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

PETITIONERS' BRIEF

Matthew C. Zorn
Shane Pennington
YETTER COLEMAN LLP
811 Main Street, Suite 4100
Houston, Texas 77002
(713) 632-8000
(713) 632-8002
mzorn@yettercoleman.com
spennington@yettercoleman.com

ATTORNEYS FOR PETITIONERS SUZANNE SISLEY, M.D.; SCOTTSDALE RESEARCH INSTITUTE, LLC; BATTLEFIELD FOUNDATION D/B/A FIELD TO HEALED; LORENZO SULLIVAN; KENDRIC SPEAGLE; AND GARY HESS

TABLE OF CONTENTS

TABLE OF AUTHORITIES 5

INTRODUCTION 14

JURISDICTIONAL STATEMENT 17

STATEMENT OF THE ISSUES PRESENTED FOR REVIEW 18

PERTINENT STATUTES AND CONSTITUTIONAL PROVISIONS 18

STATEMENT OF THE CASE 18

I. Background of the Act. 18

A. Drug scheduling 20

B. Marijuana in 1970 22

C. Responsibilities and duties under the Act 23

II. Prior rescheduling litigation 26

A. The 1972 NORML petition 26

B. *Chevron* and the five-factor test 27

C. Recent failed efforts to reschedule marijuana 31

III. Factual background 35

A. Dr. Suzanne Sisley and SRI 35

B. The NIDA monopoly and the regulatory Catch-22 37

C. The rise and stall of the Growers Program 40

IV. The 2020 Petition 44

STANDARD OF REVIEW 45

SUMMARY OF ARGUMENT 45

ARGUMENT 47

I. The 2020 Determination is contrary to law. 47

A. The 2020 Determination rests on an unlawful interpretation of § 812(b)(1)(B). 47

1. DEA's interpretation bears no connection to the statutory text. 47

2. Widespread acceptance by the States—the traditional gatekeepers of the medical profession under Our Federalism—forecloses placement in Schedule I. 56

3. Other textual clues refute DEA's interpretation. 58

4. DEA's interpretation invites absurd results. 66

B. *Chevron* does not apply. 67

C. Even if *Chevron* applied, it could not save DEA's interpretation of § 812(b)(1)(B). 69

II. Section 811(d)(1)'s double delegation of legislative Power Is unconstitutional. 76

A. Section 811(d)(1) violates the private non-delegation doctrine. 76

B. The delegation to the Attorney General is unconstitutional. 79

C. The double delegation violates separation of powers. 81

CONCLUSION 81

STATEMENT OF RELATED CASES 83

INSERT FORM 8 - CERTIFICATE COMPLIANCE 84

CERTIFICATE OF SERVICE 85

TABLE OF AUTHORITIES

Page(s)

CASES

A.L.A. Schechter Poultry Corp. v. United States,
295 U.S. 495 (1935).....77

Alliance for Cannabis Therapeutics v. DEA,
930 F.2d 936 (D.C. Cir. 1991).....29, 67, 70

Alliance for Cannabis Therapeutics v. DEA,
15 F.3d 1131 (D.C. Cir. 1994).....31

Aluminum Co. of Am. v. Cent. Lincoln Peoples' Util. Dist.,
467 U.S. 380 (1984).....54

Americans for Safe Access v. DEA,
706 F.3d 438 (D.C. Cir. 2013).....32

Bare v. Barr,
2020 WL 5541393 (9th Cir. Sept. 16, 2020).....66

BFP v. Resolution Tust. Corp.,
511 U.S. 531 (1994).....56, 74

Bond v. U.S.,
572 U.S. 844 (2014).....48

Bonds v. Tandy,
457 F.3d 409 (5th Cir. 2006).....17

Bostock v. Clayton Cty., Georgia,
140 S. Ct. 1731 (2020).....53, 60

Buckman Co. v. Plaintiffs' Legal Comm.,
531 U.S. 341 (2001).....50

Carter v. Carter Coal Co.,
298 U.S. 238 (1936).....76, 77

Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.,
467 U.S. 837 (1984).....27, 45, 70

Cuomo v. Clearing House Ass'n,
557 U.S. 519 (2009).....69

Dep't of Transp. v. Ass'n of Am. R.R.,
575 U.S. 43 (2015).....77, 78, 79

Esquivel-Quintana v. Lynch,
810 F.3d 1019 (6th Cir. 2016).....69

Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.,
537 F.3d 667 (D.C. Cir. 2008).....81

Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.,
561 U.S. 477 (2010).....79, 81

Gettman v. DEA,
290 F.3d 430 (D.C. Cir. 2002).....32

Gonzales v. Oregon,
546 U.S. 243 (2006).....*passim*

Gonzales v. Raich,
545 U.S. 1 (2005).....*passim*

Grinspoon v. DEA,
828 F.2d 881 (1st Cir. 1987).....*passim*

Gundy v. United States,
139 S. Ct. 2116 (2019).....79, 80, 81

Gustafson v. Alloyd Co.,
513 U.S. 561 (1995).....63

Henson v. Santander Consumer USA Inc.,
137 S. Ct. 1718 (2017).....49

Inland Empire Pub. Lands Council v. Glickman,
88 F.3d 697 (9th Cir. 1996).....70

Judulang v. Holder,
565 U.S. 42 (2011).....72

Left Coast Ventures Inc. v. Bill's Nursery Inc.,
2019 WL 6683518 (W.D. Wash. Dec. 6, 2019) 35

Mayo Found. for Med. Educ. and Research v. United States,
562 U.S. 44 (2011).....70

Medellin v. Texas,
552 U.S. 491 (2008).....80

Medtronic, Inc. v. Lohr,
518 U.S. 470 (1996).....52

Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,
463 U.S. 29 (1983).....71

Nat. Res. Def. Council v. EPA,
464 F.3d 1 (D.C. Cir. 2006).....78

Nat'l Org. for Reform of Marijuana Laws (NORML) v. Ingersoll,
497 F.2d 654 (D.C. Cir. 1974).....20, 21, 26

Nat'l R.R. Passenger Corp. v. Bos. & Maine Corp.,
503 U.S. 407 (1992).....63

Nebraska v. Parker,
136 S. Ct. 1072 (2016).....48

NORML v. DEA,
1980 U.S. App. Lexis 13099 (D.C. Cir. Oct. 16, 1980) 27

NORML v. DEA,
559 F.2d 735 (D.C. Cir. 1977).....20, 26, 27

PDK Labs. Inc. v. DEA,
362 F.3d 786 (D.C. Cir. 2004).....17

Riegel v. Medtronic, Inc.,
552 U.S. 312 (2008).....51

SAS Inst., Inc. v. Iancu,
138 S. Ct. 1348 (2018).....45

Sessions v. Dimaya,
138 S. Ct. 1204 (2018) 48, 79

Smith v. Goguen,
415 U.S. 566 (1974) 79

Sturgeon v. Frost,
136 S. Ct. 1061 (2016) 50

Sunshine Anthracite Coal Co. v. Adkins,
310 U.S. 381 (1940) 78

Touby v. United States,
500 U.S. 160 (1991) 80

United States v. McIntosh,
833 F.3d 1163 (9th Cir. 2016) 34

United States v. Mead Corp.,
533 U.S. 218 (2001) 68

Valenzuela Gallardo v. Barr,
968 F.3d 1053 (9th Cir. 2020) 69

Washington v. Barr,
925 F.3d 109 (2d Cir. 2019) 33

Younger v. Harris,
401 U.S. 37 (1971) 58

STATUTES

5 U.S.C. § 706 45

21 U.S.C. § 301 20

21 U.S.C. § 331 21

21 U.S.C. § 396 ..... 62, 74

21 U.S.C. § 801 19

21 U.S.C. § 802(16) 72

21 U.S.C. § 811(a) 25, 82

21 U.S.C. § 811(b) 25

21 U.S.C. § 811(d) .....*passim*

21 U.S.C. § 811(d)(1).....*passim*

21 U.S.C. § 812 58

21 U.S.C. § 812(a) 59

21 U.S.C. § 812(b)(1)(B) .....*passim*

21 U.S.C. § 812(b)(1)(C) 63

21 U.S.C. § 812(b)(2)(B) 64

21 U.S.C. § 812(c) 21

21 U.S.C. § 823 66

21 U.S.C. § 823(d) 39

21 U.S.C. § 824(a) 57

21 U.S.C. § 826 59

21 U.S.C. § 829(c) 57

21 U.S.C. § 903 51

Pub. L. No. 91-513 §§ 601, 602, 84 Stat. 1236 (Oct. 27, 1970).....22, 23, 72

Pub. L. No. 115-271 (Oct. 24, 2018) 75

OTHER AUTHORITIES

21 C.F.R. § 166.2(e).....66

116 Cong. Rec. 36,882 (1970).....53

116 Cong. Rec. 973 (1970) 19

40 Fed. Reg. 44,164 (1975) 26

44 Fed. Reg. 36,123 (June 20, 1979) 27

47 Fed. Reg. 28,141 (June 29, 1982) 49

53 Fed. Reg. 5,156 (Feb. 22, 1988) 29

54 Fed. Reg. 53,767 (Dec. 29, 1989) 29

57 Fed. Reg. 10,499 (Mar. 26, 1992) .....*passim*

59 Fed. Reg. 59,820 (Nov. 18, 1994) 62

66 Fed. Reg. 20,038 (Apr. 18, 2001) 32

74 Fed. Reg. 2,101 (Jan. 14, 2009) 39

76 Fed. Reg. 40,552 (July 8, 2011) 32

81 Fed. Reg. 53,688 (Aug. 11, 2016) .....*passim*

81 Fed. Reg. 53,767 (Aug. 12, 2016) 76

81 Fed. Reg. 53,846 (Aug. 12, 2016) 40

84 Fed. Reg. 44,920 (Aug. 27, 2019) 43

85 Fed. Reg. 16,292 (Mar. 23, 2020) 43

12 FDA Drug Bull. 4 (Apr. 1982) 50

A. Scalia & B. Garner, Reading Law: The Interpretation of Legal Texts (2012) 47, 64

Alcoholism and Narcotics, Hearings, 91st Cong., 2d Sess., on Inquiry into the Problem of Alcoholism and Narcotics (Part 5) (1970) 24, 25

B. Erickson, "Cannabis research stalled by federal inaction," 98 Chem. & Eng. News 25 (June 29, 2020) 37

Commerce, Justice, Science, and Related Agencies Appropriations for Fiscal Year 2019 Hearings, Subcommittee of the Committee of Appropriations (Apr. 25, 2018) 41

D. Musto & P. Korsmeyer, *The Quest for Drug Control, Politics and Federal Policy in a Period of Increasing Substance Abuse* (2002) 21

Drug abuse control amendments—1970, Hearings, 91st Cong., 2d Sess., on H.R. 11701 and H.R. 13743 (Part 1) (1970) 55

Drug abuse control amendments—1970, Hearings, 91st Cong., 2d Sess., on H.R. 11701 and H.R. 13743 (Part 2) (1970) 54

FDA, *Good Reprint Practices* (Jan. 2009), http://www.fda.gov/RegulatoryInformation/Guidances/ucml25126.htm 50

Federal Drug Abuse and Drug Dependence Prevention, Treatment, and Rehabilitation Act of 1970, Hearings, 91st Cong., 2d Sess., on S. 3562 (Part 2) (1970) 22

Federal Drug Abuse and Drug Dependence Prevention, Treatment, and Rehabilitation Act of 1970, Hearings, 91st Cong., 2d Sess., on S. 3562 (Part 2) (1970) 54

G. Posner, *Pharma: Greed, Lies, and the Poisoning of America* (2020) 21, 55

H.R. Rep. No. 91–1444, 91st Cong., 2d Sess. (1970) reprinted in 1970 U.S.C.C.A.N. 4566 .....24, 25, 66

H. Res. 17 (1969) 22

Hearing Before the House Committee on the Judiciary, 116th Cong., 1st Sess. (Feb. 8, 2019) 41

In the matter of Marijuana Rescheduling Petition, Docket No. 86-22 (DOJ Sept. 6, 1988) 29

L. Chafee and C. Gregoire, Rulemaking Petition to Reclassify Cannabis for Medical Use from a Schedule I Controlled Substance to a Schedule II (Nov. 30, 2011).....32

L. Sacco et al., *The Marijuana Policy Gap and the Path Forward*, Congressional Research Service, at 12-14 (Mar. 10, 2017) 34

L. Sacco, *The Schedule I Status of Marijuana* Congressional Research Service, p.1-2 (Sept. 11, 2020) *available at* https://crsreports.congress.gov/product/pdf/IN/IN11204.....34

Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs
42 Op. O.L.C. -- (June 6, 2018).....42

Ltr. to Azar, Carroll, Dhillon (Dec. 11, 2019).....43

Ltr. to Sessions (Aug. 31, 2018).....40

Ltr. to Sessions, Dhillon (Sept. 28, 2018).....40

Ltr. to Sessions (July 25, 2018).....41

Ltr. to Shea (Aug. 18, 2020).....43, 44

M. Sonnenreich to J. Dean, Memorandum re: Proposed Changes in S. 3246, the Controlled Dangerous Substances Act (DOJ Apr. 17, 1970).....60

Mandamus Petition, *In re: Scottsdale Res. Inst., LLC*, 19-1120 (D.C. Cir. June 11, 2019.....42

Michael Sonnenreich et al., Handbook of Federal Narcotic and Dangerous Drug Laws, Dep't of Justice (Jan. 1969).....19

National Conference of State Legislatures, State Medical Marijuana Laws & Table 1 (Mar. 10, 2020), *available at* https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx.....55

Order, *In re: Scottsdale Res. Inst., LLC*, 19-1120 (D.C. Cir. July 29, 2019).....42

Press Release, Drug Enforcement Administration (Aug. 26, 2019).....42

R. Bogomolny, M. Sonnenreich & A. Roccograndi, A Handbook on the 1970 Federal Drug Act: Shifting the Perspective (1975).....*passim*

R. Eisenberg, D. Leiderman, *Cannabis for Medical Use: FDA and DEA Regulation in the Hall of Mirrors*, 74 Food & Drug L.J. 246 (2019).....75

Response, *In re: Scottsdale Research Inst., LLC*, 19-1120 (D.C. Cir. July 29, 2019).....43

S. Rep. No. 813, 91st Cong., 1st Sess. (1969) 24, 25, 60

Schwabe et al., Research Grade Marijuana Supplied by the National Institute on Drug Abuse is Genetically Divergent from Commercially Available Cannabis, Pre-Print 38

Settlement Agmt., *Scottsdale Research Inst., LLC v. DEA*, 2:20-cv-00605-PHX-JJT (D. Ariz. Apr. 28, 2020) 41

Webster's New Twentieth Century Dictionary Unabridged (2d ed.) (1970) 49

INTRODUCTION

Thirty-one year old Justice Department lawyer Michael Sonnenreich faced a daunting task. Between 1914 and 1969, Congress had enacted some fifty pieces of drug legislation. Littered about the U.S. Code, these disparate laws made enforcement difficult. Sonnenreich's job was to boil this confusing patchwork down to a single, uniform framework to assist law enforcement and better protect the public from the dangers of drug abuse.

His innovation was the scheduling system. Rather than address drugs or classes of drugs in standalone laws, the scheduling system provided a single legislative scheme for all controlled substances. Drugs were sorted into schedules based on medical-utility and abuse-potential criteria. Restrictions and penalties corresponded to schedules, not particular drugs or drug classes. The schedules could then be administratively adjusted as circumstances and knowledge changed, eliminating the need for constant legislative amendments.

These schedules—the Controlled Substances Act's ("CSA" or "Act") cardinal feature—were supposed to carry out its promise: providing a flexible federal drug-control framework capable of adapting to changing times and thus eliminating the confusing patchwork of federal laws that preceded it.

Fifty years later, however, the Act has failed to deliver on that promise. More than two-thirds of States have enacted medical-marijuana laws, but marijuana remains in Schedule I. This growing schism between state and federal law has brought back the patchwork of incoherent law the Act was supposed to fix.

It did not have to be this way. The story of how the flexible scheduling framework got turned on its head is long and winding. But at its core, it sings a familiar refrain. Decades after enactment, to achieve a policy end, the Drug Enforcement Administration ("DEA") rewrote the statutory text, contrary to its plain meaning and the intent of Congress. But under *Chevron*, courts deferred.

In the twenty-five years since, DEA has brushed aside every petition to reschedule marijuana no matter the evidence by relying on its now twenty-five-year-old "five-part test" for "currently accepted medial use." For example, in 2011, the Governors of Rhode Island and Washington submitted a petition arguing marijuana's classification was "fundamentally wrong." Applying the five-part test, DEA denied the petition in 2016 ("2016 Denial"). It also concluded that U.S. treaty obligations independently required keeping marijuana in Schedules I or II.

Stephen Zyskiewicz's one-page, handwritten petition (the "2020 Petition") suffered the same fate. Zyskiewicz makes one simple, unassailable point: "the current situation of cannabis in Schedule I [is] completely untenable" because "[h]alf the states allow for medical use." 1.ER.1. He's right. But in April 2020, DEA said otherwise and denied the 2020 Petition (the "2020 Denial"). 1.ER.2. According to DEA, evidence gathered in response to a different petition submitted nearly a decade ago proves that, per its five-part test, marijuana today has no "currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(1)(B).

This final decision vests this Court with jurisdiction to right a ship that veered off course long ago. Petitioners urge this Court to grant the Petition for Review and hold the 2020 Denial unlawful for two reasons:

First, it rests on an interpretation of § 812(b)(1)(B) that cannot be squared with the plain text of the statute. The traditional tools of statutory construction demonstrate that marijuana's widespread acceptance by the States renders DEA's finding of "no currently accepted medical use in treatment in the United States" untenable.

Second, § 811(d)(1), which forms the basis for DEA's independent determination that marijuana must be placed in Schedules I or II,

unconstitutionally delegates legislative power twice: first to a non-governmental entity and then to the Attorney General.

JURISDICTIONAL STATEMENT

"[A]ny person aggrieved" by a final DEA determination may seek review of the decision in the United States Court of Appeals in the circuit in which his principal place of business is located within thirty days after notice of the decision. *Id.* § 877. On May 21, 2020, Petitioners timely petitioned for review of the 2020 Denial.

Each Petitioner suffers an injury from the 2020 Denial and seeks to vindicate interests within the statute's zone-of-interests. *See Bonds v. Tandy*, 457 F.3d 409, 412 (5th Cir. 2006); *PDK Labs. Inc. v. DEA*, 362 F.3d 786, 793 (D.C. Cir. 2004). Petitioners Sisley and Scottsdale Research Institute ("SRI") are licensed to research marijuana, but marijuana's Schedule I classification has hampered their research. *See* 6.ER.1408, Sisley Decl. Petitioners Sullivan, Speagle, and Hess are veterans with injuries stemming from marijuana's continued Schedule I placement. *See* 6.ER.1424, Sullivan Decl.; 6.ER.1422, Speagle Decl.; 6.ER.1419, Hess Decl. But for DEA's application of its unlawful interpretation of § 812(b)(1)(B), DEA could not have denied the 2020 Petition.

Jurisdictional issues are addressed in more detail at Dkt. 14 at 1-2, 8, 11-14.

STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

1. Is the interpretation of § 812(b)(1)(B) underlying the 2020 Denial, which concludes that marijuana has "no currently accepted medical use in treatment in the United States" despite its widespread acceptance by the traditional gatekeepers of the practice of medicine in Our Federalism—the States—arbitrary, capricious, or otherwise contrary to law? *Yes.*

2. Is § 811(d)(1)'s double delegation of legislative Power to a non-governmental entity and the Attorney General constitutional? *No.*

PERTINENT STATUTES AND CONSTITUTIONAL PROVISIONS

Pertinent statutes and constitutional provisions appear in the addendum.

STATEMENT OF THE CASE

I. Background of the Act.

Congress enacted the CSA in 1970 to combat "drug abuse" and control "the legitimate and illegitimate traffic in controlled substances." *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006). To that end, it made two competing findings. First, many drugs "have a useful and legitimate medical purpose

and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. § 801(1). Second, the "illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people." *Id.* § 801(2).

Congress did not legislate against a blank slate. Until the Act, the federal government regulated drugs through a "patchwork" of federal laws. 5.ER.1044-47, M. Sonnenreich et al., *Handbook of Federal Narcotic and Dangerous Drug Laws*, xiii to xvi (DOJ Jan. 1969); 2.ER.180-88, R. Bogomolny, M. Sonnenreich & A. Roccograndi, *Handbook on the 1970 Federal Drug Act: Shifting the Perspective* at 5-20 (1975) ("Handbook").[1] The Act consolidated these disparate pieces of legislation into a "comprehensive statute" to "strengthen law enforcement tools against the traffic in illicit drugs." *Gonzales v. Raich*, 545 U.S. 1, 10 (2005).

"[I]n concept, in spirit, and in detail," the CSA is "a law-enforcement measure" to curb drug abuse. 2.ER.385, 116 Cong. Rec. 973 (1970). While the Act establishes a comprehensive federal drug-control regime to facilitate law

[1] For reference and convenience, Petitioners include legislative, administrative, and secondary source authorities—some of which are not easily accessible—in the Excerpts of Record. *See also* 6.ER.1400, Zorn Decl.

enforcement, it reserves a key role for State regulation of the medical practice. *Oregon*, 546 U.S. at 270.

A. Drug scheduling

The "cardinal feature" of the Act's effort to rationalize and consolidate federal drug control is the scheduling system. *Nat'l Org. for Reform of Marijuana Laws (NORML) v. Ingersoll*, 497 F.2d 654, 656 (D.C. Cir. 1974) ("*NORML I*"). *See also* Handbook at 26-27. The Act sorts drugs among five schedules based on their accepted medical uses, potential for abuse, and effects on the body. *Raich*, 545 U.S. at 13. The schedules do not rank drugs from most to least dangerous. Rather, Schedule I contains drugs without accepted medical uses in treatment in the United States—regardless of danger—and Schedules II through V rank others from most to least dangerous based on relative potential for abuse and physical/psychological dependence. *See* 2.ER.191, 204-05, Handbook at 26-27, 73-74.

Controls and penalties track the schedules—the lower the number the more restrictive the controls and the more severe the penalties. 2.ER.205, Handbook at 75. *NORML v. DEA*, 559 F.2d 735, 737 (D.C. Cir. 1977) ("*NORML II*").

The schedules exist apart from the Food and Drug Administration's ("FDA") regulations governing the approval of new drugs for interstate

marketing under the Federal Food Drug and Cosmetic Act ("FDCA"). *See* 21 U.S.C. § 301 *et seq*. Non-FDA-approved drugs may not be marketed interstate under the FDCA regardless of their placement (or non-placement) on the CSA's schedules. *See id*. § 331. Moving a drug to a higher schedule (for example, from Schedule I to Schedule III) doesn't greenlight it for interstate marketing, but it does remove significant regulatory barriers. 2.ER.205, Handbook at 75.

Congress made the initial scheduling decisions, 21 U.S.C. § 812(c), and provided an administrative procedure for future scheduling and re-scheduling. Under § 811(a)(2), formal rulemaking procedures to transfer a drug between schedules may be initiated by the Attorney General "(1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party." "Congress contemplated that the classification set forth in the [Act] as originally passed would be subject to continuing review by the executive officials." *NORML I*, 497 F.2d at 656.

"The intent of the scheduling system and its greatest value is in the practicality and ability to adjust the regulatory framework." 2.ER.192, Handbook at 28. Its "true test," according to the 1975 Handbook,[2] "will be in

[2] Sonnenreich, one of the Handbook's authors, completed the initial draft of the bill that would become the CSA. *See* 5.ER.1028-29, 33, G. Posner, *Pharma: Greed, Lies, and the Poisoning of America* at 255-57 & n.20

loosening restraints when justified." 2.ER.205-06, *id.* at 75-76. "[A] scheme that is directed only towards tighter and tighter controls will lose its most important attributes." 2.ER.06, *id.* at 76.

B. Marijuana in 1970

Congress tentatively placed marijuana in Schedule I alongside heroin not because of danger but because at the time, marijuana had "no recognized therapeutic use" in treatment. 5.ER.1049, *Federal Drug Abuse and Drug Dependence Prevention, Treatment, and Rehabilitation Act of 1970, Hearings*, 91st Cong., 2d Sess., on S. 3562 (Part 2) at 473 (1970).

Whether that would change remained an open question. The Assistant Secretary of the United States Department of Health, Education, and Welfare ("HEW")—the predecessor to the current Department of Health and Human Services ("HHS")— recommended placing marijuana in Schedule I "at least until the completion of certain studies." *Raich*, 545 U.S. 1, 14. Along with this preliminary classification, Congress established a "Commission on

---

(2020); 6.ER.1371-72, D. Musto & P. Korsmeyer, *The Quest for Drug Control, Politics and Federal Policy in a Period of Increasing Substance Abuse, 1963-1981* at 56-58 (2002) ("Musto"). Co-author Bogomolny worked at the Bureau of Drug Abuse Control, HEW from 1967-69. *See* https://msa.maryland.gov/msa/mdmanual/25univ/ub/former/html/msa14085.html. Co-author Roccograndi was counsel at BNDD under Sonnenreich. *See* 4.ER.774-75, *Crime in America—Illicit and Dangerous Drugs, Hearings*, 91st Cong., 1st Sess., pursuant to H. Res. 17 at 4, 21 (1969).

Marihuana and Drug Abuse," Pub. L. No. 91-513 § 601, 84 Stat. 1236 (Oct. 27, 1970), and provided it $1 million to study the legal, scientific, and medical aspects of marijuana use, *id.* § 601 (d), (e). The Commission was to report back within two years with "appropriate recommendations for legislation and administrative actions." *Id.* § 601(2)(e).

C. Responsibilities and duties under the Act

As draft bills made their way through both Houses, legislators hammered out compromises. *See generally* 2.ER.188-98, Handbook at 21-41 (citing legislative materials); 6.ER.1371-78, Musto at 56-71 (citing archival documents).[3]

1. Congress legislated against the backdrop of federalism. *See Oregon*, 546 U.S. at 270. The Act "presume[s] and relies upon a functioning medical profession regulated under the States' police powers," *id*, prohibits the federal government from making "anterior judgment[s]" about what constitutes accepted medicine or medical treatment, *id.* at 272, and "manifests no intent to regulate the practice of medicine generally," *id.* at 270. In this regard, the CSA was modeled after predecessor laws like the Harrison Act, which expressly permitted physicians to prescribe narcotics for

[3] Due to COVID-19, Petitioners could not obtain copies of the archival material directly from the Nixon Library. The Musto reference includes a CD-ROM with full-text reproductions of the documents. 6.ER.1382.

"legitimate medical uses," "legitimate medical purposes," or "in the course of their professional practice." *See* 4.ER.861, H.R. Rep. No. 91-1444, 91st Cong., 2d Sess. at 14 (1970) *reprinted in* 1970 U.S.C.C.A.N. 4566 ("House Report").

2. "Considerable controversy" arose with respect to concentrating too much power with the Department of Justice ("DOJ"). House Report at 22; 5.ER.1079, S. Rep. No. 813, 91st Cong., 1st Sess. at 5 (1969) ("Senate Report") (discussing whether the DOJ has expertise to schedule drugs since "such decisions require special medical knowledge and training"); 2.ER188-89, 202-03, Handbook at 21-23, 69-70 (same).

Some warned DOJ would impede research. One witness, Dr. Norris, was "horrif[ied]." 3.ER.698, *Alcoholism and Narcotics, Hearings on Inquiry into the Problem of Alcoholism and Narcotics (Part 5)*, 91st Cong., 2d Sess. at 980 (1970). He described a harrowing experience of having his LSD research application "tied up in bureaucracy" for years without explanation. 6.ER.698-99, *id.* at 980-81 ("[W]e are talking about research .... We are talking about things that people die about because we don't have information."). He did not expect to get his research LSD from DOJ and added (prophetically) that those attempting to get "standardized quantified marihuana to do research" would likely receive similar treatment. *Id.* Senator Hughes, a key figure in the Act's passage, agreed: research "should

never be under the chief law enforcement officer in the country." 6.ER.699, *id.*

Legislators found compromise. The Act "conveys unwillingness to cede medical judgments to an executive official who lacks medical expertise." *Oregon*, 546 U.S. at 266. HHS therefore received delegated authority over medical and scientific questions, and the Attorney General is bound by its decisions on such matters. 21 U.S.C. § 811(b). *See also* 4.ER.869, House Report at 22; 5.E.R. 1079, Senate Report at 5. Final scheduling decisions remained with the Attorney General, however, because it was thought they "ha[d] more legal implications than ... medical ones." *See* 2.ER.190, Handbook at 24.

3. The Act also recognizes international treaty obligations, *see* 4.ER.853, House Report at 6, which supersede the Act's otherwise-controlling scheduling criteria and circumvent its prescribed procedures. Relevant here, when a treaty in effect on October 27, 1970 requires control of a drug, § 811(d)(1) creates a carve-out: the Attorney General "shall issue an order controlling such drug under the schedule ... he deems most appropriate to carry out [treaty] obligations," without regard to the procedures prescribed by §§ 811(a) and (b).

This reference to treaties, conventions, or protocols mainly refers to the Single Convention on Narcotic Drugs of 1961. *NORML II*, 559 F.2d at 741, n.46.

II. Prior rescheduling litigation

Despite more than two-thirds of the States having passed medical-marijuana laws, neither DEA nor the Attorney General has exercised rulemaking power under § 811(a) to remove marijuana from Schedule I.

A. The 1972 NORML petition

In 1972, NORML petitioned to remove marijuana from Schedule I. *NORML II*, 559 F.2d at 741. DEA's predecessor agency, the Bureau of Narcotics and Dangerous Drugs ("BNDD"), refused to accept the petition for filing, concluding that treaty obligations required marijuana remain in Schedule I. *Id.* (citing 21 U.S.C. § 811(d)(1)).

The *NORML I* court reversed and remanded, concluding the agency had erred by rejecting the petition without "reflective consideration and analysis." 497 F.2d at 661. On remand, the newly-formed DEA concluded that while marijuana could theoretically move to Schedule II, it had no currently accepted medical use and thus had to remain in Schedule I. In support of that decision, DEA relied on a one-page letter from HEW's Acting Assistant Secretary. *NORML II*, 559 F.2d at 742 (quoting 40 Fed. Reg. 44,164, 44,168 (1975)).

The D.C. Circuit vacated this decision as well. *Id.* DEA's reliance on a terse letter addressed to a member of the agency's legal staff but not solicited by the Acting Administrator, the court emphasized, could "hardly take the place of the elaborate referral machinery contemplated by Congress," which required a hearing and determination on the record. *Id.* at 749.

On remand, DEA referred the petition to HEW, which concluded marijuana could be placed in *either* Schedule I or II, but recommended Schedule I as a better "fit." 44 Fed. Reg. 36,123 at 36,127 (June 20, 1979). Ten days later, DEA denied the petition without a hearing. *Id.* at 36,125. That resulted in a third remand. 4.ER.988, *NORML v. DEA*, 1980 U.S. App. Lexis 13099 (D.C. Cir. Oct. 16, 1980) ("*NORML III*"). "[R]egrettably," the order began, the Court found it necessary to remind the agency 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.'" *Id.* (citation omitted).

With that, the *NORML III* court instructed DEA to reconsider all issues accounting for new evidence concerning medical use. *Id.*

B. *Chevron* and the five-factor test

The Supreme Court decided *Chevron* in 1984, ushering in a new doctrine of judicial deference to agency interpretations of statutes. *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984). Soon after,

following the *NORML III* remand, DEA unveiled a new interpretation of "no currently accepted medical use in treatment in the United States" via a series of circuitous judicial and administrative proceedings.

1. DEA first interpreted the phrase in proceedings placing MDMA in Schedule I because it lacked FDA approval for interstate marketing and therefore had "no currently accepted medical use." *Grinspoon v. DEA*, 828 F.2d 881, 884 (1st Cir. 1987).

The First Circuit rejected DEA's reliance on the absence of FDA approval as contrary to congressional intent. *Id.* at 890. But it also concluded that it "appear[ed]" as if Congress had "implicitly delegated" to DEA "the authority to interpret these portions of the CSA." *Id.* at 892. Accordingly, the Court remanded to DEA for reconsideration, instructing the agency that the absence of FDA approval could not be used as conclusive evidence of lacking accepted medical use. *Id.*

On remand, DEA returned to FDA criteria anyway, outlining eight "characteristics of a drug or other substance with an accepted medical use" cribbed from FDA standards. Applying this eight-factor test, DEA once again concluded that MDMA belonged in Schedule I because it lacked FDA approval and had no "currently accepted medical use in treatment in the

United States." 2.ER.230, 53 Fed. Reg. 5,156 (Feb. 22, 1988). The petitioner didn't pursue the matter further.

2. Nearly seven years after the *NORML III* remand, hearings on the 1972 NORML petition began. They focused on two issues: whether marijuana had a "currently accepted medical use in treatment in the United States" and whether there was a lack of "accepted safety for use of the marijuana plant under medical supervision." 3.ER.708, *In the matter of Marijuana Rescheduling Petition*, Dkt. 86-22 at 7 (DOJ Sept. 6, 1988) ("ALJ Opinion"). After hearing extensive evidence, the ALJ issued a detailed opinion, explaining, among other things, how marijuana use prevented or diminished chemotherapy-induced nausea, and thus concluding marijuana had an accepted medical use in treatment of certain cancer patients. 3.ER768-69, *see id.* 67-68.

Using the eight FDA-centric characteristics for "currently accepted medical use" developed after *Grinspoon*, DEA rejected the ALJ Opinion and denied NORML's petition a fourth time. *See* 2.ER.249-52, 54 Fed. Reg. 53,767 at 53,783-85 (Dec. 29, 1989).

3. Two more appeals followed. In *Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936 (D.C. Cir. 1991) ("*ACT I*"), petitioners challenged the eight-factor test. Like the court in *Grinspoon*, the D.C. Circuit

found no textual support for DEA's interpretation but deferred to it under *Chevron* anyway. *Id.* at 939. Although the Court found DEA's interpretation "in the main acceptable," it explained that another remand was necessary because three of the eight factors were "logically impossible to satisfy." *Id.* at 937.

Following remand four, DEA remained convinced that "Congress equated the term 'currently accepted medical use in treatment in the United States' as used in the [Act] with the core FDCA standards for acceptance of drugs for medical use." 1.ER.165, 57 Fed. Reg. 10,499 at 10,504 (Mar. 26, 1992) ("1992 Rule"). Thus, it discarded the three impossible factors and applied a conjunctive five-factor test for "currently accepted medical use," 1.ER.170-72, *id.* at 10,504-06:

1) The drug's chemistry is known and reproducible;
2) There are adequate safety studies;
3) There are adequate and well-controlled studies showing efficacy;
4) The drug is accepted by qualified experts; and
5) The scientific evidence is widely available.

Applying this slimmed-down test, DEA denied the NORML petition again, this time explaining that "claims that marijuana is medicine are false, dangerous and cruel," that "[m]arijuana is likely to be more cancer-causing than tobacco," that "impressions or beliefs of physicians, no matter how fervently held, are treacherous," and that "[t]hose 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." 1.ER.166, 168-69, *id.* at 10,500, 02-03.

A fifth judicial proceeding followed. *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1134 (D.C. Cir. 1994) ("*ACT II*"). Petitioners again questioned DEA's interpretation of the statute but the Court declined to reconsider the issue citing the law-of-the-case doctrine. *Id.* at 1134-35.

Twenty-two years after NORML first filed its petition, it finally stood denied.

C. Recent failed efforts to reschedule marijuana

In 2005, the Supreme Court found the "evidence proffered by respondents ... regarding the effective medical uses for marijuana" noteworthy, explaining that "if found credible after trial, [it] would cast serious doubt on the accuracy of the findings that require marijuana to be listed in Schedule I." *Raich*, 545 U.S. at 27 n.37.

Today, more than two-thirds of the States have passed laws establishing comprehensive medical-marijuana programs for treating enumerated conditions, including every state in this Circuit save Idaho. But

efforts since *ACT I* and *II* to reschedule marijuana have fallen flat. Importantly, none has seriously called into question the underpinnings of DEA's five-part test.

In 1995, Jon Gettman petitioned for rescheduling of marijuana. Six years later, DEA applied the five-part test and denied his petition. 2.ER.254, 66 Fed. Reg. 20,038 (Apr. 18, 2001). The D.C. Circuit dismissed Gettman's petition for review for lack of standing. *See Gettman v. DEA*, 290 F.3d 430, 432 (D.C. Cir. 2002).

In 2002, the Coalition to Reschedule Cannabis filed a rescheduling petition. Nine years later, DEA denied it, asserting little had changed since 1992. 2.ER.327, 76 Fed. Reg. 40,552 (July 8, 2011). The D.C. Circuit's opinion rejecting the subsequent petition for review emphasized that the petitioners had not "seriously disput[ed] the propriety of the five-part test." *Americans for Safe Access v. DEA*, 706 F.3d 438, 448-50 (D.C. Cir. 2013).

In a 2011 rescheduling petition, the Governors of Rhode Island and Washington noted the growing schism between state and federal law on marijuana and declared marijuana's continued placement in Schedule I "fundamentally wrong." 5.ER.1259, Ltr. from Gov. Chafee and Gov. Gregoire, *Rulemaking Petition to Reclassify Cannabis for Medical Use from a Schedule I Controlled Substance to Schedule II* (Nov. 30, 2011). Applying the

five-part test, DEA denied the petition a half-decade later. 1.ER.7, 81 Fed. Reg. 53,688 (Aug. 11, 2016). Although it recognized that twenty-three States had laws permitting medical-marijuana use, 1.ER.19-20, 32, *id.* at 53,700-01, 53,713, in the letter accompanying the decision, DEA explained that marijuana had to remain in Schedule I under "established scientific standards" derived from the "FDA drug approval process ... as the statute demands." 6.ER.1367, Ltr. from DEA Acting Administrator Rosenberg to Gov. Raimondo, Gov. Inslee, and Krumm (Aug. 11, 2016). The agency also reiterated that under § 811(d)(1), the Single Convention required marijuana remain in Schedules I or II. 1.ER.7-8, 81 Fed. Reg. at 53,688-89.

Litigants have also tried constitutional challenges, only to be redirected to the agency. For example, in *Washington v. Barr*, 925 F.3d 109, 120 (2d Cir. 2019), a coalition of plaintiffs argued marijuana's placement in Schedule I lacked a rational basis. The Second Circuit affirmed dismissal on exhaustion grounds, agreeing that plaintiffs had to first use the administrative process. But in view of DEA's history of dilatory conduct and the health interests at stake, the panel majority comprised of Judges Calabresi and Rakoff took the extraordinary step of retaining jurisdiction over a dismissed case. *See also id.* at 109 ("[W]e are troubled by [DEA]'s history of dilatory proceedings."), 118 ("Assuming, of course, that one can get

the administrative agency to act"), 121 ("[A]lthough agencies, like legislatures, are often the best decisionmakers, this is so only when they actually do decide.").

Every year the rift between state and federal law widens. To address some of the discord, Congress has implemented annual appropriation riders without rescheduling marijuana. *See United States v. McIntosh*, 833 F.3d 1163, 1175-78 (9th Cir. 2016). And DOJ itself has turned to non-enforcement memos. *See* 4.ER.791-93, L. Sacco et al., *The Marijuana Policy Gap and the Path Forward*, Congressional Research Service, at 12-14 (Mar. 10, 2017) *available at* https://crsreports.congress.gov/product/pdf/R/R44782.

These measures address some problems, but many others remain. A recent Congressional Research Service ("CRS") report identifies four key unresolved issues: (1) institutes of higher education cannot do marijuana research without a risk of losing funding; (2) financial institutions remain reluctant to enter relationships with state-authorized medical marijuana businesses; (3) research has been impeded; and (4) legal consequences for individuals. *See* 4.ER.824-25, L. Sacco, *The Schedule I Status of Marijuana*, Congressional Research Service, at 1-2 (Sept. 11, 2020) *available at* https://crsreports.congress.gov/product/pdf/IN/IN11204.

In particular, these measures do not address the veteran Petitioners' plight. Due to marijuana's Schedule I status, the Department of Veterans Affairs ("VA") will not recommend or counsel veterans on medical-marijuana use. *See, e.g.*, 6.ER.1425, Sullivan Decl.[4]

III. Factual background

Of the four issues CRS highlighted, research is the most troubling. Because marijuana remains in Schedule I, licensed researchers cannot conduct studies involving the medical marijuana being used in treatment in this country—the same studies DEA says it needs to see under the five-part test before it will even consider holding a § 811(a) hearing to debate marijuana's proper placement.

A. Dr. Suzanne Sisley and SRI

Dr. Suzanne Sisley is an Arizona-based psychiatrist and a pioneer in the field of medical-marijuana research. For the past decade, in addition to maintaining a full-time telemedicine practice, she has dedicated her life to conducting clinical trials involving marijuana as well as educating the public

[4] This arcane administrative anachronism also vexes federal courts. *See, e.g.*, *Left Coast Ventures Inc. v. Bill's Nursery Inc.*, 2019 WL 6683518, at *3 (W.D. Wash. Dec. 6, 2019) (abstaining under *Burford* where state law conflicts with CSA).

on the barriers to marijuana research in the United States. *See generally* 6.ER.1408-18, Sisley Decl.

Long ago, she did not believe smoked marijuana had potential as medicine. The shift came from her experiences with veteran clients in her Arizona private practice. Dr. Sisley, who had been trained to think that marijuana was dangerous and addictive, quickly dismissed her clients' claims regarding marijuana's therapeutic benefits. But as she began losing clients to suicide, the anecdotes became impossible to ignore. *See* 6.ER.1409-11, *id.* at ¶¶ 5-8.

Years before Sisley turned to litigation, she did as DEA recommended in the 1992 Rule and focused her efforts on trying to conduct legitimate and robust scientific research into potential clinical applications for smoked marijuana. 1.ER.169, 57 Fed. Reg. at 10,503 ("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."). Unlike other controlled substances, clinical research with marijuana requires approval from *four* federal agencies and an Institutional Review Board. Dr. Sisley did everything by the book. In 2009, she put together a protocol; in 2011, the FDA approved the protocol; in 2012, the

University of Arizona's IRB approved the protocol; and in 2014, she secured approval from the US Public Health Service and the National Institute on Drug Abuse ("NIDA"). She expected DEA approval to follow shortly, but instead, due to political pressure, she lost her job. *See* 6.ER.1411-12, Sisley Decl. at ¶¶ 9-14.

Still, she persisted. Forming SRI to do the clinical research, in April 2016, Sisley obtained a DEA Schedule I research license. In January 2017, SRI began its triple-blind clinical study of smoked whole-plant marijuana to treat PTSD symptoms in veterans funded by a $2.1 million grant from the Colorado Department of Public Health and Environment. Phase II trials finished in February 2019. *See* 6.ER.1413, *id*. at ¶ 16.

B. The NIDA monopoly and the regulatory Catch-22

Federal law requires all researchers who do safety/efficacy trials with marijuana to use marijuana from a 12-acre farm at the University of Mississippi. *See* 4.ER.827-33, B. Erickson, "Cannabis research stalled by federal inaction," 98 Chem. & Eng. News 25 (June 29, 2020) (explaining that "no clinical studies have been conducted on cannabis products purchased from state-authorized dispensaries"). This marijuana looks more like green talcum than medical-grade marijuana sold at dispensaries nationwide, 6.ER.1414-15, Sisley Decl. at ¶¶ 18-19:

Apparently, this is *by design*. *See* 4.ER.829, Erickson (quoting supervisor as saying, "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." and explaining NIDA marijuana "is highly processed and "ground up into particles of uniform size").

Most samples SRI received for its clinical trials contained extraneous plant material like sticks and seeds; others had mold. *See* 6.ER.1414-15, Sisley Decl. at ¶¶ 18-19. Recent research suggests this mish-mash is genetically closer to hemp than medical marijuana. 5.ER.1052, Schwabe et al., Research Grade Marijuana Supplied by the National Institute on Drug

Abuse is Genetically Divergent from Commercially Available Cannabis, Pre-Print.

Because the regulatory Catch-22 at the heart of this action, researchers have no choice but to study this marijuana. Since 1992, DEA interprets "no currently accepted medical use in treatment in the United States" to require FDA-approved clinical trials. 1.ER.170-71, 57 Fed. Reg. at 10,504-05. But because DEA forces researchers to study junk marijuana, clinical research remains thin.

Next, under § 823(a), which governs registration to manufacture Schedule I and II substances, the Attorney General can only register applicants if the registration is consistent with the public interest "and with United States obligations under international treaties." Until 2016, DEA understood this statute to require a government-supervised monopoly run by NIDA. *See* 2.ER.193-96, 74 Fed. Reg. 2,101 at 2,102-04 (Jan. 14, 2009).

If marijuana were moved to Schedules III-V, however, this bottleneck would melt away. The parallel registration provision for manufacture of Schedule III-V substances does *not* require compliance with treaty obligations. *See* 21 U.S.C. § 823(d).

C. The rise and stall of the Growers Program

1. In August 2016, DEA did an about face. The same day DEA denied the Governors' 2011 petition, it issued a Policy Statement recognizing the need to improve marijuana research by addressing the supply issues resulting from the NIDA monopoly. 2.ER.365, 81 Fed. Reg. 53,846 (Aug. 12, 2016). After consulting NIDA and FDA, DEA reassessed its duty to provide an adequate supply of research-grade marijuana, declaring that it no longer viewed § 823(a) and the Single Convention as forbidding the registration of multiple manufacturers of marijuana for research. *Id.* Accordingly, DEA solicited applications from persons interested in registering as manufacturers of marijuana for research. *See id.*

SRI applied, 6.ER.1416, Sisley Decl. ¶¶ 23-24, as did more than thirty other entities. But more than four years later, the number of additional cultivators DEA has approved is *zero*.

This inaction was not for want of inquiry. Starting at year two of inaction, bipartisan members of Congress began sending letters to DEA. These numerous letters expressed deep concern with the delay and implored action. *E.g.*, 3.ER.598, Ltr. to Sessions (Aug. 31, 2018); 2.ER.209, Ltr. to Sessions, Dhillon (Sept. 28, 2018). Several asked DEA and DOJ to "share DOJ's legal analysis of the CSA and Single Convention" and to "identify and

explain" any "legal barriers" to prompt implementation of the Growers Program. *E.g.*, 3.ER.595, Ltr. to Sessions (July 25, 2018).

Neither DOJ nor DEA responded to any of these letters. Instead, during a May 2018 congressional hearing, the Attorney General testified that DEA was "moving forward" and would "add, fairly soon ... additional suppliers of marijuana under the Controlled [Substances Act]." 2.ER.208, *Commerce, Justice, Science, and Related Agencies Appropriations for Fiscal Year 2019 Hearings*, Subcommittee of the Committee of Appropriations at 28 (Apr. 25, 2018). A year later, his successor testified: "I think we're going to move forward on it" and "it's very important to get those additional suppliers." 2.ER.213, *Hearing Before the House Committee on the Judiciary*, 116th Cong., 1st Sess. at 151 (Feb. 8, 2019).

But DEA was not moving forward. It was shutting down. A secret June 6, 2018, memorandum opinion from DOJ's Office of Legal Counsel ("OLC") (released three weeks after SRI sued DOJ under the Freedom of Information Act in March 2020[5]) explains that under § 823(a), DEA can only register applicants to cultivate marijuana if the agency's registration scheme is consistent with the Single Convention. According to OLC, DEA's NIDA

[5] 5.ER.1256, Settlement Agmt., *Scottsdale Research Inst., LLC v. DEA*, 2:20-cv-00605-PHX-JJT (D. Ariz. Apr. 28, 2020).

monopoly has violated the Single Convention and the CSA for more than fifty years, leading OLC to conclude that DEA must bring the licensing framework into compliance before registering additional manufacturers. 4.ER.990, *Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs* 42 Op. O.L.C. -- (June 6, 2018). Hence, as of June 2018, DOJ says DEA's own unlawful administration of the CSA's registration provisions prevents it from approving additional cultivators.

2. Unaware that DOJ had stalled the Growers Program, SRI filed a mandamus petition in the D.C. Circuit in June 2019 to compel DEA to comply with its statutory obligation to publish a notice of SRI's application to manufacture marijuana in the Federal Register after years of unlawful delay. 3.ER.605, Mandamus Petition, *In re: Scottsdale Res. Inst., LLC*, 19-1120 (D.C. Cir. June 11, 2019). The court ordered DEA to respond by August 28, 2019. 5.ER.1241, Order, *In re: Scottsdale Research Inst., LLC*, 19-1120 (D.C. Cir. July 29, 2019).

Two days before the August deadline, the Attorney General stated that he was "pleased that DEA is moving forward with its review of applications for those who seek to grow marijuana legally to support research." 4.ER.771, Press Release, DEA (Aug. 26, 2019). The next day, DEA published the notice of application SRI had requested in the Federal Register but explained it

wouldn't begin processing the applications it had received until it had completed a notice-and-comment process necessary to promulgate new regulations to govern approval of new growers. 6.ER.1389-90, 84 Fed. Reg. 44,920 at 21-22 (Aug. 27, 2019). In its response to SRI's mandamus petition filed the next day, DEA did not defend itself. Instead, it merely argued that by filing the notice SRI had requested in the Federal Register, the agency had mooted SRI's lawsuit. 4.ER.954, Response, *In re: Scottsdale Res. Inst., LLC,* 19-1120 (D.C. Cir. July 29, 2019).

In the months that followed, Congress sent more letters expressing urgency. *E.g.*, 3.ER.601, Ltr. to Azar, Carroll, Dhillon (Dec. 11, 2019). But DEA waited to publish its proposed rules until the country was in the grip of the COVID-19 pandemic. 2.ER.368, 85 Fed. Reg. 16,292 (Mar. 23, 2020). Comments closed on May 22, 2020. *Id.*

On August 18, 2020, members of Congress sent another letter, lamenting that DEA's delays "have had potentially detrimental effects on Americans' health as untested products are being widely used for numerous medical conditions without safety or efficacy data to support these uses." 3.ER.689, Ltr. to Shea (Aug. 18, 2020).

IV. The 2020 Petition

On January 3, 2020, Stephen Zyszkiewicz, a software programmer serving a sentence for running an unlicensed cannabis operation in California, sent his own petition to reschedule marijuana to DEA. His one-page handwritten petition urges removal of marijuana from Schedule I, contending that "the current situation of cannabis in Schedule I" is "completely untenable" because "half the states allow for medical use and the FDA allows CBD and THC pharmaceuticals as well as IND Compassionate Use." 1.ER.1.

On April 25, 2020, DEA denied the petition, incorporating and reasserting the 2016 Denial wholesale. *See* 1.ER.2-4, 6, 86. DEA emphasized that "[b]ased on HHS's evaluation [in the 2016 Denial]," it "*concluded* that there is no substantial evidence that marijuana should be removed from schedule I." 1.ER.2 (emph. added). DEA dismissed the relevance of State acceptance, explaining that until "drugs containing marijuana [are] proven to be safe and effective for the treatment of certain conditions and thus approved be by [sic] the United States Food and Drug Administration for marketing," it will not entertain petitions seeking marijuana's removal from Schedule I. *Id.*

Days later, NBCNews published an article entitled "One doctor vs. the DEA: Inside the battle to study marijuana in America." 5.ER.1015. In response to a tweet linking to the article, Zyszkiewicz tweeted that DEA had denied his petition. Counsel for Petitioners reached out to Zyszkiewicz, who forwarded the denial, giving rise to this action.

STANDARD OF REVIEW

Under the Administrative Procedure Act, "a reviewing court shall ... hold unlawful and set aside agency action, findings, and conclusions found to be ... in excess of statutory jurisdiction, authority, or limitations"; "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"; or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (C), (D).

Courts generally review agency interpretations of statutes they administer under *Chevron*. 467 U.S. at 837. "Even under *Chevron*," however, courts "owe an agency's interpretation of the law no deference unless, after 'employing traditional tools of statutory construction,' we find ourselves unable to discern Congress's meaning." *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1358 (2018) (cites omitted).

SUMMARY OF ARGUMENT

Can DEA deny that marijuana has a "currently accepted medical use in treatment in the United States" when more than two-thirds of the States have

enacted legislation greenlighting marijuana's use as medicine? The unambiguous text of § 812(b)(1)(B), canons of construction, the CSA's history and purpose, and common sense all converge on a single, resounding answer: "No."

The same "background principles of our federal system" that foreclosed DEA's interpretation of the CSA as a "grant of authority to regulate areas traditionally supervised by the States' police power" in *Oregon* also foreclose DEA's State-blind approach here. There, DEA's exclusion of physician-assisted suicide from the scope of "legitimate medical practice" was at odds with just one state law. Here, DEA's denial of marijuana's "currently accepted medical use," ignores the authoritative views of more than two-thirds of the States on the same topic.

In addition, DEA's determination that marijuana must be placed in Schedules I or II, which rests on § 811(d)(1), should be set aside, because that provision unconstitutionally delegates legislative power twice: first to a non-governmental entity and second to the Attorney General.

The Court should grant the Petition for Review, vacate the 2020 Denial, and remand to DEA with instructions to reconsider the 2020 Petition consistent with § 812(b)(1)(B)'s plain mandate, which prohibits DEA from

denying that marijuana has a currently accepted medical use in the face of widespread State acceptance.

ARGUMENT

I. The 2020 Determination is contrary to law.

From state prison, Stephen Zyskiewicz read § 812(b)(1)(B) using the tools of statutory construction available to ordinary citizens: command of the English language and common sense. That was all he needed to see the problem with DEA's interpretation.

Across the country, medical professionals acting under State medical-marijuana laws recommend marijuana to patients in treatment. No one questions that they do so in the ordinary course of medical practice. Because medical marijuana is currently accepted by a growing majority of the States for use in treatment, it doesn't belong in Schedule I.

A. The 2020 Determination rests on an unlawful interpretation of § 812(b)(1)(B).

1. DEA's interpretation bears no connection to the statutory text.

1. DEA's interpretation flunks the most basic test of statutory interpretation: it cannot be squared with the ordinary meaning of the words of the statute. *See* A. Scalia & B. Garner, Reading Law: The Interpretation of Legal Texts § 6 at 172 (2012) ("The ordinary-meaning rule is the most fundamental semantic rule of interpretation.").

No user of the English language—in 1970, today, or ever—would understand "currently accepted medical use in treatment in the United States" to communicate a five-part test of any kind, much less the one DEA uses. *Cf. Bond v. U.S.*, 572 U.S. 844, 860 (2014) ("[A]s a matter of natural meaning, an educated user of English would not describe Bond's crime as involving a 'chemical weapon.'"). When an agency interprets a statute—especially one with serious criminal implications like the CSA—to mean something that no ordinary citizen would ever see coming, courts are rightly skeptical. *Cf. Sessions v. Dimaya*, 138 S. Ct. 1204, 1212 (2018) (due process requires statutes give ordinary citizens fair notice of what they require).

The origins of the test are instructive. The 1992 Rule pronouncing the five-part test argues that Congress intended FDCA standards as evidence of what drugs Congress considered "*acceptable* for medical" use under § 812(b)(1)(B). 1.ER.169, 1992 Rule at 10,503. By focusing on what DEA believes is "acceptable" instead of what the medical profession has, in fact, already "accepted," DEA's interpretation ignores the text of § 812(b)(1)(B) itself. *See Nebraska v. Parker*, 136 S. Ct. 1072, 1078 (2016) (statutory interpretation begins with the language of the statute itself).

Though other textual considerations underscore the infirmities in DEA's approach, *see infra* Argument I.A.3, its conflation of "accepted" with

"acceptable" is ground zero for error in its five-part test. As a participle, "accepted" reflects a present state. *Henson v. Santander Consumer USA Inc.*, 137 S. Ct. 1718, 1722 (2017) ("Past participles like 'owed' are routinely used as adjectives to describe the present state of a thing."). "Accepted" means "generally regarded as true," "proper," "conventional," and "valid." 5.ER.1244, Webster's New Twentieth Century Dictionary Unabridged (2d ed.) (1970). "Acceptable," in contrast, is a *forward*-looking adjective synonymous with "welcome" or "agreeable." *Id.*

Basic grammar reveals the impropriety of determining "accepted medical use in treatment in the United States" based on FDA's determination of what is "acceptable" for interstate marketing. FDA approves *new* drugs for interstate marketing to determine *acceptability* under safety/efficacy standards—a forward-looking task. But § 812(b)(1)(B) contains no hint that looking forward is relevant to whether a substance has an "*accepted* medical use." It is entirely possible for a substance to be "accepted" without qualifying for FDA approval.

Just ask FDA. Years before *Grinspoon*, it noted that drugs can "obtain accepted medical use" for purposes of § 812(b)(1)(B) "by virtue of totally intrastate production and use." 2.ER.226-27, 47 Fed. Reg. 28,141 at 150-51 (June 29, 1982). Around the same time, in a 1982 Bulletin, FDA explained

that drugs could become accepted for use in treatment without its approval. 4.ER.839-40, 12 FDA Drug Bull. 4-5 (Apr. 1982). Valid new uses for drugs are often discovered "off-label" through "serendipitous observations" and "therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigations." *Id.*

This is common knowledge. "Off-label" use is often accepted medical practice. 6.ER.1394, FDA, *Good Reprint Practices* (Jan. 2009), http://www.fda.gov/RegulatoryInformation/Guidances/ucml25126.htm ("[O]ff-label uses ... may even constitute a medically recognized standard of care."). Likewise, unapproved-but-accepted uses are "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). DEA alone contends otherwise.

2. This distinction between "accepted" and "acceptable" is important and makes the statutory scheme tick. *See Sturgeon v. Frost*, 136 S. Ct. 1061, 1070 (2016) ("[W]ords of a statute must be read in their context and with a view to their place in the overall statutory scheme.").

By keying § 812(b)(1)(B) on findings about what is currently accept*ed* and not what the Attorney General deems accept*able*, Congress demanded a fact-based inquiry focused on what the medical profession has, in fact,

accepted—not what the nation's chief law enforcement officer believes it *should* have accepted. In so doing, it sought to preserve traditional State authority over the practice of medicine. *See Oregon*, 546 U.S. at 270 ("The structure and operation of the CSA presume and rely upon a functioning medical profession regulated under the States' police powers."). *See also* 21 U.S.C. § 903 (anti-preemption provision). DEA, by focusing on an FDCA-centric standard designed to assess whether drugs are sufficiently safe and effective to be deemed *acceptable* for interstate marketing, upends the federal-state balance. *Oregon*, 546 U.S. at 270.

The FDCA and CSA address different concerns. The FDCA sets substantive standards for safety and efficacy for new drugs entering the interstate market. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). In that context, *acceptable* makes sense. The CSA has different aims: to (1) unify drug laws into one cohesive framework without interfering with the practice of medicine and (2) prevent drug diversion and the illegitimate use of drugs. *Oregon*, 546 U.S. at 250. Given these different purposes—and the fact that federal government does not determine the legitimate or illegitimate uses of medicine—the only sensible standard is the one the ordinary meaning of *accepted* fairly encompasses: a contemporary inquiry into prevailing medical practice.

This sort of inquiry aligns with the Attorney General's specified and limited role under the statute. *See id.* at 258-60. He "is not authorized to make a rule declaring illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law." *Id.* at 258. The Act gives him "limited powers, to be exercised in specific ways." *Id.* at 259. He can promulgate rules relating only to registration and control, and "for the efficient execution of his functions" under the statute. *Id.* at 259. But he may not "attempt to define standards of medical practice." *Id.*

Defining standards of medical practice includes, of course, designing standards to measure whether a drug is "acceptable." But it does not include mere fact-finding to determine whether the medical profession has "accepted" a drug's medical use in treatment. Even in the FDCA context, this distinction is paramount, which is why the Supreme Court applies a presumption against preemption to ensure the FDCA is interpreted "consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). Thus, even if FDCA standards applied under § 812(b)(1)(B), DEA's attempt to use them to ignore state law regarding issues central to the regulation of the medical practice would fail.

3. The legislative history firmly supports this understanding. "[L]egislative history can never defeat unambiguous statutory text." *Bostock v. Clayton Cty., Georgia*, 140 S. Ct. 1731, 1750 (2020). But it can offer a window into the law's ordinary meaning at the time of enactment. *Id.* Just so here.

The CSA uses the words "legitimate," "valid," and "accepted" interchangeably. *Oregon*, 546 U.S. at 257 (noting that lack of meaningful distinction between accepted medical use and legitimate medical purpose). Senator Hughes equated the word "accepted" with "recognized":

> Classification in the bill depends primarily upon whether there is an *accepted* medical use for the drug. Because heroin and marihuana have no *recognized* medical use, they are classified in the same category.

2.ER.393, 116 Cong. Rec. 36,882 (1970). Immediately after, he equated "currently accepted medical use" with "valid medical use." *Id*. *See also* 2.ER.191, Handbook at 27 (explaining Schedule I houses all drugs with "no *legitimate* medical use").

Testimony from those who drafted the bill and were originally charged with enforcing the CSA is also instructive. These contemporaneous statements reflect the original meaning of the text. *See Bostock*, 140 S. Ct. at 1750. And because Ingersoll and Sonnenreich drafted the bill and were originally charged with enforcing the CSA, their statements are also entitled

some deference. *E.g.*, *Aluminum Co. of Am. v. Cent. Lincoln Peoples' Util. Dist.*, 467 U.S. 380, 390 (1984).

Discussing "currently accepted medical use," Ingersoll spoke with clarity: Schedule I drugs were those "the medical profession *has already determined* to have no legitimate medical use in the United States." *Grinspoon*, 828 F.2d at 891-95 (emph. added / quoting hearings). If either doctors or HEW determined that there was a medical use for marijuana, the drug would have to "leave Schedule I, either with congressional action or administrative action on the part of the Attorney General." 5.ER.1049, *Federal Drug Abuse and Drug Dependence Prevention, Treatment, and Rehabilitation Act of 1970, Hearings*, 91st Cong., 2d Sess., on S. 3562 (Part 2) at 473 (1970).

Sonnenreich was equally emphatic. He explained the "basic [§ 812(b)(1)(B)] determination is not made by any part of the Federal Government" but by "the medical community." 4.ER.953, *Drug Abuse Control Amendments—1970, Hearings*, 91st Cong., 2d Sess., on H.R. 11701 and H.R. 13743 (Part 2) at 718 (1970) at 718. It is not complicated:

> [No currently accepted medical use in treatment in the United States] 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 a lawyer can find out as well as a doctor*. ***I mean it is not something that you are going to create research on***.

4.ER.951, *Drug abuse control amendments—1970, Hearings*, 91st Cong., 2d Sess., on H.R. 11701 and H.R. 13743 (Part 1) at 165 (1970).

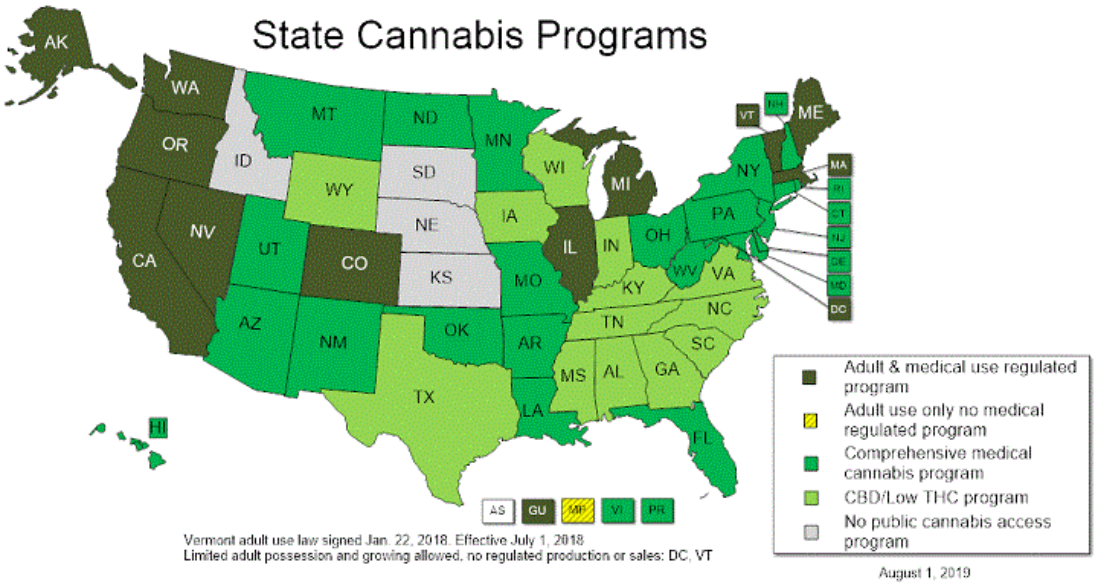
* * *

In 2020, Zyskiewicz followed the plain meaning of the text and did the survey-type exercise that the "technician" of the schedules had described fifty years earlier. 4.ER.950, *id.* at 162.[6] As the following map from the National Conference of State Legislatures[7] shows, he came to an unassailable conclusion: the notion that marijuana today has "no currently accepted medical use in treatment in the United States" is "completely untenable."

---

[6] *See also* 5.ER.1025, Posner at 255-57 (describing Sonnenreich's interactions with Attorney General Mitchell and President Nixon and his drafting of the "heart" of the Act).

[7] 5.ER.1246, National Conference of State Legislatures, State Medical Marijuana Laws & Table 1 (Mar. 10, 2020) (citing and linking to statutes establishing State medical marijuana programs) *available at* https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx.



2. Widespread acceptance by the States—the traditional gatekeepers of the medical profession under Our Federalism—forecloses placement in Schedule I.

The federalism canon of construction requires courts to avoid interpretations of federal law that would upset the traditional state-federal balance absent a clear indication that Congress intended otherwise. *BFP v. Resolution Trust Corp.*, 511 U.S. 531, 539 (1994) ("Absent a clear statutory requirement to the contrary, we must assume the validity of this state-law regulatory background and take due account of its effect.").

As *Oregon* explained, proper interpretation of the CSA requires keeping federalism principles and the States' traditional authority to regulate the medical profession squarely in view. There, the Attorney General issued a directive stating that prescribing controlled substances to assist suicide was grounds for suspending or revoking a doctor's CSA registration because

assisting suicide was not a "legitimate medical purpose" for purposes of the Act's prescription and registration provisions. *See Oregon*, 546 U.S. at 253-54. 21 U.S.C. § 829(c) (defining valid prescription as one issued for a legitimate medical purpose); *id.* § 824(a) (authority to deregister). The Supreme Court rejected that interpretation, explaining that the CSA does not provide "a single executive officer [would have] the power to effect a radical shift of authority from the States to the Federal Government to define general standards of medical practice in every locality." *Id.* at 275.

Such a result, the Court reasoned, would be at odds with the long tradition in Our Federalism of recognizing that "regulation of health and safety is 'primarily, and historically, a matter of local concern.'" *Id.* at 271 (citation omitted). The Court was not persuaded that Congress had intended the CSA to assert "expansive federal authority to regulate medicine." *Id.* Instead, it explained, the Act had a far more limited aim: preventing drug abuse and drug trafficking while relying on State regulation of medical practice. *Id.* at 273.

DEA's approach usurps the same traditional State authority over the practice of medicine that the Court denied to the Attorney General in *Oregon*. In fact, DEA's interpretation displaces the views of more than two-

thirds of the States and thus disrupts the traditional federal-state balance to a far greater extent than did the Attorney General's directive in *Oregon*.

After *Oregon*, whether State acceptance of medical marijuana demonstrates "no currently accepted medical use" can no longer be seriously disputed. The phrase literally bakes "Our Federalism"—a system "in which there is sensitivity to the legitimate interests of both State and National Governments," *Younger v. Harris*, 401 U.S. 37, 44 (1971)—directly into the centerpiece of the Act. Marijuana has an accepted medical use in treatment in the United States because the States—a primary source of authority for determining acceptable medical uses for drugs—have accepted it.

3. Other textual clues refute DEA's interpretation.

Lest there be doubt as to the patent impropriety of DEA's atextual approach, the CSA's text provides more concrete refutations.

Text. Consider "currently." A "*currently* accepted medical use," differentiates *today*'s accepted medical uses from yesterday's and tomorrow's. Recognizing that the practice of medicine is continuously evolving, Congress tethered federal drug control to the *present* views of the medical community and up-to-date science. To that end, it demanded that "the schedules established by [§ 812] be updated and republished on a semiannual basis during the two-year period beginning one year after

October 27, 1970, and ... on an annual basis thereafter." 21 U.S.C. § 812(a). Likewise, § 826(i)(3)(A) requires the Attorney General to submit "submit to Congress a report" on how he will "take into consideration *changes in the accepted medical use* of the covered controlled substances" when "fixing and adjusting production and manufacturing quotas under this section for covered controlled substances." (emph. added).

Section 812(b)(1)(B)'s focus on *currently* accepted medical use reflects this same priority on establishing a framework sufficiently nimble to change with the times. It contemplates an agency attentive to the shifting winds of medical opinion and ready to adjust the schedules annually to ensure federal law never falls out of step with the medical profession. *See also* Handbook at 5, 26-29 (discussing flexibility and adjustability of schedules).

Rather than effectuate these purposes, DEA's rigid approach renders it blind to *current* evidence of medical practice. Hence DEA's reliance in the 2020 Denial on conclusions drawn years earlier in the 2016 Denial. 1.ER.2. Because of this tunnel vision, § 812(b)(1)(B) no longer measures "*currently* accepted medical use" at all. It measures only whether another federal agency has or would approve a drug for interstate marketing under a different statute. While such approval is *sufficient* to demonstrate currently accepted medical use, it is hardly necessary.

In fact, during the drafting process, Congress considered different language. The Senate bill, S. 3426, originally stated "*well documented and approved* medical use in the United States" as the second scheduling criterion for Schedule III. 5.ER.1179, Senate Report at 105. This language was rejected in favor of the "currently accepted" standard that appeared in the more restrictive Schedule II. It was a line edit Sonnenreich made himself. 6.ER.1383, Memorandum from M. Sonnenreich to J. Dean re: Proposed Changes in S. 3246, the Controlled Dangerous Substances Act (DOJ Apr. 17, 1970) ("11. On page 20, line 23, delete the words 'well documented and approved' and insert in lieu thereof the words 'currently accepted.'"). Today, DEA conflates "well documented and approved" with "currently accepted"; but in 1970, the two meant something different. *See Bostock*, 140 S. Ct. at 1750.

DEA also rewrote "medical use" to require proof of *usefulness* for purposes of interstate marketing under the FDCA. *See* 1.ER.166, 1992 Rule at 10,500 (denying the existence of "proof of marijuana's usefulness" because of supposed flaws in various scientific studies). The 1992 Rule interprets "medical use" so narrowly as to require proof not only that marijuana is effective, but *more effective* than other drugs marketed in interstate commerce. *See id.* (study failed to prove marijuana more effective than

THC). But § 812(b)(1)(B) never mentions effectiveness at all. DEA may believe doctors or those that regulate the medical profession should not accept a substance's medical use absent such proof, but Congress did not make that the test for Schedule I placement. Under § 812(b)(1)(B), Schedule I placement hinges on what the medical profession—not any federal agency—has accepted.

Section 812(b)(1)(B)'s reference to what is occurring "in treatment," which calls for a determination focused on how physicians, in fact, treat patients, also forecloses DEA's interpretation. DEA ignores the realities and actual practice of medicine. The 1992 Rule underscores the point. *See* 1.ER.171, 1992 Rule at 10,505 (declaring "impressions of physicians" and "[t]he observations and opinions of medical practitioners who are not experts in evaluating drugs" irrelevant under § 812(b)(1)(B)); *id.* ("[T]he only body that counts is that of the experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs."). It reasoned 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." 1.ER.169, 1992 Rule at 10,503 (emph. added).

But that is demonstrably false. The FDCA has a longstanding, hard statutory stop on regulating how physicians use drugs in treatment, 21 U.S.C. § 396: "Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." "In treatment" focuses the question on how physicians use drugs in practice, not whether pharmaceutical companies have permission from a federal agency to market them interstate.

This is no minor distinction, either. As the FDCA expressly recognizes, "in treatment" use of a drug can (and does) diverge from approved uses precisely because FDA controls only "indicated" uses—the ones that appear on drug labels. 21 U.S.C. § 396. FDA does *not* control how doctors recommend their patients use drugs "in treatment." FDA also expressly recognizes off-label uses as "accepted medical practice." *E.g.*, 59 Fed. Reg. 59,820 (Nov. 18, 1994) (citing 4.ER.839-40, FDA Drug Bull. at 4-5 (1982)).

Grinspoon's analysis of "*in the* United States" remains pertinent. 828 F.2d at 886. In using this language, the First Circuit held, Congress did not intend to require a finding of recognized medical use in every state. *See id.* Confronted with this holding, DEA abandoned a rigid FDA-approval

standard on remand, but the problem with its FDCA-centric five-part test remains: It is a uniform federal standard that purports to trump the views of every State and practicing physician to the contrary.

Structure. "In ascertaining whether the agency's interpretation is a permissible construction of the language, a court must look to the structure and language of the statute as a whole." *Nat'l R.R. Passenger Corp. v. Bos. & Maine Corp.*, 503 U.S. 407, 417 (1992). Looking beyond § 812(b)(1)(B) reveals additional infirmities in DEA's interpretation.

DEA's read of § 812(b)(1)(B) renders § 812(b)(1)(C) superfluous—a red flag that its interpretation cannot be right. *E.g.*, *Gustafson v. Alloyd Co.*, 513 U.S. 561, 574 (1995). This third requirement for placing a substance in Schedule I expressly requires a finding regarding a substance's safety for use. 21 U.S.C. § 812(b)(1)(C). Given this, DEA's insistence that currently accepted medical use must also hinge on a five-part test focused almost entirely on safety and efficacy makes no sense.

This redundancy does not escape DEA. In the 1992 Rule, DEA acknowledged that "[t]he scheduling criteria ... appear to treat the lack of medical use and lack of safety as separate considerations," but chose to ignore the plain language of the Act, declaring it "inconsistent with scientific reality." 1.ER.170, 1992 Rule at 10,504. Carrying out the redundancy decades

later, in 2016, to support a lack of "accepted safety for use under medical supervision" under § 812(b)(2)(C), DEA copy-and-pasted its findings for § 812(b)(2)(B), noting that because marijuana did not have a "currently accepted medical use," it also did not have "an accepted safety for use under medical supervision." 1.ER.7, 81 Fed. Reg. at 53,688. This surplusage problem alone forecloses DEA's interpretation.

Next, Part (B) of schedules I and II parallel one another. The schedule II provision requires a finding that a "drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions." 21 U.S.C. § 812(b)(2)(B).

"Currently accepted medical use" must be interpreted consistently across these adjoining provisions giving meaning to the words "with severe restriction." Scalia & Garner, § 25 at 145 (presumption of consistent usage). But what does it mean to have "adequate safety studies" and a "known and reproducible chemistry" but with "with severe restrictions"? The five-part test makes no sense when one tries to explain what it would mean to have a "currently accepted medical use with severe restrictions."

This lack of fit between DEA's five-part test and the text of § 812(b) points us back to the right concepts. "Severe restrictions" refers to restrictions external to the Act itself. Once FDA approves a drug as safe and

effective, doctors may prescribe it for any reason subject to State regulation, which itself generally relies on professional standards-setting organizations. The sounder view of "currently accepted medical use" links with "severe restrictions": a determination based whether the medical practice has legitimized a drug's use in treatment and whether that use is severely restricted.

Also, consider § 811(d), which further clarifies law enforcement's intended role in scheduling. Boiled down, § 811(d) charges the Attorney General with maintaining conformity with international treaty obligations. It is in the same part of the statute as §§ 811(a), (b), and (c). The only distinction between § 811(d) and § 812(b)(1)(B) is where the Attorney General must look. Section 811(d) tells the Attorney General to look outward, while § 812(b)(1)(B) directs him inward, *i.e.*, "in the United States."

Section 811(d) confirms the agency's role under § 812(b)(1)(B) is not in standard setting but assessing whether other medical authorities have accepted a drug for medical use according to their own standards. This prohibition against law enforcement making "anterior" judgments about medical practice pervades every facet of the Act. *Oregon*, 546 U.S. at 272-73.

The overall fabric of drug laws in 1970 also refutes the test. The FDCA looms in the background of the Act; many provisions of the CSA interact with

or borrow from it. For example, § 823's labeling and packaging requirements incorporate FDCA definitions. The House Report explains, "the term 'potential for abuse' is found in the definition of a 'depressant or stimulant drug' contained in section 201 (v) of the [FDCA] and is characterized further in the regulations (21 C.F.R. § 166.2(e))." 4.ER.881, House Report at 34.

While the Act repeats or borrows from the FDCA in some parts, it never does so in the centerpiece of the Act, the schedules—a powerful indication that Congress did *not* intend FDCA standards to control in § 812(b)(1)(B). *E.g.*, *Bare v. Barr*, 2020 WL 5541393, at *8 (9th Cir. Sept. 16, 2020) ("We must presume that Congress intended a different meaning when it uses different words in connection with the same subject.") (citations/quotations omitted).

4. DEA's interpretation invites absurd results.

With no connection to the text or scheme, it should come as no surprise that DEA's test invites bizarre results. Imagine a rescheduling petition bolstered by testimony from every qualified expert and medical organization in the country supporting marijuana's accepted medical use. Applying its *conjunctive* five-part test, despite the overwhelming evidence to the contrary, DEA would be compelled to find that marijuana *still* had "no

currently accepted medical use in treatment in the United States" if any *one* of the following were true:

- No repeatable chemistry;
- Insufficient safety studies;
- No "well-controlled studies proving efficacy"; or
- The "science" was not "widely available."

Take the hypothetical one step farther. Under the five-part test, *all fifty states* could accept marijuana as having a medical use in treatment, and DEA would still be *compelled* to say otherwise if any of the other four parts of the five-part test wasn't met. Congress didn't intend these absurd results.

B. *Chevron* does not apply.

Because DEA's interpretation is untenable, this Court need not decide whether it merits *Chevron* deference. But *Chevron* doesn't apply here for at least two reasons.[8]

First, in *Oregon*, the Supreme Court held that *Chevron* didn't apply to the Attorney General's interpretation of the CSA "declaring illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law." 546 U.S. at 245. Deference comes into play, the

[8] The D.C. Circuit deferred to DEA's interpretation of § 812(b)(1)(B) under *Chevron* in its 1991 *ACT I* decision. 930 F.2d at 939. In the decades since, however, the Supreme Court has held *Chevron* doesn't apply in this context for several reasons, some of which we discuss below.

Court explained, only "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *Id.* at 255-56 (quoting *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001)). Because the CSA refutes the notion that Congress intended to delegate to the Attorney General any authority to make binding judgments regarding the practice of medicine or science, the Court held the Attorney General's views on what constitutes a "legitimate medical purpose" merited no deference. *Id.*

Oregon controls here. Actually, long before *Oregon*, DEA itself acknowledged that it had no delegated authority to make medical judgments or to regulate the practice of medicine:

> 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 determining whether others accept a drug for medical use. Any other construction would have the effect of reading the word "accepted" out of the statutory standard.

1.ER.171, 1992 Rule at 10,505. Precisely right.

Second, *Chevron* does not apply to a law-enforcement agency's interpretation of a dual-application statute like the CSA. *See Esquivel-Quintana v. Lynch*, 810 F.3d 1019, 1027-32 (6th Cir. 2016) (Sutton, J.)

(concurring in part, dissenting in part). Recently, in *Valenzuela Gallardo v. Barr*, 968 F.3d 1053, 1059 (9th Cir. 2020), this Court acknowledged *Esquivel-Quintana* and the constitutional issues with *Chevron* deference and criminal statutes. Because a prior panel had already decided the issue, it did not revisit the issue under the law of the case. No such limitations exist here.

C. Even if *Chevron* applied, it could not save DEA's interpretation of § 812(b)(1)(B).

Even if *Chevron* applied, DEA's interpretation would fail for the reasons already explained. At Step One, § 812(b)(1)(B) unambiguously forbids DEA from overruling the views of most of the States on issues of medical judgment like whether marijuana has a currently accepted medical use in treatment in the United States. Phrases like "legitimate medical purpose" and "accepted medical use" may be ambiguous in some respects yet still sufficiently clear to evince Congress's intent on certain other issues. *E.g.*, *Cuomo v. Clearing House Ass'n, L.L.C.*, 557 U.S. 519, 525 (2009) (Scalia, J.) ("[T]he presence of some uncertainty does not expand *Chevron* deference to cover virtually any interpretation.").

That is the case here. The question is not whether the statute "precisely defines *the term*," *ACT I*, 930 F.2d at 939 (emph. added),[9] but whether Congress has "directly spoken to the *precise question at issue*," *Chevron*, 467 U.S. at 837 (emph. added). And here, with certainty, it did: acceptance by the States, the traditional regulators of the medical profession, precludes the no-currently-accepted-medical-use finding. *See generally Oregon*, 546 U.S. at 249.

But even if this Court were convinced that § 812(b)(1)(B) is genuinely ambiguous as to this question, DEA's interpretation would still fail at Step Two for at least five reasons. 467 U.S. at 844 (only permissible construction of ambiguous statute merits deference). *See also Mayo Found. for Med. Educ. and Research v. United States*, 562 U.S. 44, 53 (2011) (agency rule fails at *Chevron* step two if it is "arbitrary or capricious in substance").

First, "[a]n agency's decision is arbitrary and capricious if 'the agency has relied on factors which Congress has not intended it to consider [or] entirely failed to consider an important aspect of the problem.'" *Inland Empire Pub. Lands Council v. Glickman*, 88 F.3d 697, 701 (9th Cir. 1996)

[9] *ACT I* also noted the court's holding was "on [that] record," 930 F.2d at 939, which said nothing about widespread acceptance among States.

(quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). The 2020 Determination errs in both directions.

DEA relied on its 2016 Denial as the sole basis for concluding that there was no substantial evidence of *currently* accepted medical use in 2020. But a lot has changed, including the number of States that have accepted marijuana's medical use. Today, it is a supermajority. Congress intended scheduling determinations to be based on what is happening in treatment *currently*, not years ago.

Then there's what DEA failed to consider: that a growing majority of States have accepted marijuana, resulting in widespread use of marijuana in treatment in the United States. As discussed above, Congress presumed the States would play an important role under the CSA, but DEA's 2020 Determination treats that as entirely irrelevant. That is the very essence of arbitrary and capricious agency decision making.

Second, the notion that a drug's chemistry must be known and reproducible—a requirement of the five-part test—is arbitrary and capricious. DEA says the purpose of this FDA-derived requirement is to permit standardized doses. 1.ER.19, 81 Fed. Reg. 53,700. That makes sense for FDA's consumer-protection mission, but it bears no connection to DEA's mandate. DEA is a law-enforcement agency, not a public-health or

consumer-protection agency. Under the Act, it is charged with preventing drug diversion. This repeatable-chemistry requirement is "unmoored from the purposes and concerns" of the Act, and thus does not "pass muster." *Judulang v. Holder*, 565 U.S. 42, 64 (2011).

DEA itself has implicitly acknowledged that the repeatable-chemistry requirement is "manifestly contrary to the statute." "Different marijuana samples derived from various cultivated strains may have very different chemical constituents" so "when considering all Cannabis strains together ... reproducing consistent standardized doses is not possible." 1.ER.19, 81 Fed. Reg. at 53,700. According to DEA, "marihuana," which Congress defined as including all strains together, 21 U.S.C. § 802(16), is inherently a Schedule I drug and always will be. *See id.*

The notion the Congress placed "marihuana" in Schedule I permanently is demonstrably false. Congress placed marijuana in Schedule I "until the completion of certain research," *Raich*, 545 U.S. at 14, then established a Commission to do research and charged it with submitting a recommendation for legislation or administrative action as to "marihuana" as a class. Pub. L. No. 91-513 § 601, 602. Presumably, Congress didn't fund a pointless endeavor. It was aware that marijuana is a plant. Had that reality meant locking "marihuana" in Schedule I and throwing away the key because

of an implied repeatable-chemistry requirement, Congress's tentative placement of marijuana in Schedule I pending a million-dollar commission investigation and recommendation would have made no sense.

This sort of arbitrary requirement reduces the statute to an "empty formality" and "an exercise in futility." *Grinspoon*, 828 F.2d at 890. It is hardly a coincidence that in the three decades since the advent of the five-part test, there has not been a single hearing under § 811 to consider the evidence supporting and opposing changing marijuana's scheduling status even though DEA has received scores of petitions, including a petition submitted by *state Governors*. "[T]he hearing requirement should be given full effect rather than being short-circuited by blind reliance on the absence of FDA approval." *Id.* at 991. This remark applies with full force to blind reliance on "reproducible chemistry."

Third, DEA's interpretation turns the Act against itself. Congress enacted the CSA to replace "most of the earlier antidrug laws in favor of a comprehensive regime to combat the international and interstate traffic in illicit drugs." *Oregon*, 546 U.S. at 269 (quoting *Raich*, 545 U.S. at 12). "In doing so, Congress sought to 'conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances.'" *Id.*

More than two-thirds of the States have passed laws legitimizing medical marijuana. But federal law continues to prohibit not only medical-marijuana use but even research using the marijuana currently used in treatment across the country. Due to the disparity, DOJ has curtailed enforcement of federal law against the medical marijuana use in States that permit it—initially as a matter of DOJ policy and later because of legislative appropriations bills circumscribing use of funds. As a result, doctors are currently recommending and patients are currently using marijuana in treatment in the United States. At bottom, DEA's interpretation makes § 812(b)(1)(B) more effective at deterring medical marijuana research than supposed diversion, manifestly contrary to the intent of Congress.

Fourth, setting aside the five-part test, DEA counts acceptance by FDA, which has no authority over the practice of medicine (*see* 21 U.S.C. § 396) as "accepted medical use," but ignores acceptance by the States—the primary regulators of the medical profession in this country for centuries. 1.ER.59, 1.ER.81 Fed. Reg. at 53,740. What non-arbitrary reason justifies this disparity? Nothing supports the notion that Congress intended the CSA to turn the federal-state balance on a core police power on its head. And given that courts presume that Congress intends to preserve the federal-state balance in these areas absent a clear statement to the contrary, *see BFP*, 511

U.S. at 539, DEA's usurpation of traditional state police power cannot stand. If DEA recognizes acceptance by FDA as "accepted medical use," it must also recognize acceptance by States.

Finally, highlighting the arbitrary nature of DEA's approach, it is *harder* to show a drug has an accepted medical use under the five-factor test than it is to show the same drug is safe and effective for interstate marketing under the FDCA. FDA has approved products without a known and reproducible chemistry, such as hormone-based drugs and biologics. *See* R. Eisenberg, D. Leiderman, *Cannabis for Medical Use: FDA and DEA Regulation in the Hall of Mirrors*, 74 Food & Drug L.J. 246, 279 n.94 (2019). It regulates these products under the Public Health Service Act. *See id.* (citing Public L. No. 115-271 (Oct. 24, 2018)).

Despite FDA approval, none of these drugs qualifies as having a currently accepted medical use under the five-part test. No one—not even DEA—thinks Congress intended such a bizarre result. In the 1992 Rule, DEA declared 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." 1.ER.170, 1992 Rule at 10,504 (quoting 21 U.S.C. § 812(b)(1)(B)). While Petitioners strongly disagree with DEA's stated interpretation, the point for present

purposes is that even assuming it is correct, the five-part test is dysfunctional on its own terms and therefore arbitrary and capricious.

II. Section 811(d)(1)'s double delegation of legislative Power Is unconstitutional.

Per § 811(d)(1), the Attorney General must place drugs in the schedule "he deems most appropriate" to carry out international treaty obligations in effect on October 27, 1970, without regard to the procedures and findings in §§ 811 and 812. DEA says this section and the Single Convention mandate marijuana's placement in Schedules I or II. 1.ER.86-87, 81 Fed. Reg. at 53,767-68.

Although the Supreme Court routinely approves delegations, the unusual double-delegation in § 811(d)(1) exceeds permissible limits. First, the statute violates the private non-delegation doctrine. Second, it delegates to the Attorney General the power to execute non-fixed treaty obligations, providing no guidance beyond that. And even if each step of this unusual delegation could separately stand, together they must fall.

A. Section 811(d)(1) violates the private non-delegation doctrine.

Congress may not assign lawmaking authority to non-governmental entities. This is "delegation in its most obnoxious form." *Carter v. Carter Coal Co.*, 298 U.S. 238, 311 (1936). And it is what § 811(d)(1) does.

In *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935), the Court struck down a delegation to the President to approve "codes of fair competition" proposed by trade or industry groups because it gave the President "unfettered discretion to make whatever laws he thinks may be needed." *Id.* at 537-38. In so holding, the Court noted that a delegation of legislative power to private associations "is unknown to our law and is utterly inconsistent with the constitutional prerogatives and duties of Congress." *Id.*

One year later, in *Carter Coal*, 298 U.S. at 311, the Court faced that unknown delegation. There, the statute permitted a group of coal producers to set binding regulations for the entire industry. This delegation violated non-delegation principles as well as the Due Process Clause of the Fifth Amendment. *Carter Coal* remains good law; it stands for the principle that Congress cannot delegate power to non-governmental parties who are neither accountable to other government officials nor to the electorate. *Dep't of Transp. v. Ass'n of Am. R.R.*, 575 U.S. 43, 62 (2015) (Alito, J. concurring).

Section 811(d)(1) returns us to the unknown. The statute delegates regulatory authority to the *World Health Organization* ("WHO") to set binding codes of domestic criminal law. Handbook at 72. And "[s]ubsequent modification or amendment to these international treaties would, of course, become controlling as federal law" as well. *Id.* at 65. This violates *Carter*

Coal. See Nat. Res. Def. Council v. EPA, 464 F.3d 1, 9 (D.C. Cir. 2006) ("A holding that the Parties' post-ratification side agreements were 'law' would raise serious constitutional questions.").

Subsequent cases have narrowed *Carter Coal*. For example, in *Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381, 388 (1940), the Court approved a scheme that permitted local coal producers to recommend rules governing coal sales. Unlike *Carter Coal*, however, the coal boards at issue operated as "subordinate[s]" to the government agency, and the government retained the power to modify the proposed regulations and determine the final prices. In these cases, the government retained a supervisory role in ratification or repudiation of the private decision, even if perfunctory.

Not so here. WHO does what it wants. The Attorney General does not participate in and has no discretion to undercut WHO's decision. He cannot, for example, place fewer restrictions than international obligations demand. This is what DEA means when it says it cannot move marijuana below Schedule II: WHO-dictated treaty obligations create an impenetrable floor.

"Liberty requires accountability." *Dep't of Transp.*, 575 U.S. at 57 (Alito, J. concurring). "When citizens cannot readily identify the source of legislation or regulation that affects their lives," however, "[g]overnment officials can wield power without owning up to the consequences." *Id.*

Moreover, "[l]egislators may not 'abdicate their responsibilities for setting the standards of the criminal law.'" *Dimaya*, 138 S. Ct. at 1227 (Gorsuch, J. concurring-in-part) (quoting *Smith v. Goguen*, 415 U.S. 566, 575 (1974)).

If government wants to maintain barriers to researching the real-world marijuana that millions use daily, so be it. But some government official in this country must be accountable for that unpopular choice. *Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477, 499 (2010) ("Our Constitution was adopted to enable the people to govern themselves, through their elected leaders."). Allowing government to evade the consequences of unpopular decisions by resort to arcane international schedules is repugnant to the democratic values that underlie our Constitution.

B. The delegation to the Attorney General is unconstitutional.

"The nondelegation doctrine bars Congress from transferring its legislative power to another branch of Government." *Gundy v. United States*, 139 S. Ct. 2116, 2121 (2019). That principle is violated here.

First, § 811(d)(1) transfers a quintessential legislative power—the power to execute treaties—to the Attorney General. International drug treaties are not self-executing. They merely create international law commitments. Thus, they do not have domestic effect until Congress enacts legislation under an enumerated power. *Medellin v. Texas*, 552 U.S. 491,

505, 521 (2008). Section 811(d)(1) charges the Attorney General with executing this quintessential legislative power with respect to domestic criminal law by choosing the schedule "he deems most appropriate."

An even more serious delegation problem arises next: after handing treaty-execution authority to the Attorney General, the statute disclaims the so-called intelligible principle to choose among schedules. In *Touby*, the Supreme Court upheld the CSA's delegation of power to the Attorney General to temporarily schedule substances because the Act provided concrete constraints on his discretion. *See Gundy*, 139 S. Ct. at 2141 (Gorsuch, J. dissenting) (citing *Touby v. United States*, 500 U.S. 160, 166 (1991)). But § 811(d)(1) unambiguously removes those restraints. If it applies, as it does with marijuana, the Attorney General must place a drug in the schedule "he deems most appropriate to carry out such obligations, *without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section*." 21 U.S.C. § 811(d) (emph. added). There is nothing else.

On either side of the *Gundy* line—the traditional intelligible principle test or the approach outlined in the *Gundy* dissent, *Gundy*, 139 S. Ct. at 2141—this second delegation in § 811(d)(1) falters.

C. The double delegation violates separation of powers.

In *Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477, 495-96 (2010) the Court, struck down the Sarbanes-Oxley Act's dual for-cause limitation on removing of members of the Public Company Accounting Oversight Board. Two levels of protected tenure violated separation of powers. *Id. See also Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 537 F.3d 667, 712 (D.C. Cir. 2008) (Kavanaugh, J. dissenting) (discussing whether a combination of separation of powers issues, "taken as a whole," could violate separation of powers).

The closest analogue to § 811(d)(1)'s unusual double-delegation was the one struck down in *Schechter*. The statute here is more offensive. It runs to both extremes. The Attorney General has no discretion to override the floor dictated by an unelected international body. But he has unfettered discretion to schedule above that point. Even if these two handoffs could stand independently, together they plainly violate established Separation of Powers norms.

CONCLUSION

Petitioners request that the Court grant the Petition for Review, vacate the 2020 Denial, and remand to DEA with instructions to (1) take the steps necessary to initiate rulemaking proceedings under § 811(a); (2) complete the formal rulemaking process required under § 811(a) within one year from

the date of this Court's order; and (3) ensure that marijuana's placement, if any, on the schedules is consistent with § 812(b)(1)(B)'s plain mandate, which prohibits DEA from denying that marijuana has a currently accepted medical use in the face of widespread State acceptance.

In addition, Petitioners request that this Court declare § 811(d)(1) unconstitutional.

Dated: September 29, 2020

Respectfully submitted,

/s/Matthew C. Zorn
Matthew C. Zorn

/s/Shane Pennington
Shane Pennington
YETTER COLEMAN LLP
811 Main Street, Suite 4100
Houston, Texas 77002
Tel. (713) 632-8000
Fax (713) 632-8002
mzorn@yettercoleman.com
spennington@yettercoleman.com

STATEMENT OF RELATED CASES

Petitioners are unaware of any related pending appeals within the meaning of Circuit Rule 28-2.6.

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 8. Certificate of Compliance for Briefs

Instructions for this form: http://www.ca9.uscourts.gov/forms/form08instructions.pdf

9th Cir. Case Number(s) 20-71433

I am the attorney or self-represented party.

This brief contains 13,910 **words**, excluding the items exempted by Fed. R. App. P. 32(f). The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6).

I certify that this brief *(select only one)*:

- (•) complies with the word limit of Cir. R. 32-1.
- ( ) is a **cross-appeal** brief and complies with the word limit of Cir. R. 28.1-1.
- ( ) is an **amicus** brief and complies with the word limit of Fed. R. App. P. 29(a)(5), Cir. R. 29-2(c)(2), or Cir. R. 29-2(c)(3).
- ( ) is for a **death penalty** case and complies with the word limit of Cir. R. 32-4.
- ( ) complies with the longer length limit permitted by Cir. R. 32-2(b) because *(select only one):*
  - ( ) it is a joint brief submitted by separately represented parties;
  - ( ) a party or parties are filing a single brief in response to multiple briefs; or
  - ( ) a party or parties are filing a single brief in response to a longer joint brief.
- ( ) complies with the length limit designated by court order dated _____.
- ( ) is accompanied by a motion to file a longer brief pursuant to Cir. R. 32-2(a).

Signature /s/Matthew C. Zorn **Date** Sep 29, 2020

*(use "*s/[typed name]*" to sign electronically-filed documents)*

Feedback or questions about this form? Email us at forms@ca9.uscourts.gov

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed this document with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on September 29, 2020. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Mark B. Stern
Daniel Aguilar
Attorneys, Appellate Staff
Civil Division, Room 7266
Department of Justice
950 Pennsylvania, NW
Washington, DC 20530

Counsel for Respondents

/s/ Matthew C. Zorn
Matthew C. Zorn

1009755

ADDENDUM

ADDENDUM TABLE OF CONTENTS

5 U.S.C. 706 ..... Add. 1

21 U.S.C. § 811..... Add. 3

21 U.S.C. § 812 ..... Add. 11

U.S. Const., Article I ..... Add. 26

KeyCite Yellow Flag - Negative Treatment
Unconstitutional or PreemptedLimitation Recognized by Krafsur v. Davenport, 6th Cir.(Tenn.), Dec. 04, 2013

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 5. Government Organization and Employees (Refs & Annos)
Part I. The Agencies Generally
Chapter 7. Judicial Review (Refs & Annos)

5 U.S.C.A. § 706

§ 706. Scope of review

Currentness

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall--

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be--

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

CREDIT(S)

(Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 393.)

Notes of Decisions (4705)

5 U.S.C.A. § 706, 5 USCA § 706
Current through P.L. 116-158.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 21. Food and Drugs (Refs & Annos)
Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)
Subchapter I. Control and Enforcement
Part B. Authority to Control; Standards and Schedules

21 U.S.C.A. § 811

§ 811. Authority and criteria for classification of substances

Effective: November 25, 2015
Currentness

(a) Rules and regulations of Attorney General; hearing

The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter. Except as provided in subsections (d) and (e), the Attorney General may by rule--

(1) add to such a schedule or transfer between such schedules any drug or other substance if he--

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of Title 5. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

(b) Evaluation of drugs and other substances

The Attorney General shall, before initiating proceedings under subsection (a) to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) and any scientific or medical considerations involved in paragraphs

(1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a).

(c) Factors determinative of control or removal from schedules

In making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

(d) International treaties, conventions, and protocols requiring control; procedures respecting changes in drug schedules of Convention on Psychotropic Substances

(1) If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section.

(2)(A) Whenever the Secretary of State receives notification from the Secretary-General of the United Nations that information has been transmitted by or to the World Health Organization, pursuant to article 2 of the Convention on Psychotropic Substances,

which may justify adding a drug or other substance to one of the schedules of the Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State shall immediately transmit the notice to the Secretary of Health and Human Services who shall publish it in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the scientific and medical evaluations which he is to prepare respecting such drug or substance. The Secretary of Health and Human Services shall prepare for transmission through the Secretary of State to the World Health Organization such medical and scientific evaluations as may be appropriate regarding the possible action that could be proposed by the World Health Organization respecting the drug or substance with respect to which a notice was transmitted under this subparagraph.

(B) Whenever the Secretary of State receives information that the Commission on Narcotic Drugs of the United Nations proposes to decide whether to add a drug or other substance to one of the schedules of the Convention, transfer a drug or substance from one schedule to another, or delete it from the schedules, the Secretary of State shall transmit timely notice to the Secretary of Health and Human Services of such information who shall publish a summary of such information in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the recommendation which he is to furnish, pursuant to this subparagraph, respecting such proposal. The Secretary of Health and Human Services shall evaluate the proposal and furnish a recommendation to the Secretary of State which shall be binding on the representative of the United States in discussions and negotiations relating to the proposal.

(3) When the United States receives notification of a scheduling decision pursuant to article 2 of the Convention on Psychotropic Substances that a drug or other substance has been added or transferred to a schedule specified in the notification or receives notification (referred to in this subsection as a "schedule notice") that existing legal controls applicable under this subchapter to a drug or substance and the controls required by the Federal Food, Drug, and Cosmetic Act do not meet the requirements of the schedule of the Convention in which such drug or substance has been placed, the Secretary of Health and Human Services after consultation with the Attorney General, shall first determine whether existing legal controls under this subchapter applicable to the drug or substance and the controls required by the Federal Food, Drug, and Cosmetic Act, meet the requirements of the schedule specified in the notification or schedule notice and shall take the following action:

(A) If such requirements are met by such existing controls but the Secretary of Health and Human Services nonetheless believes that more stringent controls should be applied to the drug or substance, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance, pursuant to subsections (a) and (b) of this section, to apply to such controls.

(B) If such requirements are not met by such existing controls and the Secretary of Health and Human Services concurs in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance under the appropriate schedule pursuant to subsections (a) and (b) of this section.

(C) If such requirements are not met by such existing controls and the Secretary of Health and Human Services does not concur in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall--

(i) if he deems that additional controls are necessary to protect the public health and safety, recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance pursuant to subsections (a) and (b) of this section, to apply such additional controls;

(ii) request the Secretary of State to transmit a notice of qualified acceptance, within the period specified in the Convention, pursuant to paragraph 7 of article 2 of the Convention, to the Secretary-General of the United Nations;

(iii) request the Secretary of State to transmit a notice of qualified acceptance as prescribed in clause (ii) and request the Secretary of State to ask for a review by the Economic and Social Council of the United Nations, in accordance with paragraph 8 of article 2 of the Convention, of the scheduling decision; or

(iv) in the case of a schedule notice, request the Secretary of State to take appropriate action under the Convention to initiate proceedings to remove the drug or substance from the schedules under the Convention or to transfer the drug or substance to a schedule under the Convention different from the one specified in the schedule notice.

(4)(A) If the Attorney General determines, after consultation with the Secretary of Health and Human Services, that proceedings initiated under recommendations made under paragraph [1] (B) or (C)(i) of paragraph (3) will not be completed within the time period required by paragraph 7 of article 2 of the Convention, the Attorney General, after consultation with the Secretary and after providing interested persons opportunity to submit comments respecting the requirements of the temporary order to be issued under this sentence, shall issue a temporary order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application of any provision of part C of this subchapter which he finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention. In the case of proceedings initiated under subparagraph (B) of paragraph (3), the Attorney General, concurrently with the issuance of such order, shall request the Secretary of State to transmit a notice of qualified acceptance to the Secretary-General of the United Nations pursuant to paragraph 7 of article 2 of the Convention. A temporary order issued under this subparagraph controlling a drug or other substance subject to proceedings initiated under subsections (a) and (b) of this section shall expire upon the effective date of the application to the drug or substance of the controls resulting from such proceedings.

(B) After a notice of qualified acceptance of a scheduling decision with respect to a drug or other substance is transmitted to the Secretary-General of the United Nations in accordance with clause (ii) or (iii) of paragraph (3)(C) or after a request has been made under clause (iv) of such paragraph with respect to a drug or substance described in a schedule notice, the Attorney General, after consultation with the Secretary of Health and Human Services and after providing interested persons opportunity to submit comments respecting the requirements of the order to be issued under this sentence, shall issue an order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention in the case of a drug or substance for which a notice of qualified acceptance was transmitted or whichever the Attorney General determines is appropriate in the case of a drug or substance described in a schedule notice. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application of any provision of part C of this subchapter which he finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention. If, as a result of a review under paragraph 8 of article 2 of the Convention of the scheduling decision with respect to which a notice of qualified acceptance was transmitted in accordance with clause (ii) or (iii) of paragraph (3)(C)--

(i) the decision is reversed, and

(ii) the drug or substance subject to such decision is not required to be controlled under schedule IV or V to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention,

the order issued under this subparagraph with respect to such drug or substance shall expire upon receipt by the United States of the review decision. If, as a result of action taken pursuant to action initiated under a request transmitted under clause (iv) of paragraph (3)(C), the drug or substance with respect to which such action was taken is not required to be controlled under schedule IV or V, the order issued under this paragraph with respect to such drug or substance shall expire upon receipt by the United States of a notice of the action taken with respect to such drug or substance under the Convention.

(C) An order issued under subparagraph (A) or (B) may be issued without regard to the findings required by subsection (a) of this section or by section 812(b) of this title and without regard to the procedures prescribed by subsection (a) or (b) of this section.

(5) Nothing in the amendments made by the Psychotropic Substances Act of 1978 or the regulations or orders promulgated thereunder shall be construed to preclude requests by the Secretary of Health and Human Services or the Attorney General through the Secretary of State, pursuant to article 2 or other applicable provisions of the Convention, for review of scheduling decisions under such Convention, based on new or additional information.

(e) Immediate precursors

The Attorney General may, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section, place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in any other schedule with a higher numerical designation. If the Attorney General designates a substance as an immediate precursor and places it in a schedule, other substances shall not be placed in a schedule solely because they are its precursors.

(f) Abuse potential

If, at the time a new-drug application is submitted to the Secretary for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, it appears that such drug has an abuse potential, such information shall be forwarded by the Secretary to the Attorney General.

(g) Exclusion of non-narcotic substances sold over the counter without a prescription; dextromethorphan; exemption of substances lacking abuse potential

(1) The Attorney General shall by regulation exclude any non-narcotic drug which contains a controlled substance from the application of this subchapter and subchapter II of this chapter if such drug may, under the Federal Food, Drug, and Cosmetic Act, be lawfully sold over the counter without a prescription.

(2) Dextromethorphan shall not be deemed to be included in any schedule by reason of enactment of this subchapter unless controlled after October 27, 1970 pursuant to the foregoing provisions of this section.

(3) The Attorney General may, by regulation, exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part of this subchapter if he finds such compound, mixture, or preparation meets the requirements of one of the following categories:

(A) A mixture, or preparation containing a nonnarcotic controlled substance, which mixture or preparation is approved for prescription use, and which contains one or more other active ingredients which are not listed in any schedule and which are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse.

(B) A compound, mixture, or preparation which contains any controlled substance, which is not for administration to a human being or animal, and which is packaged in such form or concentration, or with adulterants or denaturants, so that as packaged it does not present any significant potential for abuse.

(C) Upon the recommendation of the Secretary of Health and Human Services, a compound, mixture, or preparation which contains any anabolic steroid, which is intended for administration to a human being or an animal, and which, because of its concentration, preparation, formulation or delivery system, does not present any significant potential for abuse.

(h) Temporary scheduling to avoid imminent hazards to public safety

(1) If the Attorney General finds that the scheduling of a substance in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, he may, by order and without regard to the requirements of subsection (b) relating to the Secretary of Health and Human Services, schedule such substance in schedule I if the substance is not listed in any other schedule in section 812 of this title or if no exemption or approval is in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act. Such an order may not be issued before the expiration of thirty days from--

(A) the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued, and

(B) the date the Attorney General has transmitted the notice required by paragraph (4).

(2) The scheduling of a substance under this subsection shall expire at the end of 2 years from the date of the issuance of the order scheduling such substance, except that the Attorney General may, during the pendency of proceedings under subsection (a)(1) with respect to the substance, extend the temporary scheduling for up to 1 year.

(3) When issuing an order under paragraph (1), the Attorney General shall be required to consider, with respect to the finding of an imminent hazard to the public safety, only those factors set forth in paragraphs (4), (5), and (6) of subsection (c), including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

(4) The Attorney General shall transmit notice of an order proposed to be issued under paragraph (1) to the Secretary of Health and Human Services. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph.

(5) An order issued under paragraph (1) with respect to a substance shall be vacated upon the conclusion of a subsequent rulemaking proceeding initiated under subsection (a) with respect to such substance.

(6) An order issued under paragraph (1) is not subject to judicial review.

(i) Temporary and permanent scheduling of recently emerged anabolic steroids

(1) The Attorney General may issue a temporary order adding a drug or other substance to the definition of anabolic steroids if the Attorney General finds that--

(A) the drug or other substance satisfies the criteria for being considered an anabolic steroid under section 802(41) of this title but is not listed in that section or by regulation of the Attorney General as being an anabolic steroid; and

(B) adding such drug or other substance to the definition of anabolic steroids will assist in preventing abuse or misuse of the drug or other substance.

(2) An order issued under paragraph (1) shall not take effect until 30 days after the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued. The order shall expire not later than 24 months after the date it becomes effective, except that the Attorney General may, during the pendency of proceedings under paragraph (6), extend the temporary scheduling order for up to 6 months.

(3) The Attorney General shall transmit notice of an order proposed to be issued under paragraph (1) to the Secretary of Health and Human Services. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph.

(4) A temporary scheduling order issued under paragraph (1) shall be vacated upon the issuance of a permanent scheduling order under paragraph (6).

(5) An order issued under paragraph (1) is not subject to judicial review.

(6) The Attorney General may, by rule, issue a permanent order adding a drug or other substance to the definition of anabolic steroids if such drug or other substance satisfies the criteria for being considered an anabolic steroid under section 802(41) of this title. Such rulemaking may be commenced simultaneously with the issuance of the temporary order issued under paragraph (1).

(j) Interim final rule; date of issuance; procedure for final rule

(1) With respect to a drug referred to in subsection (f), if the Secretary of Health and Human Services recommends that the Attorney General control the drug in schedule II, III, IV, or V pursuant to subsections (a) and (b), the Attorney General shall, not later than 90 days after the date described in paragraph (2), issue an interim final rule controlling the drug in accordance with such subsections and section 812(b) of this title using the procedures described in paragraph (3).

(2) The date described in this paragraph shall be the later of--

(A) the date on which the Attorney General receives the scientific and medical evaluation and the scheduling recommendation from the Secretary of Health and Human Services in accordance with subsection (b); or

(B) the date on which the Attorney General receives notification from the Secretary of Health and Human Services that the Secretary has approved an application under section 505(c), 512, or 571 of the Federal Food, Drug, and Cosmetic Act or section 262(a) of Title 42, or indexed a drug under section 572 of the Federal Food, Drug, and Cosmetic Act, with respect to the drug described in paragraph (1).

(3) A rule issued by the Attorney General under paragraph (1) shall become immediately effective as an interim final rule without requiring the Attorney General to demonstrate good cause therefor. The interim final rule shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, the Attorney General shall issue a final rule in accordance with the scheduling criteria of subsections (b), (c), and (d) of this section and section 812(b) of this title.

CREDIT(S)

(Pub.L. 91-513, Title II, § 201, Oct. 27, 1970, 84 Stat. 1245; Pub.L. 95-633, Title I, § 102(a), Nov. 10, 1978, 92 Stat. 3769; Pub.L. 96-88, Title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub.L. 98-473, Title II, §§ 508, 509(a), Oct. 12, 1984, 98 Stat. 2071, 2072; Pub.L. 108-358, § 2(b), Oct. 22, 2004, 118 Stat. 1663; Pub.L. 112-144, Title XI, § 1153, July 9, 2012, 126 Stat. 1132; Pub.L. 113-260, § 2(b), Dec. 18, 2014, 128 Stat. 2930; Pub.L. 114-89, § 2(b), Nov. 25, 2015, 129 Stat. 700.)

Notes of Decisions (76)

Footnotes

1 So in original. Probably should be “subparagraph”.

21 U.S.C.A. § 811, 21 USCA § 811
Current through P.L. 116-158.

End of Document

KeyCite Yellow Flag - Negative Treatment
Unconstitutional or PreemptedPrior Version's Limitation Recognized by U.S. v. Macedo, 7th Cir.(Ill.), Apr. 14, 2005

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 21. Food and Drugs (Refs & Annos)
Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)
Subchapter I. Control and Enforcement
Part B. Authority to Control; Standards and Schedules

21 U.S.C.A. § 812

§ 812. Schedules of controlled substances

Effective: December 20, 2018
Currentness

(a) Establishment

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) Schedule I--

(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.

(2) Schedule II--

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) Schedule III--

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) Schedule IV--

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) Schedule V--

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(c) Initial schedules of controlled substances

Schedules I, II, III, IV, and V shall, unless and until amended [1] pursuant to section 811 of this title, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

Schedule I

(a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol.

(2) Allylprodine.

(3) Alphacetylmathadol. [2]

(4) Alphameprodine.

(5) Alphamethadol.

(6) Benzethidine.

(7) Betacetylmethadol.

(8) Betameprodine.

(9) Betamethadol.

(10) Betaprodine.

(11) Clonitazene.

(12) Dextromoramide.

(13) Dextrorphan.

(14) Diampromide.

(15) Diethylthiambutene.

(16) Dimenoxadol.

(17) Dimepheptanol.

(18) Dimethylthiambutene.

(19) Dioxaphetyl butyrate.

(20) Dipipanone.

(21) Ethylmethylthiambutene.

(22) Etonitazene.

(23) Etoxeridine.

(24) Furethidine.

(25) Hydroxypethidine.

(26) Ketobemidone.

(27) Levomoramide.

(28) Levophenacylmorphan.

(29) Morpheridine.

(30) Noracymethadol.

(31) Norlevorphanol.

(32) Normethadone.

(33) Norpipanone.

(34) Phenadoxone.

(35) Phenampromide.

(36) Phenomorphan.

(37) Phenoperidine.

(38) Piritramide.

(39) Proheptazine.

(40) Properidine.

(41) Racemoramide.

(42) Trimeperidine.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine.

(2) Acetyldihydrocodeine.

(3) Benzylmorphine.

(4) Codeine methylbromide.

(5) Codeine-N-Oxide.

(6) Cyprenorphine.

(7) Desomorphine.

(8) Dihydromorphine.

(9) Etorphine.

(10) Heroin.

(11) Hydromorphinol.

(12) Methyldesorphine.

(13) Methylhydromorphine.

(14) Morphine methylbromide.

(15) Morphine methylsulfonate.

(16) Morphine-N-Oxide.

(17) Myrophine.

(18) Nicocodeine.

(19) Nicomorphine.

(20) Normorphine.

(21) Pholcodine.

(22) Thebacon.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 3,4-methylenedioxy amphetamine.

(2) 5-methoxy-3,4-methylenedioxy amphetamine.

(3) 3,4,5-trimethoxy amphetamine.

(4) Bufotenine.

(5) Diethyltryptamine.

(6) Dimethyltryptamine.

(7) 4-methyl-2,5-dimethoxyamphetamine.

(8) Ibogaine.

(9) Lysergic acid diethylamide.

(10) Marihuana.

(11) Mescaline.

(12) Peyote.

(13) N-ethyl-3-piperidyl benzilate.

(14) N-methyl-3-piperidyl benzilate.

(15) Psilocybin.

(16) Psilocyn.

(17) Tetrahydrocannabinols, except for tetrahydrocannabinols in hemp (as defined under section 1639*o* of Title 7).

(18) 4-methylmethcathinone (Mephedrone).

(19) 3,4-methylenedioxypyrovalerone (MDPV).

(20) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E).

(21) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D).

(22) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C).

(23) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I).

(24) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2).

(25) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4).

(26) 2-(2,5-Dimethoxyphenyl)ethanamine (2C-H).

(27) 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N).

(28) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P).

(d)(1) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of cannabimimetic agents, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

(2) In paragraph (1):

(A) The term “cannabimimetic agents” means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes:

(i) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent.

(ii) 3-(1-naphthoyl)indole or 3-(1-naphthylmethane)indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent.

(iii) 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent.

(iv) 1-(1-naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent.

(v) 3-phenylacetylindole or 3-benzoylindole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent.

(B) Such term includes--

(i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497);

(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog);

(iii) 1-pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678);

(iv) 1-butyl-3-(1-naphthoyl)indole (JWH-073);

(v) 1-hexyl-3-(1-naphthoyl)indole (JWH-019);

(vi) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200);

(vii) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250);

(viii) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081);

(ix) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122);

(x) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398);

(xi) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201);

(xii) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694);

(xiii) 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19 and RCS-4);

(xiv) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8); and

(xv) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH-203).

Schedule II

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances 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 and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

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

(3) Opium poppy and poppy straw.

(4) coca [3] leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed; cocaine, its salts, optical and geometric isomers, and salts of isomers; ecgonine, its derivatives, their salts, isomers, and salts of isomers; or any compound, mixture, or preparation which contains any quantity of any of the substances referred to in this paragraph.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine.

(2) Anileridine.

(3) Bezitramide.

(4) Dihydrocodeine.

(5) Diphenoxylate.

(6) Fentanyl.

(7) Isomethadone.

(8) Levomethorphan.

(9) Levorphanol.

(10) Metazocine.

(11) Methadone.

(12) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.

(13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.

(14) Pethidine.

(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.

(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.

(17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.

(18) Phenazocine.

(19) Piminodine.

(20) Racemethorphan.

(21) Racemorphan.

(c) Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

Schedule III

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.

(2) Phenmetrazine and its salts.

(3) Any substance (except an injectable liquid) which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

(4) Methylphenidate.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.

(2) Chorhexadol.

(3) Glutethimide.

(4) Lysergic acid.

(5) Lysergic acid amide.

(6) Methyprylon.

(7) Phencyclidine.

(8) Sulfondiethylmethane.

(9) Sulfonethylmethane.

(10) Sulfonmethane.

(c) Nalorphine.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts.

(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(e) Anabolic steroids.

Schedule IV

(1) Barbital.

(2) Chloral betaine.

(3) Chloral hydrate.

(4) Ethchlorvynol.

(5) Ethinamate.

(6) Methohexital.

(7) Meprobamate.

(8) Methylphenobarbital.

(9) Paraldehyde.

(10) Petrichloral.

(11) Phenobarbital.

Schedule V

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

CREDIT(S)

(Pub.L. 91-513, Title II, § 202, Oct. 27, 1970, 84 Stat. 1247; Pub.L. 95-633, Title I, § 103, Nov. 10, 1978, 92 Stat. 3772; Pub.L. 98-473, Title II, §§ 507(c), 509(b), Oct. 12, 1984, 98 Stat. 2071, 2072; Pub.L. 99-570, Title I, § 1867, Oct. 27, 1986, 100 Stat. 3207-55; Pub.L. 99-646, § 84, Nov. 10, 1986, 100 Stat. 3619; Pub.L. 101-647, Title XIX, § 1902(a), Nov. 29, 1990, 104 Stat. 4851; Pub.L. 112-144, Title XI, § 1152, July 9, 2012, 126 Stat. 1130; Pub.L. 115-334, Title XII, § 12619(b), Dec. 20, 2018, 132 Stat. 5018.)

Notes of Decisions (154)

Footnotes

1 Revised schedules are published in the Code of Federal Regulations, Part 1308 of Title 21, Food and Drugs.

2 So in original. Probably should be “Alphacetylmethadol”.

3 So in original. Probably should be capitalized.

21 U.S.C.A. § 812, 21 USCA § 812

Current through P.L. 116-158.

End of Document

U.S.C.A. Const. Art. I

ARTICLE I. THE CONGRESS

Currentness

Section 1. All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives.

Section 2. The House of Representatives shall be composed of Members chosen every second Year by the People of the several States, and the Electors in each State shall have the Qualifications requisite for Electors of the most numerous Branch of the State Legislature.

No Person shall be a Representative who shall not have attained to the Age of twenty five Years, and been seven Years a Citizen of the United States, and who shall not, when elected, be an Inhabitant of that State in which he shall be chosen.

[Representatives and direct Taxes shall be apportioned among the several States which may be included within this Union, according to their respective Numbers, which shall be determined by adding to the whole Number of free Persons, including those bound to Service for a Term of Years, and excluding Indians not taxed, three fifths of all other Persons.] [1] The actual Enumeration shall be made within three Years after the first Meeting of the Congress of the United States, and within every subsequent Term of ten Years, in such Manner as they shall by Law direct. The Number of Representatives shall not exceed one for every thirty Thousand, but each State shall have at Least one Representative; and until such enumeration shall be made, the State of New Hampshire shall be entitled to chuse three, Massachusetts eight, Rhode-Island and Providence Plantations one, Connecticut five, New-York six, New Jersey four, Pennsylvania eight, Delaware one, Maryland six, Virginia ten, North Carolina five, South Carolina five, and Georgia three.

When vacancies happen in the Representation from any State, the Executive Authority thereof shall issue Writs of Election to fill such Vacancies.

The House of Representatives shall chuse their Speaker and other Officers; and shall have the sole Power of Impeachment.

Section 3. [The Senate of the United States shall be composed of two Senators from each State, chosen by the Legislature thereof, for six Years; and each Senator shall have one Vote.] [2]

Immediately after they shall be assembled in Consequence of the first Election, they shall be divided as equally as may be into three Classes. The Seats of the Senators of the first Class shall be vacated at the Expiration of the second Year, of the second Class at the Expiration of the fourth Year, and of the third Class at the Expiration of the sixth Year, so that one third may be chosen every second Year; [and if Vacancies happen by Resignation, or otherwise, during the Recess of the Legislature of any State, the Executive thereof may make temporary Appointments until the next Meeting of the Legislature, which shall then fill such Vacancies.] [3]

No Person shall be a Senator who shall not have attained to the Age of thirty Years, and been nine Years a Citizen of the United States, and who shall not, when elected, be an Inhabitant of that State for which he shall be chosen.

The Vice President of the United States shall be President of the Senate, but shall have no Vote, unless they be equally divided.

The Senate shall chuse their other Officers, and also a President pro tempore, in the Absence of the Vice President, or when he shall exercise the Office of President of the United States.

The Senate shall have the sole Power to try all Impeachments. When sitting for that Purpose, they shall be on Oath or Affirmation. When the President of the United States is tried, the Chief Justice shall preside: And no Person shall be convicted without the Concurrence of two thirds of the Members present.

Judgment in Cases of Impeachment shall not extend further than to removal from Office, and disqualification to hold and enjoy any Office of honor, Trust or Profit under the United States: but the Party convicted shall nevertheless be liable and subject to Indictment, Trial, Judgment and Punishment, according to Law.

Section 4. The Times, Places and Manner of holding Elections for Senators and Representatives, shall be prescribed in each State by the Legislature thereof; but the Congress may at any time by Law make or alter such Regulations, except as to the Places of chusing Senators.

The Congress shall assemble at least once in every Year, and such Meeting shall be on the [first Monday in December], [4] unless they shall by Law appoint a different Day.

Section 5. Each House shall be the Judge of the Elections, Returns and Qualifications of its own Members, and a Majority of each shall constitute a Quorum to do Business; but a smaller Number may adjourn from day to day, and may be authorized to compel the Attendance of absent Members, in such Manner, and under such Penalties as each House may provide.

Each House may determine the Rules of its Proceedings, punish its Members for disorderly Behaviour, and, with the Concurrence of two thirds, expel a Member.

Each House shall keep a Journal of its Proceedings, and from time to time publish the same, excepting such Parts as may in their Judgment require Secrecy; and the Yeas and Nays of the Members of either House on any question shall, at the Desire of one fifth of those Present, be entered on the Journal.

Neither House, during the Session of Congress, shall, without the Consent of the other, adjourn for more than three days, nor to any other Place than that in which the two Houses shall be sitting.

Section 6. The Senators and Representatives shall receive a Compensation for their Services, to be ascertained by Law, and paid out of the Treasury of the United States. They shall in all Cases, except Treason, Felony and Breach of the Peace, be privileged from Arrest during their Attendance at the Session of their respective Houses, and in going to and returning from the same; and for any Speech or Debate in either House, they shall not be questioned in any other Place.

No Senator or Representative shall, during the Time for which he was elected, be appointed to any civil Office under the Authority of the United States, which shall have been created, or the Emoluments whereof shall have been encreased during such time; and no Person holding any Office under the United States, shall be a Member of either House during his Continuance in Office.

Section 7. All Bills for raising Revenue shall originate in the House of Representatives; but the Senate may propose or concur with Amendments as on other Bills.

Every Bill which shall have passed the House of Representatives and the Senate, shall, before it becomes a Law, be presented to the President of the United States; If he approve he shall sign it, but if not he shall return it, with his Objections to that House in which it shall have originated, who shall enter the Objections at large on their Journal, and proceed to reconsider it. If after such Reconsideration two thirds of that House shall agree to pass the Bill, it shall be sent, together with the Objections, to the other House, by which it shall likewise be reconsidered, and if approved by two thirds of that House, it shall become a Law. But in all such Cases the Votes of both Houses shall be determined by Yeas and Nays, and the Names of the Persons voting for and against the Bill shall be entered on the Journal of each House respectively. If any Bill shall not be returned by the President within ten Days (Sundays excepted) after it shall have been presented to him, the Same shall be a Law, in like Manner as if he had signed it, unless the Congress by their Adjournment prevent its Return, in which Case it shall not be a Law.

Every Order, Resolution, or Vote to which the Concurrence of the Senate and House of Representatives may be necessary (except on a question of Adjournment) shall be presented to the President of the United States; and before the Same shall take Effect, shall be approved by him, or being disapproved by him, shall be repassed by two thirds of the Senate and House of Representatives, according to the Rules and Limitations prescribed in the Case of a Bill.

Section 8. The Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States; but all Duties, Imposts and Excises shall be uniform throughout the United States;

To borrow Money on the credit of the United States;

To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes;

To establish an uniform Rule of Naturalization, and uniform Laws on the subject of Bankruptcies throughout the United States;

To coin Money, regulate the Value thereof, and of foreign Coin, and fix the Standard of Weights and Measures;

To provide for the Punishment of counterfeiting the Securities and current Coin of the United States;

To establish Post Offices and post Roads;

To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries;

To constitute Tribunals inferior to the supreme Court;

To define and punish Piracies and Felonies committed on the high Seas, and Offences against the Law of Nations;

To declare War, grant Letters of Marque and Reprisal, and make Rules concerning Captures on Land and Water;

To raise and support Armies, but no Appropriation of Money to that Use shall be for a longer Term than two Years;

To provide and maintain a Navy;

To make Rules for the Government and Regulation of the land and naval Forces;

To provide for calling forth the Militia to execute the Laws of the Union, suppress Insurrections and repel Invasions;

To provide for organizing, arming, and disciplining, the Militia, and for governing such Part of them as may be employed in the Service of the United States, reserving to the States respectively, the Appointment of the Officers, and the Authority of training the Militia according to the discipline prescribed by Congress;

To exercise exclusive Legislation in all Cases whatsoever, over such District (not exceeding ten Miles square) as may, by Cession of particular States, and the Acceptance of Congress, become the Seat of the Government of the United States, and to exercise like Authority over all Places purchased by the Consent of the Legislature of the State in which the Same shall be, for the Erection of Forts, Magazines, Arsenals, dock-Yards, and other needful Buildings;--And

To make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers, and all other Powers vested by this Constitution in the Government of the United States, or in any Department or Officer thereof.

Section 9. The Migration or Importation of such Persons as any of the States now existing shall think proper to admit, shall not be prohibited by the Congress prior to the Year one thousand eight hundred and eight, but a Tax or duty may be imposed on such Importation, not exceeding ten dollars for each Person.

The Privilege of the Writ of Habeas Corpus shall not be suspended, unless when in Cases of Rebellion or Invasion the public Safety may require it.

No Bill of Attainder or ex post facto Law shall be passed.

No Capitation, or other direct, Tax shall be laid, unless in Proportion to the Census or Enumeration herein before directed to be taken. [5]

No Tax or Duty shall be laid on Articles exported from any State.

No Preference shall be given by any Regulation of Commerce or Revenue to the Ports of one State over those of another; nor shall Vessels bound to, or from, one State, be obliged to enter, clear, or pay Duties in another.

No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law; and a regular Statement and Account of the Receipts and Expenditures of all public Money shall be published from time to time.

No Title of Nobility shall be granted by the United States: And no Person holding any Office of Profit or Trust under them, shall, without the Consent of the Congress, accept of any present, Emolument, Office, or Title, of any kind whatever, from any King, Prince, or foreign State.

Section 10. No State shall enter into any Treaty, Alliance, or Confederation; grant Letters of Marque and Reprisal; coin Money; emit Bills of Credit; make any Thing but gold and silver Coin a Tender in Payment of Debts; pass any Bill of Attainder, ex post facto Law, or Law impairing the Obligation of Contracts, or grant any Title of Nobility.

No State shall, without the Consent of the Congress, lay any Imposts or Duties on Imports or Exports, except what may be absolutely necessary for executing it's inspection Laws: and the net Produce of all Duties and Imposts, laid by any State on Imports or Exports, shall be for the Use of the Treasury of the United States; and all such Laws shall be subject to the Revision and Controul of the Congress.

No State shall, without the Consent of Congress, lay any Duty of Tonnage, keep Troops, or Ships of War in time of Peace, enter into any Agreement or Compact with another State, or with a foreign Power, or engage in War, unless actually invaded, or in such imminent Danger as will not admit of delay.

Footnotes

1 The portion of the clause enclosed in brackets was amended, as to the mode of apportionment of representatives among the several states, by the Fourteenth Amendment, § 2, and as to taxes on incomes without apportionment, by the Sixteenth Amendment.

2 The clause enclosed in brackets was superseded by the Seventeenth Amendment.

3 The portion of the clause enclosed in brackets was superseded by the Seventeenth Amendment.

4 The portion of the clause enclosed in brackets was superseded by the Twentieth Amendment.

5 This clause has been affected by the Sixteenth Amendment.

U.S.C.A. Const. Art. I, USCA CONST Art. I

Current through P.L. 116-158.