

104<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 2618

To provide for the therapeutic use of marihuana in situations involving life-threatening or sense-threatening illnesses and to provide adequate supplies of marihuana for such use.

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## IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 10, 1995

Mr. FRANK of Massachusetts (for himself, Mr. JOHNSTON of Florida, and Ms. PELOSI) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To provide for the therapeutic use of marihuana in situations involving life-threatening or sense-threatening illnesses and to provide adequate supplies of marihuana for such use.

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. DEFINITIONS.**

4 Section 102(16) of the Controlled Substances Act is  
5 amended by adding at the end thereof the following new  
6 sentence: “Such term also does not include

1 tetrahydrocannabinols not derived, extracted, or prepared  
2 from plant *Cannabis sativa* L.”.

3 **SEC. 2. AUTHORIZING THE MEDICAL PRESCRIPTION OF**  
4 **MARIHUANA.**

5 (a) SCHEDULE I AMENDMENT.—Paragraph (c) of  
6 schedule I of section 202(c) of the Controlled Substances  
7 Act is amended—

8 (1) by striking out subparagraph (10);

9 (2) by redesignating subparagraphs (11)  
10 through (17) as subparagraphs (10) through (16),  
11 respectively; and

12 (3) by amending subparagraph (16) (as so re-  
13 designated) to read as follows:

14 “(16) Tetrahydrocannabinols not derived, man-  
15 ufactured, or prepared from the plant *Cannabis*  
16 *sativa* L.”.

17 (b) SCHEDULE II AMENDMENT.—Paragraph (a) of  
18 schedule II of section 202(c) of the Controlled Substances  
19 Act is amended by adding at the end thereof the following  
20 new subparagraph:

21 “(5) Marihuana.”.

22 **SEC. 3. PRODUCTION AND DISTRIBUTION OF MEDICINAL**  
23 **MARIHUANA.**

24 (a) RULEMAKING.—Section 301 of the Controlled  
25 Substances Act is amended by adding at the end thereof

1 the following: “, except that rules and regulations specifi-  
2 cally relating to the regulation and control of the produc-  
3 tion, distribution, and dispensing of marihuana to sections  
4 312 and 313 shall be promulgated by the Secretary.”.

5 (b) PRODUCTION AND DISTRIBUTION.—Part C of the  
6 Controlled Substances Act is amended by adding at the  
7 end the following:

8 “OFFICE FOR THE SUPPLY OF INTERNATIONALLY  
9 CONTROLLED DRUGS

10 “SEC. 311. (a) There is established in the Depart-  
11 ment of Health and Human Services an office to be known  
12 as the Office for the Supply of Internationally Controlled  
13 Drugs (hereinafter referred to in this section and sections  
14 312 and 313 as the ‘Office’). The Office shall be respon-  
15 sible for regulating, administering, and supervising the do-  
16 mestic production of marihuana and, in accordance with  
17 section 313, for the distribution of marihuana for medical,  
18 scientific, and research purposes.

19 “(b) The Office shall be under the direction of a Chief  
20 Officer who shall be appointed by the Secretary. The Sec-  
21 retary is authorized to delegate his powers and responsibil-  
22 ities under sections 312 and 313 to the Chief Officer.

23 “PRODUCTION OF MEDICINAL MARIHUANA

24 “SEC. 312. (a) The Secretary shall take all necessary  
25 actions to secure and maintain a supply of marihuana ade-  
26 quate for the legitimate medical, research, scientific, and

1 export needs of the United States. The Secretary shall de-  
2 termine the total quantity of marihuana to be produced  
3 each calendar year to provide for the estimated medical,  
4 scientific, and research needs of the United States, for the  
5 establishment of reserve stocks, and for any lawful export  
6 requirements established by the Attorney General under  
7 section 1003. Based on the determination under the pre-  
8 ceding sentence, the Secretary shall recommend to the At-  
9 torney General the aggregate production quotas that must  
10 be established for marihuana under section 306(a). The  
11 recommendations of the Secretary concerning aggregate  
12 production quotas for marihuana shall be binding on the  
13 Attorney General.

14       “(b)(1) In order to maintain an adequate supply of  
15 marihuana, the Secretary shall periodically publish notices  
16 soliciting bids on a contract or contracts for the domestic  
17 cultivation and delivery of marihuana. All bids submitted  
18 must specify the areas in which, and the land on which,  
19 cultivation of marihuana will be conducted. All bids sub-  
20 mitted must be accompanied by an application for reg-  
21 istration under section 302.

22       “(2) The Secretary shall forward a copy of the reg-  
23 istration application to the Attorney General. The Sec-  
24 retary, after consultation with the Attorney General, shall  
25 recommend to the Attorney General that the application

1 for registration be granted or denied, taking into account  
2 the factors set forth in section 303(a). The recommenda-  
3 tions of the Secretary concerning the registration of appli-  
4 cants to produce marihuana shall be binding on the Attor-  
5 ney General.

6       “(3) The Secretary may accept or reject any bid that  
7 is submitted by registered bidders, taking into consider-  
8 ation (A) the factors set forth in section 303(a), and (B)  
9 price. Marihuana may be produced only by accepted bid-  
10 ders, solely on the land specified in the applicants’ bids.  
11 The Secretary shall provide persons whose bids have been  
12 accepted with marihuana seeds capable of germination.  
13 Such seeds shall be obtained by the Secretary from legiti-  
14 mate commercial producers of marihuana or, if this is not  
15 feasible, the National Institute on Drug Abuse, the Attor-  
16 ney General through the Drug Enforcement Administra-  
17 tion, or the Secretary of Agriculture shall provide the Sec-  
18 retary with an adequate supply of seeds capable of germi-  
19 nation.

20       “(c) Upon acceptance of a bid for the production of  
21 marihuana, the Secretary shall establish an individual  
22 quota for the production of marihuana for the bidder and  
23 shall recommend to the Attorney General that this quota  
24 be assigned to the bidder where required under section  
25 306. The recommendations of the Secretary concerning in-

1 individual quotas for the production of marihuana, including  
2 recommendations that such a quota be decreased or in-  
3 creased, shall be binding on the Attorney General.

4       “(d) The Secretary may revoke or suspend the ac-  
5 ceptance of any bid for the production of marihuana prior  
6 to the expiration of the contract executed on the basis of  
7 the bid upon a finding by the Secretary (1) that the bidder  
8 has materially breached the terms of the contract relating  
9 to the maintenance of effective controls against diversion  
10 of marihuana into other than legitimate medical, scientific,  
11 and industrial channels; or (2) that any of the reasons  
12 specified in section 304(a) are applicable. Upon such rev-  
13 ocation or suspension, the Secretary shall recommend to  
14 the Attorney General that the bidder’s registration for the  
15 production of marihuana be revoked or suspended pursu-  
16 ant to section 304 and such recommendations by the Sec-  
17 retary shall be binding on the Attorney General.

18       “(e) Within four months of the end of the harvest  
19 of marihuana grown by registered bidders pursuant to  
20 contract with the Office, the Office or its delegate or dele-  
21 gates shall take physical possession of the marihuana har-  
22 vested.

23       “(f)(1) The Secretary may, at his discretion, periodi-  
24 cally publish notices soliciting bids on a contract or con-  
25 tracts for the physical collection, processing, and shipping

1 of marihuana crops produced under contracts entered into  
2 under subsection (b) or of imported or forfeited stocks de-  
3 scribed in subsections (g) and (h). All bids submitted must  
4 be accompanied by an application for registration under  
5 section 302.

6 “(2) The Secretary shall forward a copy of the reg-  
7 istration application to the Attorney General. The Sec-  
8 retary, after consultation with the Attorney General, shall  
9 recommend to the Attorney General that the application  
10 for registration be granted or denied, taking into account  
11 the factors set forth in section 303(b) and such rec-  
12 ommendations of the Secretary shall be binding on the At-  
13 torney General.

14 “(3) The Secretary may accept or reject any bids sub-  
15 mitted by registered bidders, taking into consideration (A)  
16 the factors set forth in section 303(b); (B) the provisions  
17 in the bid for the processing of raw marihuana into medi-  
18 cally usable forms, including the provisions for the mainte-  
19 nance of controlled amounts of tetrahydrocannabinols in  
20 each dosage unit; and (C) price.

21 “(g) If a supply of marihuana adequate to meet do-  
22 mestic medical, scientific, and research needs is not ob-  
23 tained through contractual arrangements with domestic  
24 registered bidders, the Secretary shall declare that a state  
25 of emergency exists. The declaration by the Secretary of

1 a state of emergency due to inadequate domestic supplies  
2 of marihuana shall have the same effect as a finding by  
3 the Attorney General of an emergency due to inadequate  
4 domestic supplies under section 1002(a)(2)(A). If no ap-  
5 plicants are registered to import marihuana under sections  
6 1007 and 1008 within sixty days of the date of the dec-  
7 laration by the Secretary that a state of emergency exists,  
8 the Secretary shall make arrangements for the direct im-  
9 portation by the Office of a supply of marihuana adequate  
10 for domestic medical, scientific, and research needs.

11 “(h) If, while a state of emergency declared under  
12 subsection (g) exists, the Secretary finds that a supply of  
13 marihuana adequate for domestic medical, scientific, and  
14 research needs cannot be obtained through importation,  
15 then the Secretary may request that the Attorney General  
16 forward to the Office forfeited stocks of marihuana that  
17 are unadulterated with other substances, pursuant to sec-  
18 tion 511(e).

19 “DISTRIBUTION OF MEDICINAL MARIHUANA

20 “SEC. 313. (a) Marihuana shall be distributed only  
21 to hospitals and pharmacies that are—

22 “(1) registered under section 303(f) to dispense  
23 drugs in schedule II of section 202; and

24 “(2) specified by

25 “(A) an eligible physician who plans to use  
26 marihuana in the treatment of the nausea of

1 patients who are undergoing cancer chemo-  
2 therapy or radiology or in the treatment of pa-  
3 tients who have glaucoma, AIDS wasting syn-  
4 drome, or muscle spasms from certain spastic  
5 disorders, including multiple sclerosis, paraple-  
6 gia, and quadriplegia; or

7 “(B) a person who has obtained approval  
8 by the Secretary of an investigational new drug  
9 application under section 505(i) of the Federal  
10 Food, Drug, and Cosmetic Act for research in-  
11 volving the use of marihuana.

12 “(b) In order to be certified as a physician eligible  
13 for purposes of subsection (a)(2)(A), the physician must  
14 file a written application with the Office seeking permis-  
15 sion to use marihuana in his practice. Such an application  
16 shall be approved or denied within thirty days of its receipt  
17 by the Office, or, where possible, within such shorter time  
18 as is deemed essential by the applicant in cases of medical  
19 emergency. If an application is not acted upon within thir-  
20 ty days of its receipt by the Office, it shall be deemed  
21 approved. To be approved an application must affirma-  
22 tively state—

23 “(1) that the applicant is a physician registered  
24 under section 303(f) to dispense controlled drugs in  
25 schedule II of section 202;

1           “(2) the applicant’s registration number;

2           “(3) that the applicant will use the requested  
3           marihuana solely for the treatment of glaucoma,  
4           AIDS wasting syndrome, muscle spasms from cer-  
5           tain spastic disorders, including multiple sclerosis,  
6           paraplegia, and quadriplegia, or the nausea associ-  
7           ated with cancer chemotherapy or radiology;

8           “(4) the name of all pharmacies or hospitals  
9           registered to dispense schedule II drugs that the ap-  
10          pplicant is requesting that supplies of marihuana be  
11          sent to;

12          “(5) that the applicant will inform the Office of  
13          any adverse reactions by his patients to the use of  
14          marihuana; and

15          “(6) that prior to administration of marihuana  
16          to any patient, he will obtain from the patient a  
17          signed consent form stating that informed patient  
18          consent has been obtained.

19 Unless the Secretary determines that an application which  
20 makes the statements required by the preceding sentence  
21 contains a misstatement of fact, the application shall be  
22 approved upon payment of a reasonable fee to cover the  
23 costs of processing the application. Approval of a physi-  
24 cian’s application may be suspended or revoked by the  
25 Secretary for good cause shown.

1       “(c)(1) Upon certification of a physician as eligible  
2 under subsection (b), the Secretary shall issue serially  
3 numbered marihuana order forms to all registered phar-  
4 macies or hospitals listed on the eligible physician’s appli-  
5 cation form. Whenever any such form is issued to a phar-  
6 macy or hospital the Secretary shall, before delivery there-  
7 of, insert therein the name of the pharmacy or hospital,  
8 and it shall be unlawful for any other person (A) to use  
9 such form for the purpose of obtaining controlled sub-  
10 stances; or (B) to furnish such form to any person with  
11 intent thereby to procure the distribution of such sub-  
12 stances.

13       “(2) It shall be unlawful for any person to obtain by  
14 means of order forms issued under this subsection con-  
15 trolled substances for any purpose other than their use,  
16 distribution, dispensing, or administration in the conduct  
17 of a lawful business in such substances or in the course  
18 of his professional practice or research.

19       “(3) Written orders made on marihuana order forms  
20 issued under this subsection shall satisfy the requirements  
21 of section 308(a).

22       “(4) The preservation and availability requirements  
23 of section 308(c) apply to orders made on forms issued  
24 under this subsection.

1       “(d) Hospitals and pharmacies may obtain supplies  
2 of marihuana only by forwarding a written order to the  
3 Secretary on the form issued in blank in accordance with  
4 subsection (c). Upon receipt from a hospital or pharmacy  
5 of a properly completed marihuana order form requesting  
6 a supply of marihuana the Office or its delegate or dele-  
7 gates shall forward a supply of marihuana to the phar-  
8 macy or hospital within a reasonable time. If notified by  
9 an eligible physician that there is a medical urgency for  
10 immediate shipment, the Office or its delegate or delegates  
11 shall forward a supply of marihuana within five days of  
12 such notice, or sooner if feasible. Also, upon receipt by  
13 the Secretary of a written request of a person who has  
14 obtained approval of an investigational new drug applica-  
15 tion under section 505(i) of the Federal Food, Drug, and  
16 Cosmetic Act for research involving the use of marihuana,  
17 the Office or its delegate or delegates shall forward a sup-  
18 ply of marihuana to the specified pharmacy or hospital  
19 licensed to dispense schedule II drugs within a reasonable  
20 time.

21       “(e) The Secretary is directed to set a price for mari-  
22 huana that will recoup, within a reasonable time, all of  
23 the costs incurred by the Federal Government in produc-  
24 ing, processing, and distributing marihuana.

1       “(f) Within six months from the date of the enact-  
2 ment of this section, the Secretary, after consultation with  
3 the Attorney General, shall promulgate regulations con-  
4 sistent with public health and safety that are in accord  
5 with the provisions of this title to ensure an adequate sup-  
6 ply of medically usable marihuana and to ensure proper  
7 safeguards regarding the production, storage, processing,  
8 distribution, and dispensing of marihuana so as to prevent  
9 its diversion into other than legitimate medical, scientific,  
10 or research channels.”.

11       (c) PENALTY.—Section 402(a) of the Controlled Sub-  
12 stances Act is amended (1) by striking out “or” at the  
13 end of paragraph (9), (2) by striking out the period at  
14 the end of paragraph (10) and inserting in lieu thereof  
15 “; or”, and (3) by adding at the end the following new  
16 paragraph:

17               “(11) to use an order form issued under section  
18       313(c) in a manner prohibited by such section or to  
19       furnish such a form in violation of such section.”.

20 **SEC. 4. COMPLIANCE WITH THE FEDERAL FOOD, DRUG,**  
21 **AND COSMETIC ACT.**

22       The Federal Food, Drug, and Cosmetic Act is amend-  
23 ed by inserting after section 505 the following:

24               “THERAPEUTIC USE OF MARIHUANA

25       “SEC. 505A. (a) Notwithstanding section 505(a), the  
26 approval of the Secretary shall not be required for the in-

1 troduction or delivery of marihuana into interstate com-  
2 merce in compliance with the requirements of sections 312  
3 and 313 of the Controlled Substances Act.

4 “(b) Marihuana is defined as a prescription drug for  
5 purposes of section 503(b). Only physicians who are eligi-  
6 ble to obtain marihuana under section 313(b) of the Con-  
7 trolled Substances Act may issue written prescriptions au-  
8 thorizing the dispensing of marihuana under section  
9 503(b).”.

10 **SEC. 5. AUTHORIZATION OF APPROPRIATIONS.**

11 There is authorized to be appropriated not to exceed  
12 \$5,000,000 for the fiscal year 1996, and \$5,000,000 for  
13 the fiscal year 1997, for the use of the Office for the Sup-  
14 ply of Internationally Controlled Drugs in conducting,  
15 contracting for, supervising, and administering the pro-  
16 duction, testing, processing, distribution, and dispensing  
17 of marihuana.

18 **SEC. 6. INTERIM PROVISIONS.**

19 The Secretary of Health and Human Services shall  
20 procure a supply of marihuana adequate for the scientific,  
21 medical, and research needs of the United States within  
22 12 months after the date of the enactment of this Act.  
23 The Secretary of Health and Human Services and the At-  
24 torney General shall ensure that persons now receiving  
25 marihuana pursuant to research projects approved by the

1 Secretary of Health and Human Services continue to re-  
2 ceive uninterrupted supplies until the system for the proc-  
3 essing and distribution of marihuana produced pursuant  
4 to the Controlled Substances Act is fully operational.

