Public Law 99-91
99th Congress

An Act

To amend the orphan drug provisions of the Federal Food, Drug, and Cosmetic Act and related laws.

Aug. 15, 1985
[S. 1147]

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

Orphan Drug Amendments of 1985, 21 USC 301 note.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Orphan Drug Amendments of 1985".

SEC. 2. MARKET PROTECTION.

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

(1) by striking out "and for which a United States Letter of Patent may not be issued" in subsection (a);

(2) by striking out "and if a United States Letter of Patent may not be issued for the drug" in subsection (b); and

(3) by striking out "UNPATENTED" in the title of the section.

SEC. 3. ANTIBIOTIC DRUGS.

(a) DESIGNATION.—

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

(A) by striking out "or" at the end of paragraph (1), by redesignating paragraph (2) as paragraph (3), and by inserting after paragraph (1) the following:

"(2) if the drug is an antibiotic, it may be certified for such disease or condition under section 507, or";

(B) by striking out "before" in paragraph (3) (as so redesignated);

(C) by inserting after "505" in the last sentence a comma and the following: "certification of such drug for such disease or condition under section 507,"; and

(D) by striking out "licensing under section 351 of the Public Health Service Act for such disease or condition" and inserting in lieu thereof "licensing of such drug for such disease or condition under section 351 of the Public Health Service Act".

(2) Section 526(a)(1) of such Act (21 U.S.C. 360bb(a)(1)) is amended—

(A) by striking out "or" at the end of subparagraph (A) and by striking out subparagraph (B) and inserting in lieu thereof the following:

"(B) if a certification for such drug is issued under section 507, or

"(C) if a license for such drug is issued under section 351 of the Public Health Service Act,"; and

(B) by striking out "the approval or license" and inserting in lieu thereof "the approval, certification, or license".

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(3) Section 527 of such Act (21 U.S.C. 360cc) is amended—

(A) by striking out "or" at the end of paragraph (1) in subsection (a), by redesignating paragraph (2) as paragraph (3), and by inserting after paragraph (1) the following: "(2) issues a certification under section 507, or";

(B) by inserting after "505" in the first sentence of subsection (a) a comma and the following: "issue another certification under section 507,";

(C) by inserting after "holder of such approved application" in subsection (a) a comma and the following: "of such certification,";

(D) by inserting after "approval of the approved application" in subsection (a) a comma and the following: "the issuance of the certification,";

(E) by striking out "or a license" in subsection (b) and inserting in lieu thereof a comma and the following: "if a certification is issued under section 507 for such a drug, or if a license";

(F) by inserting after "application approval" in subsection (b) a comma and the following: "of the issuance of the certification under section 507,";

(G) by striking out ", if the drug is a biological product," in subsection (b);

(H) by inserting after "under section 505" in subsection (b) a comma and the following: "issue another certification under section 507,";

(I) by inserting after "holder of such approved application" in subsection (b) a comma and the following: "of such certification,";

(J) by inserting after "application" in subsection (b)(1) a comma and the following: "of the certification,"; and

(K) by inserting after "other applications" in subsection (b)(2) a comma and the following: "issuance of other certifications,".

42 USC 236 note.

SEC. 4. NATIONAL COMMISSION ON ORPHAN DISEASES.

(a) ESTABLISHMENT.—There is established the National Commission on Orphan Diseases (hereinafter referred to as the "Commission").

(b) DUTY.—The Commission shall assess the activities of the National Institutes of Health, the Alcohol, Drug Abuse, and Mental Health Administration, the Food and Drug Administration, other public agencies, and private entities in connection with—

Research and development.

(1) basic research conducted on rare diseases;

(2) the use in research on rare diseases of knowledge developed in other research;

(3) applied and clinical research on the prevention, diagnosis, and treatment of rare diseases; and

(4) the dissemination to the public, health care professionals, researchers, and drug and medical device manufacturers of knowledge developed in research on rare diseases and other diseases which can be used in the prevention, diagnosis, and treatment of rare diseases.

(c) REVIEW REQUIREMENTS.—In assessing the activities of the National Institutes of Health, the Alcohol, Drug Abuse, and Mental Health Administration, and the Food and Drug Administration in connection with research on rare diseases, the Commission shall review—

(1) the appropriateness of the priorities currently placed on research on rare diseases;

Grants. Contracts.

(2) the relative effectiveness of grants and contracts when used to fund research on rare diseases;

Research and development.

(3) the appropriateness of specific requirements applicable to applications for funds for research on rare diseases taking into consideration the reasonable capacity of applicants to meet such requirements;

(4) the adequacy of the scientific basis for such research, including the adequacy of the research facilities and research resources used in such research and the appropriateness of the scientific training of the personnel engaged in such research;

(5) the effectiveness of activities undertaken to encourage such research;

(6) the organization of the peer review process applicable to applications for funds for such research to determine if the organization of the peer review process could be revised to improve the effectiveness of the review provided to proposals for research on rare diseases;

(7) the effectiveness of the coordination between the national research institutes of the National Institutes of Health, the institutes of the Alcohol, Drug Abuse, and Mental Health Administration, the Food and Drug Administration, and private entities in supporting such research; and

(8) the effectiveness of activities undertaken to assure that knowledge developed in research on nonrare diseases is, when appropriate, used in research on rare diseases.

(d) COMPOSITION.—The Commission shall be composed of twenty members appointed by the Secretary of Health and Human Services as follows:

(1) Ten members shall be appointed from individuals who are not officers or employees of the Government and who by virtue of their training or experience in research on rare diseases or in the treatment of rare diseases are qualified to serve on the Commission.

(2) Five members shall be appointed from individuals who are not officers or employees of the Government and who have a rare disease or are employed to represent or are members of an organization concerned about rare disease.

(3) Four nonvoting members shall be appointed from—

(A) the directors of the national research institutes of the National Institutes of Health; or

(B) the directors of the institutes of the Alcohol, Drug Abuse, and Mental Health Administration,

which the Secretary determines are involved with rare diseases.

(4) One nonvoting member shall be appointed from officers or employees of the Food and Drug Administration who the Secretary determines are involved with rare diseases.

A vacancy in the Commission shall be filled in the manner in which the original appointment was made. If any member of the Commission who was appointed to the Commission as a director of a national research institute or an institute of the Alcohol, Drug Abuse, and Mental Health Administration or as an officer or employee of the Food and Drug Administration leaves that office or position, or if any member of the Commission who was appointed from persons who are not officers or employees of the Government becomes an officer or employee of the Government, such member may continue as a member of the Commission for not longer than the ninety-day period beginning on the date such member leaves that office or position or becomes such an officer or employee, as the case may be.

(e) TERM.—Members shall be appointed for the life of the Commission.

(f) COMPENSATION.—

(1) Except as provided in paragraph (2), members of the Commission shall each be entitled to receive compensation at a rate not to exceed the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties as members of the Commission.

5 USC 5332.

(2) Members of the Commission who are full-time officers or employees of the Government shall receive no additional pay by reason of their service on the Commission.

(g) CHAIRMAN.—The Chairman of the Commission shall be designated by the members of the Commission.

(h) STAFF.—Subject to such rules as may be prescribed by the Commission, the Commission may appoint and fix the pay of such personnel as it determines are necessary to enable the Commission to carry out its functions. Personnel shall be appointed subject to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid in accordance with the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

5 USC 5101 *et seq.*, 5331.

(i) EXPERTS AND CONSULTANTS.—Subject to such rules as may be prescribed by the Commission, the Commission may procure temporary and intermittent services under section 3109(b) of title 5 of the United States Code, but at rates for individuals not to exceed the daily equivalent of the basic pay payable for grade GS-15 of the General Schedule.

Government organization and employees.

(j) DETAIL OF PERSONNEL.—Upon request of the Commission, the head of any Federal agency is authorized to detail, on a reimbursable basis, any of the personnel of such agency to the Commission to assist the Commission in carrying out its functions.

(k) ADMINISTRATIVE SUPPORT SERVICES.—The Administrator of General Services shall provide to the Commission on a reimbursable basis such administrative support services as the Commission may request.

(l) GENERAL AUTHORITY.—The Commission may, for the purpose of carrying out this section, hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence, as the Commission considers appropriate.

(m) INFORMATION.—The Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out this section. Upon request of the Chairman, the head of such department or agency shall furnish such information to the Commission.

(n) REPORT.—The Commission shall transmit to the Secretary and to each House of the Congress a report not later than September 30, 1987, on the activities of the Commission. The report shall contain a detailed statement of the findings and conclusions of the Commission, together with its recommendations for—

(1) a long range plan for the use of public and private resources to improve research into rare diseases and to assist in the prevention, diagnosis, and treatment of rare diseases; and

(2) such legislation or administrative actions as it considers appropriate.

(o) TERMINATION.—The Commission shall terminate 90 days after the date of the submittal of its report under subsection (n).

(p) FUNDS.—The Director of the National Institutes of Health shall make available $1,000,000 to the Commission from appropriations for fiscal year 1986 for the National Institutes of Health.

SEC. 5. FINANCIAL ASSISTANCE.

(a) QUALIFIED TESTING.—Section 5 of the Orphan Drug Act (21 U.S.C. 360ee) is amended—

(1) in subsection (a) by striking out "clinical"; and

(2) by amending subsection (b)(1) to read as follows:

"(1) The term 'qualified testing' means—

"(A) human clinical testing—

"(i) which is carried out under an exemption for a drug for a rare disease or condition under section 505(i) of the Federal Food, Drug, and Cosmetic Act (or regulations issued under such section); and 21 USC 355.

"(ii) which occurs after the date such drug is designated under section 526 of such Act and before the date on which an application with respect to such drug is submitted under section 505(b) or 507 of such Act or under section 351 of the Public Health Service Act; and 21 USC 360bb. 21 USC 357. 42 USC 262.

"(B) preclinical testing involving a drug for a rare disease or condition which occurs after the date such drug is designated under section 526 of such Act and before the date on which an application with respect to such drug is submitted under section 505(b) or 507 of such Act or under section 351 of the Public Health Service Act.".

(b) AUTHORIZATION.—Subsection (c) of such section 5 is amended to read as follows: 21 USC 360ee.

"(c) For grants and contracts under subsection (a) there are authorized to be appropriated $4,000,000 for fiscal year 1986, $4,000,000 for fiscal year 1987, and $4,000,000 for fiscal year 1988.".

SEC. 6. TECHNICAL CORRECTIONS.

(a) PUBLIC LAW 98-619.—The paragraph following the heading "EDUCATION FOR THE HANDICAPPED" under title III of the Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriation Act, 1985 (Public Law 98-619) is amended— 98 Stat. 3324.

(1) by inserting after "shall" the first time it appears a comma and the following: "except for part D of such Act,", and

(2) by adding at the end thereof the following: "The amounts available for such part D shall be available for obligation on October 1, 1984, and shall remain available until September 30, 1985.".

(b) PUBLIC LAW 98-527.—Section 122(b)(4)(C) of the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6022(b)(4)(C)) is amended to read as follows: 98 Stat. 2670.

"(C) Notwithstanding subparagraph (E)(i), upon application of a State, which under section 133(b)(4)(C) of this Act (as in effect on October 18, 1984) was permitted to make expenditures for services without regard to the requirements of section 133(b)(4)(B) of this Act (as so in effect) the Secretary, pursuant to regulations which the Secretary shall prescribe, may permit a portion of the funds which, pursuant to subparagraph (E)(i), must otherwise be expended under 42 USC 6063.

the State plan of such State for service activities in the priority services, to be expended in fiscal years 1985, 1986, and 1987 for the additional services for which expenditure was permitted under section 133(b)(4)(C) (as so in effect) if the Secretary determines that—

42 USC 6063.

"(i) such additional services are not priority services;

"(ii) such additional services are not services for which funds are otherwise available under part C, D, or E; and

98 Stat. 2679.
42 USC 6041, 6061, 6081.

"(iii) the expenditures of such State on service activities in the priority services has reasonably met the need for those services in such State in comparison to the extent to which the need for such additional services has been met in such State.".

SEC. 7. AREA HEALTH EDUCATION CENTERS.

42 USC 295g-l.

Section 781(a)(2) of the Public Health Service Act (42 U.S.C. 295g-7(a)(2)) is amended by redesignating subparagraphs (A), (B), and (C) as clauses (i), (ii), and (iii), respectively, and by striking out all that precedes clause (i) (as so redesignated) and inserting in lieu thereof the following:

Contracts.
Schools and colleges.

"(2)(A) The Secretary shall enter into contracts with schools of medicine and osteopathy—

"(i) which have previously received Federal financial assistance for an area health education center program under section 802 of the Health Professionals Educational Assistance Act of 1976 in fiscal year 1979 or under paragraph (1), or

42 USC 295g-l note.

"(ii) which are receiving assistance under paragraph (1),

to carry out projects described in subparagraph (B) through area health education centers for which Federal financial assistance was provided under paragraph (1) and which are no longer eligible to receive such assistance.

"(B) Projects for which assistance may be provided under subparagraph (A) are—".

21 USC 360aa note.

SEC. 8. EFFECTIVE DATE.

(a) GENERAL RULE.—Except as provided in subsection (b), this Act and the amendments made by this Act shall take effect October 1, 1985.

(b) EXCEPTION.—The amendments made by sections 2, 3, and 6(a) shall take effect on the date of the enactment of this Act. The amendment made by section 6(b) shall take effect October 19, 1984. The amendments made by section 7 shall take effect October 1, 1984 and shall cease to be in effect after September 30, 1985.

Approved August 15, 1985.

LEGISLATIVE HISTORY—S. 1147 (H.R. 2290):

HOUSE REPORT No. 99-153 accompanying H.R. 2290 (Comm. on Energy and Commerce).

CONGRESSIONAL RECORD, Vol. 131 (1985):

May 23, considered and passed Senate.

June 17, 18, H.R. 2290 considered and passed House; S. 1147, amended, passed in lieu.

July 25, Senate concurred in House amendment with amendments.

July 31, House concurred in Senate amendments.