

MEDICAL MARIJUANA RESEARCH ACT

DECEMBER 7, 2020.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. PALLONE, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 3797]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3797) to amend the Controlled Substances Act to make marijuana accessible for use by qualified marijuana researchers for medical purposes, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

CONTENTS

	Page
I. Purpose and Summary	5
II. Background and Need for the Legislation	6
III. Committee Hearings	8
IV. Committee Consideration	8
V. Committee Votes	8
VI. Oversight Findings	8
VII. New Budget Authority, Entitlement Authority, and Tax Expenditures	9
VIII. Federal Mandates Statement	9
IX. Statement of General Performance Goals and Objectives	9
X. Duplication of Federal Programs	9
XI. Committee Cost Estimate	9
XII. Earmarks, Limited Tax Benefits, and Limited Tariff Benefits	9
XIII. Advisory Committee Statement	9
XIV. Applicability to Legislative Branch	10
XV. Section-by-Section Analysis of the Legislation	10
XVI. Changes in Existing Law Made by the Bill, as Reported	12

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Medical Marijuana Research Act”.

SEC. 2. FACILITATING MARIJUANA RESEARCH.

(a) PRODUCTION AND SUPPLY.—The Secretary of Health and Human Services—

(1) until the date on which the Secretary determines that manufacturers and distributors (other than the Federal Government) can ensure a sufficient supply of marijuana (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802), as amended by section 8) intended for medical research for qualified marijuana researchers registered pursuant to paragraph (3) of section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)), as added by section 3, shall—

(A) continue, through grants, contracts, or cooperative agreements, to produce marijuana through the National Institute on Drug Abuse Drug Supply Program; and

(B) offer to qualified marijuana researchers marijuana products available through State authorized marijuana programs that are consistent with the guidance issued under subsection (c); and

(2) beyond the date specified in paragraph (1), may, at the Secretary's discretion, continue through grants, contracts, or cooperative agreements, to so produce and supply marijuana.

(b) REQUIREMENT TO VERIFY REGISTRATION.—Before supplying marijuana to any person through the National Institute on Drug Abuse Drug Supply Program or from State authorized marijuana programs, the Secretary of Health and Human Services shall—

(1) require the person to submit documentation demonstrating that the person is a qualified marijuana researcher seeking to conduct research pursuant to section 303(f)(3) of the Controlled Substances Act, as added by subsection (e) of this section; and

(2) not later than 60 days after receipt of such documentation, review such documentation and verify that the marijuana will be used for such research (and for no other purpose authorized pursuant to this Act).

(c) GUIDANCE ON USE OF STATE AUTHORIZED MARIJUANA PROGRAMS.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue guidance related to the use of marijuana from State authorized marijuana programs, including necessary quality or production standards for marijuana intended for use in medical research.

(d) COMPLIANCE WITH GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall ensure that a qualified marijuana researcher is in compliance with guidance issued by the Food and Drug Administration related to botanical drug development.

(e) RESEARCH.—Section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)) is amended—

(1) by redesignating paragraphs (1) through (5) as subparagraphs (A) through (E), respectively;

(2) by striking “(f) The Attorney General” and inserting “(f)(1) The Attorney General”;

(3) by striking “Registration applications” and inserting the following:

“(2) Registration applications”;

(4) in paragraph (2), as so designated, by striking “schedule I” each place that term appears and inserting “schedule I, except marijuana,”;

(5) by striking “Article 7” and inserting the following:

“(4) Article 7”; and

(6) by inserting before paragraph (4), as so designated, the following:

“(3)(A) The Attorney General shall register a practitioner to conduct research with marijuana if—

“(i) the applicant is authorized to dispense, or conduct research with respect to, controlled substances in schedules II, III, IV, and V under the laws of the State in which the applicant practices;

“(ii) the applicant's research protocol has been reviewed and approved by the Secretary under section 505(i) of the Federal Food, Drug, and Cosmetic Act; and

“(iii) the Secretary has determined the applicant is qualified to conduct bona fide research.

A practitioner so registered shall be referred to in this Act as a ‘qualified marijuana researcher’.

“(B)(i) Not later than 60 days after the date on which the Attorney General receives a complete application for registration under this paragraph, the Attorney General shall approve or deny the application.

“(ii) For purposes of clause (i), an application shall be deemed complete when the applicant has submitted documentation showing that the requirements under subparagraph (A) are satisfied.

“(iii) In the case of a denial under clause (i), the Attorney General shall provide a written explanation of the basis for the denial.

“(C) The Attorney General shall grant an application for registration under this paragraph unless the Attorney General determines that the issuance of the registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

“(i) The applicant’s experience in dispensing, or conducting research with respect to, controlled substances.

“(ii) The applicant’s conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

“(iii) Compliance with applicable State or local laws relating to controlled substance misuse or diversion.

“(D)(i) A qualified marijuana researcher shall store marijuana to be used in research in a securely locked, substantially constructed cabinet.

“(ii) Except as provided in clause (i), any security measures required by the Attorney General for practitioners conducting research with marijuana pursuant to a registration under this paragraph shall be consistent with the security measures for practitioners conducting research on other controlled substances in schedule II that have a similar risk of diversion and abuse.

“(E)(i) If the Attorney General grants an application for registration under this paragraph, the applicant may amend or supplement the research protocol without reapplying if the applicant does not change the type of marijuana, the source of the marijuana, or the conditions under which the marijuana is stored, tracked, or administered.

“(ii) If an applicant amends or supplements the research protocol or initiates research on a new research protocol under clause (i), the applicant shall, in order to renew the registration under this paragraph, provide notice to the Attorney General of the amended or supplemented research protocol or any new research protocol in the applicant’s renewal materials.

“(iii)(I) If an applicant amends or supplements a research protocol and the amendment or supplement involves a change to the type of marijuana, the source of the marijuana, or conditions under which the marijuana is stored, tracked, or administered or otherwise increases the risk of diversion, the applicant shall provide notice to the Attorney General not later than 30 days before proceeding on such amended or supplemental research or new research protocol, as the case may be.

“(II) If the Attorney General does not object during the 30-day period following a notification under subclause (I), the applicant may proceed with the amended or supplemental research or new research protocol.

“(iv) The Attorney General may object to an amended or supplemental protocol or a new research protocol under clause (i) or (iii) only if additional security measures are needed to safeguard against diversion or abuse.

“(F) If marijuana or a compound of marijuana is listed on a schedule other than schedule I, the provisions of paragraphs (1), (2), and (4) that apply to research with a controlled substance in the applicable schedule shall apply to research with marijuana or that compound, as applicable, in lieu of the provisions of subparagraphs (A) through (E) of this paragraph.

“(G) Nothing in this paragraph shall be construed as limiting the authority of the Secretary under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or over requirements related to research protocols, including changes in—

“(i) the method of administration of marijuana;

“(ii) the dosing of marijuana; and

“(iii) the number of individuals or patients involved in research.”.

SEC. 3. MANUFACTURE AND DISTRIBUTION OF MARIJUANA FOR USE IN LEGITIMATE, MEDICAL RESEARCH.

Section 303 of the Controlled Substances Act (21 U.S.C. 823), as amended by section 2, is further amended by adding at the end the following:

“(1) REGISTRATION OF PERSONS TO MANUFACTURE AND DISTRIBUTE MARIJUANA FOR USE IN LEGITIMATE, MEDICAL RESEARCH.—

“(1) REGISTRATION OF MANUFACTURERS.—Beginning not later than the day that is 1 year after the date of enactment of the Medical Marijuana Research Act, the Attorney General shall register an applicant to manufacture marijuana (including any derivative, extract, preparation, and compound thereof) that is intended for the ultimate and exclusive use by qualified marijuana researchers for research pursuant to subsection (f)(3), unless the Attorney General determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the Attorney General shall take into consideration—

“(A) maintenance of effective controls against diversion of marijuana and any controlled substance compounded therefrom into other than legitimate medical, scientific, or research channels;

“(B) compliance with applicable State and local laws relating to controlled substance misuse and diversion; and

“(C) prior conviction record of the applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances.

“(2) REGISTRATION OF DISTRIBUTORS.—Beginning not later than the day that is 1 year after the date of enactment of the Medical Marijuana Research Act, the Attorney General shall register an applicant to distribute marijuana (including any derivative, extract, preparation, and compound thereof) that is intended for the ultimate and exclusive use by qualified marijuana researchers for research pursuant to subsection (f)(3), unless the Attorney General determines that the issuance of such registration is inconsistent with the public interest.

“(3) PUBLIC INTEREST.—In determining the public interest under paragraph (2), the Attorney General shall take into consideration—

“(A) the factors specified in subparagraphs (A), (B), and (C) of such paragraph; and

“(B) past experience in the distribution of controlled substances, and the existence of effective controls against diversion.

“(4) NO LIMIT ON NUMBER OF MANUFACTURERS AND DISTRIBUTORS.—Notwithstanding any other provision of law, the Attorney General shall not impose or implement any limit on the number of persons eligible to be registered to manufacture or distribute marijuana pursuant to paragraph (1) or (2).

“(5) REQUIREMENT TO VERIFY USE FOR LEGITIMATE, MEDICAL RESEARCH.—As a condition on registration under this section to manufacture or distribute marijuana, the Attorney General shall require the registrant—

“(A) to require any person to whom the marijuana will be supplied to submit documentation demonstrating that the marijuana (including any derivative, extract, preparation, and compound thereof) will be ultimately used exclusively by qualified marijuana researchers for research pursuant to subsection (f)(3);

“(B) in the case of distribution, to complete, with respect to that distribution, the DEA Controlled substance order form in accordance with section 308 and to upload such forms to the system used by the Drug Enforcement Agency for such distribution;

“(C) to include in the labeling of any marijuana so manufactured or distributed—

“(i) the following statement: ‘This material is for biomedical and scientific research purposes only.’; and

“(ii) the name of the requestor of the marijuana;

“(D) to limit the transfer and sale of any marijuana manufactured under this subsection—

“(i) to researchers who are registered under this Act to conduct research with marijuana; and

“(ii) for purposes of use in preclinical research or in a clinical investigation pursuant to an investigational new drug exemption under 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)); and

“(E) to transfer or sell any marijuana manufactured under this subsection only with prior, written consent for the transfer or sale by the Attorney General.

“(6) TIMING.—Not later than 60 days after receipt of a request for registration under this subsection to manufacture or distribute marijuana, the Attorney General shall—

“(A) grant or deny the request; and

“(B) in the case of a denial, provide a written explanation of the basis for the denial.

“(7) DEEMED APPROVAL.—If the Attorney General fails to grant or deny a request for registration under this subsection to manufacture or distribute marijuana within the 60-day period referred to in paragraph (5), such request is deemed approved.”

SEC. 4. TERMINATION OF INTERDISCIPLINARY REVIEW PROCESS FOR NON-NIH-FUNDED QUALIFIED MARIJUANA RESEARCHERS.

The Secretary of Health and Human Services may not—

(1) reinstate the Public Health Service interdisciplinary review process described in the guidance entitled “Guidance on Procedures for the Provision of Marijuana for Medical Research” (issued on May 21, 1999); or

(2) create an additional review of scientific protocols that is only conducted for research on marijuana other than the review of research protocols performed at the request of a qualified marijuana researcher conducting nonhuman research that is not federally funded, in accordance with section

303(f)(3)(A)(iii)(II) of the Controlled Substances Act, as added by section 2 of this Act.

SEC. 5. CONSIDERATION OF RESULTS OF RESEARCH.

Immediately upon the approval by the Food and Drug Administration of an application for a drug that contains marijuana under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and (irrespective of whether any such approval is granted) not later than the date that is 5 years after the date of enactment of this Act, the Secretary of Health and Human Services shall—

- (1) conduct a review of existing medical and other research with respect to marijuana;
- (2) submit a report to the Congress on the results of such review; and
- (3) include in such report whether, taking into consideration the factors listed in section 201(c) of the Controlled Substances Act (21 U.S.C. 811(c)), as well as any potential for medical benefits, any gaps in research, and any impacts of Federal restrictions and policy on research, marijuana should be transferred to a schedule other than schedule I (if marijuana has not been so transferred already).

SEC. 6. PRODUCTION QUOTAS FOR MARIJUANA GROWN FOR LEGITIMATE, SCIENTIFIC RESEARCH.

Section 306 of the Controlled Substances Act (21 U.S.C. 826) is amended by adding at the end the following:

“(j) The Attorney General may only establish a quota for production of marijuana that is manufactured and distributed in accordance with the Medical Marijuana Research Act that meets the changing medical, scientific, and industrial needs for marijuana.”

SEC. 7. ARTICLE 28 OF THE SINGLE CONVENTION ON NARCOTIC DRUGS.

Article 28 of the Single Convention on Narcotic Drugs shall not be construed to prohibit, or impose additional restrictions upon, research involving marijuana, or the manufacture, distribution, or dispensing of marijuana, that is conducted in accordance with the Controlled Substances Act (21 U.S.C. 801 et seq.), this Act, and the amendments made by this Act.

SEC. 8. DEFINITIONS.

(a) **QUALIFIED MARIJUANA RESEARCHER.**—In this Act, the term “qualified marijuana researcher” has the meaning given the term in section 303(f)(3) of the Controlled Substances Act, as added by section 2(d) of this Act.

(b) **UPDATING TERM.**—Section 102(16) of the Controlled Substances Act (21 U.S.C. 802(16)) is amended—

- (1) in subparagraph (A), by striking “the term ‘marihuana’ means” and inserting “the terms ‘marihuana’ and ‘marijuana’ mean”; and
- (2) in subparagraph (B), by striking “The term ‘marihuana’ does not” and inserting “The terms ‘marihuana’ and ‘marijuana’ do not”.

I. PURPOSE AND SUMMARY

H.R. 3797, the “Medical Marijuana Research Act”, introduced by Representatives Earl Blumenauer (D–OR), Andy Harris (R–MD), Zoe Lofgren (D–CA), H. Morgan Griffith (R–VA), Rob Bishop (R–UT), and Debbie Dingell (D–MI), would facilitate research with marijuana for medical purposes by streamlining the registration process under the Controlled Substances Act (CSA) for researchers and directing the U.S. Department of Health and Human Services’ (HHS) Secretary (the Secretary) to ensure a supply of marijuana for research purposes through the National Institute on Drug Abuse (NIDA) Drug Supply Program and from State authorized marijuana programs. Currently, marijuana is listed in schedule I of the CSA, which has more stringent requirements for approval and access for research. Further, today researchers who do have a schedule I registration are only able to use marijuana supplied through one approved supplier.

Among other provisions, the bill would authorize the Attorney General to register practitioners to conduct research if the applicant is already authorized to conduct research with controlled sub-

stances for schedules II through V, has had their research protocol reviewed and approved by the Secretary, and the Secretary has determined the applicant is qualified to conduct bona fide research. The bill also directs NIDA and HHS to act on marijuana research registration applications within 60 days prior to supplying marijuana through the NIDA Drug Supply Program or a State authorized marijuana program, and directs the Drug Enforcement Administration (DEA) to also approve or deny CSA registration applications within 60 days of receipt. The bill would subject researchers conducting research on marijuana to the same security requirements for research on other controlled substances in schedules II through V. The bill prevents HHS from reinstating additional review processes related to marijuana research. The bill also directs the Secretary to conduct a review of existing marijuana research and submit a report to Congress on such review.

II. BACKGROUND AND NEED FOR THE LEGISLATION

The CSA regulates the manufacture, possession, use, importation, and distribution of certain drugs, substances, and precursor chemicals.¹ The CSA includes five schedules in which controlled substances must be classified.² Schedule I substances are defined as drugs with no currently accepted medical use and have a high potential for abuse.³ Among the items regulated under schedule I of the CSA, which is the most stringently regulated, are parts of the marijuana plant, defined as “marihuana” in statute.⁴

Researchers seeking to investigate marijuana must seek approval to do so through certain protocols with the Food and Drug Administration (FDA), NIDA, and DEA. Due to its inclusion on the list of schedule I, researchers who wish to study marijuana must fulfill a number of additional requirements, including: obtaining a separate DEA registration for schedule I substances; meeting production quota limitations; and fulfilling security specifications, among other protocols.⁵ The United States is also subject to marijuana policies set out by three United Nations drug control treaties that set international standards for marijuana and tetrahydrocannabinol (THC). These treaties, aimed at reducing abuse of narcotic drugs and combatting international drug trafficking, place strict limitations on the possession, use, trade, distribution, import, export, manufacture, and production of these substances.⁶

In addition to the waiting periods associated with the registration process, researchers at institutions of higher education have expressed frustration over difficulties they have experienced in conducting marijuana research.⁷ For example, the Council on Government Relations (COGR), which is an association of research universities and other entities, states that for a schedule I registration, “the approval process is lengthy, often requiring six to twelve

¹P.L. 91-513, as amended.

²*Id.*

³Drug Enforcement Administration, *Drug Scheduling* (www.dea.gov/drug-scheduling) (accessed September 21, 2020).

⁴21 U.S.C. § 802(16)(A).

⁵21 U.S.C. § 823; 21 U.S.C. § 826; 21 C.F.R. § 1301.72; 21 C.F.R. § 1301.18.

⁶United Nations General Assembly, 1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961; United Nations Convention on Psychotropic Substances, 1971; United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

⁷*Risk of Losing Federal Funding Reason Why Medical Marijuana Research Won't Happen*, The Lantern (August 23, 2017).

months.”⁸ In addition, a National Academies of Sciences, Engineering, and Medicine report on the health effects of marijuana found that, “[t]he substantial layers of bureaucracy that emerge from cannabis’s schedule I categorization are reported to have discouraged a number of cannabis researchers from applying for grant funding or pursuing additional research efforts.”⁹

The supply of research-grade marijuana is subject to the Single Convention on Narcotic Drugs,¹⁰ which imposes obligations related to governmental oversight of its cultivation. NIDA has long acted as the agency responsible for overseeing the cultivation of marijuana for research. Currently, marijuana researchers must use marijuana products sourced through the NIDA’s Drug Supply Program single DEA licensee for the cultivation and procurement of research-grade marijuana: the University of Mississippi’s School of Pharmacy’s National Center for Natural Products Research.¹¹ This requirement not only limits the supply, but also limits the diversity in quality, potency, chemical composition, and methods of consumption, thus preventing researchers from studying marijuana products used in commercial development and from other sources, such as from widely used State-legal dispensaries that, as NIDA Director Nora Volkow said in congressional testimony, “[results] in a gap in our understanding of their impact on health.”¹² For example, Dr. Volkow stated that the outbreak of e-cigarette or vaping product use associated lung injury (EVALI), which was linked to vape products containing THC, underscores the importance of facilitating researcher access to different product sources.¹³

COGR also states that the restricted supply presents “a serious impediment to understanding pivotal emerging issues such as, for example, (a) the health risks associated with the escalating availability of very high THC content marijuana strains, and (b) the potential health benefits of varying THC/CBD ratios.” Further, an Arizona researcher at the Scottsdale Research Institute said that the single Federally-authorized source of marijuana for research purposes is “really detrimental to science when you have one drug supply for all of the U.S.”¹⁴

According to testimony from the DEA, the agency identified 605 active marijuana researchers as of October 2019.¹⁵ In comparison, however, one marijuana industry trade group has a membership of nearly 2,000 businesses.¹⁶ Expanding the number of registered manufacturers of research-grade marijuana is therefore critical to fully understanding both the potential benefits and possible risks

⁸ Council on Government Relations, *Cannabis Research Frequently Asked Questions* (April 13, 2018).

⁹ National Academies of Sciences, Engineering, and Medicine. *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research* (2017).

¹⁰ U.N. General Assembly, *1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961* (Dec. 9, 1975), (www.unodc.org/pdf/convention_1961_en.pdf).

¹¹ National Institute on Drug Abuse, *NIDA’s Role in Providing Marijuana for Research* (www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research) (accessed September 10, 2020).

¹² House Committee on Energy and Commerce, Testimony of Nora D. Volkow, M.D., Director, National Institute on Drug Abuse, National Institutes of Health, *Hearing on Cannabis Policies for the New Decade* (January 15, 2020).

¹³ *Id.*

¹⁴ *Why we don’t know much about pot*. POLITICO (October 14, 2019).

¹⁵ House Committee on Energy and Commerce, Testimony of Matthew Strait, Senior Policy Advisor, Diversion Control Division, Drug Enforcement Administration, *Hearing on Cannabis Policies for the New Decade* (January 15, 2020).

¹⁶ National Cannabis Industry Association, *About Us* (<https://thecannabisindustry.org/about-us/>) (accessed September 14, 2020).

associated with marijuana use, as researchers must be able to study actual products that are currently used by consumers for both medical and recreational use.

III. COMMITTEE HEARINGS

For the purposes of section 103(i) of H. Res. 6 of the 116th Congress, the following hearing was used to develop or consider H.R. 3797:

The Subcommittee on Health held a legislative hearing on January 15, 2020, to consider H.R. 3797, the “Medical Marijuana Research Act of 2019” and five other bills. The hearing was entitled, “Cannabis Policies for the New Decade.” The Subcommittee received testimony from the following witnesses:

- Matthew J. Strait, Senior Policy Advisor, Diversion Control Division, Drug Enforcement Administration
- Douglas Throckmorton, M.D., Deputy Director for Regulatory Programs, Center for Drug Evaluation and Research Food and Drug Administration
- Nora D. Volkow, M.D., Director, National Institute on Drug Abuse National Institutes of Health

IV. COMMITTEE CONSIDERATION

Representatives Blumenauer (D–OR), Harris (R–MD), Lofgren (D–CA), Griffith (R–VA), Bishop (R–UT), and Dingell (D–MI) introduced H.R. 3797, the “Medical Marijuana Research Act of 2019”, on July 17, 2019, and the bill was referred to the Committee on Energy and Commerce. H.R. 3797 was then referred to the Subcommittee on Health on July 18, 2019. A legislative hearing was held on the bill on January 15, 2020.

On September 9, 2020, H.R. 3797 was discharged from further consideration by the Subcommittee on Health as it was called up for consideration by the full Committee on Energy and Commerce. The full Committee met in virtual open markup session on September 9, 2020, pursuant to notice, to consider H.R. 3797. During consideration of the bill, an amendment in the nature of a substitute offered by Mr. Griffith, on behalf of himself and Mrs. Dingell, was agreed to by a voice vote. Upon conclusion of consideration of the bill, the full Committee agreed to a motion on final passage by Mr. Pallone, Chairman of the committee, to order H.R. 3797 reported favorably to the House, amended, by a voice vote, a quorum being present.

V. COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. The Committee advises that there were no record votes taken on H.R. 3797, including the motion for final passage of the bill.

VI. OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the oversight find-

ings and recommendations of the Committee are reflected in the descriptive portion of the report.

VII. NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of new budget authority, entitlement authority, or tax expenditures or revenues contained in the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

The Committee has requested but not received from the Director of the Congressional Budget Office a statement as to whether this bill contains any new budget authority, spending authority, credit authority, or an increase or decrease in revenues or tax expenditures.

VIII. FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

IX. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to amend the Controlled Substances Act to make marijuana accessible for use by qualified marijuana researchers for medical purposes.

X. DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 3797 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111-139 or the most recent Catalog of Federal Domestic Assistance.

XI. COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

XII. EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 3797 contains no earmarks, limited tax benefits, or limited tariff benefits.

XIII. ADVISORY COMMITTEE STATEMENT

No advisory committee within the meaning of section 5(b) of the Federal Advisory Committee Act was created by this legislation.

XIV. APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

XV. SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 designates that the short title may be cited as the “Medical Marijuana Research Act”.

Sec. 2. Facilitating marijuana research

Subsection (a) of section 2 directs the Secretary of Health and Human Services (the Secretary) to ensure a sufficient supply of marijuana for medical research purposes through grants, contracts, or cooperative agreements through the NIDA Drug Supply Program. The Secretary is also directed to offer marijuana products available through State authorized marijuana programs.

Subsection (b) directs the Secretary to require a person seeking marijuana from the NIDA Drug Abuse Supply Program or from a State authorized marijuana program to submit documentation demonstrating that they are a qualified marijuana researcher seeking to conduct research under section 303(f)(3) of the Controlled Substances Act. The Secretary is directed to review such documentation and verify that the marijuana will be used for research purposes not later than 60 days after receiving such documentation.

Subsection (c) directs the Secretary to issue guidance on the use of marijuana from State authorized marijuana programs, including necessary quality or production standards for marijuana intended for use in medical research.

Subsection (d) directs the Secretary, acting through the Commissioner of Food and Drugs, to ensure that a qualified marijuana researcher follows guidance issued by the Food and Drug Administration related to botanical drug development.

Subsection (e) amends section 303(f) of the Controlled Substances Act, creating a separate registration process for marijuana researchers, while preserving the Secretary’s authorities under the Federal Food, Drug, and Cosmetic Act. Under this new process, the Attorney General is directed to register a practitioner to conduct research with marijuana if: the applicant is authorized to dispense, or conduct research with respect to, controlled substances in schedules II, III, IV, and V under the laws of the States in which the applicant practices; the applicant’s research protocol has been reviewed and approved by the Secretary under section 505(i) of the Federal Food, Drug, and Cosmetic Act; and the Secretary has determined the application is qualified to conduct bona fide research. The Attorney General must approve or deny an application not later than 60 days after receiving it, and the application is deemed complete when the applicant has submitted documentation showing that the necessary requirements are satisfied. In the case of a denial, the Attorney General is directed to provide a written explanation of the basis for the denial. The Attorney General must grant an application for registration unless the issuance of the registra-

tion is inconsistent with the public interest. In determining the public interest, the Attorney General is directed to consider: the applicant's experience with dispensing or conducting research with controlled substances; the applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances; and compliance with applicable State or local laws relating to controlled substance misuse or diversion. Qualified marijuana researchers are required to store marijuana to be used for research in a securely locked, substantially constructed cabinet, and the Attorney General is directed to ensure that security measures for research-grade marijuana are consistent with security measures for schedule II substances.

Subsection (e) also permits an applicant to amend or supplement the research protocol without reapplying if the applicant does not change the type of marijuana, the source of marijuana, or the conditions under which the marijuana is stored, tracked, or administered. If the applicant amends or supplements the research protocol or initiates research on a new protocol, the applicant must notify the Attorney General. In addition, if the applicant changes the type of marijuana, the source of marijuana, or conditions under which the marijuana is stored, tracked, or administered, the applicant must notify the Attorney General not later than 30 days before proceeding with the amended, supplemented, or new research. If the Attorney General does not object during the 30-day period, the applicant may proceed with the intended research. The Attorney General may only object if additional security measures are needed to safeguard against diversion or abuse. If marijuana is rescheduled to another schedule other than schedule I, subparagraph (F) of paragraph (3) says registration requirements, applications, and the provision of Article 7 of the Convention on Psychotropic Substances that apply to research would apply in lieu of the provisions in this subsection.

Sec. 3. Manufacture and distribution of marijuana for use in legitimate, medical research

Section 3 amends section 303 of the Controlled Substances Act by directing the Attorney General to register an applicant to manufacture marijuana that is intended for the ultimate and exclusive use by qualified marijuana researchers, unless the Attorney General determines that such registration would be inconsistent with the public interest. In determining the public interest, the Attorney General is directed to take into consideration: controls against diversion; compliance with State and local laws relating to controlled substances; and prior conviction record of the applicant. The Attorney General must also register marijuana distributors in a similar manner while also considering an applicant's previous controlled substances distribution experience. Paragraph (4) of subsection (1) says that the Attorney General may not impose or implement a limit on the number of persons eligible to be registered to manufacture or distribute marijuana. This section also sets the conditions in which the Attorney General may provide a registration, which include: the submission of documentation demonstrating that the marijuana will be ultimately used exclusively by qualified marijuana researchers; in the case of distribution, the use of the proper Drug Enforcement Administration forms and systems; the labeling

of any marijuana that will be manufactured or distributed; and the limitation on the transfer and sale of marijuana. The Attorney General must act on a request for registration within 60 days by granting or denying the request. If a request is denied, the Attorney General is directed to provide a written explanation of the basis for the denial. Registration requests that are not acted on within the 60-day period will be deemed approved.

Sec. 4. Termination of interdisciplinary review process for non-NIH funded qualified marijuana researchers

Section 4 prevents the Secretary from reinstating the Public Health Service interdisciplinary review process described in guidance entitled “Guidance on Procedures for the provision of Marijuana for Medical Research” issued on May 21, 1999 and prevents the Secretary from creating an additional review of scientific protocols for marijuana research.

Sec. 5. Consideration of research results

Section 5 requires that upon approval by FDA of an application for a drug that contains marijuana, or not later than five years after the date of enactment, the Secretary shall conduct a review of existing medical and other marijuana research; submit a report to Congress on the potential medical benefits, gaps in research, and impacts of Federal restrictions on such research; and whether marijuana should be transferred to a schedule other than schedule I (if applicable).

Sec. 6. Production quotas for marijuana grown for legitimate, scientific research

Section 6 states that the Attorney General may only establish quotas for the production of marijuana that is manufactured and distributed in accordance with this Act that meet the changing medical, scientific, and industrial needs.

Sec. 7. Article 28 of the single convention on narcotic drugs

Section 7 prevents Article 28 of the Single Convention on Narcotic Drugs from being construed to prohibit, or impose additional restrictions on research involving marijuana, or the manufacture, distribution, or dispensing of marijuana that is conducted in accordance with the Controlled Substances Act, this Act, and amendments made by this Act.

Sec. 8. Definitions

Subsection (a) of section 8 defines a qualified marijuana researcher as outlined in section 303(f)(3) of the Controlled Substances Act, as added by section 2(d) of this Act. Subsection (b) of section 8 updates the term “marijuana” to include “marijuana” in the Controlled Substances Act.

XVI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics,

and existing law in which no change is proposed is shown in roman):

CONTROLLED SUBSTANCES ACT

TITLE II—CONTROL AND ENFORCEMENT

PART A—SHORT TITLE; FINDINGS AND DECLARATION; DEFINITIONS

* * * * *

DEFINITIONS

SEC. 102. As used in this title:

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

(2) The term “administer” refers to the direct application of a controlled substance to the body of a patient or research subject by—

(A) a practitioner (or, in his presence, by his authorized agent), or

(B) the patient or research subject at the direction and in the presence of the practitioner,
whether such application be by injection, inhalation, ingestion, or any other means.

(3) The term “agent” means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier’s or warehouseman’s business.

(4) The term “Drug Enforcement Administration” means the Drug Enforcement Administration in the Department of Justice.

(5) The term “control” means to add a drug or other substance, or immediate precursor, to a schedule under part B of this title, whether by transfer from another schedule or otherwise.

(6) The term “controlled substance” means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this title. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1954.

(7) The term “counterfeit substance” means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.

(8) The terms “deliver” or “delivery” mean the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship.

(9) The term “depressant or stimulant substance” means—

(A) a drug which contains any quantity of barbituric acid or any of the salts of barbituric acid; or

(B) a drug which contains any quantity of (i) amphetamine or any of its optical isomers; (ii) any salt of amphetamine or any salt of an optical isomer of amphetamine; or (iii) any substance which the Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system; or

(C) lysergic acid diethylamide; or

(D) any drug which contains any quantity of a substance which the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(10) The term “dispense” means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery. The term “dispenser” means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term “distribute” means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term “distributor” means a person who so delivers a controlled substance or a listed chemical.

(12) The term “drug” has the meaning given that term by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act.

(13) The term “felony” means any Federal or State offense classified by applicable Federal or State law as a felony.

(14) The term “isomer” means the optical isomer, except as used in schedule I(c) and schedule II(a)(4). As used in schedule I(c), the term “isomer” means any optical, positional, or geometric isomer. As used in schedule II(a)(4), the term “isomer” means any optical or geometric isomer.

(15) The term “manufacture” means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term “manufacturer” means a person who manufactures a drug or other substance.

(16)(A) Subject to subparagraph (B), [the term “marihuana” means] *the terms “marihuana” and “marijuana” mean all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin.*

(B) **[The term “marihuana” does not]** *The terms “marihuana” and “marijuana” do not include—*

(i) hemp, as defined in section 297A of the Agricultural Marketing Act of 1946; or

(ii) the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

(17) The term “narcotic drug” means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(B) Poppy straw and concentrate of poppy straw.

(C) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed.

(D) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(E) Ecgonine, its derivatives, their salts, isomers, and salts of isomers.

(F) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subparagraphs (A) through (E).

(18) The term “opiate” or “opioid” means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

(19) The term “opium poppy” means the plant of the species *Papaver somniferum* L., except the seed thereof.

(20) The term “poppy straw” means all parts, except the seeds, of the opium poppy, after mowing.

(21) The term “practitioner” means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(22) The term “production” includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(23) The term “immediate precursor” means a substance—

(A) which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(B) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and

- (C) the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substance.
- (24) The term "Secretary", unless the context otherwise indicates, means the Secretary of Health and Human Services.
- (25) The term "serious bodily injury" means bodily injury which involves—
- (A) a substantial risk of death;
 - (B) protracted and obvious disfigurement; or
 - (C) protracted loss or impairment of the function of a bodily member, or organ, or mental faculty.
- (26) The term "State" means a State of the United States, the District of Columbia, and any commonwealth, territory, or possession of the United States.
- (27) The term "ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.
- (28) The term "United States", when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States.
- (29) The term "maintenance treatment" means the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.
- (30) The term "detoxification treatment" means the dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.
- (31) The term "Convention on Psychotropic Substances" means the Convention on Psychotropic Substances signed at Vienna, Austria, on February 21, 1971; and the term "Single Convention on Narcotic Drugs" means the Single Convention on Narcotic Drugs signed at New York, New York, on March 30, 1961.
- (32)(A) Except as provided in subparagraph (C), the term "controlled substance analogue" means a substance—
- (i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II;
 - (ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or
 - (iii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.
- (B) The designation of gamma butyrolactone or any other chemical as a listed chemical pursuant to paragraph (34) or (35) does

not preclude a finding pursuant to subparagraph (A) of this paragraph that the chemical is a controlled substance analogue.

(C) Such term does not include—

- (i) a controlled substance;
- (ii) any substance for which there is an approved new drug application;
- (iii) with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person, under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to the extent conduct with respect to such substance is pursuant to such exemption; or
- (iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

(33) The term “listed chemical” means any list I chemical or any list II chemical.

(34) The term “list I chemical” means a chemical specified by regulation to the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this title and is important to the manufacture of the controlled substances, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following:

- (A) Anthranilic acid, its esters, and its salts.
- (B) Benzyl cyanide.
- (C) Ephedrine, its salts, optical isomers, and salts of optical isomers.
- (D) Ergonovine and its salts.
- (E) Ergotamine and its salts.
- (F) N-Acetylanthranilic acid, its esters, and its salts.
- (G) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.
- (H) Phenylacetic acid, its esters, and its salts.
- (I) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.
- (J) Piperidine and its salts.
- (K) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.
- (L) 3,4-Methylenedioxyphenyl-2-propanone.
- (M) Methylamine.
- (N) Ethylamine.
- (O) Propionic anhydride.
- (P) Isosafrole.
- (Q) Safrole.
- (R) Piperonal.
- (S) N-Methylephedrine.
- (T) N-methylpseudoephedrine.
- (U) Hydriodic acid.
- (V) Benzaldehyde.
- (W) Nitroethane.
- (X) Gamma butyrolactone.
- (Y) Any salt, optical isomer, or salt of an optical isomer of the chemicals listed in subparagraphs (M) through (U) of this paragraph.

(35) The term “list II chemical” means a chemical (other than a list I chemical) specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this title, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following chemicals:

- (A) Acetic anhydride.
- (B) Acetone.
- (C) Benzyl chloride.
- (D) Ethyl ether.
- (F) Potassium permanaganate.
- (G) 2-Butanone (or Methyl Ethyl Ketone).
- (H) Toluene.
- (I) Iodine.
- (J) Hydrochloric gas.

(36) The term “regular customer” means, with respect to a regulated person, a customer with whom the regulated person has an established business relationship that is reported to the Attorney General.

(37) The term “regular importer” means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Attorney General.

(38) The term “regulated person” means a person who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine.

(39) The term “regulated transaction” means—

(A) a distribution, receipt, sale, importation, or exportation of, or an international transaction involving shipment of, a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical, a threshold amount, including a cumulative threshold amount for multiple transactions (as determined by the Attorney General, in consultation with the chemical industry and taking into consideration the quantities normally used for lawful purposes), of a listed chemical, except that such term does not include—

(i) a domestic lawful distribution in the usual course of business between agents or employees of a single regulated person;

(ii) a delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this clause does not relieve a distributor, importer, or exporter from compliance with section 310;

(iii) any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Attorney General as excluded from this definition as unnecessary for enforcement of this title or title III;

(iv) any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act, subject to clause (v), unless—

(I) the Attorney General has determined under section 204 that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(II) the quantity of the listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Attorney General;

(v) any transaction in a scheduled listed chemical product that is a sale at retail by a regulated seller or a distributor required to submit reports under section 310(b)(3); or

(vi) any transaction in a chemical mixture which the Attorney General has by regulation designated as exempt from the application of this title and title III based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered; and

(B) a distribution, importation, or exportation of a tableting machine or encapsulating machine.

(40) The term “chemical mixture” means a combination of two or more chemical substances, at least one of which is not a list I chemical or a list II chemical, except that such term does not include any combination of a list I chemical or a list II chemical with another chemical that is present solely as an impurity.

(41)(A) The term “anabolic steroid” means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone), and includes—

(i) androstenediol—

(I) $3\beta,17\beta$ -dihydroxy- 5α -androstane; and

(II) $3\alpha,17\beta$ -dihydroxy- 5α -androstane;

(ii) androstenedione (5α -androst-3,17-dione);

(iii) androstenediol—

(I) 1-androstenediol ($3\beta,17\beta$ -dihydroxy- 5α -androst-1-ene);

(II) 1-androstenediol ($3\alpha,17\beta$ -dihydroxy- 5α -androst-1-ene);

(III) 4-androstenediol ($3\beta,17\beta$ -dihydroxy-androst-4-ene);

and

(IV) 5-androstenediol ($3\beta,17\beta$ -dihydroxy-androst-5-ene);

(iv) androstenedione—

(I) 1-androstenedione ($[5\alpha]$ -androst-1-en-3,17-dione);

(II) 4-androstenedione (androst-4-en-3,17-dione); and

(III) 5-androstenedione (androst-5-en-3,17-dione);

(v) bolasterone ($7\alpha,17\alpha$ -dimethyl- 17β -hydroxyandrost-4-en-3-one);

(vi) boldenone (17β -hydroxyandrost-1,4,-diene-3-one);

(vii) calusterone ($7\beta,17\alpha$ -dimethyl- 17β -hydroxyandrost-4-en-3-one);

(viii) clostebol (4-chloro- 17β -hydroxyandrost-4-en-3-one);

- (ix) dehydrochloromethyltestosterone (4-chloro-17 β -hydroxy-17 α -methyl-androst-1,4-dien-3-one);
- (x) Δ 1-dihydrotestosterone (a.k.a. "1-testosterone") (17 β -hydroxy-5 α -androst-1-en-3-one);
- (xi) 4-dihydrotestosterone (17 β -hydroxy-androstan-3-one);
- (xii) drostanolone (17 β -hydroxy-2 α -methyl-5 α -androstan-3-one);
- (xiii) ethylestrenol (17 α -ethyl-17 β -hydroxyestr-4-ene);
- (xiv) fluoxymesterone (9-fluoro-17 α -methyl-11 β ,17 β -dihydroxyandrost-4-en-3-one);
- (xv) formebolone (2-formyl-17 α -methyl-11 α ,17 β -dihydroxyandrost-1,4-dien-3-one);
- (xvi) furazabol (17 α -methyl-17 β -hydroxyandrostan-2,3-c-furazan);
- (xvii) 13 β -ethyl-17 β -hydroxygon-4-en-3-one;
- (xviii) 4-hydroxytestosterone (4,17 β -dihydroxy-androst-4-en-3-one);
- (xix) 4-hydroxy-19-nortestosterone (4,17 β -dihydroxy-estr-4-en-3-one);
- (xx) mestanolone (17 α -methyl-17 β -hydroxy-5 α -androstan-3-one);
- (xxi) mesterolone (1 α -methyl-17 β -hydroxy-[5 α]-androstan-3-one);
- (xxii) methandienone (17 α -methyl-17 β -hydroxyandrost-1,4-dien-3-one);
- (xxiii) methandriol (17 α -methyl-3 β ,17 β -dihydroxyandrost-5-ene);
- (xxiv) methenolone (1-methyl-17 β -hydroxy-5 α -androst-1-en-3-one);
- (xxv) 17 α -methyl-3 β , 17 β -dihydroxy-5 α -androstan-3-one;
- (xxvi) 17 α -methyl-3 α ,17 β -dihydroxy-5 α -androstan-3-one;
- (xxvii) 17 α -methyl-3 β ,17 β -dihydroxyandrost-4-ene.
- (xxviii) 17 α -methyl-4-hydroxynandrolone (17 α -methyl-4-hydroxy-17 β -hydroxyestr-4-en-3-one);
- (xxix) methyldienolone (17 α -methyl-17 β -hydroxyestra-4,9(10)-dien-3-one);
- (xxx) methyltrienolone (17 α -methyl-17 β -hydroxyestra-4,9-11-trien-3-one);
- (xxxi) methyltestosterone (17 α -methyl-17 β -hydroxyandrost-4-en-3-one);
- (xxxii) mibolerone (7 α ,17 α -dimethyl-17 β -hydroxyestr-4-en-3-one);
- (xxxiii) 17 α -methyl- Δ 1-dihydrotestosterone (17 β -hydroxy-17 α -methyl-5 α -androst-1-en-3-one) (a.k.a. "17- α -methyl-1-testosterone");
- (xxxiv) nandrolone (17 β -hydroxyestr-4-en-3-one);
- (xxxv) norandrostenediol—
 - (I) 19-nor-4-androstenediol (3 β , 17 β -dihydroxyestr-4-ene);
 - (II) 19-nor-4-androstenediol (3 α , 17 β -dihydroxyestr-4-ene);
 - (III) 19-nor-5-androstenediol (3 β , 17 β -dihydroxyestr-5-ene); and
 - (IV) 19-nor-5-androstenediol (3 α , 17 β -dihydroxyestr-5-ene);
- (xxxvi) norandrostenedione—

- (I) 19-nor-4-androstenedione (estr-4-en-3,17-dione); and
 (II) 19-nor-5-androstenedione (estr-5-en-3,17-dione);
 (xxxvii) norbolethone (13 β ,17 α -diethyl-17 β -hydroxygon-4-en-3-one);
 (xxxviii) norclostebol (4-chloro-17 β -hydroxyestr-4-en-3-one);
 (xxxix) norethandrolone (17 α -ethyl-17 β -hydroxyestr-4-en-3-one);
 (xl) normethandrolone (17 α -methyl-17 β -hydroxyestr-4-en-3-one);
 (xli) oxandrolone (17 α -methyl-17 β -hydroxy-2-oxa-[5 α]-androstan-3-one);
 (xlii) oxymesterone (17 α -methyl-4,17 β -dihydroxyandrost-4-en-3-one);
 (xliii) oxymetholone (17 α -methyl-2-hydroxymethylene-17 β -hydroxy-[5 α]-androstan-3-one);
 (xliv) stanozolol (17 α -methyl-17 β -hydroxy-[5 α]-androst-2-eno[3,2-c]-pyrazole);
 (xlv) stenbolone (17 β -hydroxy-2-methyl-[5 α]-androst-1-en-3-one);
 (xlvi) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone);
 (xlvii) testosterone (17 β -hydroxyandrost-4-en-3-one);
 (xlviii) tetrahydrogestrinone (13 β ,17 α -diethyl-17 β -hydroxygon-4,9,11-trien-3-one);
 (xlix) trenbolone (17 β -hydroxyestr-4,9,11-trien-3-one);
 (l) 5 α -Androstan-3,6,17-trione;
 (li) 6-bromo-androstan-3,17-dione;
 (lii) 6-bromo-androsta-1,4-diene-3,17-dione;
 (liii) 4-chloro-17 α -methyl-androsta-1,4-diene-3,17 β -diol;
 (liv) 4-chloro-17 α -methyl-androst-4-ene-3 β ,17 β -diol;
 (lv) 4-chloro-17 α -methyl-17 β -hydroxy-androst-4-en-3-one;
 (lvi) 4-chloro-17 α -methyl-17 β -hydroxy-androst-4-ene-3,11-dione;
 (lvii) 4-chloro-17 α -methyl-androsta-1,4-diene-3,17 β -diol;
 (lviii) 2 α ,17 α -dimethyl-17 β -hydroxy-5 α -androstan-3-one;
 (lix) 2 α ,17 α -dimethyl-17 β -hydroxy-5 β -androstan-3-one;
 (lx) 2 α ,3 α -epithio-17 α -methyl-5 α -androstan-17 β -ol;
 (lxi) [3,2-c]-furazan-5 α -androstan-17 β -ol;
 (lxii) 3 β -hydroxy-estra-4,9,11-trien-17-one;
 (lxiii) 17 α -methyl-androst-2-ene-3,17 β -diol;
 (lxiv) 17 α -methyl-androsta-1,4-diene-3,17 β -diol;
 (lxv) Estra-4,9,11-triene-3,17-dione;
 (lxvi) 18a-Homo-3-hydroxy-estra-2,5(10)-dien-17-one;
 (lxvii) 6 α -Methyl-androst-4-ene-3,17-dione;
 (lxviii) 17 α -Methyl-androstan-3-hydroxyimine-17 β -ol;
 (lxix) 17 α -Methyl-5 α -androstan-17 β -ol;
 (lxx) 17 β -Hydroxy-androstano[2,3-d]isoxazole;
 (lxxi) 17 β -Hydroxy-androstano[3,2-c]isoxazole;
 (lxxii) 4-Hydroxy-androst-4-ene-3,17-dione[3,2-c]pyrazole-5 α -androstan-17 β -ol;
 (lxxiii) [3,2-c]pyrazole-androst-4-en-17 β -ol;
 (lxxiv) [3,2-c]pyrazole-5 α -androstan-17 β -ol; and
 (lxxv) any salt, ester, or ether of a drug or substance described in this paragraph.

The substances excluded under this subparagraph may at any time be scheduled by the Attorney General in accordance with the authority and requirements of subsections (a) through (c) of section 201.

(B)(i) Except as provided in clause (ii), such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for such administration.

(ii) If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of subparagraph (A).

(C)(i) Subject to clause (ii), a drug or hormonal substance (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone) that is not listed in subparagraph (A) and is derived from, or has a chemical structure substantially similar to, 1 or more anabolic steroids listed in subparagraph (A) shall be considered to be an anabolic steroid for purposes of this Act if—

(I) the drug or substance has been created or manufactured with the intent of producing a drug or other substance that either—

(aa) promotes muscle growth; or

(bb) otherwise causes a pharmacological effect similar to that of testosterone; or

(II) the drug or substance has been, or is intended to be, marketed or otherwise promoted in any manner suggesting that consuming it will promote muscle growth or any other pharmacological effect similar to that of testosterone.

(ii) A substance shall not be considered to be a drug or hormonal substance for purposes of this subparagraph if it—

(I) is—

(aa) an herb or other botanical;

(bb) a concentrate, metabolite, or extract of, or a constituent isolated directly from, an herb or other botanical; or

(cc) a combination of 2 or more substances described in item (aa) or (bb);

(II) is a dietary ingredient for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

(III) is not anabolic or androgenic.

(iii) In accordance with section 515(a), any person claiming the benefit of an exemption or exception under clause (ii) shall bear the burden of going forward with the evidence with respect to such exemption or exception.

(42) The term “international transaction” means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.

(43) The terms “broker” and “trader” mean a person that assists in arranging an international transaction in a listed chemical by—

(A) negotiating contracts;

(B) serving as an agent or intermediary; or

(C) bringing together a buyer and seller, a buyer and transporter, or a seller and transporter.

(44) The term “felony drug offense” means an offense that is punishable by imprisonment for more than one year under any law of the United States or of a State or foreign country that prohibits or restricts conduct relating to narcotic drugs, marihuana, anabolic steroids, or depressant or stimulant substances.

(45)(A) The term “scheduled listed chemical product” means, subject to subparagraph (B), a product that—

(i) contains ephedrine, pseudoephedrine, or phenylpropanolamine; and

(ii) may be marketed or distributed lawfully in the United States under the Federal, Food, Drug, and Cosmetic Act as a nonprescription drug.

Each reference in clause (i) to ephedrine, pseudoephedrine, or phenylpropanolamine includes each of the salts, optical isomers, and salts of optical isomers of such chemical.

(B) Such term does not include a product described in subparagraph (A) if the product contains a chemical specified in such subparagraph that the Attorney General has under section 201(a) added to any of the schedules under section 202(c). In the absence of such scheduling by the Attorney General, a chemical specified in such subparagraph may not be considered to be a controlled substance.

(46) The term “regulated seller” means a retail distributor (including a pharmacy or a mobile retail vendor), except that such term does not include an employee or agent of such distributor.

(47) The term “mobile retail vendor” means a person or entity that makes sales at retail from a stand that is intended to be temporary, or is capable of being moved from one location to another, whether the stand is located within or on the premises of a fixed facility (such as a kiosk at a shopping center or an airport) or whether the stand is located on unimproved real estate (such as a lot or field leased for retail purposes).

(48) The term “at retail”, with respect to the sale or purchase of a scheduled listed chemical product, means a sale or purchase for personal use, respectively.

(49)(A) The term “retail distributor” means a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to ephedrine, pseudoephedrine, or phenylpropanolamine products are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.

(B) For purposes of this paragraph, entities are defined by reference to the Standard Industrial Classification (SIC) code, as follows:

(i) A grocery store is an entity within SIC code 5411.

(ii) A general merchandise store is an entity within SIC codes 5300 through 5399 and 5499.

(iii) A drug store is an entity within SIC code 5912.

(50) The term “Internet” means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocol to

such protocol, to communicate information of all kinds by wire or radio.

(51) The term “deliver, distribute, or dispense by means of the Internet” refers, respectively, to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the Internet.

(52) The term “online pharmacy”—

(A) means a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet; and

(B) does not include—

(i) manufacturers or distributors registered under subsection (a), (b), (d), or (e) of section 303 who do not dispense controlled substances to an unregistered individual or entity;

(ii) nonpharmacy practitioners who are registered under section 303(f) and whose activities are authorized by that registration;

(iii) any hospital or other medical facility that is operated by an agency of the United States (including the Armed Forces), provided such hospital or other facility is registered under section 303(f);

(iv) a health care facility owned or operated by an Indian tribe or tribal organization, only to the extent such facility is carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act;

(v) any agent or employee of any hospital or facility referred to in clause (iii) or (iv), provided such agent or employee is lawfully acting in the usual course of business or employment, and within the scope of the official duties of such agent or employee, with such hospital or facility, and, with respect to agents or employees of health care facilities specified in clause (iv), only to the extent such individuals are furnishing services pursuant to the contracts or compacts described in such clause;

(vi) mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance;

(vii) a person, entity, or Internet site that is not in the United States and does not facilitate the delivery, distribution, or dispensing of a controlled substance by means of the Internet to any person in the United States;

(viii) a pharmacy registered under section 303(f) whose dispensing of controlled substances via the Internet consists solely of—

(I) refilling prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph (55); or

(II) filling new prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph (56); or

(ix) any other persons for whom the Attorney General and the Secretary have jointly, by regulation, found it to be consistent with effective controls against diversion and

otherwise consistent with the public health and safety to exempt from the definition of an “online pharmacy”.

(53) The term “homepage” means the opening or main page or screen of the website of an online pharmacy that is viewable on the Internet.

(54) The term “practice of telemedicine” means, for purposes of this title, the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1834(m) of the Social Security Act, which practice—

(A) is being conducted—

(i) while the patient is being treated by, and physically located in, a hospital or clinic registered under section 303(f); and

(ii) by a practitioner—

(I) acting in the usual course of professional practice;

(II) acting in accordance with applicable State law; and

(III) registered under section 303(f) in the State in which the patient is located, unless the practitioner—

(aa) is exempted from such registration in all States under section 302(d); or

(bb) is—

(AA) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and

(BB) registered under section 303(f) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

(B) is being conducted while the patient is being treated by, and in the physical presence of, a practitioner—

(i) acting in the usual course of professional practice;

(ii) acting in accordance with applicable State law; and

(iii) registered under section 303(f) in the State in which the patient is located, unless the practitioner—

(I) is exempted from such registration in all States under section 302(d); or

(II) is—

(aa) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and

(bb) registered under section 303(f) in any State or is using the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

(C) is being conducted by a practitioner—

(i) who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under its contract or compact with the Indian

- Health Service under the Indian Self-Determination and Education Assistance Act;
- (ii) acting within the scope of the employment, contract, or compact described in clause (i); and
 - (iii) who is designated as an Internet Eligible Controlled Substances Provider by the Secretary under section 311(g)(2);
- (D)(i) is being conducted during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act; and
- (ii) involves patients located in such areas, and such controlled substances, as the Secretary, with the concurrence of the Attorney General, designates, provided that such designation shall not be subject to the procedures prescribed by subchapter II of chapter 5 of title 5, United States Code;
- (E) is being conducted by a practitioner who has obtained from the Attorney General a special registration under section 311(h);
- (F) is being conducted—
- (i) in a medical emergency situation—
 - (I) that prevents the patient from being in the physical presence of a practitioner registered under section 303(f) who is an employee or contractor of the Veterans Health Administration acting in the usual course of business and employment and within the scope of the official duties or contract of that employee or contractor;
 - (II) that prevents the patient from being physically present at a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);
 - (III) during which the primary care practitioner of the patient or a practitioner otherwise practicing telemedicine within the meaning of this paragraph is unable to provide care or consultation; and
 - (IV) that requires immediate intervention by a health care practitioner using controlled substances to prevent what the practitioner reasonably believes in good faith will be imminent and serious clinical consequences, such as further injury or death; and
 - (ii) by a practitioner that—
 - (I) is an employee or contractor of the Veterans Health Administration acting within the scope of that employment or contract;
 - (II) is registered under section 303(f) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f); and
 - (III) issues a controlled substance prescription in this emergency context that is limited to a maximum of a 5-day supply which may not be extended or refilled; or
- (G) is being conducted under any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against

diversion and otherwise consistent with the public health and safety.

(55) The term “refilling prescriptions for controlled substances in schedule III, IV, or V”—

(A) means the dispensing of a controlled substance in schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of subsections (b) and (c) of section 309, as appropriate; and

(B) does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.

(56) The term “filling new prescriptions for controlled substances in schedule III, IV, or V” means filling a prescription for an individual for a controlled substance in schedule III, IV, or V, if—

(A) the pharmacy dispensing that prescription has previously dispensed to the patient a controlled substance other than by means of the Internet and pursuant to the valid prescription of a practitioner that meets the applicable requirements of subsections (b) and (c) of section 309 (in this paragraph referred to as the “original prescription”);

(B) the pharmacy contacts the practitioner who issued the original prescription at the request of that individual to determine whether the practitioner will authorize the issuance of a new prescription for that individual for the controlled substance described in subparagraph (A); and

(C) the practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.

(57) The term “suspicious order” may include, but is not limited to—

(A) an order of a controlled substance of unusual size;

(B) an order of a controlled substance deviating substantially from a normal pattern; and

(C) orders of controlled substances of unusual frequency.

(57) The term “serious drug felony” means an offense described in section 924(e)(2) of title 18, United States Code, for which—

(A) the offender served a term of imprisonment of more than 12 months; and

(B) the offender’s release from any term of imprisonment was within 15 years of the commencement of the instant offense.

(58) The term “serious violent felony” means—

(A) an offense described in section 3559(c)(2) of title 18, United States Code, for which the offender served a term of imprisonment of more than 12 months; and

(B) any offense that would be a felony violation of section 113 of title 18, United States Code, if the offense were committed in the special maritime and territorial jurisdiction of the United States, for which the offender served a term of imprisonment of more than 12 months.

* * * * *

PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND
DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING

* * * * *

REGISTRATION REQUIREMENTS

SEC. 303. (a) The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(c) Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those con-

trolled substances in excess of the quota assigned pursuant to section 306.

(d) The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

- (1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;
- (2) compliance with applicable State and local law;
- (3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;
- (4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
- (5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and
- (6) such other factors as may be relevant to and consistent with the public health and safety.

(e) The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

- (1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;
- (2) compliance with applicable State and local law;
- (3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
- (4) past experience in the distribution of controlled substances; and
- (5) such other factors as may be relevant to and consistent with the public health and safety.

[(f) The Attorney General] (f) (1) *The Attorney General* shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration or such modification of registration if the Attorney General determines that the issuance of such registration or modification would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

- [(1)]** (A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

[(2)] (B) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

[(3)] (C) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

[(4)] (D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

[(5)] (E) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. [Registration applications]

(2) *Registration applications* by practitioners wishing to conduct research with controlled substances in schedule I, *except marijuana*, shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I, *except marijuana*, by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 304(a). [Article 7]

(3)(A) *The Attorney General shall register a practitioner to conduct research with marijuana if—*

(i) *the applicant is authorized to dispense, or conduct research with respect to, controlled substances in schedules II, III, IV, and V under the laws of the State in which the applicant practices;*

(ii) *the applicant's research protocol has been reviewed and approved by the Secretary under section 505(i) of the Federal Food, Drug, and Cosmetic Act; and*

(iii) *the Secretary has determined the applicant is qualified to conduct bona fide research.*

A practitioner so registered shall be referred to in this Act as a "qualified marijuana researcher".

(B)(i) *Not later than 60 days after the date on which the Attorney General receives a complete application for registration under this paragraph, the Attorney General shall approve or deny the application.*

(ii) *For purposes of clause (i), an application shall be deemed complete when the applicant has submitted documentation showing that the requirements under subparagraph (A) are satisfied.*

(iii) *In the case of a denial under clause (i), the Attorney General shall provide a written explanation of the basis for the denial.*

(C) *The Attorney General shall grant an application for registration under this paragraph unless the Attorney General determines that the issuance of the registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:*

(i) *The applicant's experience in dispensing, or conducting research with respect to, controlled substances.*

(ii) *The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.*

(iii) *Compliance with applicable State or local laws relating to controlled substance misuse or diversion.*

(D)(i) *A qualified marijuana researcher shall store marijuana to be used in research in a securely locked, substantially constructed cabinet.*

(ii) *Except as provided in clause (i), any security measures required by the Attorney General for practitioners conducting research with marijuana pursuant to a registration under this paragraph shall be consistent with the security measures for practitioners conducting research on other controlled substances in schedule II that have a similar risk of diversion and abuse.*

(E)(i) *If the Attorney General grants an application for registration under this paragraph, the applicant may amend or supplement the research protocol without reapplying if the applicant does not change the type of marijuana, the source of the marijuana, or the conditions under which the marijuana is stored, tracked, or administered.*

(ii) *If an applicant amends or supplements the research protocol or initiates research on a new research protocol under clause (i), the applicant shall, in order to renew the registration under this paragraph, provide notice to the Attorney General of the amended or supplemented research protocol or any new research protocol in the applicant's renewal materials.*

(iii)(I) *If an applicant amends or supplements a research protocol and the amendment or supplement involves a change to the type of marijuana, the source of the marijuana, or conditions under which the marijuana is stored, tracked, or administered or otherwise increases the risk of diversion, the applicant shall provide notice to the Attorney General not later than 30 days before proceeding on such amended or supplemental research or new research protocol, as the case may be.*

(II) *If the Attorney General does not object during the 30-day period following a notification under subclause (I), the applicant may proceed with the amended or supplemental research or new research protocol.*

(iv) *The Attorney General may object to an amended or supplemental protocol or a new research protocol under clause (i) or (iii) only if additional security measures are needed to safeguard against diversion or abuse.*

(F) *If marijuana or a compound of marijuana is listed on a schedule other than schedule I, the provisions of paragraphs (1), (2), and (4) that apply to research with a controlled substance in the applicable schedule shall apply to research with marijuana or that compound, as applicable, in lieu of the provisions of subparagraphs (A) through (E) of this paragraph.*

(G) *Nothing in this paragraph shall be construed as limiting the authority of the Secretary under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or over requirements related to research protocols, including changes in—*

- (i) the method of administration of marijuana;*
- (ii) the dosing of marijuana; and*

(iii) *the number of individuals or patients involved in research.*

(4) *Article 7* of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this title.

(g)(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)—

(A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 307) on such drugs; and

(C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

(i) The practitioner is a qualifying practitioner (as defined in subparagraph (G)).

(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to provide directly, by referral, or in such other manner as determined by the Secretary—

(I) all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including for maintenance, detoxification, overdose reversal, and relapse prevention; and

(II) appropriate counseling and other appropriate ancillary services.

(iii)(I) The total number of such patients of the practitioner at any one time will not exceed the applicable number. Except as provided in subclause (II), the applicable number is 30.

(II) The applicable number is—

(aa) 100 if, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients;

(bb) 100 if the practitioner holds additional credentialing, as defined in section 8.2 of title 42, Code of Federal Regulations (or successor regulations);

(cc) 100 if the practitioner provides medication-assisted treatment (MAT) using covered medications (as such terms are defined in section 8.2 of title 42, Code of Federal Regulations (or successor regulations)) in a qualified practice setting (as described in section 8.615 of title 42, Code of Federal Regulations (or successor regulations)); or

(dd) 275 if the practitioner meets the requirements specified in sections 8.610 through 8.655 of title 42, Code of Federal Regulations (or successor regulations).

(III) The Secretary may by regulation change such applicable number.

(IV) The Secretary may exclude from the applicable number patients to whom such drugs or combinations of drugs are directly administered by the qualifying practitioner in the office setting.

(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:

(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, been approved for use in maintenance or detoxification treatment.

(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

(II) The notification identifies the registration issued for the practitioner pursuant to subsection (f).

(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f).

(ii) Upon receiving a determination from the Secretary under clause (iii) finding that a practitioner meets all requirements for a waiver under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the registration issued for the practitioner pursuant to subsection (f). The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).

(iii) Not later than 45 days after the date on which the Secretary receives a notification under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B) and shall forward such determination to the Attorney General. If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the practitioner an identification number described in clause (ii) at the end of such period.

(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 304(a)(4), consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) to be inconsistent with the public interest.

(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph

(1), including with respect to the number of patients who may be served under such a registration.

(G) For purposes of this paragraph:

(i) The term “group practice” has the meaning given such term in section 1877(h)(4) of the Social Security Act.

(ii) The term “qualifying physician” means a physician who is licensed under State law and who meets one or more of the following conditions:

(I) The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.

(II) The physician holds an addiction certification or board certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine.

(III) The physician holds a board certification in addiction medicine from the American Osteopathic Association.

(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause. Such training shall include—

(aa) opioid maintenance and detoxification;

(bb) appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder;

(cc) initial and periodic patient assessments (including substance use monitoring);

(dd) individualized treatment planning, overdose reversal, and relapse prevention;

(ee) counseling and recovery support services;

(ff) staffing roles and considerations;

(gg) diversion control; and

(hh) other best practices, as identified by the Secretary.

(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause

shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

(VIII) The physician graduated in good standing from an accredited school of allopathic medicine or osteopathic medicine in the United States during the 5-year period immediately preceding the date on which the physician submits to the Secretary a written notification under subparagraph (B) and successfully completed a comprehensive allopathic or osteopathic medicine curriculum or accredited medical residency that—

(aa) included not less than 8 hours of training on treating and managing opioid-dependent patients; and

(bb) included, at a minimum—

(AA) the training described in items (aa) through (gg) of subclause (IV); and

(BB) training with respect to any other best practice the Secretary determines should be included in the curriculum, which may include training on pain management, including assessment and appropriate use of opioid and non-opioid alternatives.

(iii) The term “qualifying practitioner” means—

(I) a qualifying physician, as defined in clause (ii);

(II) a qualifying other practitioner, as defined in clause (iv), who is a nurse practitioner or physician assistant; or

(III) for the period beginning on October 1, 2018, and ending on October 1, 2023, a qualifying other practitioner, as defined in clause (iv), who is a clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife.

(iv) The term “qualifying other practitioner” means a nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant who satisfies each of the following:

(I) The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain.

(II) The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant has—

(aa) completed not fewer than 24 hours of initial training addressing each of the topics listed in clause (ii)(IV) (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American

Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Assistants, or any other organization that the Secretary determines is appropriate for purposes of this subclause; or

(bb) has such other training or experience as the Secretary determines will demonstrate the ability of the nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant to treat and manage opiate-dependent patients.

(III) The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is supervised by, or works in collaboration with, a qualifying physician, if the nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is required by State law to prescribe medications for the treatment of opioid use disorder in collaboration with or under the supervision of a physician.

The Secretary may, by regulation, revise the requirements for being a qualifying other practitioner under this clause.

(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

(I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

(II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

(III) Such other elements of the requirements under this paragraph as the Secretary determines necessary for purposes of implementing such requirements.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

(ii) Not later than 18 months after the date of enactment of the Opioid Use Disorder Treatment Expansion and Modernization Act, the Secretary shall update the treatment improvement protocol containing best practice guidelines for the treatment of opioid-dependent patients in office-based settings. The Secretary shall update such protocol in consultation with experts in opioid use disorder research and treatment.

(I) Notwithstanding section 708, nothing in this paragraph shall be construed to preempt any State law that—

(i) permits a qualifying practitioner to dispense narcotic drugs in schedule III, IV, or V, or combinations of such drugs, for maintenance or detoxification treatment in accordance with this paragraph to a total number of patients that is more than 30 or less than the total number applicable to the qualifying

practitioner under subparagraph (B)(iii)(II) if a State enacts a law modifying such total number and the Attorney General is notified by the State of such modification; or

(ii) requires a qualifying practitioner to comply with additional requirements relating to the dispensing of narcotic drugs in schedule III, IV, or V, or combinations of such drugs, including requirements relating to the practice setting in which the qualifying practitioner practices and education, training, and reporting requirements.

(h) The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under clause (iv) or (v) of section 102(39)(A). In determining the public interest for the purposes of this subsection, the Attorney General shall consider—

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

(i)(1) For purposes of registration to manufacture a controlled substance under subsection (d) for use only in a clinical trial, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), not later than 180 days after the date on which the application is accepted for filing.

(2) For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), unless the Attorney General has granted a hearing on the application under section 1008(i) of the Controlled Substances Import and Export Act.

(j) EMERGENCY MEDICAL SERVICES THAT ADMINISTER CONTROLLED SUBSTANCES.—

(1) REGISTRATION.—For the purpose of enabling emergency medical services professionals to administer controlled substances in schedule II, III, IV, or V to ultimate users receiving emergency medical services in accordance with the requirements of this subsection, the Attorney General—

(A) shall register an emergency medical services agency if the agency submits an application demonstrating it is

authorized to conduct such activity under the laws of each State in which the agency practices; and

(B) may deny an application for such registration if the Attorney General determines that the issuance of such registration would be inconsistent with the requirements of this subsection or the public interest based on the factors listed in subsection (f).

(2) OPTION FOR SINGLE REGISTRATION.—In registering an emergency medical services agency pursuant to paragraph (1), the Attorney General shall allow such agency the option of a single registration in each State where the agency administers controlled substances in lieu of requiring a separate registration for each location of the emergency medical services agency.

(3) HOSPITAL-BASED AGENCY.—If a hospital-based emergency medical services agency is registered under subsection (f), the agency may use the registration of the hospital to administer controlled substances in accordance with this subsection without being registered under this subsection.

(4) ADMINISTRATION OUTSIDE PHYSICAL PRESENCE OF MEDICAL DIRECTOR OR AUTHORIZING MEDICAL PROFESSIONAL.—Emergency medical services professionals of a registered emergency medical services agency may administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if the administration is—

(A) authorized by the law of the State in which it occurs;

and

(B) pursuant to—

(i) a standing order that is issued and adopted by one or more medical directors of the agency, including any such order that may be developed by a specific State authority; or

(ii) a verbal order that is—

(I) issued in accordance with a policy of the agency; and

(II) provided by a medical director or authorizing medical professional in response to a request by the emergency medical services professional with respect to a specific patient—

(aa) in the case of a mass casualty incident;

or

(bb) to ensure the proper care and treatment of a specific patient.

(5) DELIVERY.—A registered emergency medical services agency may deliver controlled substances from a registered location of the agency to an unregistered location of the agency only if the agency—

(A) designates the unregistered location for such delivery; and

(B) notifies the Attorney General at least 30 days prior to first delivering controlled substances to the unregistered location.

(6) STORAGE.—A registered emergency medical services agency may store controlled substances—

(A) at a registered location of the agency;

(B) at any designated location of the agency or in an emergency services vehicle situated at a registered or designated location of the agency; or

(C) in an emergency medical services vehicle used by the agency that is—

(i) traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency; or

(ii) otherwise actively in use by the agency under circumstances that provide for security of the controlled substances consistent with the requirements established by regulations of the Attorney General.

(7) NO TREATMENT AS DISTRIBUTION.—The delivery of controlled substances by a registered emergency medical services agency pursuant to this subsection shall not be treated as distribution for purposes of section 308.

(8) RESTOCKING OF EMERGENCY MEDICAL SERVICES VEHICLES AT A HOSPITAL.—Notwithstanding paragraph (13)(J), a registered emergency medical services agency may receive controlled substances from a hospital for purposes of restocking an emergency medical services vehicle following an emergency response, and without being subject to the requirements of section 308, provided all of the following conditions are satisfied:

(A) The registered or designated location of the agency where the vehicle is primarily situated maintains a record of such receipt in accordance with paragraph (9).

(B) The hospital maintains a record of such delivery to the agency in accordance with section 307.

(C) If the vehicle is primarily situated at a designated location, such location notifies the registered location of the agency within 72 hours of the vehicle receiving the controlled substances.

(9) MAINTENANCE OF RECORDS.—

(A) IN GENERAL.—A registered emergency medical services agency shall maintain records in accordance with subsections (a) and (b) of section 307 of all controlled substances that are received, administered, or otherwise disposed of pursuant to the agency's registration, without regard to subsection 307(c)(1)(B).

(B) REQUIREMENTS.—Such records—

(i) shall include records of deliveries of controlled substances between all locations of the agency; and

(ii) shall be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

(10) OTHER REQUIREMENTS.—A registered emergency medical services agency, under the supervision of a medical director, shall be responsible for ensuring that—

(A) all emergency medical services professionals who administer controlled substances using the agency's registra-

tion act in accordance with the requirements of this subsection;

(B) the recordkeeping requirements of paragraph (9) are met with respect to a registered location and each designated location of the agency;

(C) the applicable physical security requirements established by regulation of the Attorney General are complied with wherever controlled substances are stored by the agency in accordance with paragraph (6); and

(D) the agency maintains, at a registered location of the agency, a record of the standing orders issued or adopted in accordance with paragraph (9).

(11) REGULATIONS.—The Attorney General may issue regulations—

(A) specifying, with regard to delivery of controlled substances under paragraph (5)—

(i) the types of locations that may be designated under such paragraph; and

(ii) the manner in which a notification under paragraph (5)(B) must be made;

(B) specifying, with regard to the storage of controlled substances under paragraph (6), the manner in which such substances must be stored at registered and designated locations, including in emergency medical service vehicles; and

(C) addressing the ability of hospitals, emergency medical services agencies, registered locations, and designated locations to deliver controlled substances to each other in the event of—

(i) shortages of such substances;

(ii) a public health emergency; or

(iii) a mass casualty event.

(12) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed—

(A) to limit the authority vested in the Attorney General by other provisions of this title to take measures to prevent diversion of controlled substances; or

(B) to override the authority of any State to regulate the provision of emergency medical services consistent with this subsection.

(13) DEFINITIONS.—In this section:

(A) The term “authorizing medical professional” means an emergency or other physician, or another medical professional (including an advanced practice registered nurse or physician assistant)—

(i) who is registered under this Act;

(ii) who is acting within the scope of the registration; and

(iii) whose scope of practice under a State license or certification includes the ability to provide verbal orders.

(B) The term “designated location” means a location designated by an emergency medical services agency under paragraph (5).

(C) The term “emergency medical services” means emergency medical response and emergency mobile medical services provided outside of a fixed medical facility.

(D) The term “emergency medical services agency” means an organization providing emergency medical services, including such an organization that—

(i) is governmental (including fire-based and hospital-based agencies), nongovernmental (including hospital-based agencies), private, or volunteer-based;

(ii) provides emergency medical services by ground, air, or otherwise; and

(iii) is authorized by the State in which the organization is providing such services to provide emergency medical care, including the administering of controlled substances, to members of the general public on an emergency basis.

(E) The term “emergency medical services professional” means a health care professional (including a nurse, paramedic, or emergency medical technician) licensed or certified by the State in which the professional practices and credentialed by a medical director of the respective emergency medical services agency to provide emergency medical services within the scope of the professional’s State license or certification.

(F) The term “emergency medical services vehicle” means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an emergency medical services agency for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances to and from the registered and designated locations.

(G) The term “hospital-based” means, with respect to an agency, owned or operated by a hospital.

(H) The term “medical director” means a physician who is registered under subsection (f) and provides medical oversight for an emergency medical services agency.

(I) The term “medical oversight” means supervision of the provision of medical care by an emergency medical services agency.

(J) The term “registered emergency medical services agency” means—

(i) an emergency medical services agency that is registered pursuant to this subsection; or

(ii) a hospital-based emergency medical services agency that is covered by the registration of the hospital under subsection (f).

(K) The term “registered location” means a location that appears on the certificate of registration issued to an emergency medical services agency under this subsection or subsection (f), which shall be where the agency receives controlled substances from distributors.

(L) The term “specific State authority” means a governmental agency or other such authority, including a regional oversight and coordinating body, that, pursuant to State law or regulation, develops clinical protocols regard-

ing the delivery of emergency medical services in the geographic jurisdiction of such agency or authority within the State that may be adopted by medical directors.

(M) The term “standing order” means a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services.

(N) The term “verbal order” means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

(k) In this section, the phrase “factors as may be relevant to and consistent with the public health and safety” means factors that are relevant to and consistent with the findings contained in section 101.

(l) REGISTRATION OF PERSONS TO MANUFACTURE AND DISTRIBUTE MARIJUANA FOR USE IN LEGITIMATE, MEDICAL RESEARCH.—

(1) REGISTRATION OF MANUFACTURERS.—Beginning not later than the day that is 1 year after the date of enactment of the Medical Marijuana Research Act, the Attorney General shall register an applicant to manufacture marijuana (including any derivative, extract, preparation, and compound thereof) that is intended for the ultimate and exclusive use by qualified marijuana researchers for research pursuant to subsection (f)(3), unless the Attorney General determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the Attorney General shall take into consideration—

(A) maintenance of effective controls against diversion of marijuana and any controlled substance compounded therefrom into other than legitimate medical, scientific, or research channels;

(B) compliance with applicable State and local laws relating to controlled substance misuse and diversion; and

(C) prior conviction record of the applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances.

(2) REGISTRATION OF DISTRIBUTORS.—Beginning not later than the day that is 1 year after the date of enactment of the Medical Marijuana Research Act, the Attorney General shall register an applicant to distribute marijuana (including any derivative, extract, preparation, and compound thereof) that is intended for the ultimate and exclusive use by qualified marijuana researchers for research pursuant to subsection (f)(3), unless the Attorney General determines that the issuance of such registration is inconsistent with the public interest.

(3) PUBLIC INTEREST.—In determining the public interest under paragraph (2), the Attorney General shall take into consideration—

(A) the factors specified in subparagraphs (A), (B), and (C) of such paragraph; and

(B) past experience in the distribution of controlled substances, and the existence of effective controls against diversion.

(4) *NO LIMIT ON NUMBER OF MANUFACTURERS AND DISTRIBUTORS.*—Notwithstanding any other provision of law, the Attorney General shall not impose or implement any limit on the number of persons eligible to be registered to manufacture or distribute marijuana pursuant to paragraph (1) or (2).

(5) *REQUIREMENT TO VERIFY USE FOR LEGITIMATE, MEDICAL RESEARCH.*—As a condition on registration under this section to manufacture or distribute marijuana, the Attorney General shall require the registrant—

(A) to require any person to whom the marijuana will be supplied to submit documentation demonstrating that the marijuana (including any derivative, extract, preparation, and compound thereof) will be ultimately used exclusively by qualified marijuana researchers for research pursuant to subsection (f)(3);

(B) in the case of distribution, to complete, with respect to that distribution, the DEA Controlled substance order form in accordance with section 308 and to upload such forms to the system used by the Drug Enforcement Agency for such distribution;

(C) to include in the labeling of any marijuana so manufactured or distributed—

(i) the following statement: “This material is for biomedical and scientific research purposes only.”; and

(ii) the name of the requestor of the marijuana;

(D) to limit the transfer and sale of any marijuana manufactured under this subsection—

(i) to researchers who are registered under this Act to conduct research with marijuana; and

(ii) for purposes of use in preclinical research or in a clinical investigation pursuant to an investigational new drug exemption under 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)); and

(E) to transfer or sell any marijuana manufactured under this subsection only with prior, written consent for the transfer or sale by the Attorney General.

(6) *TIMING.*—Not later than 60 days after receipt of a request for registration under this subsection to manufacture or distribute marijuana, the Attorney General shall—

(A) grant or deny the request; and

(B) in the case of a denial, provide a written explanation of the basis for the denial.

(7) *DEEMED APPROVAL.*—If the Attorney General fails to grant or deny a request for registration under this subsection to manufacture or distribute marijuana within the 60-day period referred to in paragraph (5), such request is deemed approved.

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QUOTAS APPLICABLE TO CERTAIN SUBSTANCES

SEC. 306. (a)(1) The Attorney General shall determine the total quantity and establish production quotas for each basic class of

controlled substance in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. Except as provided in paragraph (2), production quotas shall be established in terms of quantities of each basic class of controlled substance and not in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance.

(2) The Attorney General may, if the Attorney General determines it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance, establish an aggregate or individual production quota under this subsection, or a procurement quota established by the Attorney General by regulation, in terms of pharmaceutical dosage forms prepared from or containing the controlled substance.

(b) The Attorney General shall limit or reduce individual manufacturing quotas to the extent necessary to prevent the aggregate of individual quotas from exceeding the amount determined necessary each year by the Attorney General under subsection (a). The quota of each registered manufacturer for each basic class of controlled substance in schedule I or II or for ephedrine, pseudoephedrine, or phenylpropanolamine shall be revised in the same proportion as the limitation or reduction of the aggregate of the quotas. However, if any registrant, before the issuance of a limitation or reduction in quota, has manufactured in excess of his revised quota, the amount of the excess shall be subtracted from his quota for the following year.

(c) On or before December 1 of each year, upon application therefor by a registered manufacturer, the Attorney General shall fix a manufacturing quota for the basic classes of controlled substances in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine that the manufacturer seeks to produce. The quota shall be subject to the provisions of subsections (a) and (b) of this section. In fixing such quotas, the Attorney General shall determine the manufacturer's estimated disposal, inventory, and other requirements for the calendar year; and, in making his determination, the Attorney General shall consider the manufacturer's current rate of disposal, the trend of the national disposal rate during the preceding calendar year, the manufacturer's production cycle and inventory position, the economic availability of raw materials, yield and stability problems, emergencies such as strikes and fires, and other factors.

(d) The Attorney General shall, upon application and subject to the provisions of subsections (a) and (b) of this section, fix a quota for a basic class of controlled substance in schedule I or II for any registrant who has not manufactured that basic class of controlled substance or ephedrine, pseudoephedrine, or phenylpropanolamine during one or more preceding calendar years. In fixing such quota, the Attorney General shall take into account the registrant's reasonably anticipated requirements for the current year; and, in making his determination of such requirements, he shall consider such factors specified in subsection (c) of this section as may be relevant.

(e) At any time during the year any registrant who has applied for or received a manufacturing quota for a basic class of controlled substance in schedule I or II or for ephedrine, pseudoephedrine, or phenylpropanolamine may apply for an increase in that quota to meet his estimated disposal, inventory, and other requirements during the remainder of that year. In passing upon the application the Attorney General shall take into consideration any occurrences since the filing of the registrant's initial quota application that may require an increased manufacturing rate by the registrant during the balance of the year. In passing upon the application the Attorney General may also take into account the amount, if any, by which the determination of the Attorney General under subsection (a) of this section exceeds the aggregate of the quotas of all registrants under this section.

(f) Notwithstanding any other provisions of this title, no registration or quota may be required for the manufacture of such quantities of controlled substances in schedules I and II or ephedrine, pseudoephedrine, or phenylpropanolamine as incidentally and necessarily result from the manufacturing process used for the manufacture of a controlled substance or of ephedrine, pseudoephedrine, or phenylpropanolamine with respect to which its manufacturer is duly registered under this title. The Attorney General may, by regulation, prescribe restrictions on the retention and disposal of such incidentally produced substances or chemicals.

(g) Each reference in this section to ephedrine, pseudoephedrine, or phenylpropanolamine includes each of the salts, optical isomers, and salts of optical isomers of such chemical.

(h)(1) Not later than 30 days after the receipt of a request described in paragraph (2), the Attorney General shall—

(A) complete review of such request; and

(B)(i) as necessary to address a shortage of a controlled substance, increase the aggregate and individual production quotas under this section applicable to such controlled substance and any ingredient therein to the level requested; or

(ii) if the Attorney General determines that the level requested is not necessary to address a shortage of a controlled substance, the Attorney General shall provide a written response detailing the basis for the Attorney General's determination.

The Secretary shall make the written response provided under subparagraph (B)(ii) available to the public on the Internet Web site of the Food and Drug Administration.

(2) A request is described in this paragraph if—

(A) the request pertains to a controlled substance on the list of drugs in shortage maintained under section 506E of the Federal Food, Drug, and Cosmetic Act;

(B) the request is submitted by the manufacturer of the controlled substance; and

(C) the controlled substance is in schedule II.

(i)(1)(A) In establishing any quota under this section, or any procurement quota established by the Attorney General by regulation, for fentanyl, oxycodone, hydrocodone, oxymorphone, or hydromorphone (in this subsection referred to as a "covered controlled substance"), the Attorney General shall estimate the

amount of diversion of the covered controlled substance that occurs in the United States.

(B) In estimating diversion under this paragraph, the Attorney General—

(i) shall consider information the Attorney General, in consultation with the Secretary of Health and Human Services, determines reliable on rates of overdose deaths and abuse and overall public health impact related to the covered controlled substance in the United States; and

(ii) may take into consideration whatever other sources of information the Attorney General determines reliable.

(C) After estimating the amount of diversion of a covered controlled substance, the Attorney General shall make appropriate quota reductions, as determined by the Attorney General, from the quota the Attorney General would have otherwise established had such diversion not been considered.

(2)(A) For any year for which the approved aggregate production quota for a covered controlled substance is higher than the approved aggregate production quota for the covered controlled substance for the previous year, the Attorney General, in consultation with the Secretary of Health and Human Services, shall include in the final order an explanation of why the public health benefits of increasing the quota clearly outweigh the consequences of having an increased volume of the covered controlled substance available for sale, and potential diversion, in the United States.

(B) Not later than 1 year after the date of enactment of this subsection, and every year thereafter, the Attorney General shall submit to the Committee on the Judiciary, the Committee on Health, Education, Labor, and Pensions, and the Committee on Appropriations of the Senate and the Committee on the Judiciary, the Committee on Energy and Commerce, and the Committee on Appropriations of the House of Representatives the following information with regard to each covered controlled substance:

(i) An anonymized count of the total number of manufacturers issued individual manufacturing quotas that year for the covered controlled substance.

(ii) An anonymized count of how many such manufacturers were issued an approved manufacturing quota that was higher than the quota issued to that manufacturer for the covered controlled substance in the previous year.

(3) Not later than 1 year after the date of enactment of this subsection, the Attorney General shall submit to Congress a report on how the Attorney General, when fixing and adjusting production and manufacturing quotas under this section for covered controlled substances, will—

(A) take into consideration changes in the accepted medical use of the covered controlled substances; and

(B) work with the Secretary of Health and Human Services on methods to appropriately and anonymously estimate the type and amount of covered controlled substances that are submitted for collection from approved drug collection receptacles, mail-back programs, and take-back events.

(j) *The Attorney General may only establish a quota for production of marijuana that is manufactured and distributed in accord-*

*ance with the Medical Marijuana Research Act that meets the
changing medical, scientific, and industrial needs for marijuana.*

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