

114TH CONGRESS
2D SESSION

S. _____

To improve medical research on marijuana.

IN THE SENATE OF THE UNITED STATES

Mr. SCHATZ (for himself, Mr. HATCH, Mr. TILLIS, and Mr. COONS) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To improve medical research on marijuana.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. MARIJUANA RESEARCH.**

4 (a) IN GENERAL.—Section 303(f) of the Controlled
5 Substances Act (21 U.S.C. 823(f)) is amended—

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

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

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

1 “(2) Registration applications”;

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

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

7 “(4) Article 7”; and

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

10 “(3)(A) The Attorney General shall register a practi-
11 tioner to conduct research with marijuana if—

12 “(i) the applicant is authorized to dispense, or
13 conduct research with respect to, controlled sub-
14 stances in schedules II, III, IV, and V under the
15 laws of the State in which the applicant practices;

16 “(ii) the applicant’s research protocol—

17 “(I) has been reviewed and allowed by—

18 “(aa) the Secretary under section
19 505(i) of the Federal Food, Drug, and
20 Cosmetic Act (21 U.S.C. 355(i)); or

21 “(bb) the National Institutes of
22 Health or another Federal agency that
23 funds scientific research; or

24 “(II) in the case of nonhuman research
25 that is not federally funded, has been volun-

1 tarily submitted by the applicant to, and ap-
2 proved by, the National Institutes of Health;
3 and

4 “(iii) the applicant has demonstrated that there
5 are effective procedures in place to adequately safe-
6 guard against diversion of the marijuana from legiti-
7 mate medical or scientific use, in accordance with
8 subparagraph (E).

9 “(B) The Attorney General shall grant an application
10 for registration under this paragraph unless the Attorney
11 General determines that the issuance of the registration
12 would be inconsistent with the public interest. In deter-
13 mining the public interest, the following factors shall be
14 considered:

15 “(i) The applicant’s experience in dispensing, or
16 conducting research with respect to, controlled sub-
17 stances.

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

21 “(iii) Compliance with applicable State, Fed-
22 eral, or local laws relating to controlled substances.

23 “(iv) Such other conduct by the applicant that
24 may threaten the public health and safety.

1 “(C) Not later than 90 days after the date of enact-
2 ment of this paragraph, for purposes of subparagraph
3 (A)(ii)(II), the National Institutes of Health shall estab-
4 lish a process that—

5 “(i) allows a researcher to voluntarily submit
6 the research protocol of the researcher for review
7 and approval; and

8 “(ii) provides a researcher described in clause
9 (i) with a decision not later than 30 days after the
10 date on which the research protocol is submitted.

11 “(D)(i) Not later than 60 days after the date on
12 which the Attorney General receives a complete applica-
13 tion for registration under this paragraph, the Attorney
14 General shall—

15 “(I) approve the application; or

16 “(II) serve an order to show cause upon the ap-
17 plicant in accordance with section 304(c).

18 “(ii) For purposes of clause (i), an application shall
19 be deemed complete when the applicant has submitted
20 documentation showing that the requirements under sub-
21 paragraph (A) are satisfied.

22 “(E)(i) A researcher registered under this paragraph
23 shall store marijuana to be used in research in a securely
24 locked, substantially constructed cabinet.

1 “(ii) Any other security measures required by the At-
2 torney General under this paragraph to safeguard against
3 diversion shall be consistent with those required for practi-
4 tioners conducting research on other controlled substances
5 in schedules I and II that have a similar risk of diversion
6 and abuse.

7 “(F)(i) If the Attorney General grants an application
8 for registration under this paragraph, the applicant may
9 amend or supplement the research protocol without re-
10 applying if the applicant does not—

11 “(I) change the type of drug, the source of the
12 drug, or the conditions under which the drug is
13 stored, tracked, or administered; or

14 “(II) otherwise increase the risk of diversion.

15 “(ii) If an applicant amends or supplements the re-
16 search protocol under clause (i), the applicant shall, in
17 order to renew the registration under this paragraph, pro-
18 vide notice to the Attorney General of the amended or sup-
19 plemented research protocol in the applicant’s renewal ma-
20 terials.

21 “(iii)(I) If an applicant amends or supplements the
22 research protocol in a manner that involves a change to
23 the type of drug, the source of the drug, or conditions
24 under which the drug is stored, tracked, or administered
25 or otherwise increases the risk of diversion, the applicant

1 shall provide notice to the Attorney General not later than
2 30 days before proceeding on such amended or supple-
3 mental research protocol.

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

8 “(iv) The Attorney General may object to an amend-
9 ed or supplemental research protocol under clause (i) or
10 (iii) if additional security measures are needed to safe-
11 guard against diversion or abuse.

12 “(G) Article 28 of the Single Convention on Narcotic
13 Drugs shall not be construed to prohibit, or impose addi-
14 tional restrictions upon, research involving marijuana that
15 is conducted in accordance with this paragraph and other
16 applicable provisions of this title.

17 “(H) If marijuana or a compound of marijuana is
18 listed on a schedule other than schedule I—

19 “(i) the provisions of this subsection that apply
20 to research with a controlled substance in the appli-
21 cable schedule shall apply to research with mari-
22 juana or that compound, as applicable; and

23 “(ii) subparagraphs (A) through (G) of this
24 paragraph shall not apply to research with mari-
25 juana or that compound, as applicable.”.

1 (b) CONFORMING AMENDMENT.—Section 102(16) of
2 the Controlled Substances Act (21 U.S.C. 802(16)) is
3 amended by inserting “or ‘marijuana’” after “The term
4 ‘marihuana’”.

5 **SEC. 2. MANUFACTURING OF MARIJUANA FOR CLINICAL**
6 **USE.**

7 Section 303 of the Controlled Substances Act (21
8 U.S.C. 823) is amended by adding at the end the fol-
9 lowing:

10 “(j) REGISTRATION OF PERSONS TO MANUFACTURE
11 AND DISTRIBUTE MARIJUANA.—

12 “(1) MANUFACTURE AND DISTRIBUTION FOR
13 USE IN RESEARCH.—The Attorney General shall reg-
14 ister an applicant to manufacture or distribute mari-
15 juana on behalf of the Federal Government to the
16 extent that the marijuana is intended to be used ex-
17 clusively for legitimate research and scientific uses,
18 in accordance with the applicable requirements
19 under subsection (a) or (b) of this section for reg-
20 istration of manufacturers or distributors of con-
21 trolled substances in schedule I or II.

22 “(2) MANUFACTURE AND DISTRIBUTION FOR
23 COMMERCIAL PRODUCTION OF FDA-APPROVED
24 DRUGS.—The Attorney General shall register an ap-
25 plicant to manufacture or distribute marijuana on

1 behalf of the Federal government exclusively for the
2 purpose of commercial production of a drug con-
3 taining or derived from marijuana that is approved
4 by the Secretary under section 505 of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 355), in
6 accordance with the applicable requirements under
7 subsection (a) or (b) of this section for registration
8 of manufacturers or distributors of controlled sub-
9 stances in schedule I or II.

10 “(3) NO LIMIT ON NUMBER OF MANUFACTUR-
11 ERS AND DISTRIBUTORS.—The Attorney General
12 shall not impose a limit on the number of applicants
13 eligible to be registered under paragraph (1) or (2).

14 “(4) TIMING.—Not later than 30 days after the
15 date on which the Attorney General receives an ap-
16 plication for registration under paragraph (1) or (2),
17 the Attorney General shall—

18 “(A) grant the application; or

19 “(B) serve an order to show cause upon
20 the applicant in accordance with section 304(c).

21 “(5) DETERMINATION OF SUPPLY.—In consid-
22 ering the factors under subsection (a) or (b), as ap-
23 plicable, for the purposes of registering an applicant
24 eligible under paragraph (1) or (2) of this sub-
25 section, the Attorney General shall consider the de-

1 mand from researchers for an adequate and uninter-
2 rupted supply of specific strains of marijuana and
3 for marijuana grown pursuant to specific manufac-
4 turing processes.

5 “(6) RELATION TO THE SINGLE CONVENTION
6 ON NARCOTIC DRUGS.—

7 “(A) CONSTRUCTIVE POSSESSION AND
8 CONTROL.—The registration of manufacturers
9 and distributors of marijuana under paragraphs
10 (1) and (2) shall constitute constructive posses-
11 sion and control by the Federal Government for
12 the purposes of the obligations under the Single
13 Convention on Narcotic Drugs.

14 “(B) ARTICLE 28.—Article 28 of the Sin-
15 gle Convention on Narcotic Drugs shall not be
16 construed to prohibit, or impose additional re-
17 strictions upon, the manufacturing of mari-
18 juana that is conducted in accordance with
19 paragraph (1) or (2), as applicable, and other
20 applicable provisions of this title.”.

21 **SEC. 3. GOOD MANUFACTURING PRACTICES.**

22 Not later than 180 days after the date of enactment
23 of this Act, the National Institute for Drug Abuse shall
24 develop and publish recommendations for good manufac-
25 turing practices for growing and producing marijuana (as

1 defined in section 102 of the Controlled Substance Act (21
2 U.S.C. 802), as amended by this Act) for research.

3 **SEC. 4. QUOTAS.**

4 Section 306(e) of the Controlled Substances Act (21
5 U.S.C. 826(e)) is amended in the third sentence by strik-
6 ing “exceeds the aggregate of the quotas of all registrants
7 under this section” and inserting “should be increased to
8 meet the changing medical, scientific, and industrial needs
9 for the controlled substance”.

10 **SEC. 5. TERMINATION OF INTERDISCIPLINARY REVIEW**

11 **PROCESS FOR NON-NIH-FUNDED RESEARCH-**
12 **ERS.**

13 The Secretary of Health and Human Services may
14 not—

15 (1) reinstate the Public Health Service inter-
16 disciplinary review process described in the guidance
17 entitled “Guidance on Procedures for the Provision
18 of Marijuana for Medical Research” (issued on May
19 21, 1999); or

20 (2) create an additional review of scientific pro-
21 tocols that is conducted only for research on mari-
22 juana (as defined in section 102 of the Controlled
23 Substances Act (21 U.S.C. 802), as amended by sec-
24 tion 1(b)) other than the review of research proto-
25 cols performed at the request of a researcher con-

1 ducting nonhuman research that is not federally
2 funded, in accordance with section
3 303(f)(3)(A)(ii)(II) of the Controlled Substances Act
4 (21 U.S.C. 823(f)(3)(A)(ii)(II)), as amended by sec-
5 tion 1(a).