice will allow for a comment period, and 90 days after the comment period ends, the Administrator will "register the applicant, or serve an order to show cause upon the applicant in accordance with" section 824(c). *Id.* If the Administrator issues a show cause order, then the Administrator will provide "a statement of the basis for the denial" of the application, will direct the applicant to appear at a hearing, and will notify the applicant "of the opportunity to submit a corrective action plan on or before" the hearing date. *Id.* § 824(c)(2). A hearing under the show cause order is governed by the Administrative Procedure Act. *Id.* § 824(c)(4).

II. PETITIONER'S APPLICATION TO MANUFACTURE MARIJUANA

Petitioner Scottsdale Research Institute submitted an application to manufacture marijuana on October 1, 2016. Am. Pet. A2-4. DEA asked Scottsdale to answer a series of questions concerning its application, and Scottsdale submitted those answers on January 24, 2017. Am. Pet. A7.

On June 6, 2019, Scottsdale filed a petition for mandamus, seeking to compel DEA "to issue a 'notice of application.'" Pet. 4. Scottsdale argued that, under 21 U.S.C. § 823(i)(2), it was entitled to have DEA publish "a notice regarding its application in the Federal Register to commence the process for determining whether [Scottsdale] should be registered under the Act." Pet. 21. Scottsdale later filed an amended petition that seeks the same relief based on the same arguments. *See* Am. Pet. 4, 21.

III. DEA'S ADMINISTRATIVE ACTIONS

In 2016, DEA issued a policy statement that provided information on how it intended to expand the number of registrations for bulk manufacturers of marijuana, and described in general terms the way it would oversee those additional growers. 81 Fed. Reg. 53846 (Aug. 12, 2016). Since issuing that policy statement, DEA has received 33 pending applications to grow marijuana, marijuana extract, and tetrahydrocannabinols in bulk, with the most recent application filed May 2, 2019.

On August 27, 2019, DEA published a notice of petitioner's application to manufacture marijuana extract. 84 Fed. Reg. 44920, 44923. In the same document, DEA also published notices for 32 other applicants who seek to manufacture marijuana, marijuana extract, and tetrahydrocannabinols. *Id.* at 44922-23. DEA explained that it "anticipates evaluating the applications" and, of those that are legally compliant, "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." *Id.* at 44921.

DEA also explained that, as a result of an inter-agency "policy review process to ensure that the marihuana growers program is consistent with applicable laws and treaties," "adjustments to DEA's policies and practices related to the marihuana growers program may be necessary." 84 Fed. Reg. at 44921. "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." *Id.* That notice of proposed rulemaking was submitted to the Office of Management and Budget for review on August 22, 2019. Office of Information and Regulatory Affairs, Office of Management and Budget, *Pending EO 12866 Regulatory Review for Proposed Rule re: Controls to Satisfy the Requirements of the Controlled Substances Act Applicable to the Manufacture of Marihuana*, https://go.usa.gov/xVjk2 (accessed August 28, 2019); *see also* Executive Order No. 12866, 58 Fed. Reg. 51735, 51737 § 2(b) (Oct. 4, 1993) (coordinating review of proposed agency rules within the Office of Management and Budget).

SUMMARY OF ARGUMENT

This action is moot because DEA has published a notice of Scottsdale's application, thereby granting the relief requested by the mandamus petition. As the preceding discussion indicates, DEA has sent to the Office of Management and Budget a draft notice of proposed rulemaking that may bear on subsequent action on applications, including Scottsdale's. As relevant here, however, the agency has taken the only action sought in the mandamus petition.

STANDARD OF REVIEW

Whether a case is moot is a question of law the Court determines de novo. *Gul v. Obama*, 652 F.3d 12, 15 (D.C. Cir. 2011). "The burden of establishing mootness rests on the party that raises the issue." *Motor & Equip. Mfrs. Ass'n v. Nichols*, 142 F.3d 449, 459 (D.C. Cir. 1998).

ARGUMENT

THE PETITION IS MOOT BECAUSE DEA HAS PUBLISHED A NOTICE OF PETITIONER'S APPLICATION IN THE FEDERAL REGISTER

Under Article III of the Constitution, federal courts may exercise jurisdiction over a case only if a litigant has "suffered, or [been] threatened with, an actual injury traceable to the defendant and likely to be redressed by a favorable judicial decision." *Lewis v. Continental Bank Corp.,* 494 U.S. 472, 477 (1990). Thus, there is "no case or controversy, and a suit becomes moot, when the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome." *Chafin v. Chafin*, 568 U.S.

165, 172 (2013) (quotation marks omitted). Accordingly, this Court has held that a mandamus action becomes moot when "all substantive objectives which could be served by a writ of mandamus have been served." *Gordon v. Gray*, 193 F.2d 367, 367 (D.C. Cir. 1951). In particular, a mandamus action that seeks to compel agency action becomes moot when the agency takes the requested action. *See In re American Fed'n of Gov't Employees, AFL-CIO*, 837 F.2d 503, 505 (D.C. Cir. 1988) (holding that mandamus petition to compel an agency to decide certain "appeals within thirty days is moot" because "all the negotiability appeals listed in the petition have been decided").

The relief requested in Scottsdale's petition is to require DEA to publish a notice of Scottsdale's application to manufacture marijuana. *See* Am. Pet. 4 (petitioner "seeks a writ of mandamus directing the" respondents "to issue a 'notice of application'"); *id.* at 5 (describing the issue presented as whether "this Court [should] issue a writ of mandamus under 28 U.S.C. § 1651(a) to compel the agency to issue the statutorily required notice"); *id.* at 37 (concluding with a request that the "Court issue a writ of mandamus compelling" respondents "to issue a 'notice of application'"). DEA has granted that relief by publishing a notice of Scottsdale's application in the Federal Register. 84 Fed. Reg. 44920, 44923 (Aug. 27, 2019). Because "the court can

grant no meaningful relief" beyond that which DEA has already granted, "the case must be dismissed as moot." *Pulphus v. Ayers*, 909 F.3d 1148, 1152 (D.C. Cir. 2018).[2]

The petition notes that "[t]he agency still maintains discretion to deny or delay the application." Am. Pet. 37. As discussed above, that process may be affected by DEA's forthcoming notice of proposed rulemaking, which may result in changes that could affect DEA's consideration of applicants who seek to manufacture marijuana. *See supra* p.5. As relevant here, however, the only requested action has been taken, and the petition to compel that action is moot.

CONCLUSION

The petition should be dismissed as moot.

Respectfully submitted,

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August 2019

[2] The Court has routinely dismissed mandamus actions against government agencies as moot when the respondent agency subsequently grants the requested relief. *See Schirripa v. Sharpless*, 2019 WL 3229439, at *1 (D.C. Cir. June 25, 2019); *Bundy v. Sessions*, 2018 WL 4147462, at *1 (D.C. Cir. July 23, 2018); *Abdussamadi v. Harris*, 2003 WL 880993, at *1 (D.C. Cir. Feb. 25, 2003).

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6) because it has been prepared in 14-point Garamond, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitation of the Court's July 29, 2019 Order because it contains 1,722 words, excluding the parts of the brief exempted under Federal Rule of Appellate Procedure 32(f) and D.C. Circuit Rule 32(e)(1), according to the count of Microsoft Word.

/s/ Daniel Aguilar
Daniel Aguilar

CERTIFICATE OF SERVICE

I hereby certify that on August 28, 2018, I electronically filed the foregoing response with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ Daniel Aguilar
Daniel Aguilar

ADDENDUM

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties

Petitioner is Scottsdale Research Institute, LLC. Respondents are William P. Barr, in his official capacity as Attorney General; Uttam Dhillon, in his official capacity as Acting Administrator of the Drug Enforcement Administration (DEA); and DEA. Amicus Iraq and Afghanistan Veterans of America have filed a brief in this matter. There have been no intervenors.

B. Rulings Under Review

Petitioner seeks a writ of mandamus compelling DEA to publish a notice of its application to manufacture a controlled substance under 21 U.S.C. § 823(i)(2).

C. Related Cases

This case has not previously been before this Court or any other court, and there are no related cases pending in this Court or any other court. *See* D.C. Cir. R. 28(a)(1)(C) (defining "any other court" to mean a U.S. Court of Appeals or a court in the District of Columbia).

57 FR 10499-02, 1992 WL 57777(F.R.)

NOTICES

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

(Docket No. 86-22)

Marijuana Scheduling Petition; Denial of Petition; Remand

Thursday, March 26, 1992

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final order.

SUMMARY: This is a final order of the Administrator of the Drug Enforcement Administration (DEA) concluding the plant material marijuana has no currently accepted medical use and denying the petition of the National Organization for Reform of Marijuana Laws (NORML) to reschedule marijuana from Schedule I to Schedule II of the Controlled Substances Act.

EFFECTIVE DATE: March 26, 1992.

FOR FURTHER INFORMATION CONTACT: Office of Congressional and Public Affairs, 202-307-7363.

SUPPLEMENTARY INFORMATION:

Background

On December 21, 1989, the former Administrator of DEA, following rulemaking on the record, which included a hearing before an administrative law judge, issued a final order concluding the plant material marijuana has no currently accepted medical use, and denying the petition of NORML to reschedule marijuana from Schedule I to Schedule II of the Controlled Substances Act. 54 FR 63767. On April 26, 1991, the United States Court of Appeals for the District of Columbia Circuit remanded the matter to the Administrator for clarification of DEA's interpretation of the term "currently accepted medical use in treatment in the United States." Alliance for Cannabis Therapeutics v. DEA, 930 F.2d 936.

Following a review of the entire record in this matter, and a comprehensive re-examination of the relevant statutory standard, I conclude that marijuana has no currently accepted medical use and must remain in Schedule I. Further hearings are unnecessary since the record is extraordinarily complete, all parties had ample opportunity and wide latitude to present evidence and to brief all relevant issues, and the narrow question on remand centers exclusively on this Agency's legal interpretation of a statutorily-created standard.

Summary of the Decision

Does the marijuana plant have any currently accepted medical use in treatment in the United States, within the meaning of the Federal Controlled Substances Act, 21 U.S.C. 801, et seq.? Put simply, is marijuana good medicine for illnesses we all fear, such as multiple sclerosis (MS), glaucoma and cancer?

The answer might seem obvious based simply on common sense. Smoking causes lung cancer and other deadly diseases. Americans take their medicines in pills, solutions, sprays, shots, drops, creams and sometimes in suppositories, but never by smoking. No medicine prescribed for us today is smoked.

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With a little homework, one can learn that marijuana has been rejected as medicine by the American Medical Association, the National Multiple Sclerosis Society, the American Glaucoma Society, the American Academy of Ophthalmology the American Cancer Society. Not one American health association accepts marijuana as medicine.

For the last half century, drug evaluation experts at the United States Food and Drug Administration (FDA) have been responsible for protecting Americans from unsafe and ineffective new medicines. Relying on the same scientific standards used to judge all other drugs, FDA experts repeatedly have rejected marijuana for medical use.

Yet claims persist that marijuana has medical value. Are these claims true, What are the facts?

Between 1987 and 1988, DEA and NORML, under the guidance of an administrative law judge, collected all relevant information on this subject. Stacked together it stands nearly five feet high. Is there reliable scientific evidence that marijuana is medically ***10500** effective, If it has medical value, do its benefits outweight its risks? What do America's top medical and scientific experts say? Would they prescribe it for their patients, their families, their friends?

As the current Administrator of Drug Enforcement, and as a former United States District Judge, I have made a detailed review of the evidence in this record to find the answers.

There are significant short-term side effects and long-term risks linked to smoking marijuana. Marijuana is likely to be more cancer-causing than tobacco; damages brain cells; causes lung problems, such as bronchitis and emphysema; may weaken the body's antibacterial defenses in the lungs; lowers overall blood pressure, which could adversely affect the supply of blood to the head; causes sudden drops in blood pressure (orthostatic hypotension), rapid heart beat (tachycardia), and heart palpitations; suppresses luteinizing hormone secretion in women, which affects the production of progesterone, an important female hormone; causes anxiety and panic in some users because of its mind-altering effects; produces dizziness, trouble with thinking, trougle with concentrating, fatigue, and sleepiness; and impairs motor skills.

As a plant, marijuana can contain bacteria capable of causing serious infections in humans, such as salmonella enteritidis, Klebsiella pneumoniae, group D Streptoccoccus and pathogenic aspergillus.

Several of these risk stand out. The immune systems of cancer patients are weakened by radiation and chemotherapy, leaving them susceptible to infection. If they experiment with marijuana to control nausea, they risk weakening their immune systems further and exposing themselves to the infection-causing bacteria in the plant. It is estimated, for example, that at Memorial Sloan-Kettering Cancer Center 60 patients die each year from pathogenic aspergillus infections.

Glaucoma patients face possible blindness caused by very high fluid pressures within their eyes. If they experiment with marijuana to lower their eye fluid pressure, it can cause dramatic drops in their blood pressure and reduce the blood supply to their heads. Glaucoma experts testified this reduced the blood supply to the optic nerves and could speed up, rather than slow down, their loss of eyesight.

MS, glaucoma and cancer patients who have undiagnosed heart problems risk heart palpitations, very rapid heart beats and sudden dramatic drops in blood pressure if they experiment with marijuana. For MS and glaucoma patients who must take medications for the rest of their lives, experimenting with marijuana poses the additional risks of lung cancer, emphysema, bladder cancer and leukemia.

Many risks remain unknown. Marijuana contains over 400 separately identified chemicals. No one knows all the effects of burning these chemicals together and inhaling the burnt mix. Are these risks outweighed by medical benefits?

There are scientific studies showing pure THC (Delta-9-Tetrahydrocannabinol), one of the many chemicals found in marijuana, has some effect in controlling nausea and vomiting. Pure THC is pharmaceutically made in a clean capsule form, called Marinol,

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and is available for use by the medical community. More information on Marinol can be found in the "Physicians' Desk Reference," available in most libraries.

Since marijuana contains THC, you might think marijuana also would be effective. However, the effect of taking a drug in combination with other chemicals is seldom the same as taking just the pure drug. As already noted, marijuana contains over 400 other chemicals, not just THC. There are no reliable scientific studies that show marijuana to be significantly effective in controlling nausea and vomiting. People refer to the Sallan study as proving marijuana's effectiveness. They are mistaken. The Sallan study involved pure THC, not marijuana. People refer to the Chang study to support marijuana's effectiveness. They also are mistaken. Doctor Chang tested the combination of pure THC and marijuana to treat nausea and vomiting. The preliminary results he got were probably due to the THC, not the marijuana. Because he tested the combination, we cannot tell just what effects can be attributed to marijuana alone. People cite a third study, done by Doctor Levitt, as proof marijuana is effective. They are mistaken. Doctor Levitt compared marijuana to THC in controlling nausea and vomiting, and he concluded that THC was the more effective drug.

A librarian can help locate copies of thes studies should you want to see them for yourself. Sallan, et al., "Antiemetic Effect of Delta-9-Tetrahydrocannibinol in Patients Receiving Cancer Chemotherapy," 293 New England Journal of Medicine 795-797 (1975); Chang, et al., "Delta-9-Tetrahydrocannabinol as an Antiemetic in Cancer Patients Receiving High-Dose Methotrexate," 91 Annals of Internal Medicine 819-824 (1979); Levitt, et al., "Randomized Double Blind Comparison of Delta-9-Tetrahydrocannabinol (THC) and Marijuana As Chemotherapy Antiemetics," (Meeting Abstract) 3 Proceedings of the Annual Meeting of the American Society of Clinical Oncology 91 (1984).

During the 1970's and 1980's, a number of states set up research programs to give marijuana to cancer and glaucoma patients, on the chance it might help. Some people point to these programs as proof of marijuana's usefulness. Unfortunately, all research is not necessarily good scientific research. These state programs failed to follow responsible scientific methods. Patients took marijuana together with their regular medicines, so it is impossible to say whether marijuana helped them. Observations or results were not scientifically measured. Procedures were so poor that much critical research data were lost or never recorded. Although these programs were well-intentioned, they are not scientific proof of anything.

Some people refer to a study by Doctor Thomas Ungerleider as proof marijuana reduced nausea in bone marrow transplant patients. Unfortunately, Doctor Ungerleider neglected to follow responsible scientific methods in his study. Like the state programs, it proves nothing. Doctor Ungerleider chose not to publish his study evidently because of its serious weaknesses. He admitted as much when questioned under oath.

Those who say there are reliable scientific studies showing marijuana is an effective drug for teating nausea and vomiting are wrong. No such studies exist.

Our nation's top cancer experts reject marijuana for medical use. Doctor David S. Ettinger, a professor of oncology at the Johns Hopkins University School of Medicine, an author of over 100 scholarly articles on cancer treatment, and a nationally respected cancer expert, testified:

There is no indication that marijuana is effective in treating nausea and vomiting resulting from radiation treatment or other causes. No legitimate studies have been conducted which make such conclusions.

Doctor Richard J. Gralla, a professor of medicine at Cornell University Medical College, an associate attending physician at the Memorial Sloan-Kettering Cancer Center, and an expert in cancer research, testified:

Most experts would say, and our studies support, that the cannabinoids in general are not very effective against the major causes of nausea and vomiting.

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***10501** Doctor Gralla added:

I have found that because of the negative side effects and problems associated with marijuana * * *, most medical oncologists and researchers have little interest in marijuana for the treatment of nausea and vomiting in their patients.

Doctor John Laszlo, Vice President of Research for the American Cancer Society, an expert who has spent 37 years researching cancer treatments, and who has written a leading textbook on the subject, "Antiemetics and Cancer Chemotherapy," testified there is not enough scientific evidence to justify using marijuana to treat nausea and vomiting. Not one nationally-recognized cancer expert could be found to testify on marijuana's behalf.

To be an effective treatment for glaucoma, a drug must: (i) Lower the pressure within the eye (intraocular pressure), (ii) for prolonged periods of time, and (iii) actually preserve sight (visual fields). Five scientific studies are cited as evidence marijuana is an effective glaucoma treatment. Those who cite these studies are mistaken. These studies tested pure THC, not marijuana. W.D. Purnell and J.M. Gregg, "Delta-9-Tetrahydorcannabinol, Euphoria and Intraocular Pressure in Man," 7 Annals of Ophthalmology 921-923 (1975); M. Perez-Reyes, D. Wagner, M.E. Wall, and K.H. Davis, "Intravenous Administration of Cannabinoids on Intraocular Pressure," The Pharmacology of Marijuana 829-832 (M.C. Braude and S. Szara eds. 1976); J.C. Merritt, S.M. McKinnon, J.R. Armstrong, G. Hatem, and L.A. Reid, "Oral Delta-9-Tetrahydrocannabinol in Hyperogeneous Glaucomas," 12 Annals of Ophthalmology 947 (1980); K. Green and M. Roth, "Ocular Effects of Topical Administration of Delta-9-Tetrahydrocannabinol in Man," 100 Archives of Ophthalmology 265-267 (1982); and W.M. Jay and K. Green, "Multiple-Drop Study of Topically Applied 1% Delta-9-Tetrahydrocannabinol in Human Eyes," 101 Archives of Ophthalmology 591-593 (1983).

Threee studies show very heavy doses of marijuana, taken for short periods of time, can reduce eye pressure. R.S. Hepler, I.M. Frank, and T.J. Ungerleider, "Pupillary Constriction After Marijuana Smoking," 74 American Journal of Ophthalmology 1185-1190 (1972); R.S. Hepler, I.M. Frank, and R. Petrus, "Ocular Effects of Marijuana Smoking," The Pharmacology of Marijuana 815-824 (1976); and J.C. Merritt, W.J. Crawford, P.C. Alexander, A.L. Anduze and S.S. Gelbart, "Effect of Marijuana on Intraocular and Blood Pressure in Glaucoma," 87 Ophthalmology 222-228 (1980)

Unusally large doses or marijuana were needed in these three studies to achieve the desired effect. Heavy marijuana use produces dizziness, trouble with thinking, impaired motor skills, fatigue and sleepiness. The 1976 study by Doctors Hepler, Frank and Petrus emphasized "Our subjects were sometimes too sleepy to permit measurement of intraocular pressures * * * 3 hours after intoxication." If a glaucoma patient were to smoke marijuana 8 to 10 times every day for the rest of his life, would he be alert and energetic enough to live a relatively normal life? Would he develop other diseases? No scientific studies exist to answer these questions. Robert Randall claims to have saved his sight by smoking 8 to 10 marijuana cigarettes every day. Under oath he admits he stays at home most days, follows no daily schedule or routine, and has not held a regular job in over 15 years. He also has avoided having a comprehensive medical examination since 1975.

No scientific studies have shown marijuana can reduce eye pressure over long periods of time.

No scientific studies have shown marijuana can save eyesight.

America's top glaucoma experts reject marijuana as medicine. Doctor Keith Green is a professor of Ophthalmology who serves, or has served, on the editorial boards of eight prestigious eye journals (Ophthalmic Research, Oftalmo Abstracto, Current Eye Research, Experimental Eye Research, Investigative Opthalmology, American Journal of Ophthalmology, Archives of Ophthalmology, and Survey of Ophthalmology). Doctor Green has conducted extensive basic and clinical research using marijuana and THC to treat glaucoma patients. He has authored over 200 books or research articles in ophthalmology and is a highly respected expert on this subject. Doctor Green testified:

There is no scientific evidence * * * that indicates that marijuana is effective in regulating the progression of symptoms associated with glaucoma. * * * It is clear that there is no evidence that marijuana use prevents the progression of visual loss in glaucoma. * * * The quantities of the drug required to reduce intraocular pressure in glaucoma sufferers are large, and would require the inhalation of at least six marijuana cigarettes each day. * * * Smoking is not a desirable form of treatment for many reasons * * * (M)arijuana . . . has little potential future as a glaucoma medication.

Doctor George Spaeth is the Director of the Glaucoma Service at Wills Eye Hospital in Philadelphia, the largest service in the United States devoted to researching and treating glaucoma and to teaching other doctors about this disease. Doctor Spaeth is President of the American Glaucoma Society. He is a professor of ophthalmology, the editor of a scholarly eye journal (Ophthalmic Surgery), and the author of over 200 research articles on glaucoma. He testified:

I have not found any documentary evidence which indicates that a single patient has had his or her natural history of the disease altered by smoking marijuana.

Amputees and victims of MS can suffer from extreme muscle spasms. It is claimed marijuana is useful in treating spasticity. Three unusually small, inconclusive studies have tried using pure THC, not marijuana, to treat spasticity. D.J. Petro and C. Ellenberger, "Treatment of Human Spasticity with Delta-9-Tetrahydro-cannabinol," 21 Journal of Clinical Pharmacology 413S-416S (1981) (included only nine patients). Two of the studies are mere abstracts, or short digests, without much detail. Hanigan, Destee & Troung Abstr. B45, Clin. Pharmacol. Ther. 198 (1986) (included only five patients), and Sandyk, Cannoe, Stern and Snider Abstr. PP 331, 36 Neurology 342 (1986) (included only three patients).

No scientific studies exist which test marijuana to relieve spasticity.

National experts on MS reject marijuana as medicine. Doctor Kenneth P. Johnson is Chariman of the Department of Neurology at the University of Maryland School of Medicine. He manages that Maryland Center for MS, one of the most active MS research and treatment centers in the United States. He sits on the editiorial boards of noted medical journals related to MS (Neurology and Journal of Neuroimmunology). He is the author of over 100 scientific and medical articles on MS. Doctor Johnson has spent most of his long career researching MS and has diagnosed and treated more than 6,000 patients with MS. Doctor Johnson testified:

At this time, I am not aware of * * * any legitimate medical research in which marijuana was used to treat the symptoms of multiple sclerosis. * * * To conclude that marijuana is therapeutically effective without conducting rigorous testing would be professionally irresponsible.

Doctor Stephen Reingold is Assistant Vice President of Research for the National Multiple Sclerosis Society, which spends over $7 million each year ***10502** on MS research. Only the Federal Government spends more. Doctor Reingold testified:

I could find no actual published research which has used marijuana * * * In the existing research using THC, the results were inconclusive * * * In the absence of any well-designed, well-controlled research * * *, the National Multiple Sclerosis Society * * * does not endorse or advocate its use * * *.

Doctor Donald H. Silberberg is Chairman of the Department of Neurology at the University of Pennsylvania School of Medicine and Chief of the Neurology Service at the Hospital of Pennsylvania. Doctor Silberberg is on the editorial board of Annals of Neurology and is President of the National Medical Advisory Board for the National Multiple Sclerosis Society. He has been actively researching and treating MS for most of his career, has written over 130 medical articles on MS and is Co-Director of a large MS research center at the University of Pennsylvania. Doctor Silberberg testified:

I have not found any legitimate medical or scientific works which show that marijuana * * * is medically effective in treating multiple sclerosis or spasticity. * * * The long-term treatment of the symptoms of multiple sclerosis through the use of marijuana

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could be devastating. * * * (T)he use of (marijuana), especially for long-term treatment * * * would be worse than the original disease itself.

The only favorable evidence that could be found by NORML and DEA consists of stories by marijuana users who claim to have been helped by the drug. Scientists call these stories anecdotes. They do not accept them as reliable proofs. The FDA's regulations, for example, provide that in deciding whether a new drug is a safe and effective medicine, "isolated case reports * * * will not be considered." 21 CFR 314.126(e). Why do scientists consider stories from patients and their doctors to be unreliable?

First, sick people are not objective scientific observers, especially when it comes to their own health. We all have heard of the placebo effect. Patients have a tendency to respond to drugs as they believe is expected of them. Imagine how magnified this placebo effect can be when a suffering person experiments on himself, praying for some relief. Many stories no doubt are due to the placebo effect, not to any real medical effects of marijuana.

Second, most of the stories come from people who took marijuana at the same time they took prescription drugs for their symptoms. For example, Robert Randall claims marijuana has saved his sight, yet he has taken standard glaucoma drugs continuously since 1972. There is no objective way to tell from these stories whether it is marijuana that is helpful, or the proven, traditional medicines. Even these users can never know for sure.

Third, any mind-altering drug that produces euphoria can make a sick person think he feels better. Stories from patients who claim marijuana helps them may be the result of the mind-altering effects of the drug, not the results of improvements in their conditions.

Fourth, long-time abusers of marijuana are not immune to illness. Many eventually get cancer, glaucoma, MS and other diseases. People who become dependent on mind-altering drugs tend to rationalize their behavior. They invent excuses, which they can come to believe, to justify their drug dependence. Stories of marijuana's benefits from sick people with a prior history of marijuana abuse may be based on rationalizations caused by drug dependence, not on any medical benefits caused by the drug. Robert Randall, for example, admits under oath to becoming a regular user in 1968, four years before he showed the first signs of, and was diagnosed as having, glaucoma. Since then he has smoked marijuana 8 to 10 times every day.

A century ago many Americans relied on stories to pick their medicines, especially from snake oil salesmen. Thanks to scientific advances and to the passage of the Federal Food, Drug and Cosmetic Act (FDCA) in 1906, 21 U.S.C. 301 et seq., we now rely on rigorous scientific proof to assure the safety and effectiveness of new drugs. Mere stories are not considered an acceptable way to judge whether dangerous drugs should be used as medicines.

There are doctors willing to testify that marijuana has medical uses. NORML found over a dozen to testify in this case. We have a natural tendency to believe doctors. We assume their opinions are entitled to respect. But what if a doctor is giving an opinion beyond his professional competence? Evaluating the safety and effectiveness of drugs is a specialized area. Does the doctor have this specialized expertise? Is he familiar with all the published scientific studies? Or is he improperly basing his opinion on mere stories or anecdotal evidence? Does he really know what he is talking about? Does he have a personal motive to exaggerate or lie? Questions like these led the United States Supreme Court, in 1973, to warn about the opinions of doctors concerning the value of drugs as medicine, when not supported by rigorous scientific testing, Weinberger v. Hynson, Etc., 412 U.S. 609, 639:

(I)mpressions or beliefs of physicians, no matter how fervently held, are treacherous.

Nearly half the doctors who testified for NORML are psychiatrists. They do not specialize in treating or researching cancer, glaucoma or MS. One is a general practitioner who works as a wellness counselor at a health spa. Under oath he admits to using every illegal, mind-altering drug he has ever studied, and he prides himself on recommending drugs that would never be recommended by medical schools or reputable physicians. Another is a general practitioner who quit practicing in 1974. He admits he has not kept up on new medical and scientific information about marijuana for 18 years.

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Only one of the doctors called by NORML is a nationally-recognized expert. Doctor John C. Merritt is a board-certified ophthalmologist and researcher who has authored articles on the use of marijuana and cannabinoids to reduce eye pressure. He is in private practice and sees mostly children who suffer from glaucoma. Doctor Merritt testified, "(M)arijuana is a highly effective IOP-lowering drug which may be of critical value to some glaucoma patients who, without marijuana, would progressively go blind." The last scientific study using marijuana in glaucoma patients, published by Doctor Merritt in 1979, concluded:

It is because of the frequency and severity with which the untoward events occurred that marijuana inhalation is not an ideal therapeutic modality for glaucoma patients.

One year later, in 1980, Doctor Merritt gave the following testimony, under oath, before the United States Congress, House Select Committee on Narcotics Abuse and Control:

For me to sit here and say that the lowering pressure effects occurred repeatedly, day in and day out, I have no data, and neither does anyone else, and that is the real crux of the matter. When we are talking about treating a disease like glaucoma, which is a chronic disease, the real issue is, does the marijuana repeatedly lower the intraocular pressure? I have shown you no * * * studies, and to my knowledge there is no data to that effect.

Doctor Merritt was unable to explain, under oath, the contradictory positions he has taken on this subject.

Each of NORML's doctors testified his opinion is based on the published scientific studies. With one exception, none of them could identify under oath the scientific studies they swore they relied on. Only one had enough knowledge to discuss the scientific technicalities involved. Eventually, each ***10503** one admitted he was basing his opinion on anecdotal evidence, on stories he heard from patients, and on his impressions about the drug.

Sadly, Doctor Ivan Silverberg, an oncologist from San Francisco, exaggerated while on the witness stand. At first he swore "there is voluminous medical research which shows marijuana is effective in easing nausea and vomiting." Pushed on cross-examination to identify this voluminous research, Doctor Silverberg replied, "Well * * *, I'm going to have to back off a little bit from that." How far would Doctor Silverberg back off? Was he aware, at least, of the approximate number of scientific studies that have been done using marijuana to treat nausea? Under oath, he replied, "I would doubt very few. But, no, I'm not."

Beyond doubt, the claims that marijuana is medicine are false, dangerous and cruel.

Sick men, women and children can be fooled by these claims and experiment with the drug. Instead of being helped, they risk serious side effects. If they neglect their regular medicines while trying marijuana, the damage could be irreversible. It is a cruel hoax to offer false hope to desperately ill people.

Those who insist marijuana has medical uses would serve society better by promoting or sponsoring more legitimate scientific research, rather than throwing their time, money and rhetoric into lobbying, public relations campaigns and perennial litigation.

Clarification of Currently Accepted Medical Use

The Controlled Substances Act of 1970 divides the universe of all durgs of abuse into five sets or schedules. Drugs in Schedule I are subject to the most severe controls, because they have a high potential for abuse and no currently accepted medical use in treatment in the United States. 21 U.S.C. 812 (b)(1). Drugs of abuse which have currently accepted medical use in treatment in the United States are placed in Schedules II, III, IV and V. Regrettably, the Controlled Substances Act does not speak directly to what is meant by "currently accepted medical use."

A century before the Controlled Substances Act was enacted, the determination of what drugs to accept as medicine was totally democratic and totally standardless. Each patient and each physician was free to decide for himself, often based on no more

than anecdotal evidence. This state of affairs became unsatisfactory to a majority of the American people. In 1906, Congress intervened with the passage of the Food, Drug and Cosmetic Act (FDCA). A shift began away from anecdotal evidence to objectively conducted scientific research, away from uninformed opinions of lay persons and local doctors to expert opinions of specialists trained to evaluate the safety and effectiveness of drugs, and away from totally democratic decision-making to oversight by the Federal Government.

By 1969, Congress had developed detailed Federal statutory criteria under the FDCA to determine whether drugs are acceptable for medical use. Those deemed acceptable can be marketed nationally. Those deemed unacceptable are subject to Federal seizure if marketed interstate. The FDCA is a very complex regulatory scheme not easily summarized. However, it is fair to say that drugs falling into one of four FDCA categories were accepted by Congress for medical use.

First, Congress accepted new drugs which have been approved by FDA's experts as safe and effective for use in treatment, based on substantial scientific evidence. 21 U.S.C. 321(p) and 355 (so-called "NDA-approved drugs").

Second, Congress accepted those drugs "generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective," based on substantial scientific evidence. 21 U.S.C. 321(p) and 355; Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645 (1973). An acronym for this category is "human GRASE drugs" (Generally Recognized As Safe and Effective). These drugs achieve acceptance through rigorous scientific proof, through a past history of widespread use in treatment in the United States, and through recognition by a consensus of drug experts outside the FDA.

Third, Congress accepted for use in veterinary medicine those drugs "generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective," based on substantial scientific evidence. 21 U.S.C. 321(w) and 355. An acronym for these is "animal GRASE drugs." They achieve acceptance through rigorous scientific evidence and through recognition by a consensus of drug experts outside the FDA. Unlike human GRASE drugs, animal GRASE drugs need not have a past history of widespread use.

Finally, Congress accepted those drugs marketed prior to 1938 which had been subject to the 1906 provisions of the FDCA, provided these very old drugs retain their exact formulations and are never promoted for new uses. 21 U.S.C. 321(p) and (w). These are politically "grandfathered" drugs. They need not meet modern standards for safety and effectiveness.

A fifth group of drugs was accepted for research use only, not for use in treatment of patients. 21 U.S.C. 355(i) (so-called "IND or approved investigational new drugs").

Drugs intended for medical use and shipped interstate are subject to Federal seizure under the FDCA if they do not fit within one of the above accepted sets or groupings. It seems fair to say that seizable drugs were rejected by Congress for medical uses.

In enacting the Controlled Substances Act in 1970, could Congress have intended to create a totally new Federal standard for determining whether drugs have accepted medical uses? Or did Congress intend to rely on standards it had developed over the prior 64 years under the FDCA? There is nothing in the Controlled Substances Act, its legislative history, or its purposes that would indicate Congress intended to depart radically from existing Federal law.

Indeed, it seems likely that the core standards developed under the FDCA represent a long-term consensus of expert medical and scientific opinion concerning when a drug should be accepted by anyone as safe and effective for medical use.

Fortunately, there is a way to corroborate what Congress intended. Congress did more than just announce criteria for scheduling drugs of abuse under the Controlled Substances Act; Congress applied those criteria to an initial listing of drugs that it placed into the original five schedules of the Act.

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NDA-approved drugs were placed by Congress into Schedules II, III, IV and V of the Act. For example, pethidine (also known as meperidine) received New Drug Application (NDA) approval in 1942. Congress put it into Schedule II(b)(14). Methamphetamine had an approved NDA. Congress put it into Schedule III(a)(3). I am not aware of any drug with an approved NDA that Congress originally put into Schedule I.

Drugs with medical uses, but without approved NDA's also were placed by Congress into Schedules II, III, IV and V. For example, cocaine was put into Schedule II(a)(4). Codeine combinations were put into Schedules III(d)(1) and V. Morphine combinations were put into Schedule III(d)(8). Phenobarbital was put into Schedule IV(11). Barbiturates were put into Schedule III(b)(1). Amphetamines were put into Schedule III(a)(1).

The Court of Appeals for the First Circuit was correct when it decided in ***10504** Grinspoon v. DEA, 828 F.2d 881 (1987) that NDA approval is not the only method by which drugs can achieve Federal recognition as having medical uses. Congress put both GRASE drugs and pre-1938-grandfathered drugs into Schedules II, III, IV and V of the CSA.

Drugs recognized under the FDCA for research use only, not for use in treatment, such as alphacetylmethadol and marijuana, were placed by Congress into Schedule I.

Unfortunately, Federal records are not complete enough to do a comprehensive mathematical mapping, tracing every drug in the initial Controlled Substances Act schedules back to its legal status under the FDCA. Nevertheless, determining legislative intent does not require mathematical certainty. Probability based on circumstantial evidence, on samplings, and on inductive reasoning can suffice, especially when there is nowhere else to turn.

The pattern of initial scheduling of drugs in the Controlled Substance Act, viewed in light of the prior legal status of these drugs under the FDCA, convinces me that Congress equated the term “currently accepted medical use in treatment in the United States” as used in the Controlled Substances Act with the core FDCA standards for acceptance of drugs for medical use.

This is not to say that every FDCA requirement for GRASE status, or for NDA approval, is pertinent to scheduling determinations under the Controlled Substances Act. There are differences. But the core FDCA criteria appear to have guided the Congress in the decisions it made concerning the initial scheduling of drugs in the Act.

These same core FDCA criteria served as the basis for an eight-point test used by my predecessor as Administrator to describe drugs with currently accepted medical uses. 54 FR 53783 (December 29, 1989):

1. Scientifically determined and accepted knowledge of its chemistry;

2. The toxicology and pharmacology of the substance in animals;

3. Establishment of its effectiveness in humans through scientifically designed clinical trials;

4. General availability of the substance and information regarding the substance and its use;

5. Recognition of its clinical use in generally accepted pharmacopeia, medical references, jounals or textbooks;

6. Specific indications for the treatment of recognized disorders;

7. Recognition of the use of the substance by organizations or associations of physicians; and

8. Recognition and use of the substance by a substantial segment of the medical practitioners in the United States.

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Some uncertainty remains over the precise meaning and application of parts of this test. Therefore, the Court of Appeals for the District of Columbia Circuit remanded these proceedings for a further explanation. In addition to addressing those parts of the test that concerned the Court of Appeals, it would be useful to clarify the entire test, pinpoint its origins, and identify which elements are both necessary and sufficient to establish a prima facie case of currently accepted medical use. This is not an effort to change the substantive law. The statutory meaning of currently accepted medical use remains the same as enacted by Congress in 1970. My purpose simply is to clarify this Agency's understanding of the law.

A. The Drug's Chemistry Must Be Known and Reproducible

The ability to recreate a drug in standardized dosages is fundamental to testing that drug and to using it as a medicine. Knowing the composition, properties, methods of production, and methods of analysis of a drug is essential to reproducing it in standardized dosages. To be GRASE or to receive NDA approval, a drug's chemistry must be known and reproducible. See e.q., 21 CFR 314.50(d)(1) and 314.126(b)(7)(d); Dorovic v. Richardson, 749 F.2d 242, 251 (7th Cir. 1973). The listing of a drug in a current edition of one of the official compendia normally satisfies this requirement. 21 U.S.C. 321(j); 21 CFR 314.50(d)(1).

The first element of our eight-point test, namely, “scientifically determined and acccepted knowledge of its chemistry,” should be clarified to read:

The substance's chemistry must be scientifically established to permit it to be reproduced into dosages which can be standardized. The listing of the substance in a current edition of one of the official compendia, as defined by section 201(j) of the Food, Drug and Cosmetic Act, 21 U.S.C. 321(j), is sufficient generally to meet this requirement.

Acceptance of this knowledge will be discussed elsewhere.

B. There Must Be Adequate Safety Studies

No drug can be considered safe in the abstract. Safety has meaning only when judged against the intended use of the drug, its known effectiveness, its known and potential risks, the severity of the illness to be treated, and the availability of alternative therapies. Hess & Clark Division of Rhodia, Inc. v. FDA, 495 F.2d 975, 993 (D.C. Cir. 1974). To know the risks, there must be adequate studies, by all methods reasonably applicable, to show the pharmacological and toxicological effects of the drug. 21 CFR 314.125(b)(2). This includes animal studies and clinical trials in large numbers of humans. 21 CFR 312.21. The studies need not be well-controlled, but they must be adequate. Edison Pharmaceuticals Co. v. FDA, 600 F.2d 831 (D.C. Cir. 1979). Short term (acute) studies of a drug intended to treat long-term (chronic) illnesses, such as glaucoma or MS, are clearly inadequate. United States v. Naremco, Inc., 553 F.2d 1138, 1143 (8th Cir. 1977). The second element of our eight-point test, namely, “the toxicology and pharmacology of the substance in animals,” should be clarified as follows:

There must be adequate pharmacological and toxicological studies, done by all methods reasonably applicable, on the basis of which it could fairly and responsibly be concluded, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that the substance is safe for treating a specific, recognized disorder.

It must be emphasized that while the existence of adequate safety tests is a separate analytical question, the ultimate determination of whether a drug is safe for a specific use is not a distinct issue. Safety and effectiveness are inextricably linked in a risks-benefits calculation. A determination that a drug is ineffective is tantamount to a determination that it is unsafe. United States v. Rutherford, 442 U.S. 544 (1970).

The scheduling criteria of the Controlled Substances Act appear to treat the lack of medical use and lack of safety as separate considerations. Prior rulings of this Agency purported to treat safety as a distinct factor. 53 FR 5156 (February 22, 1988). In retrospect, this is inconsistent with scientific reality. Safety cannot be treated as a separate analytical question.

C. There Must Be Adequate and Well-Controlled Studies Proving Efficacy

Since 1962, Congress has prohibited the FDA to approve an NDA unless the applicant submits adequate, well-contolled, well-designed, well-conducted, and well-documented studies, performed by qualified investigators, which prove the efficacy of a drug for its intended use. 21 U.S.C. 355(d); 21 CFR 314.126. Similarly, a drug cannot be considered GRASE unless it is supported by this same quantity and quality of scienfitic proof. 21 CFR 314.200(e)(i); Weinberger v. Hynson, Etc., 412 U.S. 609, 629 (1973).

***10505** Studies involving related, but not identical, drugs are irrelevant. United States v. Articles of Food & Drug, 518 F.2d 743, 747 (5th Cir. 1975). Studies involving the same drug combined with other drugs are irrelevant. United States v. Articles of Drug * * * Promise Toothpaste, 826 F.2d 564, 570 (7th Cir. 1987). Incomplete studies are insufficient. United States v. Articles of Food & Drug, supra. Uncontrolled studies are insufficient. 21 U.S.C. 355(d); Cooper Labs v. FDA, 501 F.2d 772, 778 (D.C. Cir. 1974). Statistically insignificant studies are insufficient. 21 CFR 312.21, 314.50(d)(6) and 314.126(b)(7). Poorly designed studies are insufficient. 21 CFR 314.126(b)(2). Poorly conducted studies are insufficient. 21 CFR part 58—Good Laboratory Practices. Poorly documented studies are insufficient. 21 CFR 312.58 and 314.200(e)(4). Studies by investigators who are not qualified, both to conduct and to evaluate them are insufficient. 21 U.S.C. 355(d). Moreover, since scientific reliability requires a double examination with similar results, one valid study is insufficient. There must be two or more valid studies which corroborate each other. See 1 J. O'Reilley "Food and Drug Administration" 13-55 n.12 (1985).

Lay testimonials, impressions of physicians, isolated case studies, random clinical experience, reports so lacking in details they cannot be scientifically evaluated, and all other forms of anecdotal proof are entirely irrelevant. 21 CFR 314.126(e); Weingerger v. Hynson, Etc., 412 U.S. 609, 630 (1973).

Element three of our eight-point test, namely, "establishment of its effectiveness in humans through scientifically designed clinical trials," should be restated as:

There must be adequate, well-controlled, well-designed, well-conducted and well-documented studies, including clinical investigations, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, on the basis of which it could fairly and responsibly be concluded by such experts that the substance will have the intended effect in treating a specific, recognized disorder.

D. Acceptance by Qualified Experts Is Required

The opinions of lay persons are totally irrelevant to whether a drug is GRASE or meets NDA requirements. The observations and opinions of medical practioners who are not experts in evaluating drugs also are irrelevant to whether a drug is GRASE or meets NDA requirements. Weinberger v. Hynson, Etc., 412 U.S. 609, 619 (1973). By explicit requirements in the FDCA since 1938, the only body of opinion that counts is that of experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs. 21 U.S.C. 321 (p) and (w).

From this, one would conclude that expert acceptance of a drug as safe and effective for its intended use is essential to a drug having a currently accepted medical use under the CSA. How widespread must this expert acceptance be?

To be GRASE, a drug must be "generally recognized" among experts as safe and effective for its intended use. The drug must be known or familiar to the national community of relevant experts. United States v. Articles of Drug* * * Furestrol Vaginal Suppositories, 294 F. Supp. 1307, 1309 (N.D. Ga. 1968) aff'd, 415 F.2d 390 (5th Cir. 1969). To determine if a drug is known to the community of experts, courts have looked to whether there is widely available scientific literature about the drug, Premo Pharmaceutical Laboratories, Inc. v. United States, 629 F.2d 795, 803 (2d Cir. 1980), whether it is widely taught in medical schools, Lemmon Pharmaceuticals Co. v. Richardson, 319 F. Sup. 375, 378 (E.D. Pa. 1970), and whether it is widely discussed by experts. United States v. Bentex Ulcerine, 469 F. 2d 875, 880 (5th Cir. 1972).

The recognition of a drug as GRASE need not be universal. General recognition is sufficient. United States v. 41 Cartons* **Ferro-Lac, 420 F.2d 1126, 1132 (5th Cir. 1970). The Supreme Court has interpreted this to mean a consensus of experts is familiar with and accepts a drug as safe and effective. Weinberger v. Hynson, Etc., 412 U.S. 609, 629 (1973). However, if there is a serious dispute among the experts, a drug cannot be considered GRASE. United States v. An Article of Food***Coco Rico, 752 F.2d 11, 15 (1st Cir. 1985); Merrit Corp. v. Folsom, 165 F. Supp. 418, 421 (D.D.C. 1958).

During the NDA process, the FDA may reach out to the expert community for its views. 21 CFR 314.103(c)(3). The FDA need not determine that a drug is generally known and accepted by the expert community. Nor must the FDA develop a consensus of opinion among outside experts. The FDA has both the experts and the statutory mandate to resolve conflicts over the safety and efficacy of new drugs. Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S.C 638, 653 (1973).

In drafting the Controlled Substances Act, Congress appears to have accommodated, rather than chosen from these different FDCA standards. Clearly, the Controlled Substances Act does not authorize the Attorney General, nor by delegation the DEA Administrator, to make the ultimate medical and policy decision as to whether a drug should be used as medicine. Instead, he is limited to determing whether others accept a drug for medical use. Any other construction would have the efect of reading the word “accepted” out of the statutory standard. Since Congress recognized NDA-approved drugs as having currently accepted medical uses, without any need for a national consensus of experts, FDA acceptance of a drug through the NDA process would seem to satisfy the Controlled Substances Act. And, since Congress recognized GRASE drugs as having currently accepted medical uses, without the need for NDA approval, acceptance of a drug by a national consensus of experts also would seem to satisfy the Act.

When a drug lacks NDA approval and is not accepted by a consensus of experts outside FDA, it cannot be found by the Attorney General or his delegate to have a currently accepted medical use. To do so would require the Attorney Genral to resolve complex scientific and medical disputes among experts, to decide the ultimate medical policy question, rather than merely determine whether the drug is accepted by others.

Because the recognition of a drug by non-experts is irrelevant to GRASE status, to NDA approval, and to currently accepted medical use under the Controlled Substances Act, points seven and eight of our eight-point test should be combined and restated as follows:

The drug has a New Drug Application (NDA) approved by the Food and Drug Administration pursuant to the Food, Drug and Cosmetic Act, 21 U.S.C. 355. Or, a consensus of the national community of experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, accepts the safety and effectiveness of the substance for use in treating a specific, recognized disorder. A material conflict of opinion among experts precludes a finding of consensus.

This restatement also incorporates the component of part one of our eight-point test concerning “accepted knowledge of its chemistry.”

E. The Scientific Evidence Must Be Widely Available

Nothing in the FDCA, nor in FDA's regulations, requires that scientific evidence supporting an NDA be published. This stems from the fact that a consensus of experts outside FDA is ***10506** not required for NDA approval. In contrast, most courts have held that a drug cannot be considered GRASE unless the supporting scientific evidence appears in the published scientific and medical literature. Without published studies, it would be difficult for the community of experts outside FDA to develop an informed acceptance of a drug for medical use. Cooper Labs Inc. v. FDA, 501 F.2d 772, 786 (D.C. Cir. 1974).

Point four of the eight-point test focuses, in part, on the “general availability of information regarding the substance and its use.” This should be clarified to read:

In the absence of NDA approval, information concerning the chemistry, pharmacology, toxicology and effectiveness of the substance must be reported, published, or otherwise widely available, in sufficient detail to permit experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, to fairly and responsibly conclude the substance is safe and effective for use in treating a specific, recognized disorder.

F. General Availability of a Drug Is Irrelevant

The second component of point four of the eight--point test involves the "general availability of the substance" for use in treatment. The second component of point eight focuses on "use of the substance by a substantial segment of the medical practitioners in the United States." These elements justifiably concerned the Court of Appeals, leading to the remand in this case.

Under the FDCA, a human GRASE drug must have a material history of past use in treatment in the United States. 21 U.S.C. 321(p)(2) (which has * * *, otherwise than in such investigations, been used to a material extent or a material time); Weinberger v. Hynson, Etc., 412 U.S. 609, 631 (1973). Rigorous scientific proofs and current unanimous acceptance by the medical and scientific community are not enough for a human drug to be GRASE. Tri-Bio Labs, Inc. v. United States, 836 F.2d 135, 142 n.8 (3d Cir. 1987). The general availability of a drug for use in treatment is a factor courts have considered to determine if a human drug is GRASE.

In contrast, a drug can achieve current acceptance for human medical use through the NDA process without a past history of use in treatment. Also, animal drugs can become accepted as GRASE without any past history of medical use. Given this conflict in FDCA standards, which did Congress choose when drafting the CSA?

As the Court of Appeals points out, requiring a material history of past use in treatment before recognizing a drug as having a currently accepted medical use, would permanently freeze all Schedule I drugs into Schedule I. 930 F.2d at 940. Clearly, Congress did not intend this result. Moreover, the use of the word "currently" before the term "accepted medical use" would indicate Congress rejected the human GRASE requirement of past material use in treatment. I conclude that the general availability of a drug is irrelevant to whether it has a currently accepted medical use in treatment within the meaning of the Controlled Substances Act.

G. Recognition in Generally Accepted Texts Is Irrelevant

Point five of the eight-point test deals with "recognition of its clinical use in generally accepted pharmacopeia, medical references, journals or textbooks." The listing of a drug in an official compendium is sufficient to show its chemistry is scientifically established. This appears in my clarification to point one. The requirement that information concerning the chemistry, pharmacology, toxicology and effectiveness of the substance be reported, published or otherwise widely available, is explained adequately in revised point four. To the extent the scheduling of a drug directly influences its recognition in publications, this element is subject to the same criticism identified by the Court of Appeals concerning point four. Therefore, this should not be treated as a distinct requirement.

H. Specific, Recognized Disorders Are the Referent

It is impossible to judge the safety and effectiveness of a drug except in relation to a specific intended use. A drug cannot obtain NDA approval or GRASE status except in relation to the treatment of a specific, recognized disorder. This is an essential aspect of whether a drug has currently accepted medical use. Rather than standing alone, this requirement will be more clearly understood by incorporating it into the other critical elements.

To summarize, the five necessary elements of a drug with currently accepted medical use in treatment in the United States are:

(i) The Drug's Chemistry Must Be Known and Reproducible

The substance's chemistry must be scientifically established to permit it to be reproduced into dosages which can be standardized. The listing of the substance in a current edition of one of the official compendia, as defined by section 201(j) of the Food, Drug and Cosmetic Act, 21 U.S.C. 321(j), is sufficient generally to meet this requirement.

(ii) There Must Be Adequate Safety Studies

There must be adequate pharmacological and toxicological studies done by all methods reasonably applicable on the basis of which it could fairly and responsibly be concluded, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that the substance is safe for treating a specific, recognized disorder.

(iii) There Must Be Adequate and Well-Controlled Studies Proving Efficacy

There must be adequate, well-controlled, well-designed, well-conducted and well-documented studies, including clinical investigations, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs on the basis of which it could fairly and responsibly be concluded by such experts, that the substance will have its intended effect in treating a specific, recognized disorder.

(iv) The Drug Must Be Accepted by Qualified Experts

The drug must have a New Drug Application (NDA) approved by the Food and Drug Administration, pursuant to the Food, Drug and Cosmetic Act. 21 U.S.C. 355. Or, a consensus of the national community of experts, qualified by scientific training and experience to evaluate the safety and effectivenss of drugs, must accept the safety and effectiveness of the substance of use in treating a specific, recognized disorder. A material conflict of opinion among experts precludes a finding of consensus.

(v) The Scientific Evidence Must Be Widely Available

In the absence of NDA approval, information concerning the chemistry, pharmacology, toxicology and effectiveness of the substance must be reported, published, or otherwise widely available in sufficient detail to permit experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, to fairly and responsibly conclude the substance is safe and effective for use in treating a specific, recognized disorder.

Together these five elements constitute prima facie evidence that a drug has currently accepted medical use in treatment in the United States. In the interest of total clarity, let me emphasize those proofs that are irrelevant to the determination of currently accepted medical use, and that will not be considered by the Administrator:

(i) Isolated case reports;

(ii) Clinical impressions of practitioners;

(iii) Opinions of persons not qualified by scientific training and experience to evaluate the safety and effectiveness of the substance at issue;

(iv) Studies or reports so lacking in detail as to preclude responsible scientific evaluation;

***10507** (v) Studies or reports involving drug substances other than the precise substance at issue;

(vi) Studies or reports involving the substance at issue combined with other drug substances;

(vii) Studies conducted by persons not qualified by scientific training and experience to evaluate the safety and effectivness of the substance at issue;

(viii) Opinions of experts based entirely on unrevealed or unspecified information;

(ix) Opinions of experts based entirely on theoretical evaluations of safety or effectiveness.

Bad Medicine By Any Standard

My predecessor as DEA Adminstrator developed and relied upon an eight-point test to determine whether marijuana has accepted medical uses. 54 FR 53783 (December 29, 1989):

1. Scientifically determined and accepted knowledge of its chemistry;

2. the toxicology and pharmacology of the substance in animals;

3. Establishment of its effectiveness in humans through scientifically designed clinical trials;

4. General availability of the substance and information regarding the substance and its use;

5. Recognition of its clincial use in generally accepted pharmacopeia, medical references, journals or textbooks;

6. Specific indications for the treatment of recognized disorders;

7. Recognition of the use of the substance by organizations or associations of physicians; and

8. Recognition and use of the substance by a substantial segment of the medical practitioners in the United States.

The Court of Appeals remanded the decision of my predecessor for clarification of what role factors (4), (5) and (8) of the initial eight-point test played in his reasoning. For ease of discussion, these factors can be divided as follows:

(4)(a) General availability of the substance * * *;

(4)(b) General availability of * * * information regarding the substance and its use;

(5) Recognition of its clinical use in generally accepted pharmacopeia, medical references, journals or textbooks;

(8)(a) Recognition * * * of the substance by a substantial segment of the medical practitioners in the United States; and

(8)(b) (U)use of the substance by a substantial segment of the medical practitioners in the United States.

I have found no evidence indicating initial factors (4)(a) or (8)(b) played any role in my predecessor's decision. In light of my understanding of the legal standard involved, these factors are irrelevant to whether marijuana has a currently accepted medical use.

My predecessor emphasized the lack of scientific evidence of marijuana's effectiveness, and the limited data available on its risks, as reflected in the published scientific studies. He also emphasized the importance of this data to the conclusions reached by experts concerning the drug. 54 FR 53783. I take this to mean that, under initial factor (4)(b), he believed the information available to experts is insufficient for them responsibly and fairly to conclude the marijuana is safe and effective for use as medicine.

Marijuana is not recognized as medicine in generally accepted pharmacopeia, medical references and textbooks, as noted by my predecessor. 54 FR 53784. I take this to mean, under initial factor (5), that he determined that marijuana's chemistry is neither known, nor reproducible, as evidenced by its absence from the official pharmacopeia. Finally, my predecessor concluded, under initial factor (8)(a), that the vast majority of physicians does not accept marijuana as having medical use. 54 FR 53784. Along the way, he found that highly respected oncologists and antiemetic researchers reject marijuana for use in controlling nausea and vomiting, 54 FR 53777, that experts experienced in researching glaucoma medications reject marijuana for use in treating glaucoma, 54 FR 53779, and that noted neurologists who specialize in treating and conducting research in spasticity reject marijuana for use by MS patients, 54 FR 53780. I take this to mean my predecessor found no national consensus of qualified experts accepts marijuana's value as medicine.

Certainly I cannot know my predecessor's unstated reasoning. However, I have reviewed the entire record de novo, and I am convinced that his application of the initial eight-point test to this record correctly resulted in the conclusion that marijuana has no currently accepted medical use in treatment in the United States. Therefore, I adopt in their entirety the findings of facts and conclusions of law reached by the former Administrator in his final order of December 21, 1989, 54 FR 53767.

Pursuant to the remand of the Court of Appeals, I have condensed and clarified the initial standard into a five-point test. My application of the refined, five-point test to this record is set out briefly below.

First, marijuana's chemistry is neither fully known, nor reproducible. Thus far, over 400 different chemicals have been identified in the plant. The proportions and concentrations differ from plant to plant, depending on growing conditions, age of the plant, harvesting and storage factors. THC levels can vary from less than 0.2% to over 10%. It is not known how smoking or burning the plant material affects the composition of all these chemicals. It is not possible to reproduce the drug in dosages which can be considered standardized by any currently accepted scientific criteria. Marijuana is not recognized in any current edition of the official compendia. 21 U.S.C. 321(j).

Second, adequate safety studies have not been done. All reasonably applicable pharmacological and toxicological studies have not been carried out. Most of the chronic animal studies have been conducted with oral or intravenous THC, not with marijuana. Pharmacological data on marijuana's bioavailability, metabolic pathways and pharmacokinetics in inadequate. Studies in humans are too small and too few. Sophisticated epidemiological studies of marijuana use in large populations are required, similar to those done for tobacco use. Far too many questions remain unknown for experts fairly and responsibly to conclude marijuana is safe for any use.

Third, there are no adequate, well-controlled scientific studies proving marijuana is effective for anything.

Fourth, marijuana is not accepted for medical use in treatment by even a respectable minority, much less a consenus, of experts trained to evaluate drugs. The FDA's expert drug evaluators have rejected marijuana for medical use. No NDA has been approved by FDA for marijuana. The testimony of nationally recognized experts overwhelmingly rejects marijuana as medicine, compared to the scientifically empty testimony of the psychiatrists, a wellness counselor and general practitioners presented by NORML.

Fifth, given my conclusions on points one, two and three, it follows that the published scientific evidence is not adequate to permit experts to fairly and responsibly conclude that marijuana is safe and effective for use in humans.

A failure to meet just one of the five points precludes a drug from having a currently accepted medical use. Marijuana fails all five points of the test.

NORML has argued, unsuccessfully, that the legal standard for currently accepted medical use should be whether a respectable minority of physicians accepts the drug. The key to this medical malpractice defense is that the minority opinion must be recognized as respectable, as competent, by members of the profession.

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In the absence of reliable evidence adequately establishing marijuana's chemistry, pharmacology, toxicology and effectiveness, no responsible physician could conclude that marijuana ***10508** is safe and effective for medical use. To quote Doctor Kenneth P. Johnson, Chairman of the Department of Neurology at the University of Maryland, and the author of over 100 scientific and medical articles on MS: "To conclude that marijuana is therapeutically effective without conducting rigorous testing would be professionally irresponsible."

By any modern scientific standard, marijuana is no medicine.

Under the authority vested in the Attorney General by section 201(a) of the Controlled Substances Act, 21 U.S.C. 811(a), and delegated to the Administrator of the Drug Enforcement Administration by regulations of the Department of Justice, 28 CFR 0.100(b), the Administrator hereby orders that marijuana remain in Schedule I as listed in 21 CFR 1308.11(d)(14).

Dated: March 18, 1992.

Robert C. Bonner,

Administrator.

(FR Doc. 92-6714 Filed 3-25-92; 8:45 am)

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Cited
As of: June 9, 2020 3:57 AM Z

National Org. for the Reform of Marijuana Laws v. DEA

United States Court of Appeals for the District of Columbia Circuit

October 16, 1980, Filed

No. 79-1660

Reporter
1980 U.S. App. LEXIS 13099 *

The National Organization for the Reform of Marijuana Laws (NORML), Petitioner v. Drug Enforcement Administration, U.S. Department of Justice, and U.S. Department of Health, Education and Welfare, Respondents

Notice: **[*1]** UNPUBLISHED DISPOSITION - NOT TO BE CITED AS PRECEDENT. SEE LOCAL RULE 11(c).

Prior History: PETITION FOR REVIEW OF AN ORDER OF THE DRUG ENFORCEMENT ADMINISTRATION

Core Terms

partial, parties

Judges: Before: TAMM, ROBINSON and MIKVA, Circuit Judges

Opinion by: PER CURIAM

Opinion

JUDGMENT

This cause came on to be heard on a petition for review of an order of the Drug Enforcement Administration, briefs and other pleadings, including a motion for partial remand, were filed by the parties, and the case was called for oral argument. Counsel for the parties were asked to address the Court as to the present status of this case and did so. In view of respondents' motion for partial remand of this case to the Drug Enforcement Administration, this Court finds, *sua sponte,* that reconsideration of all the issues in this case would be appropriate. Upon consideration of the foregoing, it is

ORDERED AND ADJUDGED, by this Court, that this case be remanded in its entirety to the Drug Enforcement Administration. It is

FURTHER ORDERED, that the Drug Enforcement Administration refer all the substances at issue to the Department of Health and Human Resources for that Department's scientific and medical findings and recommendations on scheduling, **[*2]** as provided by *21 U.S.C. § 811(b) (1976)*. These proceedings shall take into account new evidence concerning medical use of the substances at issue, and shall be consistent with both this order and the prior decisions of this Court in *National Organization for the Reform of Marijuana Laws v. Drug Enforcement Administration, 182 U.S. App. D.C. 114, 559 F.2d 735 (D.C. Cir. 1977)*, and *National Organization for the Reform of Marijuana Laws v. Ingersoll, 162 U.S. App. D.C. 67, 497 F.2d 654 (D.C. Cir. 1974)*. We regrettably find it necessary to remind respondents of an agency's obligation on remand not to "do anything which is contrary to either the letter or spirit of the mandate construed in the light of the opinion of [the] court deciding the case." *City of Cleveland v. Federal Power Commission, 182 U.S. App. D.C. 346, 561 F.2d 344, 346 (D.C. Cir. 1977)* (quoting *Yablonski v. UMW, 147 U.S. App. D.C. 193, 454 F.2d 1036, 1038*

(D.C. Cir. 1971), cert. denied, 406 U.S. 906, 31 L. Ed. 2d 816, 92 S. Ct. 1609 (1972).

Per Curiam

For the Court

End of Document

(Slip Opinion)

Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs

Under the Controlled Substances Act, the Drug Enforcement Administration may register an applicant to cultivate marijuana only if the registration scheme is consistent with the Single Convention on Narcotic Drugs. To comply with the Single Convention, DEA's licensing framework must provide for a system in which DEA or its legal agent has physical possession and ownership over the cultivated marijuana and assumes control of the distribution of marijuana no later than four months after harvesting.

June 6, 2018

MEMORANDUM OPINION FOR THE ACTING CHIEF COUNSEL
DRUG ENFORCEMENT ADMINISTRATION

Under the Controlled Substances Act, the Attorney General is authorized to license marijuana cultivation if he determines that it would be "consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971." 21 U.S.C. § 823(a). Such obligations include those under the Single Convention on Narcotic Drugs ("Single Convention"), Mar. 30, 1961, 18 U.S.T. 1407. As relevant here, the Single Convention requires parties either to prohibit marijuana cultivation altogether or, if they permit cultivation, to establish "a single government agency" to oversee marijuana growers and generally to monopolize the wholesale trade in the marijuana crop. *Id*. arts. 22, 23(3), 28(1). That single agency must strictly regulate any lawful cultivation of marijuana by, among other things, "purchas[ing] and tak[ing] physical possession of [the] crops as soon as possible, but not later than four months after the end of the harvest." *Id*. art. 23(2)(d).

This opinion considers whether the Drug Enforcement Administration ("DEA"), which exercises the Attorney General's licensing authority, must alter existing licensing practices to comply with the Single Convention. At present, DEA does not purchase or take physical possession of lawfully grown marijuana at any point in the distribution process. Instead, the only currently licensed marijuana cultivator grows and distributes the marijuana itself pursuant to a contract with, and under the supervision of, the National Institute on Drug Abuse ("NIDA"), a component of the Department of Health and Human Services' National Institutes of Health. In 2016, DEA revised this process and announced that it would increase the number of licensees and supervise the additional growers itself.

See Applications To Become Registered Under the Controlled Substances Act To Manufacture Marijuana To Supply Researchers in the United States, 81 Fed. Reg. 53,846, 53,848 (Aug. 12, 2016) ("Applications To Manufacture Marijuana"). Under the new policy, DEA would not purchase or possess the marijuana before licensees distributed it to government-approved researchers. Several entities have applied for licenses under the new policy, but no applications have been approved.

We conclude that DEA must change its current practices and the policy it announced in 2016 to comply with the Single Convention. DEA must adopt a framework in which it purchases and takes possession of the entire marijuana crop of each licensee after the crop is harvested. In addition, DEA must generally monopolize the import, export, wholesale trade, and stock maintenance of lawfully grown marijuana.[1] There may well be more than one way to satisfy those obligations under the Single Convention, but the federal government may not license the cultivation of marijuana without complying with the minimum requirements of that agreement.

I.

The Single Convention entered into force for the United States on June 24, 1967, after the Senate had given its advice and consent to the United States' accession. *See* Single Convention, 18 U.S.T. 1407. The Convention requires parties to impose stringent controls on the cultivation, manufacture, and distribution of narcotic drugs, including "cannabis," which it defines as "the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the

[1] In preparing this opinion, we considered the views of DEA, the Office of the General Counsel of the Department of Health and Human Services, and the Department of State's Office of the Legal Adviser. *See* Applications To Manufacture Marijuana, 81 Fed. Reg. at 53,846–48 (discussing requirements of the Single Convention applicable to licensing marijuana cultivation); Lyle E. Craker, PhD, 76 Fed. Reg. 51,403, 51,409–11 (DEA Aug. 18, 2011) (same); Lyle E. Craker, 74 Fed. Reg. 2101, 2114–18 (DEA Jan. 14, 2009) (same); Memorandum for Steven A. Engel, Assistant Attorney General, Office of Legal Counsel, from Matthew S. Bowman, Deputy General Counsel, Department of Health and Human Services (Apr. 13, 2018) ("HHS Mem."); Office of Law Enforcement and Intelligence and Office of Treaty Affairs, *Single Convention Analysis* (Jan. 29, 2018) ("State Mem."); Letter for Steven A. Engel, Assistant Attorney General, Office of Legal Counsel, from Jennifer G. Newstead, Legal Adviser, Department of State (Apr. 17, 2018) ("State Supp. Mem.").

resin has not been extracted, by whatever name they may be designated." Single Convention art. 1(1)(b). Parties must, among other things, establish quotas on the import and manufacture of cannabis, generally prohibit the possession of cannabis, and adopt penal provisions making violations of those controls punishable offenses. *Id*. arts. 21, 33, 36.

Article 28 of the Single Convention requires that any lawful cultivation of the cannabis plant be subject to the same system of strict controls "as provided in article 23 respecting the control of the opium poppy." *Id*. art. 28. The cross-referenced provisions in Article 23 provide as follows:

> 1. A Party that permits the cultivation of the opium poppy for the production of opium shall establish, if it has not already done so, and maintain, one or more government agencies (hereafter in this article referred to as the Agency) to carry out the functions required under this article.
>
> 2. Each such Party shall apply the following provisions to the cultivation of the opium poppy for the production of opium and to opium:
>
> a. The Agency shall designate the area in which, and the plots of land on which, cultivation of the opium poppy for the purpose of producing opium shall be permitted.
>
> b. Only cultivators licensed by the Agency shall be authorized to engage in such cultivation.
>
> c. Each license shall specify the extent of the land on which the cultivation is permitted.
>
> d. All cultivators of the opium poppy shall be required to deliver their total crops of opium to the Agency. The Agency shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest.
>
> e. The agency shall, in respect of opium, have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers of opium alkaloids, medicinal opium, or opium preparations. Parties need not extend this exclusive right to medicinal opium and opium preparations.

> 3. The governmental functions referred to in paragraph 2 shall be discharged by a single government agency if the constitution of the Party concerned permits it.

The agency's "exclusive right[s]" over the harvested marijuana need not extend to "medicinal" marijuana or marijuana "preparations," but the national cannabis agency must still purchase and take physical possession of all marijuana grown for such purposes. *Id*. art. 23(2)(d)(e); *see* Report of the International Narcotics Control Board for 2014, at 35 (Mar. 3, 2015) ("2014 INCB Report"); Secretary-General of the United Nations, *Commentary on the Single Convention on Narcotic Drugs, 1961*, at 284, 314 (1973) ("*Commentary*").[2]

Three years after the United States acceded to the Single Convention, Congress in 1970 enacted the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq*., "a comprehensive statute designed to rationalize federal control of dangerous drugs." *Nat'l Org. for Reform of Marijuana Laws (NORML) v. DEA*, 559 F.2d 735, 737 (D.C. Cir. 1977). "[A] number of the provisions of [the CSA] reflect Congress' intent to comply with the obligations imposed by the Single Convention." *Control of Papaver Bracteatum*, 1 Op. O.L.C. 93, 95 (1977); *see, e.g*., 21 U.S.C. §§ 801(7), 811(d)(1), 958(a); *see also* S. Rep. No. 91-613, at 4 (1969) ("The United States has international commitments to help control the worldwide drug traffic. To honor those commitments, principally those established by the Single Convention on Narcotic Drugs of 1961, is clearly a Federal responsibility.").

The CSA imposes strict controls on marijuana, which is defined to include "all parts of the plant Cannabis sativa L." and all compounds and derivatives thereof, with certain exceptions not relevant here. 21 U.S.C. § 802(16). The statute classifies marijuana as a schedule I substance, the most stringent classification available, reflecting a determination that marijuana "has a high potential for abuse" and "no currently accepted medical use." 21 U.S.C. § 812(b); *see Craker v. DEA*, 714 F.3d 17, 19 (1st Cir. 2013); 21 C.F.R. § 1308.11. The CSA makes the unauthorized

[2] The United Nations' Economic and Social Council requested that the Secretary-General prepare the *Commentary* "in the light of the relevant conference proceedings and other material" in order to aid governments in applying the Single Convention. Economic and Social Council Resolution 1962/914(XXXIV)D (Aug. 3, 1962).

possession, manufacture, and distribution of marijuana a crime punishable by severe penalties. 21 U.S.C. §§ 841, 844.

Although federal law recognizes no currently accepted medical use for marijuana, *see United States v. Oakland Cannabis Buyers' Co-op.*, 532 U.S. 483, 491 (2001), it does permit the cannabis plant to be cultivated lawfully for research purposes pursuant to a DEA license. *See* 21 U.S.C. §§ 822(a)(1), 823(a); 21 C.F.R. pt. 1301.[3] Since its founding in 1973, DEA has licensed only one such grower to supply researchers with marijuana—the National Center for Natural Products Research ("National Center"), a division of the University of Mississippi. *See* Lyle E. Craker, 74 Fed. Reg. at 2104; Applications To Manufacture Marijuana, 81 Fed. Reg. at 53,846. The National Center cultivates marijuana pursuant to a contract administered by NIDA. Besides overseeing the cultivation of marijuana, NIDA also plays a role in determining which researchers may obtain marijuana for medical or scientific use. *See* 21 U.S.C. § 823(f); Announcement of Revision to the Department of Health and Human Services Guidance on Procedures for the Provision of Marijuana for Medical Research as Published on May 21, 1999, 80 Fed. Reg. 35,960 (June 23, 2015).

The current contract between NIDA and the National Center, which became effective on March 23, 2015, provides that the National Center will, among other things, "cultivate and harvest, process, analyze, store, and distribute cannabis . . . for research." Award/Contract Issued by Nat'l Inst. on Drug Abuse, to the University of Mississippi, Contract No. HHSN271201500023C, at 4 (effective Mar. 23, 2015) ("2015 NIDA Contract"). The National Center must also "[p]rovide an adequate DEA approved storage facility" for the harvested cannabis and may ship it to researchers only "as required by NIDA." *Id.* at 17. All work under the contract is to be "monitored" by the Government Contracting Officer's Representative, an employee at NIDA's headquarters in Bethesda, Maryland. *Id.* at 16, 34. The contract requires the NIDA representative to monitor technical progress based on the National Center's monthly progress reports, to evaluate the National Center's work, to perform technical evaluations and inspections of a sample of the marijuana shipped to NIDA, and to assist in resolving technical problems. *Id.* at 17, 26, 34.

[3] Sections 822(a) and 823(a) vest authority over registration for such licenses in the Attorney General. Pursuant to 21 U.S.C. § 871(a), the Attorney General delegated this function to DEA. 28 C.F.R. § 0.100(b).

In 2016, in response to increasing public interest in marijuana research, DEA announced a new policy reflecting its intention to increase the number of federally authorized growers. *See* Applications To Manufacture Marijuana, 81 Fed. Reg. at 53,846–48. Under the new policy, a grower, if approved for a license, would "be permitted to operate independently, provided the grower agrees (through a written memorandum of agreement with DEA) that it will only distribute marijuana with prior, written approval from DEA." *Id*. at 53,848. NIDA would not be involved in monitoring the additional licensees. We understand that DEA has several currently pending requests from entities that seek to register as marijuana growers under that policy.

II.

Under the CSA, DEA may register an applicant to cultivate marijuana only if the registration scheme is consistent with the Single Convention. We address whether DEA's practices and policy for licensing marijuana cultivation comply with the Single Convention and, if not, what changes DEA must make to conform to the treaty.

A.

An international agreement has the force of domestic U.S. law if it is self-executing or if Congress has implemented it by legislation. *See Medellín v. Texas*, 552 U.S. 491, 504–05 (2008). Here, Congress has executed the Single Convention in the CSA. In that Act, Congress provided that the Attorney General "shall" license the cultivation of marijuana "if he determines that such registration is consistent with . . . United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971." 21 U.S.C. § 823(a).[4] The Attorney General is thus required to determine that the licensing scheme is consistent with the Single Convention before exercising his authority to register an applicant to cultivate marijuana. *See Control of Papaver Bracteatum*, 1 Op. O.L.C. at 99; Memorandum for John E. Ingersoll, Director, Bureau of Narcotics and Dangerous Drugs, from Mary C. Lawton, Deputy Assistant Attorney General, Office of Legal Counsel, *Petition to Decontrol Marihuana*—

[4] The Single Convention was amended by a 1972 protocol, but the amendments are not material to the obligations discussed in this opinion. *See* Protocol Amending the Single Convention on Narcotic Drugs, Mar. 25, 1972, 26 U.S.T. 1439.

Interpretation of Section 201 of the Controlled Substances Act of 1970, at 4 (Aug. 21, 1972) ("[I]n making determinations as to the fitness of registrants to receive licenses for manufacture or export and import of controlled substances, the Attorney General is instructed to ensure consistency 'with United States obligations under international treaties.'").

Article 23(2) of the Single Convention, made applicable to marijuana cultivation by Article 28, contains five requirements for the supervision, licensing, and distribution of marijuana. *See* Single Convention art. 23(2)(a)–(e). Under current regulations and practice, DEA satisfies the first three requirements. The Convention specifies that the agency must designate the land on which cannabis cultivation is permitted, limit cultivators to those licensed by the agency, and specify the extent of the land on which cultivation is permitted. *Id*. art. 23(2)(a), (b), (c). Federal regulations implement those requirements by mandating that a marijuana manufacturer obtain a DEA license annually for each physical location at which marijuana is grown. 21 U.S.C. § 822(a)(1); 21 C.F.R §§ 1301.11(a), 1301.12(a). DEA establishes annual production quotas for lawful marijuana cultivation, and it has exercised that authority by setting the annual quotas for the National Center, the only entity ever registered by DEA to grow marijuana to supply researchers in the United States. 21 U.S.C. § 826; 21 C.F.R. § 1303.11. DEA has ample authority under this framework to specify the areas and circumstances under which a licensee may cultivate marijuana and in fact satisfies the first three requirements of Article 23(2) of the Single Convention in registering applicants under the CSA pursuant to those requirements.

Article 23 of the Single Convention also imposes control requirements beyond those currently carried out by DEA. Under Article 23(2)(d), "all cultivators shall be required to deliver their total crops" to the agency, and the agency "shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest." Article 23(2)(e) requires the agency to "have the exclusive right of importing, exporting, wholesale trading and maintaining stocks." The United States currently attempts to comply with those requirements through NIDA's contract with the National Center, under which NIDA's contracting officials supervise the National Center's cultivation of marijuana and distribution of marijuana to researchers. Article 23's final requirement, however, provides that the "governmental functions" in Article 23(2) must be "discharged by a single government agency if the constitution of the Party concerned permits it." Single Convention art. 23(3).

We conclude that the existing licensing framework departs from Article 23 in three respects. First, the division of responsibilities between DEA and NIDA, a component of the Department of Health and Human Services ("HHS"), contravenes Article 23(2)'s requirement that all Article 23 functions be carried out by a single government agency. Second, neither of the two government agencies "take[s] physical possession" of the marijuana grown by the National Center, as required by Article 23(2)(d). Third, no federal agency exercises a monopoly over the wholesale trade in marijuana, as required by Article 23(2)(e). We discuss each departure in turn.

1.

Current practice diverges from the Single Convention's requirement that a single agency undertake each of the listed control functions unless the constitution of the treaty party forbids it. As explained, DEA is responsible for the controls required by Article 23(2)(a), (b), and (c) because it effectively designates the area where marijuana cultivation is permitted, limits cultivators to those licensed by the agency, and specifies the extent of the land on which cultivation is permitted. NIDA, for its part, attempts to satisfy the physical-possession and government-monopoly-control requirements of Article 23(2)(d) and (e) by supervising cultivation under its contract with the National Center. That division of authority is contrary to Article 23(3), because nothing in the Constitution would preclude the United States from discharging all of those controls through one government agency.

DEA agrees that "the United States fails to adhere strictly" to the single government agency provision because "both DEA and HHS carry out certain functions set forth in article 23, paragraph 2." Lyle E. Craker, PhD, 76 Fed. Reg. at 51,409.[5] For the current framework to be in compli-

[5] Members of Congress and the American Bar Association have also recognized that the division of regulatory responsibilities among federal agencies fails to comply with the Single Convention. *See* 129 Cong. Rec. 7434 (Mar. 24, 1983) (Rep. McKinney) (recognizing that the current division of responsibilities is in "violation of the [S]ingle [C]onvention" and introducing a bill that would create an "Office for the Supply of Internationally Controlled Drugs" within the Department of Health and Human Services to "comply[] with the [S]ingle [C]onvention on [N]arcotic [D]rugs"); *Report No. 1 of the Section of Administrative Law*, 109 Ann. Rep A.B.A. 447, 482 (1984) (noting that the Single Convention "requires that a *single* government agency license all domestic pro-

ance with the single-agency requirement of the treaty, we would have to view NIDA as performing the physical-possession and government-monopoly functions on behalf of DEA. *See* State Mem. at 5. But we do not believe that NIDA acts for DEA, and it is unlikely that DEA could lawfully supervise NIDA in the performance of its functions. We are aware of no statute that gives DEA that authority. And the President may not delegate to DEA his constitutional authority to supervise NIDA in the exercise of its statutory responsibilities. *See Centralizing Border Control Policy Under the Attorney General*, 26 Op. O.L.C. 22, 24–25 (2002).

2.

We turn next to the requirement that the single government agency "purchase and take physical possession" of the marijuana. Single Convention art. 23(2)(d). As noted above, NIDA contracts with, and partially oversees, the cultivation of marijuana by the National Center, which is licensed by DEA. But under that contractual arrangement, neither NIDA nor DEA takes physical possession of the marijuana. Rather, the National Center itself stores the marijuana on the premises of the University of Mississippi and ships it to researchers approved by DEA. Neither NIDA nor DEA accepts delivery of the harvested crops. That contractual arrangement does not satisfy the United States' obligations under Article 23(d). The contract at most results in a federal government agency's having constructive, rather than physical, possession of the marijuana crop.

a.

The Single Convention does not define "physical possession." In construing that term we should "begin with the text of the treaty and the context in which the written words are used." *Water Splash, Inc. v. Menon*, 137 S. Ct. 1504, 1508–09 (2017) (internal quotation marks omitted); *see also Restatement (Third) of the Foreign Relations Law of the United States* § 325(1) (Am. Law Inst. 1987) ("*Restatement of Foreign Relations*") ("An international agreement is to be interpreted in good faith according to the ordinary meaning to be given to its terms in their context and in light of its object and purpose."); Vienna Convention on the Law of

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duce[r]s of marijuana, specify the particular plots of land on which it is to be grown, and collect the crops of all domestic producers of marijuana" and that "at present the authority to control marijuana production is split between" government agencies).

Treaties art. 31(1), *opened for signature* May 23, 1969, 1155 U.N.T.S. 331("Vienna Convention") (similar).[6]

We think it evident from the treaty's text and context that "physical possession" requires growers licensed under the CSA to transfer the crops to the physical, and not merely legal, control of the federal government. Article 23(2)(d) says that "cultivators" must "deliver their total crops" to the government—a clear indication that the treaty contemplates the physical transfer of control from one party to another. The Single Convention's *Commentary* reinforces that point in emphasizing that "the time between the harvest and *delivery of the crop* should be as short as possible" and recommending that parties "set a final date after which possession of harvested [crops] by a private cultivator is in any event illegal and [the crop] subject to confiscation." *Commentary* at 283 (emphasis added). And this understanding of the words used in the Single Convention is further confirmed by the decisions of U.S. courts, which have consistently distinguished constructive possession from physical possession, with the latter requiring direct physical control over the item in question.[7]

One might argue that NIDA, through its contract, satisfies the treaty requirements of physical possession via the pervasive influence and control NIDA exercises over the National Center's cultivation operations. *See* State Mem. at 5; State Supp. Mem. at 2. NIDA's contract does provide that the National Center serves as "NIDA's cannabis drug repository." 2015 NIDA Contract at 16. DEA regulations also include detailed specifications for the material, size, and accessibility of the storage facility. *See* 21 C.F.R. §§ 1301.71–1301.76. The contract further specifies particular temperatures for the storage facility and notes that "[l]ocal DEA agents will determine the exact type of security required." 2015 NIDA

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[6] The United States is not a party to the Vienna Convention, but this Office has relied on Article 31 as generally reflecting customary international law and practice. *See Interpretation of Article 17* Bis *of the US-EU Air Transport Agreement*, 40 Op. O.L.C. __, at *5 (Apr. 14, 2016); *"Protected Person" Status in Occupied Iraq Under the Fourth Geneva Convention*, 28 Op. O.L.C. 35, 53 n.21 (2004).

[7] *See, e.g.*, *United States v. Hunter*, 558 F.3d 495, 503–04 (6th Cir. 2009) ("Actual possession exists when an individual knowingly has direct physical control over a thing at a given time[.]"); *United States v. Derose*, 74 F.3d 1177, 1185 (11th Cir. 1996) (defining "actual possession" as "physical possession or . . . actual personal dominion over the thing allegedly possessed"); *United States v. Raper*, 676 F.2d 841, 848 (D.C. Cir. 1982) (finding constructive possession even though the drugs were in another's "physical possession"); *United States v. Moreno*, 649 F.2d 309, 313 (5th Cir. Unit A June 1981) (same).