

Public Law 97-414
97th Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act to facilitate the development of drugs for rare diseases and conditions, and for other purposes.

Jan. 4, 1983

[H.R. 5238]

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

Orphan Drug Act.

SHORT TITLE; FINDINGS

SECTION 1. (a) This Act may be cited as the "Orphan Drug Act".
 (b) The Congress finds that—

21 USC 301 note.
 21 USC 360aa note.

(1) there are many diseases and conditions, such as Huntington's disease, myoclonus, ALS (Lou Gehrig's disease), Tourette syndrome, and muscular dystrophy which affect such small numbers of individuals residing in the United States that the diseases and conditions are considered rare in the United States;

(2) adequate drugs for many of such diseases and conditions have not been developed;

(3) drugs for these diseases and conditions are commonly referred to as "orphan drugs";

(4) because so few individuals are affected by any one rare disease or condition, a pharmaceutical company which develops an orphan drug may reasonably expect the drug to generate relatively small sales in comparison to the cost of developing the drug and consequently to incur a financial loss;

(5) there is reason to believe that some promising orphan drugs will not be developed unless changes are made in the applicable Federal laws to reduce the costs of developing such drugs and to provide financial incentives to develop such drugs; and

(6) it is in the public interest to provide such changes and incentives for the development of orphan drugs.

AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

SEC. 2. (a) Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end the following:

"SUBCHAPTER B—DRUGS FOR RARE DISEASES OR CONDITIONS

"RECOMMENDATIONS FOR INVESTIGATIONS OF DRUGS FOR RARE DISEASES OR CONDITIONS

"SEC. 525. (a) The sponsor of a drug for a disease or condition which is rare in the States may request the Secretary to provide written recommendations for the non-clinical and clinical investigations which must be conducted with the drug before—

21 USC 360aa.

"(1) it may be approved for such disease or condition under section 505, or

21 USC 355.

"(2) if the drug is a biological product, before it may be licensed for such disease or condition under section 351 of the Public Health Service Act.

42 USC 262.

If the Secretary has reason to believe that a drug for which a request is made under this section is a drug for a disease or condition which is rare in the States, the Secretary shall provide the person making the request written recommendations for the non-clinical and clinical investigations which the Secretary believes, on the basis of information available to the Secretary at the time of the request under this section, would be necessary for approval of such drug for such disease or condition under section 505 or licensing under section 351 of the Public Health Service Act for such disease or condition.

21 USC 355.

"(b) The Secretary shall by regulation promulgate procedures for the implementation of subsection (a).

"DESIGNATION OF DRUGS FOR RARE DISEASES OR CONDITIONS

21 USC 360bb.

"SEC. 526. (a)(1) The manufacturer or the sponsor of a drug may request the Secretary to designate the drug as a drug for a rare disease or condition. If the Secretary finds that a drug for which a request is submitted under this subsection is being or will be investigated for a rare disease or condition and—

"(A) if an application for such drug is approved under section 505, or

"(B) if the drug is a biological product, a license is issued under section 351 of the Public Health Service Act, the approval or license would be for use for such disease or condition, the Secretary shall designate the drug as a drug for such disease or condition. A request for a designation of a drug under this subsection shall contain the consent of the applicant to notice being given by the Secretary under subsection (b) respecting the designation of the drug.

"Rare disease or condition."

"(2) For purposes of paragraph (1), the term 'rare disease or condition' means any disease or condition which occurs so infrequently in the United States that there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug. Determinations under the preceding sentence with respect to any drug shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug under this subsection is made.

Notice.

"(b) Notice respecting the designation of a drug under subsection (a) shall be made available to the public.

"(c) The Secretary shall by regulation promulgate procedures for the implementation of subsection (a).

"PROTECTION FOR UNPATENTED DRUGS FOR RARE DISEASES OR CONDITIONS

21 USC 360cc.

"SEC. 527. (a) Except as provided in subsection (b), if the Secretary—

"(1) approves an application filed pursuant to section 505(b), or

"(2) issues a license under section 351 of the Public Health Service Act

for a drug designated under section 526 for a rare disease or condition and for which a United States Letter of Patent may not be issued, the Secretary may not approve another application under section 505(b) or issue another license under section 351 of the Public Health Service Act for such drug for such disease or condition for a person who is not the holder of such approved application or of such license until the expiration of seven years from the date of the approval of the approved application or the issuance of the license. Section 505(c)(2) does not apply to the refusal to approve an application under the preceding sentence.

Ante, p. 2050.

21 USC 355.

42 USC 262.

"(b) If an application filed pursuant to section 505(b) is approved for a drug designated under section 526 for a rare disease or condition or a license is issued under section 351 of the Public Health Service Act for such a drug and if a United States Letter of Patent may not be issued for the drug, the Secretary may, during the seven-year period beginning on the date of the application approval or of the issuance of the license, approve another application under section 505(b), or, if the drug is a biological product, issue a license under section 351 of the Public Health Service Act, for such drug for such disease or condition for a person who is not the holder of such approved application or of such license if—

"(1) The Secretary finds, after providing the holder notice and opportunity for the submission of views, that in such period the holder of the approved application or of the license cannot assure the availability of sufficient quantities of the drug to meet the needs of persons with the disease or condition for which the drug was designated; or

"(2) such holder provides the Secretary in writing the consent of such holder for the approval of other applications or the issuance of other licenses before the expiration of such seven-year period.

"OPEN PROTOCOLS FOR INVESTIGATIONS OF DRUGS FOR RARE DISEASES OR CONDITIONS

"SEC. 528. If a drug is designated under section 526 as a drug for a rare disease or condition and if notice of a claimed exemption under section 505(i) or regulations issued thereunder is filed for such drug, the Secretary shall encourage the sponsor of such drug to design protocols for clinical investigations of the drug which may be conducted under the exemption to permit the addition to the investigations of persons with the disease or condition who need the drug to treat the disease or condition and who cannot be satisfactorily treated by available alternative drugs."

21 USC 360dd.

(b) Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting before section 501 the following:

"SUBCHAPTER A—DRUGS AND DEVICES."

ORPHAN PRODUCTS BOARD

SEC. 3. Title II of the Public Health Service Act is amended by adding at the end the following:

"ORPHAN PRODUCTS BOARD

Establishment.
42 USC 236.

"SEC. 227. (a) There is established in the Department of Health and Human Services a board for the development of drugs (including biologics) and devices (including diagnostic products) for rare diseases or conditions to be known as the Orphan Products Board. The Board shall be comprised of the Assistant Secretary for Health of the Department of Health and Human Services and representatives, selected by the Secretary, of the Food and Drug Administration, the National Institutes of Health, the Centers for Disease Control, and any other Federal department or agency which the Secretary determines has activities relating to drugs and devices for rare diseases or conditions. The Assistant Secretary for Health shall chair the Board.

"(b) The function of the Board shall be to promote the development of drugs and devices for rare diseases or conditions and the coordination among Federal, other public, and private agencies in carrying out their respective functions relating to the development of such articles for such diseases or conditions.

"(c) In the case of drugs for rare diseases or conditions the Board shall—

"(1) evaluate—

"(A) the effect of subchapter B of the Federal Food, Drug, and Cosmetic Act on the development of such drugs, and

"(B) the implementation of such subchapter;

"(2) evaluate the activities of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration for the development of drugs for such diseases or conditions,

"(3) assure appropriate coordination among the Food and Drug Administration, the National Institutes of Health, the Alcohol, Drug Abuse, and Mental Health Administration, and the Centers for Disease Control in the carrying out of their respective functions relating to the development of drugs for such diseases or conditions to assure that the activities of each agency are complementary,

"(4) assure appropriate coordination among all interested Federal agencies, manufacturers, and organizations representing patients, in their activities relating to such drugs,

"(5) with the consent of the sponsor of a drug for a rare disease or condition exempt under section 505(i) of the Federal Food, Drug, and Cosmetic Act or regulations issued under such section, inform physicians and the public respecting the availability of such drug for such disease or condition and inform physicians and the public respecting the availability of drugs approved under section 505(c) of such Act or licensed under section 351 of this Act for rare diseases or conditions,

"(6) seek business entities and others to undertake the sponsorship of drugs for rare diseases or conditions, seek investigators to facilitate the development of such drugs, and seek business entities to participate in the distribution of such drugs, and

"(7) recognize the efforts of public and private entities and individuals in seeking the development of drugs for rare diseases or conditions and in developing such drugs.

"(d) The Board shall consult with interested persons respecting the activities of the Board under this section and as part of such

Ante, p. 2049.

21 USC 355.

42 USC 262.

consultation shall provide the opportunity for the submission of oral views.

"(e) The Board shall submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives an annual report—

Report to congressional committees.

"(1) identifying the drugs which have been designated under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition,

"(2) describing the activities of the Board, and

"(3) containing the results of the evaluations carried out by the Board.

The Director of the National Institutes of Health and the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration shall submit to the Board for inclusion in the annual report a report on the rare disease and condition research activities of the Institutes of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration; the Secretary of the Treasury shall submit to the Board for inclusion in the annual report a report on the use of the credit against tax provided by section 44H of the Internal Revenue Code of 1954; and the Secretary of Health and Human Services shall submit to the Board for inclusion in the annual report a report on the program of assistance under section 5 of the Orphan Drug Act for the development of drugs for rare diseases and conditions. Each annual report shall be submitted by June 1 of each year for the preceding calendar year."

Infra.

Post, p. 2056

TAX CREDIT FOR TESTING EXPENSES FOR DRUGS FOR RARE DISEASES OR CONDITIONS

SEC. 4. (a) Subpart A of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1954 (relating to credits allowable) is amended by inserting after section 44G the following new section:

"SEC. 44H. CLINICAL TESTING EXPENSES FOR CERTAIN DRUGS FOR RARE DISEASES OR CONDITIONS.

26 USC 44H.

"(a) GENERAL RULE.—There shall be allowed as a credit against the tax imposed by this chapter for the taxable year an amount equal to 50 percent of the qualified clinical testing expenses for the taxable year.

"(b) QUALIFIED CLINICAL TESTING EXPENSES.—For purposes of this section—

"(1) QUALIFIED CLINICAL TESTING EXPENSES.—

"(A) IN GENERAL.—Except as otherwise provided in this paragraph, the term 'qualified clinical testing expenses' means the amounts which are paid or incurred by the taxpayer during the taxable year which would be described in subsection (b) of section 44F if such subsection were applied with the modifications set forth in subparagraph (B).

"(B) MODIFICATIONS.—For purposes of subparagraph (A), subsection (b) of section 44F shall be applied—

"(i) by substituting 'clinical testing' for 'qualified research' each place it appears in paragraphs (2) and (3) of such subsection, and

"(ii) by substituting '100 percent' for '65 percent' in paragraph (3)(A) of such subsection.

"(C) EXCLUSION FOR AMOUNTS FUNDED BY GRANTS, ETC.—The term 'qualified clinical testing expenses' shall not include any amount to the extent such amount is funded by any grant, contract, or otherwise by another person (or any governmental entity).

"(D) SPECIAL RULE.—For purposes of this paragraph, section 44F shall be deemed to remain in effect for periods after December 31, 1985.

"(2) CLINICAL TESTING.—

"(A) IN GENERAL.—The term 'clinical testing' means any human clinical testing—

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

"(ii) which occurs—

"(I) after the date of such drug is designated under section 526 of such Act, and

"(II) before the date on which an application with respect to such drug is approved under section 505(b) of such Act, and

"(iii) which is conducted by or on behalf of the taxpayer to whom the designation under such section 526 applies.

"(B) TESTING MUST BE RELATED TO USE FOR RARE DISEASE OR CONDITION.—Human clinical testing shall be taken into account under subparagraph (A) only to the extent such testing is related to the use of a drug for the rare disease or condition for which it was designated under section 526 of the Federal Food, Drug, and Cosmetic Act.

"(c) COORDINATION WITH CREDIT FOR INCREASING RESEARCH EXPENDITURES.—

"(1) IN GENERAL.—Except as provided in paragraph (2), any qualified clinical testing expenses for a taxable year to which an election under this section applies shall not be taken into account for purposes of determining the credit allowable under section 44F for such taxable year.

"(2) EXPENSES INCLUDED IN DETERMINING BASE PERIOD RESEARCH EXPENSES.—Any qualified clinical testing expenses for any taxable year which are qualified research expenses (within the meaning of section 44F(b)) shall be taken into account in determining base period research expenses for purposes of applying section 44F to subsequent taxable years.

"(d) DEFINITION AND SPECIAL RULES.—

"(1) RARE DISEASE OR CONDITION.—For purposes of this section, the term 'rare disease or condition' means any disease or condition which occurs so infrequently in the United States that there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug. Determinations under the preceding sentence with respect to any drug shall be made on the basis of the facts and circumstances as of the date such drug is designated under section 526 of the Federal Food, Drug, and Cosmetic Act.

"(2) LIMITATION BASED ON AMOUNT OF TAX.—The credit allowed by this section for any taxable year shall not exceed the amount of the tax imposed by this chapter for the taxable year

21 USC 355.

Ante, p. 2050.

reduced by the sum of the credits allowable under a section of this subpart having a lower number or letter designation than this section, other than the credits allowable by sections 31, 39, and 43. For purposes of the preceding sentence, the term 'tax imposed by this chapter' shall not include any tax treated as not imposed by this chapter under the last sentence of section 53(a).

"(3) SPECIAL LIMITATIONS ON FOREIGN TESTING.—

"(A) IN GENERAL.—No credit shall be allowed under this section with respect to any clinical testing conducted outside the United States unless—

"(i) such testing is conducted outside the United States because there is an insufficient testing population in the United States, and

"(ii) such testing is conducted by a United States person or by any other person who is not related to the taxpayer to whom the designation under section 526 of the Federal Food, Drug, and Cosmetic Act applies.

"(B) SPECIAL LIMITATION FOR CORPORATIONS TO WHICH SECTION 934(b) OR 936 APPLIES.—No credit shall be allowed under this section with respect to any clinical testing conducted by a corporation to which section 934(b) applies or to which an election under section 936 applies.

"(4) CERTAIN RULES MADE APPLICABLE.—Rules similar to the rules of paragraphs (1) and (2) of section 44F(f) shall apply for purposes of this section.

"(5) ELECTION.—This section shall apply to any taxpayer for any taxable year only if such taxpayer elects (at such time and in such manner as the Secretary may by regulations prescribe) to have this section apply for such taxable year.

"(e) TERMINATION.—This section shall not apply to any amount paid or incurred after December 31, 1987."

(b)(1) Section 280C of such Code (relating to denial of deduction for portion of wages for which credit is claimed under section 40 or 44B) is amended by adding at the end thereof the following new subsection:

26 USC 280C.

"(c) CREDIT FOR QUALIFIED CLINICAL TESTING EXPENSES FOR CERTAIN DRUGS.—

"(1) IN GENERAL.—No deduction shall be allowed for that portion of the qualified clinical testing expenses (as defined in section 44H(b)) otherwise allowable as a deduction for the taxable year which is equal to the amount of the credit allowable for the taxable year under section 44H (determined without regard to subsection (d)(2) thereof).

"(2) SIMILAR RULE WHERE TAXPAYER CAPITALIZES RATHER THAN DEDUCTS EXPENSES.—If—

"(A) the amount of the credit allowable for the taxable year under section 44H (determined without regard to subsection (d)(2) thereof), exceeds

"(B) the amount allowable as a deduction for the taxable year for qualified clinical testing expenses (determined without regard to paragraph (1)),
the amount chargeable to capital account for the taxable year for such expenses shall be reduced by the amount of such excess.

"(3) CONTROLLED GROUPS.—In the case of a corporation which is a member of a controlled group of corporations (within the meaning of section 44F(f)(5)) or a trade or business which is

treated as being under common control with other trades or business (within the meaning of section 44F(f)(1)(B)), this subsection shall be applied under rules prescribed by the Secretary similar to the rules applicable under subparagraphs (A) and (B) of section 44F(f)(1)."

(2)(A) The section heading of section 280C of such Code is amended to read as follows:

"SEC. 280C. CERTAIN EXPENSES FOR WHICH CREDITS ARE ALLOWABLE."

(B) The table of sections for part IX of subchapter B of chapter 1 of such Code is amended by striking out the item relating to section 280C and inserting in lieu thereof the following:

"Sec. 280C. Certain expenses for which credits are allowable."

(c)(1) The table of sections for subpart A of part IV of subchapter A of chapter 1 of such Code is amended by inserting after the item relating to section 44G the following new item:

"Sec. 44H. Clinical testing expenses for certain drugs for rare diseases or conditions."

26 USC 6096.

(2) Subsection (b) of section 6096 of such Code is amended by striking out "and 44G" and inserting in lieu thereof "44G, and 44H".

26 USC 44H
note.

(d) The amendments made by this section shall apply to amounts paid or incurred after December 31, 1982, in taxable years ending after such date.

GRANTS AND CONTRACTS FOR DEVELOPMENT OF DRUGS FOR RARE DISEASES AND CONDITIONS

21 USC 360ee.

SEC. 5. (a) The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist in defraying the costs of qualified clinical testing expenses incurred in connection with the development of drugs for rare diseases and conditions.

(b) For purposes of subsection (a):

"Qualified
clinical
testing."

(1) The term "qualified clinical testing" means any human clinical testing—

(A) 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),

(B) which occurs—

Ante, p. 2050.

(i) after the date such drug is designated under section 526 of such Act, and

(ii) before the date on which an application with respect to such drug is submitted under section 505(b) of such Act.

21 USC 355.

"Rare disease or
condition."

(2) The term "rare disease or condition" means any disease or condition which occurs so infrequently in the United States that there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug. Determinations under the preceding sentence with respect to any drug shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug under this subsection is made.

(c) For grants and contracts under subsection (a) there are authorized to be appropriated \$4,000,000 for fiscal year 1983 and for each of the next two fiscal years.

Appropriation
authorization.

HOME HEALTH SERVICES

SEC. 6. (a) Part D of title III of the Public Health Service Act is amended by inserting after subpart II the following new subpart:

"SUBPART III—HOME HEALTH SERVICES

"HOME HEALTH SERVICES

"SEC. 339. (a)(1) For the purpose of encouraging the establishment and initial operation of home health programs to provide home health services in areas in which such services are inadequate or not readily accessible, the Secretary may, in accordance with the provisions of this section, make grants to public and nonprofit private entities and loans to proprietary entities to meet the initial costs of establishing and operating such home health programs. Such grants and loans may include funds to provide training for paraprofessionals (including homemaker home health aides) to provide home health services.

Grants.
42 USC 255.

"(2) In making grants and loans under this subsection, the Secretary shall—

"(A) consider the relative needs of the several States for home health services;

"(B) give preference to areas in which a high percentage of the population proposed to be served is composed of individuals who are elderly, medically indigent, or disabled; and

"(C) give special consideration to areas with inadequate means of transportation to obtain necessary health services.

"(3)(A) No loan may be made to a proprietary entity under this section unless the application of such entity for such loan contains assurances satisfactory to the Secretary that—

"(i) at the time the application is made the entity is fiscally sound;

"(ii) the entity is unable to secure a loan for the project for which the application is submitted from non-Federal lenders at the rate of interest prevailing in the area in which the entity is located; and

"(iii) during the period of the loan, such entity will remain fiscally sound.

"(B) Loans under this section shall be made at an interest rate comparable to the rate of interest prevailing on the date the loan is made with respect to the marketable obligations of the United States of comparable maturities, adjusted to provide for administrative costs.

"(4) Applications for grants and loans under this subsection shall be in such form and contain such information as the Secretary shall prescribe.

"(5) There are authorized to be appropriated for grants and loans under this subsection \$5,000,000 for each of the fiscal years ending on September 30, 1983, and September 30, 1984.

Appropriation
authorization.

"(b)(1) The Secretary may make grants to and enter into contracts with public and private entities to assist them in developing appro-

priate training programs for paraprofessionals (including homemaker home health aides) to provide home health services.

"(2) Any program established with a grant or contract under this subsection to train homemaker home health aides shall—

"(A) extend for at least forty hours, and consist of classroom instruction and at least twenty hours (in the aggregate) of supervised clinical instruction directed toward preparing students to deliver home health services;

"(B) be carried out under appropriate professional supervision and be designed to train students to maintain or enhance the personal care of an individual in his home in a manner which promotes the functional independence of the individual; and

"(C) include training in—

"(i) personal care services designed to assist an individual in the activities of daily living such as bathing, exercising, personal grooming, and getting in and out of bed; and

"(ii) household care services such as maintaining a safe living environment, light housekeeping, and assisting in providing good nutrition (by the purchasing and preparation of food).

"(3) In making grants and entering into contracts under this subsection, special consideration shall be given to entities which establish or will establish programs to provide training for persons fifty years of age and older who wish to become paraprofessionals (including homemaker home health aides) to provide home health services.

"(4) Applications for grants and contracts under this subsection shall be in such form and contain such information as the Secretary shall prescribe.

"(5) There are authorized to be appropriated for grants and contracts under this subsection \$2,000,000 for each of the fiscal years ending September 30, 1983, and September 30, 1984.

"(c) The Secretary shall report to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives on or before January 1, 1984, with respect to—

"(1) the impact of grants made and contracts entered into under subsections (a) and (b) (as such subsections were in effect prior to October 1, 1981);

"(2) the need to continue grants and loans under subsections (a) and (b) (as such subsections are in effect on the day after the date of enactment of the Orphan Drug Act); and

"(3) the extent to which standards have been applied to the training of personnel who provide home health services.

"(d) For purposes of this section, the term 'home health services' has the meaning prescribed for the term by section 1861(m) of the Social Security Act."

(b) The Secretary shall report the results of studies currently evaluating home and community based health services, and any recommendations for legislative action which might improve the provision of such services, to the Congress prior to January 1, 1985.

(c) The Secretary of Health and Human Services shall compile and analyze the results of significant studies carried out by any public or private entity, group, or individual, relating to current and alternative reimbursement methodologies for home health services. The Secretary shall make recommendations with respect to such reimbursement methodologies as they might be applied in health care

Appropriation
authorization.

Report to
congressional
committees.

42 USC 1395x.
Report and
recommendations to
Congress.
42 USC 255 note.
42 USC 255 note.

programs funded in whole or in part by Federal funds, and report such recommendations to the Congress within 180 days after the date of the enactment of this Act.

(d) The Secretary of Health and Human Services, acting through the Inspector General of the Department of Health and Human Services, shall undertake a thorough investigation of—

Investigation.
42 USC 255 note.

(1) the methods available to stem fraud and abuse in the provision of home health services under medicare and medicaid; and

(2) the extent to which such methods are applied in stemming such fraud and abuse.

The Secretary shall report the results of the investigation to the Congress within 18 months after the date of the enactment of this Act.

Report to
Congress.

(e)(1) The Secretary of Health and Human Services shall develop and carry out demonstration projects commencing no later than January 1, 1984, to test—

42 USC 255 note.

(A) methods for identifying patients at risk of institutionalization who could be treated more cost-effectively with home health services and other non-institutional health services; and

(B) alternative reimbursement methodologies for home health agencies in order to determine the most cost-effective and efficient way of providing home health services.

(2) Methods for identifying patients at risk of institutionalization to be tested by the Secretary under paragraph (1)(A) may include, but not be limited to, the identification of hospitalized medicare patients who are candidates for early discharge due to availability of home health services and individuals in the community who could avoid institutionalization with the availability of home health services.

(3) Reimbursement methodologies to be tested by the Secretary under paragraph (1)(B) may include but not be limited to fee schedules, prospective reimbursement, and capitation payments.

(4) The Secretary shall report to Congress his findings with regard to the demonstrations carried out under paragraph (1) no later than January 1, 1985.

Report to
Congress.

(f) For purposes of this section, the term "home health services" has the meaning prescribed for the term by section 1861(m) of the Social Security Act.

"Home health
services."
42 USC 255 note.
42 USC 1395x.

ANALYSIS OF THYROID CANCER; ACTIONS BY SECRETARY

SEC. 7. (a) In carrying out section 301 of the Public Health Service Act, the Secretary of Health and Human Services shall—

42 USC 241 note.
42 USC 241.

(1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine 131;

(2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine 131 that are received by individuals from nuclear bomb fallout;

(3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine 131 that the American people received from the Nevada atmospheric nuclear bomb tests; and

Report to
Congress.

Radioepidemi-
ological tables,
publication.

(4) prepare and transmit to the Congress within one year after the date of enactment of this Act a report with respect to the activities conducted in carrying out paragraphs (1), (2), and (3).

(b)(1) Within one year after the date of enactment of this Act, the Secretary of Health and Human Services shall devise and publish radioepidemiological tables that estimate the likelihood that persons who have or have had any of the radiation related cancers and who have received specific doses prior to the onset of such disease developed cancer as a result of these doses. These tables shall show a probability of causation of developing each radiation related cancer associated with receipt of doses ranging from 1 millirad to 1,000 rads in terms of sex, age at time of exposure, time from exposure to the onset of the cancer in question, and such other categories as the Secretary, after consulting with appropriate scientific experts, determines to be relevant. Each probability of causation shall be calculated and displayed as a single percentage figure.

(2) At the time the Secretary of Health and Human Services publishes the tables pursuant to paragraph (1), such Secretary shall also publish—

(A) for the tables of each radiation related cancer, an evaluation which will assess the credibility, validity, and degree of certainty associated with such tables; and

(B) a compilation of the formulas that yielded the probabilities of causation listed in such tables. Such formulas shall be published in such a manner and together with information necessary to determine the probability of causation of any individual who has or has had a radiation related cancer and has received any given dose.

(3) The tables specified in paragraph (1) and the formulas specified in paragraph (2) shall be devised from the best available data that are most applicable to the United States, and shall be devised in accordance with the best available scientific procedures and expertise. The Secretary of Health and Human Services shall update these tables and formulas every four years, or whenever he deems it necessary to insure that they continue to represent the best available scientific data and expertise.

Update of
tables.

TECHNICAL AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT

SEC. 8. (a) Section 207(a)(1) of such Act (42 U.S.C. 209(a)(1)) is amended by inserting "psychology," after "pharmacy,".

(b) Section 306(1)(2) of such Act (42 U.S.C. 242k(1)(2)) is amended by striking out subparagraph (D) and redesignating subparagraphs (E), (F), and (G) as subparagraphs (D), (E), and (F), respectively.

(c) Section 308(d) of such Act (42 U.S.C. 242m(d)) is amended (1) by inserting "if an establishment or person supplying the information or described in it is identifiable," after "No information", and (2) by striking out "authorized by guidelines in effect under section 306(1)(2) or under regulations of the Secretary" and inserting in lieu thereof "such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose".

(d) The first sentence of section 311(c)(2) of such Act (42 U.S.C. 243(c)(2)) is amended by striking out "forty-five days" and inserting instead "six months".

(e) Section 330(d)(2) of such Act (42 U.S.C. 254c(d)(2)) is amended by inserting before "and the costs" the following: "the costs of repay-

ing loans made by the Farmers Home Administration for buildings.”

(f) Section 337(a) of such Act (42 U.S.C. 254j(a)) is amended by striking out “carrying out this subpart” and inserting in lieu thereof “carrying out this subpart (other than section 338G)”.

(g)(1) Section 338B(e) of the Public Health Service Act (42 U.S.C. 254m–(e)) is amended by inserting before the period the following: “or under section 225 as in effect on September 30, 1977”.

(2) Section 338D(b) of such Act (42 U.S.C. 294w(b)) is amended by striking out “section 338F(b)” and inserting in lieu thereof “section 338E(d)”.

42 USC 254o.

(3) Section 338E(d)(1) of such Act (42 U.S.C. 294x(d)(1)) is amended by striking out “section 338D(c)” and inserting in lieu thereof “section 338D(b)”.

42 USC 254p.

(h) Section 340(g) of the Public Health Service Act (42 U.S.C. 256(g)) is amended (1) by striking out “and” after “1980,” in paragraph (1) and by inserting before the period in that paragraph a comma and “and \$3,000,000 for the fiscal year ending September 30, 1982”, and (2) by inserting “and” after “1980,” in paragraph (2) and by striking out in that paragraph “, and \$3,000,000 for the fiscal year ending September 30, 1982”.

(i) Section 737(2) of such Act (42 U.S.C. 294j(2)) is amended by inserting “in a State” after “means a school”.

(j) Section 781(a)(2) of such Act (42 U.S.C. 295g–1(a)(2)) is amended by striking out “under area health education center programs”.

(k)(1) Section 791A(b)(3)(A) of such Act (42 U.S.C. 295h–1a(b)(3)(A)) is amended by striking out “postbaccalaureate” and inserting in lieu thereof “baccalaureate”.

(2) Section 791(c)(2)(A) of such Act (42 U.S.C. 295h(c)(2)(A)) is amended to read as follows:

“(A) such application contains assurances satisfactory to the Secretary that in the school year (as defined in regulations of the Secretary) beginning in the fiscal year for which the applicant receives a grant under subsection (a) that—

“(i) at least 25 individuals will complete the graduate educational programs of the entity for which such application is submitted; and

“(ii) such entity shall expend or obligate at least \$100,000 in funds from non-Federal sources to conduct such programs; and”.

(l) Section 831(b) of such Act (42 U.S.C. 297–1(b)) is amended by inserting before the period a comma and the following: “\$400,000 for the fiscal year ending September 30, 1983, and \$800,000 for the fiscal year ending September 30, 1984”.

(m) Title VIII of such Act is amended by adding at the end thereof the following:

“TECHNICAL ASSISTANCE

“SEC. 857. Funds appropriated under this title may be used by the Secretary to provide technical assistance in relation to any of the authorities under this title.”

42 USC 298b–4.

(n) Sections 1001(c), 1003(b), and 1005(b) of such Act (42 U.S.C. 300(c), 300a–1(b), 300a–3(b)) are each amended by striking out the comma after “1981” and inserting in lieu thereof a semicolon.

(o) Section 1101(b) of such Act (42 U.S.C. 300b(b)) (as in effect before its repeal by section 2193(b)(1) of the Omnibus Budget Reconciliation Act of 1981) is amended by inserting a comma after “1981”.

95 Stat. 826.

95 Stat. 571.

(p) Section 1536 of such Act (42 U.S.C. 300n-5) (as amended by section 935 of the Omnibus Budget Reconciliation Act of 1981) is amended by striking out "this title and" and inserting in lieu thereof "this title and—".

42 USC 300q-2.

(q) Section 1602(f)(2) of such Act (42 U.S.C. 300g-2(f)(2)) is amended by inserting after "including" the following: "selling real property pledged as security for such a loan or loan guarantee and".

(r)(1) The matter in section 1706(a) (42 U.S.C. 300u-5(a)) of the Public Health Service Act preceding paragraph (1) is amended by striking out "Health Information, Health Promotion and Physical Fitness and Sports Medicine" and inserting instead "Health promotion".

(2) The section heading for section 1706 of such Act (42 U.S.C. 300u-5) is amended to read as follows:

"OFFICE OF HEALTH PROMOTION"

(s) The second sentence of section 1904(a)(1)(F) of such Act (42 U.S.C. 300w-3(a)(1)(F)) is amended by striking out "equipment for the systems" and inserting in lieu thereof "equipment for the systems (other than systems with respect to which grants were made as prescribed by section 1905(c)(2))".

(t) Effective October 1, 1982, section 1912(b) of such Act (42 U.S.C. 300x-1(b)) is amended to read as follows:

42 USC 300x.

"(b)(1) From the remainder of the amount appropriated under section 1911 for any fiscal year, the Secretary shall allot to each State an amount which bears the same ratio to such remainder for that fiscal year as the amounts—

42 USC 241.

"(A) which would have been provided by the Secretary to the State and entities in the State under section 301 of this Act for mental health services demonstrations and under the Community Mental Health Centers Act and the Mental Health Systems Act for mental health services for fiscal year 1981 if the Secretary had obligated all the funds for such purposes available for such Acts under Public Law 96-536, and

"(B) provided by the Secretary to the State and entities in the State under the laws referred to in subparagraphs (D) and (E) of paragraph (2) for fiscal year 1980,

42 USC 2689
note, 9401
note.

bore to the total amount appropriated for mental health services demonstrations and mental health services for fiscal year 1981 under Public Law 96-536 for section 301 of this Act, the Community Mental Health Centers Act and the Mental Health Systems Act and the total amount appropriated for fiscal year 1980 for the provisions of law referred to in subparagraphs (D) and (E) of paragraph (2).

"(2) The provisions of law referred to in paragraph (1) are the following provisions of law as in effect on the day before the date of the enactment of the Omnibus Budget Reconciliation Act of 1981:

"(A) The Community Mental Health Centers Act.

"(B) The Mental Health Systems Act.

42 USC 241.

"(C) Section 301 of this Act.

"(D) Sections 301 and 312 of the Comprehensive Alcohol Abuse and Alcoholism, Prevention, Treatment, and Rehabilitation Act of 1970.

42 USC 4571,
4578.

"(E) Sections 409 and 410 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act.

95 Stat. 595.
21 USC 1176,
1177.

"(3) For purposes of paragraph (1), the total amount appropriated under Public Law 96-536 for mental health services demonstrations

under section 301 of this Act shall be deemed not to exceed \$20,000,000; and if such total amount did exceed \$20,000,000, the amount that would have been provided to each State and entities in each State shall be ratably reduced for purposes of paragraph (1)(A) to conform to the limit prescribed by this paragraph.

“(4) To the extent that all the funds appropriated under section 1911 for a fiscal year and available for allotment in such fiscal year are not otherwise allotted to States because—

“(A) one or more States have not submitted an application or description of activities in accordance with section 1915 for the fiscal year;

42 USC 300x-4.

“(B) one or more States have notified the Secretary that they do not intend to use the full amount of their allotment; or

“(C) some State allotments are offset or repaid under section 1916(b)(3);

42 USC 300x-5.

such excess shall be allotted among each of the remaining States in proportion to the amount otherwise allotted to such States for the fiscal year without regard to this paragraph.”

(u)(1) section 1915(c)(5) of such Act (42 U.S.C. 300x-4(c)(5)) is amended (1) by inserting “procedures for” before “procedural”, and (2) by striking out “review procedures” and inserting in lieu thereof “review”.

(2)(A) Section 1915(c)(6)(A)(i) of such Act (42 U.S.C. 300x-4(c)(6)(A)(i)) is amended—

(i) by striking out “for mental health services”;

(ii) by inserting “for mental health services” after “fiscal year 1981”;

(iii) by inserting “for mental health services demonstrations under section 301 of this Act” before “if the Secretary”; and

(iv) by striking out “such Acts” each place it occurs and inserting in lieu thereof “such provisions of law”.

(B) Section 1915(c)(6)(A)(ii) of such Act (42 U.S.C. 300x-4(c)(6)(A)(ii)) is amended—

(i) by striking out “for mental health services”;

(ii) by inserting “for mental health services” after “fiscal year 1981”;

(iii) by inserting “and for mental health services demonstrations under section 301 of this Act” before “if the Secretary”; and

(iv) by striking out “such Acts” and inserting in lieu thereof “such provisions of law”.

(v) Section 1932 of such Act is amended by—

(1) inserting “(a)” after “1932.”, and

(2) adding a new subsection (b) as follows:

“(b) The Secretary shall promulgate separate regulations governing the administration of this part. Such regulations shall take into account the distinctive features of the grant program authorized under this part.”

95 Stat. 559.

42 USC 300y-11.

Regulations.

(w) From the funds appropriated under section 419B of such Act or under any other applicable provision of law, the Secretary of Health and Human Services shall provide for the development and support of not less than ten comprehensive centers for sickle cell disease.

42 USC 287i

note.

42 USC 287i.

MISCELLANEOUS TECHNICAL AMENDMENTS

95 Stat. 570.
42 USC 300,
300a-1, 300a-3.

95 Stat. 572.
42 USC 300m.

95 Stat. 573.
42 USC 300e-1.

95 Stat. 593.
42 USC 4577.

95 Stat. 593.

95 Stat. 594.
42 USC 4588.

95 Stat. 922.
42 USC 295g-4.

Repeal.
42 USC 300t-11
note.

SEC. 9. (a) Section 931(a) of the Omnibus Budget Reconciliation Act of 1981 is amended by striking out "1980," in paragraphs (1), (2), and (3) and inserting in lieu thereof "1980;"

(b) Section 936(b)(1) of the Omnibus Budget Reconciliation Act of 1981 is amended by striking out "300m(d)(1)(B)(ii)" and inserting in lieu thereof "300m(d)(1)(B)".

(c) Section 942(i) of the Omnibus Budget Reconciliation Act of 1981 is amended by striking out "feasible (1)" and inserting in lieu thereof "feasible (i)".

(d)(1) Section 963(b)(4) of the Omnibus Budget Reconciliation Act of 1981 is amended by striking out "clause (2)" and inserting in lieu thereof "clause (3)".

(2) Section 311(a)(3) of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4577(b)(3)) is amended by striking out the period at the end and inserting in lieu thereof a comma.

(e) Section 965(a) of the Omnibus Budget Reconciliation Act of 1981 is amended by striking out paragraph (A) and by redesignating paragraphs (B), (C), and (D) as paragraphs (1), (2), and (3), respectively.

(f) Section 2741(a)(3) of the Omnibus Budget Reconciliation Act of 1981 is amended by striking out "and 'and'".

(g)(1) Section 709 of the Controlled Substances Act (21 U.S.C. 904) is amended (1) by striking out subsections (a) and (b), (2) by striking out "(c)", and (3) by amending the section heading to read as follows:

"PAYMENT OF TORT CLAIMS".

(2) The item relating to section 709 in the table of contents of the Comprehensive Drug Abuse Prevention and Control Act of 1970 is amended by striking out "Authorizations of Appropriations" and inserting in lieu thereof "Payment of Tort Claims".

(h) Section 302 of the Health Planning and Resources Development Amendments of 1979 (Public Law 96-79) is repealed.

(i) The paragraph beginning with "Service and supply fund:" under the heading "PUBLIC HEALTH SERVICE" in the Federal Security Agency Appropriation Act, 1946 (42 U.S.C. 231) is amended by inserting ", or in advance," after "stock furnished".

(j)(1) Section 6(b)(1) of the Consumer Product Safety Act (15 U.S.C. 2055(b)(1)) is amended by striking out "paragraph (2)" and inserting in lieu thereof "paragraph (4)".

(2) Section 11(c) of such Act (15 U.S.C. 2060(c)) is amended by striking out "section 10(e)(4)" and inserting in lieu thereof "subsection (f)".

(3) Section 15(g)(1) of such Act (15 U.S.C. 2064(g)(1)) is amended by striking out "section 12(c)(1)" and inserting in lieu thereof "12(d)(1)".

(4)(A) Section 19(a)(7) of such Act (15 U.S.C. 2068(a)(7)) is amended by striking out "section 9(d)(2)" and inserting in lieu thereof "section 9(g)(2)".

(B) Paragraph (8) of section 19(a) of such Act is repealed and paragraph (9) and the first of the two paragraphs (10) are redesignated as paragraphs (8) and (9), respectively.

(5) Section 31(b)(1) of such Act (15 U.S.C. 2080(b)(1)) is amended by striking out "The Commission" and all that follows through "Substances Act," and inserting in lieu thereof the following:

“(b)(1) The Commission may not issue—

“(A) an advance notice of proposed rulemaking for a consumer product safety rule,

“(B) a notice of proposed rulemaking for a rule under section 27(e), or

“(C) an advance notice of proposed rulemaking for regulations under section 2(q)(1) of the Federal Hazardous Substances Act.”

15 USC 1261.

(k) Section 3(a) of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1472(a)) is amended by striking out “, after consultation with the Technical Advisory Committee provided for in section 6 of this Act”.

(l) Section 15 of the Federal Hazardous Substances Act (15 U.S.C. 1274) (as amended by section 1211(f)(1) of the Omnibus Budget Reconciliation Act of 1982) is amended by adding at the end thereof the following:

95 Stat. 721.

“(e) For purposes of this section (1) the term ‘manufacturer’ includes an importer for resale, and (2) a dealer who sells at wholesale an article or substance shall with respect to that sale be considered the distributor of that article or substance.”

“Manufacturer.”

(m) Section 1211(h)(4) of the Omnibus Budget Reconciliation Act of 1981 is amended by striking out “by inserting ‘Science and Transportation’ immediately after ‘on Commerce’, and”.

95 Stat. 721.
15 USC 2064.

STUDY

SEC. 10. Of the funds available under section 706 of the Energy Security Act, there shall be made available \$800,000 for the costs of a grant or contract for a study of the water quality of the Quabbin Reservoir in Massachusetts.

42 USC 8905.

PATENT TERM EXTENSION

SEC. 11. (a) Title 35, United States Code, is amended by adding the following new section:

“§ 155. Patent term extension

35 USC 155.

“Notwithstanding the provisions of section 154, the term of a patent which encompasses within its scope a composition of matter or a process for using such composition shall be extended if such composition or process has been subjected to a regulatory review by the Federal Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act leading to the publication of regulation permitting the interstate distribution and sale of such composition or process and for which there has thereafter been a stay of regulation of approval imposed pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act which stay was in effect on January 1, 1981, by a length of time to be measured from the date such stay of regulation of approval was imposed until such proceedings are finally resolved and commercial marketing permitted. The patentee, his heirs, successors or assigns shall notify the Commissioner of Patents and Trademarks within ninety days of the date of enactment of this section or the date the stay of regulation of approval has been removed, whichever is later, of the number of the patent to be extended and the date the stay was imposed and the date commercial marketing was permitted. On receipt of such notice, the Commissioner shall promptly issue to the owner of record

35 USC 154.

21 USC 301.

21 USC 348.

of the patent a certificate of extension, under seal, stating the fact and length of the extension and identifying the composition of matter or process for using such composition to which such extension is applicable. Such certificate shall be recorded in the official file of each patent extended and such certificate shall be considered as part of the original patent, and an appropriate notice shall be published in the Official Gazette of the Patent and Trademark Office."

(b) The analysis for chapter 14 of such title 35 is amended by adding at the end the following:

"155. Patent term extension."

Approved January 4, 1983.

LEGISLATIVE HISTORY—H.R. 5238:

HOUSE REPORT No. 97-840 Pt. I (Comm. on Energy and Commerce).

CONGRESSIONAL RECORD, Vol. 128 (1982):

Sept. 28, considered and passed House.

Oct. 1, considered and passed Senate, amended.

Dec. 14, House concurred in Senate amendment with an amendment.

Dec. 16, Senate concurred in House amendment.

WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 19, No. 1 (1983):

Jan. 4, Presidential statement.