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To amend the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act to provide incentives for the development of drugs for the treatment of addiction to illegal drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 30, 1998

Mr. BIDEN introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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A BILL

To amend the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act to provide incentives for the development of drugs for the treatment of addiction to illegal drugs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''New Medications to Treat Addiction Act of 1998''.

TITLE I—PHARMACOTHERAPY RESEARCH

SEC. 101. REAUTHORIZATION FOR MEDICATION DEVELOPMENT PROGRAM.

Section 464P(e) of the Public Health Service Act (42 U.S.C. 285o–4(e)) is amended to read as follows:

''(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 1999 through 2001 of which the following amount may be appropriated from the Violent Crime Reduction Trust Fund:

''(1) $100,000,000 for fiscal year 2000; and

''(2) $100,000,000 for fiscal year 2001.''.

TITLE II—PATENT PROTECTIONS FOR PHARMACOTHERAPIES

SEC. 201. RECOMMENDATION FOR INVESTIGATION OF DRUGS.

Section 525(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aa(a)) is amended—

(1) in the first sentence, by striking ''States'' and inserting ''States, or for treatment of an addiction to illegal drugs,'';

(2) in the second sentence, by striking ''States'' and inserting ''States, or for treatment of an addiction to illegal drugs''; and

(3) by striking ''such disease or condition'' each place it appears and inserting ''such disease or condition, or treatment of such addiction,''.

SEC. 202. DESIGNATION OF DRUGS.

Section 526(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb(a)) is amended—

(1) in paragraph (1)—

(A) by inserting before the period in the first sentence the following: '', or for treatment of an addiction to illegal drugs'';

(B) in the third sentence, by striking ''rare disease or condition'' and inserting ''rare disease or condition, or for treatment of an addiction to illegal drugs,'';

(C) by striking ''such disease or condition,'' and inserting ''such disease or condition, or treatment of such addiction,''; and

(D) by striking ''such disease or condition.'' and inserting ''such disease or condition, or treatment of such addiction.''; and

(2) in paragraph (2)—

(A) by striking ''(2) For'' and inserting ''(2)(A) For'';

(B) by striking ''(A) affects'' and inserting ''(i) affects'';

(C) by striking ''(B) affects'' and inserting ''(ii) affects''; and

(D) by adding at the end the following:

''(B) For purposes of this subchapter, the term 'treatment of an addiction to illegal drugs' means treatment by any pharmacological agent or medication that—

''(i) reduces the craving for an illegal drug for an individual who—

''(I) habitually uses the illegal drug in a manner that endangers the public health, safety, or welfare; or

''(II) is so addicted to the use of the illegal drug that the individual is not able to control the addiction through the exercise of self-control;

''(ii) blocks the behavioral and physiological effects of an illegal drug for an individual described in clause (i);

''(iii) safely serves as a replacement therapy for the treatment of abuse of an illegal drug for an individual described in clause (i);

''(iv) moderates or eliminates the process of withdrawal from an illegal drug for an individual described in clause (i);

''(v) blocks or reverses the toxic effect of an illegal drug on an individual described in clause (i); or

''(vi) prevents, where possible, the initiation of abuse of an illegal drug in individuals at high risk.

''(C) The term 'illegal drug' means a controlled substance identified under schedules I, II, III, IV, and V in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)).''.

SEC. 203. PROTECTION FOR DRUGS.

Section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

(1) in subsection (a), by striking ''rare disease or condition,'' and inserting ''rare disease or condition, or for treatment of an addiction to illegal drugs,'';

(2) in subsection (b), by striking ''rare disease or condition'' and inserting ''rare disease or condition, or for treatment of an addiction to illegal drugs,'';

(3) by striking ''such disease or condition'' each place it appears and inserting ''such disease or condition, or treatment of such addiction,''; and

(4) in subsection (b)(1), by striking ''the disease or condition'' and inserting ''the disease, condition, or addiction''.

SEC. 204. OPEN PROTOCOLS FOR INVESTIGATIONS OF DRUGS.

Section 528 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360dd) is amended—

(1) by striking ''rare disease or condition'' and inserting ''rare disease or condition, or for treatment of an addiction to illegal drugs,''; and

(2) by striking ''the disease or condition'' each place it appears and inserting ''the disease, condition, or addiction''.

SEC. 205. CONFORMING AMENDMENTS.

(a) SUBCHAPTER HEADING.—The subchapter heading of subchapter B of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aa et seq.) is amended by striking ''CONDITIONS'' and inserting ''CONDITIONS, OR FOR TREATMENT OF AN ADDICTION''.

(b) SECTION HEADINGS.—The section heading of sections 525 through 528 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aa through 360dd) are

amended by striking ''CONDITIONS'' and inserting ''CONDITIONS, OR FOR TREATMENT OF AN ADDICTION''.

(c) FEES.—Section 736(a)(1)(E) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)(1)(E)) is amended—

(1) in the subparagraph heading, by striking ''ORPHAN'';

(2) by striking ''for a rare disease or condition'' each place it appears and inserting ''for a rare disease or condition, or for treatment of an addiction to illegal drugs,''; and

(3) in the first sentence, by striking ''rare disease or condition.'' and inserting ''rare disease or condition, or other than for treatment of an addiction to illegal drugs, respectively.''.

TITLE III—ENCOURAGING PRIVATE SECTOR DEVELOPMENT OF PHARMACOTHERAPIES

SEC. 301. DEVELOPMENT, MANUFACTURE, AND PROCUREMENT OF DRUGS FOR THE TREATMENT OF ADDICTION TO ILLEGAL DRUGS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"Subchapter F—Drugs for Cocaine and Heroin Addictions

"SEC. 571. CRITERIA FOR AN ACCEPTABLE DRUG TREATMENT FOR COCAINE AND HEROIN ADDICTIONS.

''(a) IN GENERAL.—Subject to subsections (b) and (c), the Secretary shall, in cooperation with the Institute of Medicine of the National Academy of Sciences, establish criteria for an acceptable drug for the treatment of an addiction to cocaine and for an acceptable drug for the treatment of an addiction to heroin. The criteria shall be used by the Secretary in making a contract, or entering into a licensing agreement, under section 572.

''(b) REQUIREMENTS.—The criteria established under subsection (a) for a drug shall include requirements—

''(1) that the application to use the drug for the treatment of addiction to cocaine or heroin was filed and approved by the Secretary under this Act after the date of enactment of this section;

''(2) that a performance based test on the drug—

''(A) has been conducted through the use of a randomly selected test group that received the drug as a treatment and a randomly se-

lected control group that received a placebo; and

''(B) has compared the long term differences in the addiction levels of control group participants and test group participants;

''(3) that the performance based test conducted under paragraph (2) demonstrates that the drug is effective through evidence that—

''(A) a significant number of the participants in the test who have an addiction to cocaine or heroin are willing to take the drug for the addiction;

''(B) a significant number of the participants in the test who have an addiction to cocaine or heroin and who were provided the drug for the addiction during the test are willing to continue taking the drug as long as necessary for the treatment of the addiction; and

''(C) a significant number of the participants in the test who were provided the drug for the period of time required for the treatment of the addiction refrained from the use of cocaine or heroin, after the date of the initial administration of the drug on the participants, for a significantly longer period than the aver-

age period of refraining from such use under currently available treatments (as of the date of the application described in paragraph (1)); and

''(4) that the drug shall have a reasonable cost of production.

''(c) REVIEW AND PUBLICATION OF CRITERIA.—The criteria established under subsection (a) shall, prior to the publication and application of such criteria, be submitted for review to the Committee on the Judiciary, and the Committee on Education and the Workplace, of the House of Representatives, and the Committee on the Judiciary, and the Committee on Labor and Human Resources, of the Senate. Not later than 90 days after notifying each of the committees, the Secretary shall publish the criteria in the Federal Register.

''SEC. 572. PURCHASE OF PATENT RIGHTS FOR DRUG DEVELOPMENT.

''(a) APPLICATION.—

''(1) IN GENERAL.—The patent owner of a drug to treat an addiction to cocaine or heroin, may submit an application to the Secretary—

''(A) to enter into a contract with the Secretary to sell to the Secretary the patent rights of the owner relating to the drug; or

''(B) in the case in which the drug is approved under section 505 by the Secretary for more than 1 indication, to enter into an exclusive licensing agreement with the Secretary for the manufacture and distribution of the drug to treat an addiction to cocaine or heroin.

''(2) REQUIREMENTS.—An application described in paragraph (1) shall be submitted at such time and in such manner, and accompanied by such information, as the Secretary may require.

''(b) CONTRACT AND LICENSING AGREEMENTS.—

''(1) REQUIREMENTS.—The Secretary may enter into a contract or a licensing agreement described in subsection (a) with a patent owner who has submitted an application in accordance with subsection (a) if the drug covered under the contract or licensing agreement meets the criteria established by the Secretary under section 551(a).

''(2) SPECIAL RULE.—The Secretary may, under paragraph (1), enter into—

''(A) not more than 1 contract or exclusive licensing agreement relating to a drug for the treatment of an addiction to cocaine; and

"(B) not more than 1 contract or licensing agreement relating to a drug for the treatment of an addiction to heroin.

"(3) COVERAGE.—A contract or licensing agreement described in subparagraph (A) or (B) of paragraph (2) shall cover not more than 1 drug.

"(4) PURCHASE AMOUNT.—Subject to amounts provided in advance in appropriations Acts—

"(A) the amount to be paid to a patent owner who has entered into a contract or licensing agreement under this subsection relating to a drug to treat an addiction to cocaine shall not exceed $100,000,000; and

"(B) the amount to be paid to a patent owner who has entered into a contract or licensing agreement under this subsection relating to a drug to treat an addiction to heroin shall not exceed $50,000,000.

"(c) TRANSFER OF RIGHTS UNDER CONTRACTS AND LICENSING AGREEMENT.—

"(1) CONTRACTS.—A contract under subsection (b)(1) to purchase the patent rights relating to a drug to treat cocaine or heroin addiction shall transfer to the Secretary—

"(A) the exclusive right to make, use, or sell the patented drug within the United States for the term of the patent;

"(B) any foreign patent rights held by the patent owner with respect to the drug;

"(C) any patent rights relating to the process of manufacturing the drug; and

"(D) any trade secret or confidential business information relating to the development of the drug, process for manufacturing the drug, and therapeutic effects of the drug.

"(2) LICENSING AGREEMENTS.—A licensing agreement under subsection (b)(1) to purchase an exclusive license relating to manufacture and distribution of a drug to treat an addiction to cocaine or heroin shall transfer to the Secretary—

"(A) the exclusive right to make, use, or sell the patented drug for the purpose of treating an addiction to cocaine or heroin within the United States for the term of the patent;

"(B) the right to use any patented processes relating to manufacturing the drug; and

"(C) any trade secret or confidential business information relating to the development of the drug, process for manufacturing the drug,

and therapeutic effects of the drug relating to use of the drug to treat an addiction to cocaine or heroin.

"SEC. 573. PLAN FOR MANUFACTURE AND DEVELOPMENT.

''(a) IN GENERAL.—Not later than 90 days after the date on which the Secretary purchases the patent rights of a patent owner, or enters into a licensing agreement with a patent owner, under section 572, relating to a drug under section 571, the Secretary shall develop a plan for the manufacture and distribution of the drug.

''(b) PLAN REQUIREMENTS.—The plan shall set forth—

''(1) procedures for the Secretary to enter into licensing agreements with private entities for the manufacture and the distribution of the drug;

''(2) procedures for making the drug available to nonprofit entities and private entities to use in the treatment of a cocaine or heroin addiction;

''(3) a system to establish the sale price for the drug; and

''(4) policies and procedures with respect to the use of Federal funds by State and local governments or nonprofit entities to purchase the drug from the Secretary.

''(c) APPLICABILITY OF PROCUREMENT AND LICENSING LAWS.—Federal law relating to procurements and licensing agreements by the Federal Government shall be applicable to procurements and licenses covered under the plan described in subsection (a).

''(d) REVIEW OF PLAN.—

''(1) IN GENERAL.—Upon completion of the plan under subsection (a), the Secretary shall notify the Committee on the Judiciary, and the Committee on Education and the Workplace, of the House of Representatives, and the Committee on the Judiciary, and the Committee on Labor and Human Resources, of the Senate, of the development of the plan and publish the plan in the Federal Register. The Secretary shall provide an opportunity for public comment on the plan for a period of not more than 30 days after the date of the publication of the plan in the Federal Register.

''(2) FINAL PLAN.—Not later than 60 days after the date of the expiration of the comment period described in paragraph (1), the Secretary shall publish in the Federal Register a final plan described in subsection (a). The implementation of the plan shall begin on the date of the publication of the final plan.

''(e) CONSTRUCTION.—The development, publication, or implementation of the plan, or any other agency action with respect to the plan, shall not be considered agency action subject to judicial review. No official or court of the United States shall have power or jurisdiction to review the decision of the Secretary on any question of law or fact relating to any agency action with respect to the plan.

''(f) REGULATIONS.—The Secretary may promulgate regulations to carry out this section.

''SEC. 574. AUTHORIZATION OF APPROPRIATIONS.

''There is authorized to be appropriated to carry out this subchapter, such sums as may be necessary in each of the fiscal years 1999 through 2001.''.

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