Public Law 99-660
99th Congress

An Act

To require States to develop, establish, and implement State comprehensive mental health plans.

Nov. 14, 1986
[S. 1744]

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

TITLE I—DRUG EXPORTS

Drug Export Amendments Act of 1986.
21 USC 301 note.

SEC. 101. SHORT TITLE, REFERENCE.

(a) SHORT TITLE.—This title may be cited as the "Drug Export Amendments Act of 1986".

(b) REFERENCE.—Whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be a reference to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

21 USC 301.

SEC. 102. EXPORT AUTHORITY.

21 USC 381 *et seq.*

Chapter VIII is amended—

(1) by inserting after the chapter heading the following:

"IMPORTS AND EXPORTS", and

(2) by inserting after section 801 the following:

"EXPORTS OF CERTAIN UNAPPROVED PRODUCTS

"SEC. 802. (a) A drug (including a biological product) intended for human or animal use—

(1) which—

"(A) requires approval by the Secretary under section 505 or section 512, or

"(B) requires licensing by the Secretary under section 351 of the Public Health Service Act or by the Secretary of Agriculture under the Act of March 4, 1913 (known as the Virus Serum Toxin Act),

before it may be introduced or delivered for introduction into interstate commerce to a country, and

"(2) which does not have such approval or license, which is not exempt from such sections or Act, and which is introduced or delivered for introduction into interstate commerce to a country,

is adulterated, misbranded, and in violation of such sections or Act unless the export of the drug is authorized under subsection (b).

"(b)(1) A drug (including a biological product) may, upon approval of an application submitted under paragraph (3), be exported if—

"(A) the drug contains the same active ingredient as a—

"(i) new drug—

Animals.
21 USC 382.
21 USC 355.
21 USC 360b.
Commerce and trade.
42 USC 262.
21 USC 151 note.

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21 USC 355.

"(I) which has an exemption under section 505(i), and

"(II) for which approval is actively being pursued by the person who has the exemption,

"(ii) biological product for human use—

"(I) which has an exemption under section 505(i), and

"(II) for which licensing of the biological product under section 351 of the Public Health Service Act is actively being pursued by the person who has the exemption,

42 USC 262.

"(iii) biological product for animal use—

"(I) for which authority has been granted under the Virus-Serum Toxin Act for the preparation of an experimental drug product, and

21 USC 151 note.

"(II) for which the licensing of the biological product under such Act is actively being pursued by the person who has the authority, or

"(iv) new animal drug—

"(I) which has an exemption under section 512(j), and

21 USC 360b.

"(II) for which approval is actively being pursued by the person who has the exemption,

"(B) except as provided in paragraph (2), the drug is exported to a country which is listed under paragraph (4) and in which the drug is approved and has not been withdrawn from sale,

"(C) an application for the drug under section 505 or 512, section 351 of the Public Health Service Act, or the Virus-Serum Toxin Act has not been disapproved by an order of the Secretary under section 505(d) or 512(d) or 351 of the Public Health Service Act or by the Secretary of Agriculture in the case of an application under the Virus-Serum Toxin Act,

"(D) the drug is manufactured, processed, packaged, and held in conformity with current good manufacturing practice and is not adulterated under paragraph (a)(1), (a)(2)(A), (a)(3), (c), or (d) of section 501,

21 USC 351.

Labeling.

"(E) the outside of the shipping package is labeled with the following statement: 'This drug may be sold or offered for sale only in the following countries: ', the blank space being filled with a list of the countries to which export of the drug is authorized under this subsection,

Safety.

"(F) the drug is not the subject of a notice by the Secretary or the Secretary of Agriculture of a determination that the manufacture of the drug in the United States for export to a country is contrary to the public health and safety of the United States,

"(G) the requirements of subparagraphs (A) through (D) of section 801(d)(1) have been met.

21 USC 381.

The Secretary shall determine that an applicant is actively pursuing the approval or licensing of a drug if the applicant has demonstrated that degree of attention and continuous directed effort as may reasonably be expected from, and are ordinarily exercised by, a person before approval or licensing of a drug, such as the preparation for and the conduct of preclinical or clinical investigations, the analysis of the results of such investigations, conferences on such investigations with government officials, and the preparation of an application of approval or licensing for the drug.

"(2) The Secretary may permit the export of a drug under paragraph (1) to a country which is listed under paragraph (4) and in which the drug is not approved if the drug is exported to such

country solely for the purpose of further export to a country listed in paragraph (4) in which the drug is approved.

"(3)(A) Any person may apply to have a drug exported under paragraph (1). Such an application shall be filed at least 90 days before the date the applicant proposes to export the drug for which the application is submitted. Before the expiration of 10 days from the date of the submission of such an application, the Secretary shall publish a notice in the Federal Register which identifies the applicant under such application, the drug proposed to be exported under such application, and the country to which the drug is proposed to be exported. Federal Register, publication.

"(B) An application for the export of a drug shall—

"(i) identify the drug to be exported,

"(ii) list each country to which the drug is to be exported and list the persons in each such country to which the drug is to be exported,

"(iii) contain a certification by the applicant that—

"(I) the applicant will export the drug only to a country which is listed in paragraph (4) and in which the drug is approved unless the drug is authorized to be exported under paragraph (2) and will export only those quantities of the drug which may reasonably be sold in each country to which it is to be exported,

"(II) the drug is approved by each country to which it is to be exported unless the drug is authorized to be exported under paragraph (2) and the drug has not been withdrawn from sale in such country,

"(III) the drug meets the requirements of paragraph (1)(D),

"(IV) the drug will be labeled in accordance with paragraph (1)(E), and

"(V) the drug meets the requirements of paragraphs (1)(C) and (1)(G),

"(iv) contain a certification by the holder of the exemption or authority for such drug described in paragraph (1)(A) that the holder will actively pursue the approval or licensing of the drug,

"(v) identify the exemption or authority for an experimental drug product in effect for such drug under the laws referred to in paragraph (1)(A),

"(vi) identify the establishments in which the drug is manufactured, and

"(vii) include a written agreement from each importer to whom the drug is to be exported from the United States that such importer will not export the drug to a country which is not listed under paragraph (4) and will provide notice to the applicant of any knowledge of an export of the drug to such a country by any person and will maintain records of the drug wholesale distributors to which the drug is sold. Contracts. Records.

"(C)(i) Before the expiration of 30 days after the date an application is submitted to the Secretary, the Secretary shall review the application to determine if the application meets the requirements of clauses (i), (ii), (iv), (v), (vi), and (vii) of subparagraph (B) and contains the certifications described in clauses (iii) (other than the certification required by clause (iii)(II)) and (iv). If the Secretary determines that the application meets such requirements and contains such certifications the Secretary shall conditionally approve the application. An application which is so conditionally approved

shall be finally approved within 5 days of the submission of the certification required by clause (iii)(II).

"(ii) If the Secretary proposes to disapprove an application, the Secretary shall provide the applicant with a written statement specifying—

"(I) the deficiencies which the applicant must correct in order to enable the Secretary to approve the application, and

"(II) that the applicant has 60 days after receiving the statement to correct such deficiencies.

"(D) If the holder of an application approved under subparagraph (C) for the export of a drug intends to export such drug to a country listed in paragraph (4) which is not listed in such application, such holder shall submit an amendment to such application to the Secretary not later than 30 days before the date of the proposed export to such country identifying the country to which the holder intends to export such drug and containing information sufficient to show that the drug is approved by such country and has not been withdrawn from sale in such country. The Secretary shall approve or disapprove the export of such drug to such country within 15 days of the receipt of the notice required by this subparagraph.

Recipient countries.

"(4)(A) The countries to which a drug may be exported under paragraph (1) are—

"(i) Australia,
"(ii) Austria,
"(iii) Belgium,
"(iv) Canada,
"(v) Denmark,
"(vi) Federal Republic of Germany,
"(vii) Finland,
"(viii) France,
"(ix) Iceland,
"(x) Ireland,
"(xi) Italy,
"(xii) Japan,
"(xiii) Luxembourg,
"(xiv) The Netherlands,
"(xv) New Zealand,
"(xvi) Norway,
"(xvii) Portugal,
"(xviii) Spain,
"(xix) Sweden,
"(xx) Switzerland, and
"(xxi) The United Kingdom,

"(B) Changes in the list contained in subparagraph (A) shall be based on the following criteria:

Safety.

"(i) Statutory or regulatory requirements which require the review of drugs for safety and effectiveness by an entity of the government of such country and which authorize the approval of only those drugs which have been determined to be safe and effective by experts employed by or acting on behalf of such entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs on the basis of adequate and well-controlled investigations, including clinical investigations, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs.

"(ii) Statutory or regulatory requirements that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of drugs in the country are adequate to preserve their identity, quality, purity, and strength.

"(iii) Statutory or regulatory requirements for the reporting of adverse reactions to drugs and procedures to withdraw approval and remove drugs found not to be safe or effective. Safety.

"(iv) Statutory or regulatory requirements that the labeling and promotion of drugs must be in accordance with the approval of the drug. Labeling. Marketing.

"(c)(1) The holder of an approved application under subsection (b) authorizing the export of a drug shall report to the Secretary— Reports.

"(A) any withdrawal of an approval of the drug by any country to which it has been exported,

"(B) any withdrawal of the drug from sale in any such country,

"(C) the withdrawal of an application by the holder under section 505 or 512, section 351 of the Public Health Service Act, or the Virus-Serum Toxin Act, and 21 USC 355, 3606; 42 USC 262.

"(D) the receipt of any credible information indicating that the drug is being or may have been exported from a country listed under subsection (b)(4) to a country which is not listed under such subsection. 21 USC 151 note.

The reporting of an event described in subparagraph (A), (B), or (C) shall be made within 15 days of the occurrence of the event and the reporting of the receipt of information under subparagraph (D) shall be made within 15 days of the receipt of such information. Reports.

"(2) The holder of an approved application under subsection (b) authorizing the export of a drug shall report annually to the Secretary after the date of the approval of the application of the actions taken by the holder in pursuit of the approval of such drug during the year reported on. Not later than 90 days from the date of the receipt of a report under this paragraph the Secretary shall determine if the holder is actively pursuing the approval of such drug. Reports.

"(d) A drug authorized to be exported to a country under an application approved under subsection (b) may not be exported to such country if—

"(1) an approval of such drug is withdrawn by such country,

"(2) the drug is withdrawn from sale in such country,

"(3) the Secretary issues an order refusing to approve an application of the holder of such application under section 505 or 512, section 351 of the Public Health Service Act, or the Virus-Serum Toxin Act, or

"(4) an application for such drug under such section or Act is withdrawn or if an exemption for such drug under section 505(i) or 512(j) or the authority granted for such drug to prepare an experimental drug product under the Virus-Serum Toxin Act is withdrawn and no application for approval of such drug has been submitted under section 505 or 512, section 351 of the Public Health Service Act, or the Virus-Serum Toxin Act.

"(e)(1) If the Secretary determines that—

"(A) a drug for which an application was approved under subsection (b) no longer complies with subparagraphs (A), (D), (E), and (G) of paragraph (1) of such subsection or with paragraph (2) of such subsection or the holder of such application has not made the reports required by subsection (c), or

Safety.

"(B) the manufacture of a drug in the United States for export is contrary to the public health and safety of the United States and an application for the export of such drug has been approved under subsection (b),

then before taking action against the holder of an application for which a determination was made under subparagraph (A) or (B), the Secretary shall notify the holder in writing of the determination and provide the holder 30 days to take such action as may be required so that the Secretary would be unable to make such determination. When the Secretary takes action against such holder because of such a determination, the Secretary shall provide the holder a written statement specifying the reasons for such determination and provide the person, on request, an opportunity for an informal hearing with respect to such determination.

"(2) If the Secretary determines that the approval of a drug is not being actively pursued as required by subsection (b)(1)(A), the Secretary shall give the holder of the application authorizing the export of such drug 60 days to assure that actions are taken to actively pursue such approval. During the 60-day period the Secretary shall give the holder an opportunity for an informal hearing on the determination of the Secretary. If upon the expiration of such 60-day period the Secretary determines that approval of such drug is not being actively pursued, the Secretary shall prohibit the export of such drug.

"(3)(A) If at any time the Secretary, or in the absence of the Secretary the individual acting as the Secretary, determines that—

"(i) the holder of an approved application under subsection (b) is exporting a drug from the United States to an importer,

"(ii) such importer is exporting the drug to a country which is not listed under subsection (b)(4), and

"(iii) such export presents an imminent hazard to the public health in such country,

the Secretary shall immediately prohibit the export of the drug to such importer, give the person exporting the drug from the United States prompt notice of the determination, and afford such person an opportunity for an expedited hearing.

"(B) The authority conferred by subparagraph (A) shall not be delegated by the Secretary. A determination by the Secretary under subparagraph (A) may not be stayed pending final action by a reviewing court.

"(4)(A) If the Secretary, or in the absence of the Secretary the individual acting as the Secretary, determines that the holder of an approved application under subsection (b) is exporting a drug to a country which is not listed under subsection (b)(4) and that the export of the drug presents an imminent hazard, the Secretary shall immediately prohibit the export of the drug to such country, give the holder prompt notice of the determination, and afford the holder an opportunity for an expedited hearing.

"(B) The authority conferred by subparagraph (A) shall not be delegated by the Secretary. A determination by the Secretary under subparagraph (A) may not be stayed pending final action by a reviewing court.

"(5) If the Secretary receives credible evidence that the holder of an application approved under subsection (b) is exporting a drug to a country which is not listed under subsection (b)(4), the Secretary shall give the holder 60 days to provide information to the Secretary respecting such evidence and shall provide the holder an oppor-

tunity for an informal hearing on such evidence. Upon the expiration of such 60 days the Secretary shall prohibit the export of such drug to such country if the Secretary determines that the holder of the application is exporting the drug to a country which is not listed under subsection (b)(4).

"(6) If the Secretary receives credible evidence that an importer is exporting a drug to a country which is not listed under subsection (b)(4), the Secretary shall notify the holder of the application authorizing the export of such drug of such evidence and shall require the holder to investigate the export by such importer and to report to the Secretary within 14 days of the receipt of such notice the findings of the holder. If the Secretary determines that the importer has exported a drug to such a country, the Secretary shall prohibit such holder from exporting such drug to the importer unless the Secretary determines that the export by the importer was unintentional. Reports.

"(f)(1) A drug (including a biological product) which is to be used in the prevention or treatment of a tropical disease may, upon approval of an application submitted under paragraph (2), be exported if—

"(A) the Secretary finds, based on credible scientific evidence, including clinical investigations, that the drug is safe and effective in the country to which it is to be exported in the prevention or treatment of a tropical disease in such country, Safety.

"(B) the drug is manufactured, processed, packaged, and held in conformity with current good manufacturing practice and is not adulterated under paragraph (a)(1), (a)(2)(A), (a)(3), (c), or (d) of section 501, 21 USC 351.

"(C) the outside of the shipping package is labeled with the following statement: 'This drug may be sold or offered for sale only in the following countries: ', the blank space being filled with a list of the countries to which export of the drug is authorized under this subsection, Labeling.

"(D) the drug is not the subject of a notice by the Secretary or the Secretary of Agriculture of a determination that the manufacture of the drug in the United States for export to a country is contrary to the public health and safety of the United States, and Safety.

"(E) the requirements of subparagraphs (A) through (D) of section 801(d)(1) have been met. 21 USC 381.

"(2) Any person may apply to have a drug exported under paragraph (1). The application shall—

"(A) describe the drug to be exported,

"(B) list each country to which the drug is to be exported,

"(C) contain a certification by the applicant that the drug will not be exported to a country for which the Secretary cannot make a finding described in paragraph (1)(A),

"(D) identify the establishments in which the drug is manufactured, and

"(E) demonstrate to the Secretary that the drug meets the requirements of paragraph (1).

"(3) The holder of an approved application for the export of a drug under this subsection shall report to the Secretary— Reports.

"(A) the receipt of any information indicating that the drug is being or may have been exported from a country for which the Secretary made a finding under paragraph (1)(A) to a country for which the Secretary cannot make such a finding, and

"(B) the receipt of any information indicating any adverse reactions to such drug.

"(4)(A) If the Secretary determines that—

"(i) a drug for which an application is approved under paragraph (2) does not continue to meet the requirements of paragraph (1),

"(ii) the holder of such application has not made the report required by paragraph (3), or

"(iii) the manufacture of such drug in the United States for export is contrary to the public health and safety of the United States and an application for the export of such drug has been approved under paragraph (2),

then before taking action against the holder of an application for which a determination was made under clause (i), (ii), or (iii), the Secretary shall notify the holder in writing of the determination and provide the holder 30 days to take such action as may be required so that the Secretary would be unable to make such determination. When the Secretary takes action against such holder because of such a determination, the Secretary shall provide the holder a written statement specifying the reasons for such determination and provide the person, on request, an opportunity for an informal hearing with respect to such determination.

"(B) If at any time the Secretary, or in the absence of the Secretary the individual acting as the Secretary, determines that—

"(i) the holder of an approved application under paragraph (2) is exporting a drug from the United States to an importer,

"(ii) such importer is exporting the drug to a country for which the Secretary cannot make a finding under paragraph (1)(A), and

"(iii) such export presents an imminent hazard to the public health in such country,

the Secretary shall immediately prohibit the export of the drug to such importer, give the person exporting the drug from the United States prompt notice of the determination, and afford such person an opportunity for an expedited hearing. A determination by the Secretary under this subparagraph may not be stayed pending final action by a reviewing court. The authority conferred by this subparagraph shall not be delegated by the Secretary.

"(C) If the Secretary, or in the absence of the Secretary the individual acting as the Secretary, determines that the holder of an approved application under paragraph (2) is exporting a drug to a country for which the Secretary cannot make a finding under paragraph (1)(A), and that the export of the drug presents an imminent hazard, the Secretary shall immediately prohibit the export of the drug to such country, give the holder prompt notice of the determination, and afford the holder an opportunity for an expedited hearing. A determination by the Secretary under this subparagraph may not be stayed pending final action by a reviewing court. The authority conferred by this subparagraph shall not be delegated by the Secretary.

"(D) If the Secretary receives credible evidence that the holder of an application approved under paragraph (2) is exporting a drug to a country for which the Secretary cannot make a finding under paragraph (1)(A), the Secretary shall give the holder 60 days to provide information to the Secretary respecting such evidence and shall provide the holder an opportunity for an informal hearing on such evidence. Upon the expiration of such 60 days the Secretary

shall prohibit the export of such drug to such country if the Secretary determines the holder is exporting the drug to a country for which the Secretary cannot make a finding under paragraph (1)(A).

"(E) If the Secretary receives credible evidence that an importer is exporting a drug to a country for which the Secretary cannot make a finding under paragraph (1)(A), the Secretary shall notify the holder of the application authorizing the export of such drug of such evidence and shall require the holder to investigate the export by such importer and to report to the Secretary within 14 days of the receipt of such notice the findings of the holder. If the Secretary determines that the importer has exported a drug to such a country, the Secretary shall prohibit such holder from exporting such drug to the importer unless the Secretary determines that the export by the importer was unintentional. Reports.

"(g) For purposes of this section—

"(1) a reference to the Secretary shall in the case of a biological product which is required to be licensed under the Virus-Serum Toxin Act be considered to be a reference to the Secretary of Agriculture, and

"(2) a reference in paragraph (3), (4), (5), or (6) of subsection (e) and in subparagraph (B), (C), (D), or (E) of subsection (f)(4) to the holder of an application shall be considered a reference to any person which is under common control with holder, is controlled by the holder, controls the holder, is owned by the holder, or owns the holder.".

SEC. 103. ENFORCEMENT. 21 USC 333 note.

For the fines authorized to be imposed under section 303 of the Federal Food, Drug, and Cosmetic Act, see section 3623 of title 18, United States Code, for the period ending October 31, 1986, and sections 3559 and 3571 of such title for the period beginning November 1, 1986. 21 USC 333.

SEC. 104. TROPICAL DISEASES.

Section 301 of the Public Health Service Act (42 U.S.C. 241) is amended by adding at the end the following:

"(c) The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.". Research and development. Grants. Contracts.

SEC. 105. PARTIALLY PROCESSED BIOLOGICAL PRODUCTS.

(a) AMENDMENT.—Section 351 of the Public Health Service Act (42 U.S.C 262) is amended by adding at the end the following: *Post*, p. 3783.

"(h)(1)(A) A partially processed biological product which is not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man, which is not intended for sale in the United States, and which is intended for further manufacture into final dosage form outside the United States in a country listed under section 802(b)(A) of the Federal Food, Drug, and Cosmetic Act may, upon approval of an application meeting the requirements of subparagraph (B), be exported to a country listed under section 802(b)(4) of the Federal Food, Drug, and Cosmetic Act. The Secretary may not approve an application to export such a product unless the Secretary determines that the product is manufactured, processed, packaged, and held in conformity with current good manufacturing practice and the outside of the shipping package is labeled with the Labeling. *Ante*, p. 3743.

following statement: 'This product may be sold or offered for sale only in the following countries: ', the blank space being filled with a list of the countries to which export of the drug is authorized.

"(B) An application for the export of a partially processed biological product shall—

"(i) describe the partially processed biological product to be exported,

"(ii) list each country to which the product is to be exported,

"(iii) contain a certification by the applicant that the product will not be exported to a country not listed under clause (ii),

"(iv) identify the establishments in which the product is manufactured, and

"(v) contain a certification by the applicant that the final product to be developed from the partially processed product is approved in the country to which it is to be exported or approval of the final product is being sought in such country.

"(2) A product described in paragraph (1) is not subject to licensure under this section.

"(3) If the Secretary determines that prohibiting the export of a product described in paragraph (1) is necessary for protection of the public health in the United States or the country to which it is to be exported, the Secretary may not approve an application under paragraph (1) for the export of such product.".

42 USC 262 note.

(b) EFFECTIVE DATE.—Paragraph (1) of section 351(h) of the Public Health Service Act as added by subsection (a) shall take effect upon the expiration of 90 days after the date of the enactment of this Act.

TITLE II—NATIONAL COMMISSION TO PREVENT INFANT MORTALITY

National Commission to Prevent Infant Mortality Act of 1986.

42 USC 289g note.

SEC. 201. SHORT TITLE.

This title may be cited as the "National Commission to Prevent Infant Mortality Act of 1986".

42 USC 289g note.

SEC. 202. DEFINITION.

For the purposes of this title, the term "infant mortality" refers to the number of infants born alive but who die before their first birthday.

42 USC 289g note.

SEC. 203. ESTABLISHMENT OF A NATIONAL COMMISSION.

(a) ESTABLISHMENT.—There is established the National Commission to Prevent Infant Mortality (hereinafter referred to as the "Commission").

(b) COMPOSITION.—The Commission shall be composed of fifteen members, as follows:

(1) Two members of the Senate, one to be selected by the majority leader of the Senate, the other to be selected by the minority leader of the Senate.

(2) Two members of the House, one to be selected by the Speaker of the House, the other to be selected by the minority leader of the House.

(3) Three representatives of State government shall be jointly selected by the majority leader of the Senate and the Speaker of the House. One shall be a Governor; one shall be a chief State official responsible for administering the State medicaid pro-

gram; and one shall be the chief State official responsible for administering the State maternal and child health programs.

(4) The Secretary of Health and Human Services shall be a member.

(5) The Comptroller General of the United States shall be a member.

(6) Six at large members, with demonstrated expertise in maternal and child health, including representatives of health care consumer and provider organizations, shall be jointly selected by the majority leader of the Senate and the Speaker of the House.

(c) CHAIRMAN AND VICE CHAIRMAN.—The Commission shall select a Chairperson and Vice Chairperson from among its members.

(d) QUORUM.—Eight members of the Commission shall constitute a quorum, but a lesser number may hold hearings.

(e) MEETINGS.—The Commission shall meet at the call of the Chairperson.

(f) VACANCIES.—Members shall be appointed for the life of the Commission. Any vacancy in the Commission shall not affect its powers, but shall be filled in the same manner as the original appointment.

SEC. 204. DUTIES OF THE COMMISSION.

42 USC 285g note.

(a) DUTIES.—The Commission shall:

(1) Identify and examine comprehensively Federal, State, local, and private resources which impact infant mortality, including but not limited to—

(A) the effectiveness and adequacy of programs such as the Supplemental Feeding Program for Women, Infants, and Children; the Maternal and Child Health Block Grant; Community Health Centers; prepregnancy services and other programs that increase access to prenatal and post-natal education, care, and nutrition;

(B) the effectiveness of current Federal and State policies under the Medicaid Program to ensure adequate access to prenatal and post-natal care for low-income pregnant women, mothers, and infants up to age one;

(C) the role of income maintenance and other programs that impact infant mortality such as Aid to Families with Dependent Children and Federal housing subsidies;

(D) the adequacy of current Federal and State efforts to enable an appropriate distribution of properly trained health care professionals to provide comprehensive maternal and child health services;

(E) the adequacy of private health care financing systems and mechanisms to enable pregnant women and infants to receive comprehensive health care; and

(F) the adequacy of the national biostatistics registration system with respect to the collection and reporting of infant health statistics.

(2) Identify current financial, intergovernmental, and within the Federal Government, interagency barriers to the health care needed to prevent high infant mortality.

(3) Review recommendations made in recent regional and national reports that promote the health status of childbearing women and their infants and carry forward such recommendations as deemed appropriate.

(4) Hold hearings, in accordance with section 205(a), in areas of the United States with high infant mortality rates.

(b) RECOMMENDATIONS.—The Commission shall—

(1) recommend a national policy designed to reduce and prevent infant mortality, including recommendations concerning populations at risk of high infant death rates and recommendations concerning appropriate roles for the Federal Government, States, local governments, and private sector;

(2) recommend to the Congress and the President the specific changes needed within Federal laws and Federal programs to achieve an effective Federal role in preventing infant mortality, including the programs specified in subparagraphs (A) and (B) of subsection (a)(1);

(3) recommend to the Congress and the President the specific changes needed to improve the national vital statistics registration system with respect to infant death statistics; and

(4) present such recommendations to the President, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Finance and Governmental Affairs of the Senate no later than one year after enactment of this Act.

42 USC 285g note.

SEC. 205. POWERS OF THE COMMISSION.

(a) HEARINGS.—The Commission, or at its direction, any subcommittee or member thereof, may for the purpose of carrying out the provisions of this title, hold such hearings, sit and act at such times and places, take such testimony, receive such evidence and administer such oaths, as the Commission or such subcommittee or member may deem advisable. Any member of the Commission may administer oaths or affirmations to witnesses appearing before the Commission, subcommittee, or member thereof.

(b) INFORMATION.—The Commission may secure directly from any Federal department or agency such information as may be necessary to enable the Commission to carry out this title. Upon request of the Chairman of the Commission, the head of such department or agency shall furnish such information to the Commission.

(c) CONTRACTS.—To carry out this title, the Commission may enter into such contracts and other arrangements to such extent or in such amounts as are provided in appropriation Acts, and without regard to the provisions of section 3709 of the Revised Statutes (41 U.S.C. 5). Contracts and other arrangements may be entered into under this subsection with or without consideration or bond.

(d) APPLICABILITY OF FEDERAL ADVISORY COMMITTEE ACT.—The provisions of the Federal Advisory Committee Act shall not apply to the Commission.

5 USC app.

42 USC 285g note.

SEC. 206. COMMISSION STAFF.

(a) EXECUTIVE DIRECTOR.—The Chairperson and Vice Chairperson of the Commission shall appoint an executive director. The employment of such executive director shall be subject to confirmation by the Commission.

(b) OTHER PERSONNEL.—The Commission may appoint and terminate the executive director selected under subsection (a) and such other personnel as it considers appropriate to assist in the performance of its duties under this title, without regard to the provisions of title 5, United States Code, governing appointments in the competi-

tive service, and may pay such executive director and other personnel without regard to the provisions of chapter 51 and subchapter 111 of chapter 53 of such title relating to classification and General Schedule pay rates, except that the rate of pay for such executive director and other personnel may not exceed the rate payable for GS-18 of the General Schedule under section 5332 of such title. 5 USC 5101 *et seq.* 5 USC 5331.

(c) APPLICABILITY OF OTHER FEDERAL LAWS.—Service of an individual as a member of the Commission or employment of an individual by the Commission on a part-time or full-time basis and with or without compensation shall not be considered as service or employment bringing such individual within the provisions of any Federal law relating to conflicts of interest or otherwise imposing restrictions, requirements, or penalties in relation to the employment of persons, the performance of services, or the payment or receipt of compensation in connection with claims, proceedings, or matters involving the United States. Service as a member of the Commission or as an employee of the Commission, shall not be considered service in an appointive or elective position in the Government for purposes of section 8344 of title 5, United States Code, or comparable provisions of Federal law.

(d) EXPERTS AND CONSULTANTS.—Subject to such rules as may be prescribed by the Commission, the Chairman of the Commission may procure temporary and intermittent services under section 3109 of title 5, United States Code, at rates for individuals not to exceed the daily rate payable for GS-18 of the General Schedule under section 5332 of such title.

SEC. 207. SUNSHINE PROVISION. 42 USC 285g note.

The Commission shall establish procedures to ensure its proceedings are open to the public to the maximum extent practicable.

SEC. 208. TERMINATION OF THE COMMISSION. 42 USC 285g note.

Ninety days after the Commission submits its recommendations as required by section 204(b)(4) the Commission shall terminate.

SEC. 209. AUTHORIZATION OF APPROPRIATIONS. 42 USC 285g note.

There are authorized to be appropriated to the Commission such sums as may be necessary. Amounts appropriated under this section shall remain available until the day on which the Commission terminates under section 208.

TITLE III—VACCINE COMPENSATION

National Childhood Vaccine Injury Act of 1986. 42 USC 201.

SEC. 301. SHORT TITLE.

This title may be cited as the "National Childhood Vaccine Injury Act of 1986".

PART A—VACCINES

SEC. 311. AMENDMENT TO PUBLIC HEALTH SERVICE ACT. 42 USC 300aa *et seq.*, 300cc *et seq.*

(a) NEW TITLE.—The Public Health Service Act is amended by redesignating title XXI as title XXIII, by redesignating sections 2101 through 2116 as sections 2301 through 2316, respectively, and by inserting after title XX the following new title:

"TITLE XXI—VACCINES

"Subtitle 1—National Vaccine Program

"ESTABLISHMENT

42 USC 300aa-1. "SEC. 2101. The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The Program shall be administered by a Director selected by the Secretary.

"PROGRAM RESPONSIBILITIES

42 USC 300aa-2. "SEC. 2102. (a) The Director of the Program shall have the following responsibilities:

"(1) VACCINE RESEARCH.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for research carried out in or through the National Institutes of Health, the Centers for Disease Control, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development on means to induce human immunity against naturally occurring infectious diseases and to prevent adverse reactions to vaccines.

"(2) VACCINE DEVELOPMENT.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for activities carried out in or through the National Institutes of Health, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development to develop the techniques needed to produce safe and effective vaccines.

"(3) SAFETY AND EFFICACY TESTING OF VACCINES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for safety and efficacy testing of vaccines carried out in or through the National Institutes of Health, the Centers for Disease Control, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development.

"(4) LICENSING OF VACCINE MANUFACTURERS AND VACCINES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for the allocation of resources in the implementation of the licensing program under section 353.

42 USC 263a.

"(5) PRODUCTION AND PROCUREMENT OF VACCINES.—The Director of the Program shall, through the plan issued under section 2103, ensure that the governmental and non-governmental production and procurement of safe and effective vaccines by the Public Health Service, the Department of Defense, and the Agency for International Development meet the needs of the United States population and fulfill commitments of the United States to prevent human infectious diseases in other countries.

"(6) DISTRIBUTION AND USE OF VACCINES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction to the Centers for Disease

Control and assistance to States, localities, and health practitioners in the distribution and use of vaccines, including efforts to encourage public acceptance of immunizations and to make health practitioners and the public aware of potential adverse reactions and contraindications to vaccines.

"(7) EVALUATING THE NEED FOR AND THE EFFECTIVENESS AND ADVERSE EFFECTS OF VACCINES AND IMMUNIZATION ACTIVITIES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction to the National Institutes of Health, the Centers for Disease Control, the Office of Biologics Research and Review of the Food and Drug Administration, the National Center for Health Statistics, the National Center for Health Services Research and Health Care Technology Assessment, and the Health Care Financing Administration in monitoring the need for and the effectiveness and adverse effects of vaccines and immunization activities.

"(8) COORDINATING GOVERNMENTAL AND NON-GOVERNMENTAL ACTIVITIES.—The Director of the Program shall, through the plan issued under section 2103, provide for the exchange of information between Federal agencies involved in the implementation of the Program and non-governmental entities engaged in the development and production of vaccines and in vaccine research and encourage the investment of non-governmental resources complementary to the governmental activities under the Program.

"(9) FUNDING OF FEDERAL AGENCIES.—The Director of the Program shall make available to Federal agencies involved in the implementation of the plan issued under section 2103 funds appropriated under section 2106 to supplement the funds otherwise available to such agencies for activities under the plan.

"(b) In carrying out subsection (a) and in preparing the plan under section 2103, the Director shall consult with all Federal agencies involved in research on and development, testing, licensing, production, procurement, distribution, and use of vaccines.

"PLAN

"SEC. 2103. The Director of the Program shall prepare and issue a plan for the implementation of the responsibilities of the Director under section 2102. The plan shall establish priorities in research and the development, testing, licensing, production, procurement, distribution, and effective use of vaccines, describe an optimal use of resources to carry out such priorities, and describe how each of the various departments and agencies will carry out their vaccine functions in consultation and coordination with the Program and in conformity with such priorities. The first plan under this section shall be prepared not later than January 1, 1987, and shall be revised not later than January 1 of each succeeding year. 42 USC 300aa-3.

"REPORT

"SEC. 2104. The Director shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate not later than January 1, 1988, and annually thereafter on the implementation of the Program and the plan prepared under section 2103. 42 USC 300aa-4.

"NATIONAL VACCINE ADVISORY COMMITTEE

42 USC 300aa-5.

"SEC. 2105. (a) There is established the National Vaccine Advisory Committee. The members of the Committee shall be appointed by the Director of the Program, in consultation with the National Academy of Sciences, from among individuals who are engaged in vaccine research or the manufacture of vaccines or who are physicians, members of parent organizations concerned with immunizations, or representatives of State or local health agencies or public health organizations.

"(b) The Committee shall—

"(1) study and recommend ways to encourage the availability of an adequate supply of safe and effective vaccination products in the States,

"(2) recommend research priorities and other measures the Director of the Program should take to enhance the safety and efficacy of vaccines,

"(3) advise the Director of the Program in the implementation of sections 2102, 2103, and 2104, and

"(4) identify annually for the Director of the Program the most important areas of government and non-government cooperation that should be considered in implementing sections 2102, 2103, and 2104.

"AUTHORIZATIONS

42 USC 300aa-6.

"SEC. 2106. (a) To carry out this subtitle other than section 2102(9) there are authorized to be appropriated $2,000,000 for fiscal year 1987, $2,500,000 for fiscal year 1988, $3,000,000 for fiscal year 1989, $3,500,000 for fiscal year 1990, $4,000,000 for fiscal year 1991.

"(b) To carry out section 2102(9) there are authorized to be appropriated $20,000,000 for fiscal year 1987, $22,500,000 for fiscal year 1988, $25,000,000 for fiscal year 1989, $27,500,000 for fiscal year 1990, $30,000,000 for fiscal year 1991.

"Subtitle 2—National Vaccine Injury Compensation Program

"PART A—PROGRAM REQUIREMENTS

"ESTABLISHMENT OF PROGRAM

42 USC 300aa-10.

"SEC. 2110. (a) PROGRAM ESTABLISHED.—There is established the National Vaccine Injury Compensation Program to be administered by the Secretary under which compensation may be paid for a vaccine-related injury or death.

"(b) ATTORNEY'S OBLIGATION.—It shall be the ethical obligation of any attorney who is consulted by an individual with respect to a vaccine-related injury or death to advise such individual that compensation may be available under the program for such injury or death.

"PETITIONS FOR COMPENSATION

42 USC 300aa-11.

"SEC. 2111. (a) GENERAL RULE.—

"(1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition with the United States district court for the district in which the petitioner resides or in which the injury or death occurred.

"(2)(A) No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subtitle, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless—

"(i) a petition has been filed, in accordance with section 2116, under subsection (b) for compensation under the Program for such injury or death,

"(ii) a district court of the United States has issued a judgment under section 2112 on such petition, and Courts, U.S.

"(iii) such person elects under section 2121(a) to file such an action.

"(B) If a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action. If a petition is filed under this section with respect to the injury or death for which such civil action was brought, the date such dismissed action was filed shall, for purposes of the limitations of actions prescribed by section 2116, be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action. Courts, U.S.

"(3) No vaccine manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subtitle.

"(4) If in a civil action brought against a vaccine manufacturer before the effective date of this subtitle damages were denied for a vaccine-related injury or death or if such civil action was dismissed with prejudice, the person who brought such action may file a petition under subsection (b) for such injury or death.

"(5)(A) A plaintiff who on the effective date of this subtitle has pending a civil action for damages for a vaccine-related injury or death may, at any time within 2 years after the effective date of this title or before judgment, whichever occurs first, elect to withdraw such action without prejudice and file a petition under subsection (b) for such injury or death.

"(B) If a plaintiff who on the effective date of this subtitle had pending a civil action for damages for a vaccine-related injury or death does not withdraw the action under subparagraph (A), such person may not file a petition under subsection (b) for such injury or death.

"(6) If a person brings a civil action after the effective date of this subtitle for damages for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this subtitle, such person may not file a petition under subsection (b) for such injury or death.

"(7) If in a civil action brought against a vaccine manufacturer for a vaccine-related injury or death damages are awarded under a judgment of a court or a settlement of such action, the person who brought such action may not file a petition under subsection (b) for such injury or death.

"(b) PETITIONERS.—

"(1)(A) Except as provided in subparagraph (B), any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of a vaccine set forth in the Vaccine Injury Table may file a petition for compensation under the Program.

"(B) No person may file a petition for a vaccine-related injury or death associated with a vaccine administered before the effective date of this subtitle if compensation has been paid under this subtitle for 3500 petitions for such injuries or deaths.

"(2) Only one petition may be filed with respect to each administration of a vaccine.

"(c) PETITION CONTENT.—A petition for compensation under the Program for a vaccine-related injury or death shall contain—

"(1) an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died—

"(A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine,

"(B)(i) if such person received a vaccine set forth in the Vaccine Injury Table—

"(I) received the vaccine in the United States or in its trust territories,

"(II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or

"(III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination,

"(ii) if such person did not receive such a vaccine but contracted polio from another person who received an oral polio vaccine, was a citizen of the United States or a dependent of such a citizen,

"(C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table, or

"(ii)(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or

"(II) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur

within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A),

"(D)(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 1 year after the administration of the vaccine, (ii) incurred unreimbursable expenses due in whole or in part to such illness, disability, injury, or condition in an amount greater than $1,000, or (iii) died from the administration of the vaccine, and

"(E) has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death,

"(2) all available relevant medical records (including autopsy reports, if any) relating to the person who suffered such injury or who died from the administration of the vaccine and an identification of any unavailable records known to the petitioner and the reasons for their unavailability, and

"(3) appropriate assessments, evaluations, and prognoses and such other records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, the person who suffered such injury or who died from the administration of the vaccine.

"COURT JURISDICTION

"SEC. 2112. (a) GENERAL RULE.—The district courts of the United States shall have jurisdiction (1) over proceedings to determine if a petitioner under section 2111 is entitled to compensation under the Program and the amount of such compensation, and (2) to issue and enforce such orders as the courts deem necessary to assure the prompt payment of any compensation awarded. 42 USC 300aa-12.

"(b) PARTIES.—

"(1) The Secretary shall be named as the respondent in all proceedings brought by the filing of a petition under section 2111(b). Except as provided in paragraph (2), no other person may intervene in any such proceeding.

"(2) Within 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the Federal Register. The special master designated with respect to such petition under subsection (c) shall afford all interested persons an opportunity to submit relevant, written information— Federal Register, publication.

"(A) relating to the existence of the evidence described in section 2113(a)(1)(B), or

"(B) relating to any allegation in a petition with respect to the matters described in section 2111(c)(1)(C)(ii).

"(c) SPECIAL MASTERS.—

"(1) Following receipt of a petition under subsection (a), the district court of the United States in which the petition is filed shall designate a special master to carry out the functions authorized by paragraph (2).

"(2) A special master shall serve as an adjunct to the court and may—

"(A) require such evidence as may be appropriate for the preparation of proposed findings of fact and conclusions of law with respect to whether compensation is to be provided

under the Program and the amount of any such compensation,

"(B) require the submission of such information as may be reasonable and necessary to determine if the petitioner is entitled to compensation,

"(C) require the testimony of any person and the production of any document as may be reasonable and necessary to determine if the petitioner is entitled to compensation,

"(D) conduct such hearings as may be appropriate, and

"(E) prepare and submit to the court proposed findings of fact and conclusions of law.

Information submitted to a special master in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express, written consent of the person who submitted the information. There may be no discovery in a proceeding on a petition other than the discovery required under this paragraph.

"(d) ACTION BY THE COURT.—

Records.

"(1) Upon objection by the petitioner or respondent to the proposed findings of fact or conclusions of law prepared by the special master or upon the court's own motion, the court shall undertake a review of the record of the proceedings and may thereafter make a de novo determination of any matter and issue its judgment accordingly, including findings of fact and conclusions of law, or remand for further proceedings.

"(2) If no objection is filed under paragraph (1) or if the court does not choose to review the proceeding, the court shall adopt the proposed findings of fact and conclusions of law of the special master as its own and render judgment thereon.

"(3) The court shall render its judgment on any petition filed under the Program as expeditiously as practicable but not later than 365 days after the date on which the petition was filed.

"(e) ADMINISTRATION OF AWARD.—The Program shall administer the payments of such compensation. The Program shall audit the payments of compensation under a judgment. A petitioner awarded compensation shall notify the Program of any changes which significantly affect the compensation to be paid.

"(f) REVISION OF AWARD.—

"(1) If the court issues a judgment awarding to a petitioner compensation described in section 2115(a)(1)(A) for unreimbursable expenses and the compensation is insufficient to meet such expenses, such petitioner may petition the court to (A) review such award, and (B) increase the award to make it sufficient to meet such expenses or amend the periodic payment schedule established under section 2115, or both.

"(2) If an audit conducted under subsection (e) discloses the improper use of compensation awarded under a judgment or the termination of a need for an item of compensation, the Program shall petition the court which awarded the compensation to make an appropriate revision in the compensation.

"(g) APPEALS.—The findings of fact and conclusions of law of a district court of the United States on a petition shall be final determinations of the matters involved, except that the Secretary or any petitioner aggrieved by the findings or conclusions of the court may obtain review of the judgment of the court in the United States court of appeals for the circuit in which the court is located upon petition filed with such court of appeals.

"DETERMINATION OF ELIGIBILITY AND COMPENSATION

"SEC. 2113. (a) GENERAL RULE.— Courts, U.S. Records. 42 USC 300aa-13.

"(1) Compensation shall be awarded under the Program to a petitioner if the court finds on the record as a whole—

"(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 2111(c)(1), and

"(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

"(2) For purposes of paragraph (1), the term 'factors unrelated to the administration of the vaccine'—

"(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

"(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

"(b) MATTERS TO BE CONSIDERED.—

"(1) In determining whether to award compensation to a petitioner under the Program, the court shall consider, in addition to all other relevant medical and scientific evidence contained in the record— Courts, U.S. Records.

"(A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and

"(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the court.

"(2) The court may find the first symptom or manifestation of onset or significant aggravation of an injury, disability, illness, condition, or death described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset or significant aggravation of the injury, disability, illness, condi-

tion, or death described in the petition did in fact occur within the time period described in the Vaccine Injury Table.

"(c) RECORD DEFINED.—For purposes of this section, the term 'record' means the record established by a distict court of the United States in a proceeding on a petition filed under section 2111.

"VACCINE INJURY TABLE

42 USC 300aa-14.

"SEC. 2114. (a) INITIAL TABLE.—The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

"VACCINE INJURY TABLE

I.	DTP; P; DTP/Polio Combination; or Any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigen(s).	
	Illness, disability, injury, or condition covered:	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)	3 days
	C. Shock-collapse or hypotonic-hyporesponsive collapse	3 days
	D. Residual seizure disorder in accordance with subsection (c)(2)	3 days
	E. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
II.	Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component; DT; Td; or Tetanus Toxoid.	
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
	C. Residual seizure disorder in accordance with subsection (c)(2)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
	D. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
III.	Polio Vaccines (other than Inactivated Polio Vaccine).	
	A. Paralytic polio	

	—in a non-immunodeficient recipient	30 days
	—in an immunodeficient recipient	6 months
	—in a vaccine-associated community case	Not applicable
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
IV.	Inactivated Polio Vaccine.	
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable

"(b) QUALIFICATIONS AND AIDS TO INTERPRETATION.—The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table in subsection (a):

"(1) A shock-collapse or a hypotonic-hyporesponsive collapse may be evidenced by indicia or symptoms such as decrease or loss of muscle tone, paralysis (partial or complete), hemiplegia or hemiparesis, loss of color or turning pale white or blue, unresponsiveness to environmental stimuli, depression of consciousness, loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest.

"(2) A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if—

"(A) in the case of a measles, mumps, or rubella vaccine or any combination of such vaccines, the first seizure or convulsion occurred within 15 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit, and

"(B) in the case of any other vaccine, the first seizure or convulsion occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

"(3)(A) The term 'encephalopathy' means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high

pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

"(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 2111(b) for a vaccine-related injury or death it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record.

"(4) For purposes of paragraphs (2) and (3), the terms 'seizure' and 'convulsion' include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs. If a provision of the table to which paragraph (1), (2), (3), or (4) applies is revised under subsection (c) or (d), such paragraph shall not apply to such provision after the effective date of the revision unless the revision specifies that such paragraph is to continue to apply.

"(c) ADMINISTRATIVE REVISION OF THE TABLE.—

Regulations.

"(1) The Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, the Secretary shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.

"(2) Any person (including the Advisory Commission on Childhood Vaccines) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

"(A) receipt of any recommendation of the Commission, or

Federal Register, publication.

"(B) 180 days after the date of the referral to the Commission,

whichever occurs first, the Secretary shall conduct a rulemaking proceeding on the matters proposed in the petition or publish in the Federal Register a statement of reasons for not conducting such proceeding.

"(3) A modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death.

"(4) Any modification under paragraph (1) of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation.

"(d) ROLE OF COMMISSION.—Except with respect to a regulation recommended by the Advisory Commission on Childhood Vaccines, the Secretary may not propose a regulation under subsection (c) or any revision thereof, unless the Secretary has first provided to the Commission a copy of the proposed regulation or revision, requested recommendations and comments by the Commission, and afforded the Commission at least 90 days to make such recommendations. Regulations.

"(e) RECOMMENDATION.—The Secretary may recommend to Congress revisions of the table to change the vaccines covered by the table.

"COMPENSATION

"SEC. 2115. (a) GENERAL RULE.—Compensation awarded under the Program to a petitioner under section 2111 for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subtitle shall include the following: 42 USC 300aa-15.

"(1)(A) Actual unreimbursable expenses incurred from the date of the judgment awarding such expenses and reasonable projected unreimbursable expenses which—

"(i) result from the vaccine-related injury for which the petitioner seeks compensation,

"(ii) have been or will be incurred by or on behalf of the person who suffered such injury, and

"(iii)(I) have been or will be for diagnosis and medical or other remedial care determined to be reasonably necessary, or

"(II) have been or will be for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

The amount of unreimbursable expenses which may be recovered under this subparagraph shall be limited to the amount in excess of the amount set forth in section 2111(c)(1)(D)(ii).

"(B) Subject to section 2116(a)(2), actual unreimbursable expenses incurred before the date of the judgment awarding such expenses which—

"(i) resulted from the vaccine-related injury for which the petitioner seeks compensation,

"(ii) were incurred by or on behalf of the person who suffered such injury, and

"(iii) were for diagnosis, medical or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

The amount of unreimbursable expenses which may be recovered under this subparagraph shall be limited to the amount in excess of the amount set forth in section 2111(c)(1)(D)(ii).

"(2) In the event of a vaccine-related death, an award of $250,000 for the estate of the deceased.

"(3)(A) In the case of any person who has sustained a vaccine-related injury after attaining the age of 18 and whose earning

capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded, compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections.

"(B) In the case of any person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

"(4) For actual and projected pain and suffering and emotional distress from the vaccine-related injury, an award not to exceed $250,000.

Payments for projected expenses shall be paid on a periodic basis (but no payment may be made for a period in excess of 1 year). Payments for pain and suffering and emotional distress and incurred expenses may be paid in a lump sum.

"(b) VACCINES ADMINISTERED BEFORE THE EFFECTIVE DATE.—Compensation awarded under the Program to a petitioner under section 2111 for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this subtitle shall only include the compensation described in paragraphs (1)(A) and (2) of subsection (a).

"(c) RESIDENTIAL AND CUSTODIAL CARE AND SERVICE.—The amount of any compensation for residential and custodial care and service expenses under subsection (a)(1) shall be sufficient to enable the compensated person to remain living at home.

"(d) TYPES OF COMPENSATION PROHIBITED.—Compensation awarded under the Program may not include the following:

"(1) Punitive or exemplary damages.

"(2) Except with respect to compensation payments under paragraphs (2) and (3) of subsection (a), compensation for other than the health, education, or welfare of the person who suffered the vaccine-related injury with respect to which the compensation is paid.

"(e) ATTORNEYS' FEES.—

Courts, U.S.

"(1) The judgment of a court on a petition filed under section 2111 awarding compensation shall include an amount to cover—

"(A) reasonable attorneys' fees, and

"(B) other costs,

incurred in any proceeding on such petition. If the judgment of a court on such a petition does not award compensation, the court may include in the judgment an amount to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the court determines that the civil action was brought in good faith and there was a reasonable basis for the claim for which the civil action was brought.

"(2) If the petitioner, before the effective date of this title, filed a civil action for damages for any vaccine-related injury or death for which compensation may be awarded under the Pro-

gram, and elected under section 2111(a)(4) to withdraw such action and to file a petition for compensation under the Program, the judgment of the court on such petition may include an amount limited to the costs and expenses incurred by the petitioner and the attorney of the petitioner before the effective date of this subtitle in preparing, filing, and prosecuting such civil action (including the reasonable value of the attorney's time if the civil action was filed under contingent fee arrangements).

"(3) No attorney may charge any fee for services in connection with a petition filed under section 2111 which is in addition to any amount included under paragraph (1) in a judgment on such petition.

"(f) PAYMENT OF COMPENSATION.—

"(1) Except as provided in paragraph (2), no compensation may be paid until an election has been made, or has been deemed to have been made, under section 2121(a) to receive compensation.

"(2) Compensation described in subsection (a)(1)(A)(iii) shall be paid from the date of the judgment of the district court of the United States under section 2112 awarding the compensation. Such compensation may not be paid after an election under section 2121(b) to file a civil action for damages for the vaccine-related injury or death for which such compensation was awarded.

"(3) Payments of compensation shall be exempt from reduction under any order issued under part C of the Balanced Budget and Emergency Deficit Control Act of 1985. 2 USC 901 *et seq.*

"(f) PROGRAM NOT PRIMARILY LIABLE.—Payment of compensation under the Program shall not be made for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program, or (2) by an entity which provides health services on a prepaid basis.

"(g) LIABILITY OF HEALTH INSURANCE CARRIERS, PREPAID HEALTH PLANS, AND BENEFIT PROVIDERS.—No policy of health insurance may make payment of benefits under the policy secondary to the payment of compensation under the Program and—

"(1) no State, and

"(2) no entity which provides health services on a prepaid basis or provides health benefits,

may make the provision of health services or health benefits secondary to the payment of compensation under the Program.

"LIMITATIONS OF ACTIONS

"SEC. 2116. (a) GENERAL RULE.—In the case of— 42 USC 300aa-16.

"(1) a vaccine set forth in the Vaccine Injury Table which is administered before the effective date of this title, if a vaccine-related injury or death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury or death after the expiration of 24 months after the effective date of this title,

"(2) a vaccine set forth in the Vaccine Injury Table which is administered after the effective date of this title, if a vaccine-related injury occurred as a result of the administration of such

vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury, and

"(3) a vaccine set forth in the Vaccine Injury Table which is administered after the effective date of this title, if a death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such death after the expiration of 24 months from the date of the death and no such petition may be filed more than 48 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of the injury from which the death resulted.

"(b) EFFECT OF REVISED TABLE.—If at any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, such person may file a petition for such compensation not later than 2 years after the effective date of the revision, except that no compensation may be provided under the Program with respect to a vaccine-related injury or death covered under the revision of the table if—

"(1) the vaccine-related death occurred more than 8 years before the date of the revision of the table, or

"(2) the vaccine-related injury occurred more than 8 years before the date of the revision of the table.

"(c) STATE LIMITATIONS OF ACTIONS.—If a petition is filed under section 2111(b) for a vaccine-related injury or death, limitations of actions under State law shall be stayed with respect to a civil action brought for such injury or death for the period beginning on the date the petition is filed and ending on the date a final judgment is entered on the petition.

"SUBROGRATION

42 USC 300aa-17.

"SEC. 2117. (a) GENERAL RULE.—

"(1) Upon payment of compensation to any petitioner under the Program, the trust fund which has been established to provide such compensation shall be subrogated to all rights of the petitioner with respect to the vaccine-related injury or death for which compensation was paid, except that the trust fund may not recover under such rights an amount greater than the amount of compensation paid to the petitioner.

Courts, U.S. Records. Claims.

"(2) In any case in which it deems such action appropriate, a district court of the United States may, after entry of a final judgment providing for compensation to be paid under section 2115 for a vaccine-related injury or death, refer the record of such proceeding to the Secretary and the Attorney General with such recommendation as the court deems appropriate with respect to the investigation or commencement of a civil action by the Secretary under paragraph (1).

"(b) DISPOSITION OF AMOUNTS RECOVERED.—Amounts recovered under subsection (a) shall be collected on behalf of, and deposited in, the trust fund which has been established to provide compensation under the Program.

"INCREASE FOR INFLATION

"SEC. 2118. The compensation under subsections (a)(2) and (a)(4) of section 2115 and the civil penalty under section 2127(b) shall, effective December 1 of each year beginning 1 year after the effective date of this title, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest 1/10 of 1 percent. For purposes of this section, the term 'base quarter', as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.

Effective date.
42 USC 300aa-18.

"ADVISORY COMMISSION ON CHILDHOOD VACCINES

"SEC. 2119. (a) ESTABLISHMENT.—There is established the Advisory Commission on Childhood Vaccines. The Commission shall be composed of:

42 USC 300aa-19.

"(1) Nine members appointed by the Secretary as follows:

"(A) Three members who are health professionals, who are not employees of the United States, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians.

"(B) Three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death.

"(C) Three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.

"(2) The Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control, and the Commissioner of Food and Drugs (or the designees of such officials), each of whom shall be a nonvoting ex officio member.

The Secretary shall select members of the Commission within 90 days of the effective date of this subtitle. The members of the Commission shall select a Chair from among the members.

"(b) TERM OF OFFICE.—Appointed members of the Commission shall be appointed for a term of office of 3 years, except that of the members first appointed, 3 shall be appointed for a term of 1 year, 3 shall be appointed for a term of 2 years, and 3 shall be appointed for a term of 3 years, as determined by the Secretary.

"(c) MEETINGS.—The Commission shall first meet within 60 days after all members of the Commission are appointed, and thereafter shall meet not less often than four times per year and at the call of the chair. A quorum for purposes of a meeting is 5. A decision at a meeting is to be made by a ballot of a majority of the voting members of the Commission.

"(d) COMPENSATION.—Members of the Commission who are officers or employees of the Federal Government shall serve as members of the Commission without compensation in addition to that received in their regular public employment. Members of the

Commission who are not officers or employees of the Federal Government shall be compensated at a rate not to exceed the daily equivalent of the rate in effect for grade GS-18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Commission. All members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703, title 5, United States Code, for employees serving intermittently.

5 USC 5332.

"(e) STAFF.—The Secretary shall provide the Commission with such professional and clerical staff, such information, and the services of such consultants as may be necessary to assist the Commission in carrying out effectively its functions under this section.

"(f) FUNCTIONS.—The Commission shall—

"(1) advise the Secretary on the implementation of the Program,

"(2) on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table,

"(3) advise the Secretary in implementing the Secretary's responsibilities under section 2127 regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions,

"(4) survey Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b), and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines, and

"(5) recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out this subtitle.

"PART B—ADDITIONAL REMEDIES

"AUTHORITY TO BRING ACTIONS

42 USC 300aa-21.

"SEC. 2121. (a) ELECTION.—After the judgment of a district court of the United States under section 2111 on a petition filed for compensation under the Program for a vaccine-related injury or death has become final, the person who filed the petition shall file with the court—

"(1) if the judgment awarded compensation, an election in writing to receive the compensation or to file a civil action for damages for such injury or death, or

"(2) if the judgment did not award compensation, an election in writing to accept the judgment or to file a civil action for damages for such injury or death.

An election shall be filed under this subsection not later than 90 days after the date of the entry of the court's judgment with respect to which the election is to be made. If a person required to file an election with a court under this subsection does not file the election within the time prescribed for filing the election, such person shall be deemed to have filed an election to accept the judgment of the court. If a person elects to receive compensation under a judgment of a court or is deemed to have accepted the judgment of a court,

such person may not bring or maintain a civil action for damages against a vaccine manufacturer for the vaccine-related injury or death for which the judgment was entered.

"(b) LIMITATIONS OF ACTIONS.—A civil action for damages arising from a vaccine-related injury or death for which a petition was filed under section 2111 shall, except as provided in section 2116(c), be brought within the period prescribed by limitations of actions under State law applicable to such civil action. State and local governments.

"STANDARDS OF RESPONSIBILITY

"SEC. 2122. (a) GENERAL RULE.—Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for a vaccine-related injury or death. State and local governments. Claims. 42 USC 300aa-22.

"(b) UNAVOIDABLE ADVERSE SIDE EFFECTS; WARNINGS.—

"(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subtitle if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

"(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows— 21 USC 301 note. 42 USC 262.

"(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 2123(d)(2), or

"(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

"(c) DIRECT WARNINGS.—No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subtitle solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

"(d) CONSTRUCTION.—The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.

"(e) PREEMPTION.—No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this subtitle. State and local governments.

"TRIAL

42 USC 300aa-23.

"SEC. 2123. (a) GENERAL RULE.—A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subtitle which is not barred by section 2111(a)(2) shall be tried in three stages.

"(b) LIABILITY.—The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 2122.

"(c) GENERAL DAMAGES.—The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 2122 shall be required to pay.

"(d) PUNITIVE DAMAGES.—

"(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 2122 shall be required to pay.

Fraud.

"(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in—

21 USC 301 note.
42 USC 201 note.

"(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 351,

42 USC 262.

Safety.

"(B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or

Safety.

"(C) other criminal or illegal activity relating to the safety and effectiveness of vaccines,

which activity related to the vaccine-related injury or death for which the civil action was brought.

"(e) EVIDENCE.—In any stage of a civil action, the Vaccine Injury Table, any finding of a district court of the United States or a master appointed by such court in a proceeding on a petition filed under section 2111 and the final judgment of a district court of the United States on such a petition shall not be admissible.

"PART C—ASSURING A SAFER CHILDHOOD VACCINATION PROGRAM IN THE UNITED STATES

"RECORDING AND REPORTING OF INFORMATION

42 USC 300aa-25.

"SEC. 2125. (a) GENERAL RULE.—Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person shall record, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine—

"(1) the date of administration of the vaccine,

"(2) the vaccine manufacturer and lot number of the vaccine,

"(3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and

"(4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.

"(b) REPORTING.—

"(1) Each health care provider and vaccine manufacturer shall report to the Secretary—

"(A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 2114(b) which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,

"(B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and

"(C) such other matters as the Secretary may by regulation require.

Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after the effective date of this subtitle. The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the reporting requirement. Federal Register, publication.

"(2) A report under paragraph (1) respecting a vaccine shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions, the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine.

"(3) The Secretary shall issue the regulations referred to in paragraph (1)(C) within 180 days of the effective date of this subtitle. Regulations.

"(c) RELEASE OF INFORMATION.—

"(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, United States Code, or otherwise, to any person except— State and local governments.

"(A) the person who received the vaccine, or

"(B) the legal representative of such person.

"(2) For purposes of paragraph (1), the term 'information which may identify an individual' shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person's legal representative and the medical records of such person relating to the administration of the vaccine, and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition resulting from the administration of the vaccine, any symptom or manifestation of such illness, disability, injury, or condition, or death resulting from the administration of the vaccine.

"(3) Except as provided in paragraph (1), all information reported under this section shall be available to the public. Public information.

"VACCINE INFORMATION

"SEC. 2126. (a) GENERAL RULE.—Not later than 1 year after the effective date of this subtitle, the Secretary shall develop and 42 USC 300aa-26.

Federal Register, publication.

disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child receiving a vaccine set forth in the Vaccine Injury Table. Such materials shall be published in the Federal Register and may be revised.

"(b) DEVELOPMENT AND REVISION OF MATERIALS.—Such materials shall be developed or revised by rule—

"(1) after notice to the public, opportunity for a public hearing, and 90 days of comment thereon, and

"(2) in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control, and the Food and Drug Administration.

"(c) INFORMATION REQUIREMENTS.—The information in such materials shall be presented in understandable terms and shall include—

"(1) the frequency, severity, and potential long-term effects of the disease to be prevented by the vaccine,

"(2) the symptoms or reactions to the vaccine which, if they occur, should be brought to the immediate attention of the health care provider,

"(3) precautionary measures legal representatives should take to reduce the risk of any major adverse reactions to the vaccine that may occur,

"(4) early warning signs or symptoms to which legal representatives should be alert as possible precursors to such major adverse reactions,

"(5) a description of the manner in which legal representatives should monitor such major adverse reactions, including a form on which reactions can be recorded to assist legal representatives in reporting information to appropriate authorities,

"(6) a specification of when, how, and to whom legal representatives should report any major adverse reaction,

"(7) the contraindications to (and bases for delay of) the administration of the vaccine,

"(8) an identification of the groups, categories, or characteristics of potential recipients of the vaccine who may be at significantly higher risk of major adverse reaction to the vaccine than the general population,

"(9) a summary of relevant State and Federal laws concerning the vaccine, including information on—

"(A) the number of vaccinations required for school attendance and the schedule recommended for such vaccinations, and

"(B) the availability of the Program, and

"(10) such other relevant information as may be determined by the Secretary.

"(d) HEALTH CARE PROVIDER DUTIES.—On and after a date determined by the Secretary which is—

"(1) after the Secretary develops the information materials required by subsection (a), and

"(2) not later than 6 months after the date such materials are published in the Federal Register,

each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child to whom such provider intends to administer such vaccine a copy of the information materials developed pursuant to subsection (a), or other written information which meets the requirements

of this section. Such materials or other information shall be provided prior to the administration of such vaccine.

"MANDATE FOR SAFER CHILDHOOD VACCINES

"SEC. 2127. (a) GENERAL RULE.—In the administration of this subtitle and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall— 42 USC 300aa-27.

"(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on the effective date of this subtitle and promote the refinement of such vaccines, and

"(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

"(b) REPORT.—Within 2 years after the effective date of this subtitle, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

"MANUFACTURER RECORDKEEPING AND REPORTING

"SEC. 2128. (a) GENERAL RULE.—Each vaccine manufacturer of a vaccine set forth in the Vaccine Injury Table or any other vaccine the administration of which is mandated by the law or regulations of any State, shall, with respect to each batch, lot, or other quantity manufactured or licensed after the effective date of this subtitle— State and local governments. 42 USC 300aa-28.

"(1) prepare and maintain records documenting the history of the manufacturing, processing, testing, repooling, and reworking of each batch, lot, or other quantity of such vaccine, including the identification of any significant problems encountered in the production, testing, or handling of such batch, lot, or other quantity,

"(2) if a safety test on such batch, lot, or other quantity indicates a potential imminent or substantial public health hazard is presented, report to the Secretary within 24 hours of such safety test which the manufacturer (or manufacturer's representative) conducted, including the date of the test, the type of vaccine tested, the identity of the batch, lot, or other quantity tested, whether the batch, lot, or other quantity tested is the product of repooling or reworking of previous batches, lots, or other quantities (and, if so, the identity of the previous batches, lots, or other quantities which were repooled or reworked), the complete test results, and the name and address of the person responsible for conducting the test, Safety.

"(3) include with each such report a certification signed by a responsible corporate official that such report is true and complete, and

"(4) prepare, maintain, and upon request submit to the Secretary product distribution records for each such vaccine by batch, lot, or other quantity number.

Fraud.

"(b) SANCTION.—Any vaccine manufacturer who intentionally destroys, alters, falsifies, or conceals any record or report required under paragraph (1) or (2) of subsection (a) shall—

"(1) be subject to a civil penalty of up to $100,000 per occurrence, or

"(2) be fined $50,000 or imprisoned for not more than 1 year, or both.

Such penalty shall apply to the person who intentionally destroyed, altered, falsified, or concealed such record or report, to the person who directed that such record or report be destroyed, altered, falsified, or concealed, and to the vaccine manufacturer for which such person is an agent, employee, or representative. Each act of destruction, alteration, falsification, or concealment shall be treated as a separate occurrence.

"PART D—GENERAL PROVISIONS

"CITIZEN'S ACTIONS

42 USC 300aa-31.

"SEC. 2131. (a) GENERAL RULE.—Except as provided in subsection (b), any person may commence in a district court of the United States a civil action on such person's own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under this subtitle.

"(b) NOTICE.—No action may be commenced under subsection (a) before the date which is 60 days after the person bringing the action has given written notice of intent to commence such action to the Secretary.

Courts, U.S.

"(c) COSTS OF LITIGATION.—The court, in issuing any final order in any action under this section, may award costs of litigation (including reasonable attorney and expert witness fees) to any party, whenever the court determines such award is appropriate.

"JUDICIAL REVIEW

Regulations. 42 USC 300aa-32.

"SEC. 2132. A petition for review of a regulation under this subtitle may be filed in a court of appeals of the United States within 60 days from the date of the promulgation of the regulation or after such date if such petition is based solely on grounds arising after such 60th day.

"DEFINITIONS

42 USC 300aa-33.

"SEC. 2133. For purposes of this subtitle:

"(1) The term 'health care provider' means any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities) under whose authority a vaccine set forth in the Vaccine Injury Table is administered.

"(2) The term 'legal representative' means a parent or an individual who qualifies as a legal guardian under State law.

"(3) The term 'manufacturer' means any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes under its label any vaccine set forth in the Vaccine Injury Table, except that, for purposes of section 2128, such term shall include the manufacturer of any other vaccine cov-

ered by that section. The term 'manufacture' means to manufacture, import, process, or distribute a vaccine.

"(4) The term 'significant aggravation' means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

"(5) The term 'vaccine-related injury or death' means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.

"(6)(A) The term 'Advisory Commission on Childhood Vaccines' means the Commission established under section 2119.

"(B) The term 'Vaccine Injury Table' means the table set out in section 2114.". *Ante*, p. 3764.

(b) CONFORMING AMENDMENTS.—

(1) Sections 217(c), 465(f), and 497 of the Public Health Service Act (42 U.S.C. 218(c), 286(f), 289(f)) are each amended by striking out "2101" and inserting in lieu thereof "2301". 42 USC 218, 286, 289f.

(2) Section 305(h) of such Act (42 U.S.C. 242c(h)) is amended by striking out "2113" each place it occurs and inserting in lieu thereof "2313".

SEC. 312. RELATED STUDIES.

(a) REVIEW OF PERTUSSIS VACCINES AND RELATED ILLNESSES AND CONDITIONS.—Not later than 3 years after the effective date of this title, the Secretary of Health and Human Services shall complete a review of all relevant medical and scientific information (including information obtained from the studies required under subsection (e)) on the nature, circumstances, and extent of the relationship, if any, between vaccines containing pertussis (including whole cell, extracts, and specific antigens) and the following illnesses and conditions: 42 USC 300aa-1 note.

(1) Hemolytic anemia.
(2) Hypsarrhythmia.
(3) Infantile spasms.
(4) Reye's syndrome.
(5) Peripheral mononeuropathy.
(6) Deaths classified as sudden infant death syndrome.
(7) Aseptic meningitis.
(8) Juvenile diabetes.
(9) Autism.
(10) Learning disabilities.
(11) Hyperactivity.
(12) Such other illnesses and conditions as the Secretary may choose to review or as the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act recommends for inclusion in such review. *Ante*, p. 3771.

The review under this subsection shall include notice and opportunity for a public hearing, consideration of written information submitted by the public, and consultation with such Advisory Commission.

(b) FINDINGS WITH RESPECT TO PERTUSSIS.—Not later than 3 years after the effective date of this title, the Secretary shall make, and publish in the Federal Register, the following specific findings: Federal Register, publication.

(1) Whether each of the illnesses or conditions set forth in subsection (a) can reasonably be determined in some circumstances to be caused or significantly aggravated, by pertussis-containing vaccines.

(2) For each illness or condition for which a finding of causation or aggravation related to vaccines containing pertussis is made under paragraph (1), the circumstances under which such causation or aggravation can reasonably be determined to occur.

(3) For each illness or condition for which a finding of causation or aggravation related to vaccines containing pertussis is made under paragraph (1), and for each illness or condition set forth in the Vaccine Injury Table under section 2114 of the Public Health Service Act, the time periods within which the first symptom or manifestation of onset or aggravation of each such illness or condition can reasonably be determined to occur after pertussis vaccination.

Ante, p. 3764.

Regulations.

(c) REVISION OF TABLE WITH RESPECT TO PERTUSSIS VACCINES.—At the same time the Secretary publishes in the Federal Register findings under subsection (b), the Secretary shall propose regulations to amend the Vaccine Injury Table under section 2114 of the Public Health Service Act as a result of such findings. Not later than 42 months after the effective date of this title, the Secretary shall promulgate such proposed regulations with such modifications as may be necessary after opportunity for public hearing.

(d) REVIEW OF MMR VACCINES AND RELATED ILLNESSES AND CONDITIONS.—Not later than 3 years after the effective date of this title, the Secretary of Health and Human Services shall complete a review similar to the review conducted under subsection (a) with respect to the potential relationship between vaccines containing rubella (including MMR) and radiculoneuritis. The review under this subsection shall include notice and opportunity for a public hearing, consultation with the Advisory Commission on Childhood Vaccines and consideration of written information submitted by the public. Not later than 3 years after the effective date of this title, the Secretary shall make and publish in the Federal Register findings similar to those required by subsection (b) and shall, if appropriate, propose similar regulations (and thereafter promulgate such regulations) to those required by subsection (c), with respect to compensation under the National Vaccine Injury Compensation Program established under section 2110 of the Public Health Service Act for radiculoneuritis caused, contributed to, or significantly aggravated by vaccines containing rubella.

Federal Register, publication.

Ante, p. 3758.

(e) PERTUSSIS AND MMR STUDIES.—

(1) In order to assist the Secretary in making the findings required under subsections (b) and (d), the Secretary shall, in accordance with subparagraph (B), arrange for the conduct of studies of—

(A) the relationship between vaccines containing pertussis (including whole cell, extracts, and specific antigens) and the illnesses or conditions set forth in paragraphs (1) through (11) of subsection (a),

(B) the relationship between vaccines containing pertussis and any other illnesses and conditions, as selected by the Secretary or the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act, and

Ante, p. 3771.

(C) the relationship between vaccines containing rubella (including MMR) and radiculoneuritis.

(2)(A) The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the studies required by paragraph (1) under an arrangement by which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary.

(B) If the Institute of Medicine is unwilling to conduct such study under such an arrangement, the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study and prepare and submit the reports thereon as provided in paragraph (3). Reports.

(C) The Institute of Medicine or other group or association conducting the studies required by paragraph (1) shall conduct such studies in consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act. *Ante*, p. 3771.

(3) Reports on the results of the studies required by paragraph (1) shall be completed and submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate and to the Secretary not later than 32 months after the effective date of this title. Upon submission to the Secretary, the reports shall be made available to the public. Reports. Public information.

(4) There are authorized to be appropriated such sums as are necessary for the purpose of making payments for the conduct of the studies required under this subsection. Appropriation authorization.

(f) DEFINITIONS.—For purposes of this section:

(1) The term "medical and scientific information" includes epidemiologic, clinical, biostatistical, pathological, toxicologic, and other laboratory data and case study information, observations, studies, and reports in peer-reviewed literature or official Government publications, as well as relevant unpublished information, data, studies, and observations.

(2) The term "MMR" means a vaccine containing material intended to prevent or confer immunity against measles, mumps, and rubella disease.

SEC. 313. STUDY OF OTHER VACCINE RISKS.

(a) STUDY.—

(1) Not later than 3 years after the effective date of this title, the Secretary shall, after consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act— 42 USC 300aa-1 note.

(A) arrange for a broad study of the risks (other than the risks considered under section 102) to children associated with each vaccine set forth in the Vaccine Injury Table under section 2114 of such Act, and *Ante*, p. 3764.

(B) establish guidelines, after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, respecting the administration of such vaccines which shall include—

(i) the circumstances under which any such vaccine should not be administered,

(ii) the circumstances under which administration of any such vaccine should be delayed beyond its usual time of administration, and

(iii) the groups, categories, or characteristics of potential recipients of such vaccine who may be at significantly higher risk of major adverse reactions to such vaccine than the general population of potential recipients.

(2)(A) The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the study required by paragraph (1) under an arrangement by which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary.

(B) If the Institute of Medicine is unwilling to conduct such study under such an arrangement, the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study.

(C) The Institute of Medicine or other group or association conducting the study required by paragraph (1) shall conduct such studies in consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act.

Ante, p. 3771.

Federal Register, publication.

(b) REVISION OF GUIDELINES.—The Secretary shall periodically, but at least every 3 years after establishing guidelines under subsection (a), review and revise such guidelines after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, unless the Secretary finds that on the basis of all relevant information no revision of such guidelines is warranted and publishes such finding in the Federal Register.

(c) FACTORS AFFECTING GUIDELINES.—Guidelines under subsection (a) shall take into account—

(1) the risk to potential recipients of the vaccines with respect to which the guidelines are established,

(2) the medical and other characteristics of such potential recipients, and

(3) the risks to the public of not having such vaccines administered.

Physicians. Hospitals. Nurses. State and local governments.

(d) DISSEMINATION.—The Secretary shall widely disseminate the guidelines established under subsection (a) to—

(1) physicians and other health care providers,

(2) professional health associations,

(3) State and local governments and agencies, and

(4) other relevant entities.

42 USC 300aa-1 note.

SEC. 314. REVIEW OF WARNINGS, USE INSTRUCTIONS, AND PRECAUTIONARY INFORMATION.

Not later than 1 year after the effective date of this title and after consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act and with other appropriate entities, the Secretary of Health and Human Services shall review the warnings, use instructions, and precautionary information presently issued by manufacturers of vaccines set forth in the Vaccine Injury Table set out in section 2114 of the Public Health Service Act and shall by rule determine whether such warnings, instructions, and information adequately warn health care providers of the nature and extent of dangers posed by such

Ante, p. 3764.

vaccines. If the Secretary determines that any such warning, instruction, or information is inadequate for such purpose in any respect, the Secretary shall at the same time require the manufacturers to revise and reissue such warning, instruction, or information as expeditiously as practical, but not later than 18 months after the effective date of this title.

SEC. 315. RECALL AUTHORITY.

Subsection (d) of section 351 of the Public Health Service Act (42 U.S.C. 262) is amended— *Ante*, p. 3751.

(1) by inserting "(1)" after "(d)", and

(2) by adding at the end thereof the following new paragraph:

"(2)(A) Upon a determination that a batch, lot, or other quantity of a product licensed under this section presents an imminent or substantial hazard to the public health, the Secretary shall issue an order immediately ordering the recall of such batch, lot, or other quantity of such product. An order under this paragraph shall be issued in accordance with section 554 of title 5, United States Code.

"(B) Any violation of subparagraph (A) shall subject the violator to a civil penalty of up to $100,000 per day of violation. The amount of a civil penalty under this subparagraph shall, effective December 1 of each year beginning 1 year after the effective date of this subparagraph, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest ⅒ of 1 percent. For purposes of this subparagraph, the term 'base quarter', as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.". Law enforcement and crime.

SEC. 316. STUDY OF IMPACT ON SUPPLY OF VACCINES. 42 USC 300aa-4 note.

On June 30, 1987, and on June 30 of each second year thereafter, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate—

(1) an assessment of the impact of the amendments made by this title on the supply of vaccines listed in the Vaccine Injury Table under section 2114 of the Public Health Service Act, and *Ante*, p. 3764.

(2) an assessment of the ability of the administrators of vaccines (including public clinics and private administrators) to provide such vaccines to children.

PART B—MISCELLANEOUS

SEC. 321. WAIVER OF PAPERWORK REDUCTION. 44 USC 3501 *et seq.*

Chapter 35 of title 44, United States Code, shall not apply to information required for purposes of carrying out this title and implementing the amendments made by this title. 42 USC 300aa-1 note.

SEC. 322. NONSEVERABILITY. 42 USC 300aa-1 note.

If any provision of this title or the application of any provision of this title to any person or circumstance is held invalid by reason of a violation of the Constitution, the entire title shall be considered invalid.

42 USC 300aa-1 note.

SEC. 323. EFFECTIVE DATE.

(a) GENERAL RULE.—Subtitle 1 of title XXI of the Public Health Service Act shall take effect on the date of the enactment of this Act and Subtitle 2 of such title and this title shall take effect on the effective date of a tax enacted after the date of the enactment of this Act to provide funds for compensation paid under such subtitle 2.

Ante, p. 3756.
Ante, p. 3758.

Claims.

(b) INSUFFICIENCY OF FUNDS.—If at any time there are insufficient funds to pay all of the claims payable under subtitle 2 of title XXI of the Public Health Service Act for 180 days, such subtitle shall cease to be in effect until sufficient funds to pay all of the claims under such subtitle become available.

Health Care Quality Improvement Act of 1986.

TITLE IV—ENCOURAGING GOOD FAITH PROFESSIONAL REVIEW ACTIVITIES

42 USC 11101 note.

SEC. 401. SHORT TITLE.

This title may be cited as the "Health Care Quality Improvement Act of 1986".

42 USC 11101.

SEC. 402. FINDINGS.

The Congress finds the following:

(1) The increasing occurrence of medical malpractice and the need to improve the quality of medical care have become nationwide problems that warrant greater efforts than those that can be undertaken by any individual State.

(2) There is a national need to restrict the ability of incompetent physicians to move from State to State without disclosure or discovery of the physician's previous damaging or incompetent performance.

(3) This nationwide problem can be remedied through effective professional peer review.

(4) The threat of private money damage liability under Federal laws, including treble damage liability under Federal antitrust law, unreasonably discourages physicians from participating in effective professional peer review.

(5) There is an overriding national need to provide incentive and protection for physicians engaging in effective professional peer review.

PART A—PROMOTION OF PROFESSIONAL REVIEW ACTIVITIES

42 USC 11111.

SEC. 411. PROFESSIONAL REVIEW.

State and local governments.

(a) IN GENERAL.—

(1) LIMITATION ON DAMAGES FOR PROFESSIONAL REVIEW ACTIONS.—If a professional review action (as defined in section 431(9)) of a professional review body meets all the standards specified in section 412(a), except as provided in subsection (b)—

(A) the professional review body,

(B) any person acting as a member or staff to the body,

(C) any person under a contract or other formal agreement with the body, and

(D) any person who participates with or assists the body with respect to the action,

shall not be liable in damages under any law of the United States or of any State (or political subdivision thereof) with respect to the action. The preceding sentence shall not apply to damages under any law of the United States or any State relating to the civil rights of any person or persons, including the Civil Rights Act of 1964, 42 U.S.C. 2000e, et seq. and the Civil Rights Acts, 42 U.S.C. 1981, et seq. Nothing in this paragraph shall prevent the United States or any Attorney General of a State from bringing an action, including an action under section 4C of the Clayton Act, 15 U.S.C. 15C, where such an action is otherwise authorized.

Physicians.

(2) PROTECTION FOR THOSE PROVIDING INFORMATION TO PROFESSIONAL REVIEW BODIES.—Notwithstanding any other provision of law, no person (whether as a witness or otherwise) providing information to a professional review body regarding the competence or professional conduct of a physician shall be held, by reason of having provided such information, to be liable in damages under any law of the United States or of any State (or political subdivision thereof) unless such information is false and the person providing it knew that such information was false.

(b) EXCEPTION.—If the Secretary has reason to believe that a health care entity has failed to report information in accordance with section 423(a), the Secretary shall conduct an investigation. If, after providing notice of noncompliance, an opportunity to correct the noncompliance, and an opportunity for a hearing, the Secretary determines that a health care entity has failed substantially to report information in accordance with section 423(a), the Secretary shall publish the name of the entity in the Federal Register. The protections of subsection (a)(1) shall not apply to an entity the name of which is published in the Federal Register under the previous sentence with respect to professional review actions of the entity commenced during the 3-year period beginning 30 days after the date of publication of the name.

Federal Register, publication.

(c) TREATMENT UNDER STATE LAWS.—

(1) PROFESSIONAL REVIEW ACTIONS TAKEN ON OR AFTER OCTOBER 14, 1989.—Except as provided in paragraph (2), subsection (a) shall apply to State laws in a State only for professional review actions commenced on or after October 14, 1989.

(2) EXCEPTIONS.—

(A) STATE EARLY OPT-IN.—Subsection (a) shall apply to State laws in a State for actions commenced before October 14, 1989, if the State by legislation elects such treatment.

(B) STATE OPT-OUT.—Subsection (a) shall not apply to State laws in a State for actions commenced on or after October 14, 1989, if the State by legislation elects such treatment.

(C) EFFECTIVE DATE OF ELECTION.—An election under State law is not effective, for purposes of subparagraphs (A) and (B), for actions commenced before the effective date of the State law, which may not be earlier than the date of the enactment of that law.

SEC. 412. STANDARDS FOR PROFESSIONAL REVIEW ACTIONS.

42 USC 11112.

(a) IN GENERAL.—For purposes of the protection set forth in section 411(a), a professional review action must be taken—

(1) in the reasonable belief that the action was in the furtherance of quality health care,

(2) after a reasonable effort to obtain the facts of the matter,

Physicians.

(3) after adequate notice and hearing procedures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances, and

(4) in the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirement of paragraph (3).

A professional review action shall be presumed to have met the preceding standards necessary for the protection set out in section 411(a) unless the presumption is rebutted by a preponderance of the evidence.

Physicians.

(b) ADEQUATE NOTICE AND HEARING.—A health care entity is deemed to have met the adequate notice and hearing requirement of subsection (a)(3) with respect to a physician if the following conditions are met (or are waived voluntarily by the physician):

(1) NOTICE OF PROPOSED ACTION.—The physician has been given notice stating—

(A)(i) that a professional review action has been proposed to be taken against the physician,

(ii) reasons for the proposed action,

(B)(i) that the physician has the right to request a hearing on the proposed action,

(ii) any time limit (of not less than 30 days) within which to request such a hearing, and

(C) a summary of the rights in the hearing under paragraph (3).

(2) NOTICE OF HEARING.—If a hearing is requested on a timely basis under paragraph (1)(B), the physician involved must be given notice stating—

(A) the place, time, and date, of the hearing, which date shall not be less than 30 days after the date of the notice, and

(B) a list of the witnesses (if any) expected to testify at the hearing on behalf of the professional review body.

(3) CONDUCT OF HEARING AND NOTICE.—If a hearing is requested on a timely basis under paragraph (1)(B)—

(A) subject to subparagraph (B), the hearing shall be held (as determined by the health care entity)—

(i) before an arbitrator mutually acceptable to the physician and the health care entity,

(ii) before a hearing officer who is appointed by the entity and who is not in direct economic competition with the physician involved, or

(iii) before a panel of individuals who are appointed by the entity and are not in direct economic competition with the physician involved;

(B) the right to the hearing may be forfeited if the physician fails, without good cause, to appear;

(C) in the hearing the physician involved has the right—

(i) to representation by an attorney or other person of the physician's choice,

Records.

(ii) to have a record made of the proceedings, copies of which may be obtained by the physician upon payment of any reasonable charges associated with the preparation thereof,

(iii) to call, examine, and cross-examine witnesses,

(iv) to present evidence determined to be relevant by the hearing officer, regardless of its admissibility in a court of law, and

(v) to submit a written statement at the close of the hearing; and

(D) upon completion of the hearing, the physician involved has the right—

(i) to receive the written recommendation of the arbitrator, officer, or panel, including a statement of the basis for the recommendations, and

(ii) to receive a written decision of the health care entity, including a statement of the basis for the decision.

A professional review body's failure to meet the conditions described in this subsection shall not, in itself, constitute failure to meet the standards of subsection (a)(3).

(c) ADEQUATE PROCEDURES IN INVESTIGATIONS OR HEALTH EMERGENCIES.—For purposes of section 411(a), nothing in this section shall be construed as—

(1) requiring the procedures referred to in subsection (a)(3)—

(A) where there is no adverse professional review action taken, or

(B) in the case of a suspension or restriction of clinical privileges, for a period of not longer than 14 days, during which an investigation is being conducted to determine the need for a professional review action; or

(2) precluding an immediate suspension or restriction of clinical privileges, subject to subsequent notice and hearing or other adequate procedures, where the failure to take such an action may result in an imminent danger to the health of any individual.

SEC. 413. PAYMENT OF REASONABLE ATTORNEYS' FEES AND COSTS IN DEFENSE OF SUIT. 42 USC 11113.

Courts, U.S.

In any suit brought against a defendant, to the extent that a defendant has met the standards set forth under section 412(a) and the defendant substantially prevails, the court shall, at the conclusion of the action, award to a substantially prevailing party defending against any such claim the cost of the suit attributable to such claim, including a reasonable attorney's fee, if the claim, or the claimant's conduct during the litigation of the claim, was frivolous, unreasonable, without foundation, or in bad faith. For the purposes of this section, a defendant shall not be considered to have substantially prevailed when the plaintiff obtains an award for damages or permanent injunctive or declaratory relief.

SEC. 414. GUIDELINES OF THE SECRETARY. 42 USC 11114.

The Secretary may establish, after notice and opportunity for comment, such voluntary guidelines as may assist the professional review bodies in meeting the standards described in section 412(a).

SEC. 415. CONSTRUCTION. 42 USC 11115.

(a) IN GENERAL.—Except as specifically provided in this part, nothing in this part shall be construed as changing the liabilities or immunities under law.

Physicians. Nurses.

(b) SCOPE OF CLINICAL PRIVILEGES.—Nothing in this part shall be construed as requiring health care entities to provide clinical privileges to any or all classes or types of physicians or other licensed health care practitioners.

State and local governments.

(c) TREATMENT OF NURSES AND OTHER PRACTITIONERS.—Nothing in this part shall be construed as affecting, or modifying any provision of Federal or State law, with respect to activities of professional review bodies regarding nurses, other licensed health care practitioners, or other health professionals who are not physicians.

State and local governments. Physicians. Hospitals.

(d) TREATMENT OF PATIENT MALPRACTICE CLAIMS.—Nothing in this title shall be construed as affecting in any manner the rights and remedies afforded patients under any provision of Federal or State law to seek redress for any harm or injury suffered as a result of negligent treatment or care by any physician, health care practitioner, or health care entity, or as limiting any defenses or immunities available to any physician, health care practitioner, or health care entity.

42 USC 11111 note.

SEC. 416. EFFECTIVE DATE.

This part shall apply to professional review actions commenced on or after the date of the enactment of this Act.

PART B—REPORTING OF INFORMATION

Claims. Physicians. Nurses. Hospitals. 42 USC 11131. Insurance. Reports.

SEC. 421. REQUIRING REPORTS ON MEDICAL MALPRACTICE PAYMENTS.

(a) IN GENERAL.—Each entity (including an insurance company) which makes payment under a policy of insurance, self-insurance, or otherwise in settlement (or partial settlement) of, or in satisfaction of a judgment in, a medical malpractice action or claim shall report, in accordance with section 424, information respecting the payment and circumstances thereof.

(b) INFORMATION TO BE REPORTED.—The information to be reported under subsection (a) includes—

(1) the name of any physician or licensed health care practitioner for whose benefit the payment is made,

(2) the amount of the payment,

(3) the name (if known) of any hospital with which the physician or practitioner is affiliated or associated,

(4) a description of the acts or omissions and injuries or illnesses upon which the action or claim was based, and

(5) such other information as the Secretary determines is required for appropriate interpretation of information reported under this section.

(c) SANCTIONS FOR FAILURE TO REPORT.—Any entity that fails to report information on a payment required to be reported under this section shall be subject to a civil money penalty of not more than $10,000 for each such payment involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A of the Social Security Act are imposed and collected under that section.

Ante, p. 2003.

(d) REPORT ON TREATMENT OF SMALL PAYMENTS.—The Secretary shall study and report to Congress, not later than two years after the date of the enactment of this Act, on whether information respecting small payments should continue to be required to be reported under subsection (a) and whether information respecting all claims made concerning a medical malpractice action should be required to be reported under such subsection.

SEC. 422. REPORTING OF SANCTIONS TAKEN BY BOARDS OF MEDICAL EXAMINERS. 42 USC 11132.

(a) IN GENERAL.—

(1) ACTIONS SUBJECT TO REPORTING.—Each Board of Medical Examiners—

(A) which revokes or suspends (or otherwise restricts) a physician's license or censures, reprimands, or places on probation a physician, for reasons relating to the physician's professional competence or professional conduct, or

(B) to which a physician's license is surrendered,

shall report, in accordance with section 424, the information described in paragraph (2).

(2) INFORMATION TO BE REPORTED.—The information to be reported under paragraph (1) is—

(A) the name of the physician involved,

(B) a description of the acts or omissions or other reasons (if known) for the revocation, suspension, or surrender of license, and

(C) such other information respecting the circumstances of the action or surrender as the Secretary deems appropriate.

(b) FAILURE TO REPORT.—If, after notice of noncompliance and providing opportunity to correct noncompliance, the Secretary determines that a Board of Medical Examiners has failed to report information in accordance with subsection (a), the Secretary shall designate another qualified entity for the reporting of information under section 423.

SEC. 423. REPORTING OF CERTAIN PROFESSIONAL REVIEW ACTIONS TAKEN BY HEALTH CARE ENTITIES. 42 USC 11133.

(a) REPORTING BY HEALTH CARE ENTITIES.—

(1) ON PHYSICIANS.—Each health care entity which—

(A) takes a professional review action that adversely affects the clinical privileges of a physician for a period longer than 30 days;

(B) accepts the surrender of clinical privileges of a physician—

(i) while the physician is under an investigation by the entity relating to possible incompetence or improper professional conduct, or

(ii) in return for not conducting such an investigation or proceeding; or

(C) in the case of such an entity which is a professional society, takes a professional review action which adversely affects the membership of a physician in the society,

shall report to the Board of Medical Examiners, in accordance with section 424(a), the information described in paragraph (3).

(2) PERMISSIVE REPORTING ON OTHER LICENSED HEALTH CARE PRACTITIONERS.—A health care entity may report to the Board of Medical Examiners, in accordance with section 424(a), the information described in paragraph (3) in the case of a licensed health care practitioner who is not a physician, if the entity would be required to report such information under paragraph (1) with respect to the practitioner if the practitioner were a physician.

(3) INFORMATION TO BE REPORTED.—The information to be reported under this subsection is—

(A) the name of the physician or practitioner involved,

(B) a description of the acts or omissions or other reasons for the action or, if known, for the surrender, and

(C) such other information respecting the circumstances of the action or surrender as the Secretary deems appropriate.

(b) REPORTING BY BOARD OF MEDICAL EXAMINERS.—Each Board of Medical Examiners shall report, in accordance with section 424, the information reported to it under subsection (a) and known instances of a health care entity's failure to report information under subsection (a)(1).

(c) SANCTIONS.—

(1) HEALTH CARE ENTITIES.—A health care entity that fails substantially to meet the requirement of subsection (a)(1) shall lose the protections of section 411(a)(1) if the Secretary publishes the name of the entity under section 411(b).

(2) BOARD OF MEDICAL EXAMINERS.—If, after notice of noncompliance and providing an opportunity to correct noncompliance, the Secretary determines that a Board of Medical Examiners has failed to report information in accordance with subsection (b), the Secretary shall designate another qualified entity for the reporting of information under subsection (b).

State and local governments.

(d) REFERENCES TO BOARD OF MEDICAL EXAMINERS.—Any reference in this part to a Board of Medical Examiners includes, in the case of a Board in a State that fails to meet the reporting requirements of section 422(a) or subsection (b), a reference to such other qualified entity as the Secretary designates.

42 USC 11134.

SEC. 424. FORM OF REPORTING.

(a) TIMING AND FORM.—The information required to be reported under sections 421, 422(a), and 423 shall be reported regularly (but not less often than monthly) and in such form and manner as the Secretary prescribes. Such information shall first be required to be reported on a date (not later than one year after the date of the enactment of this Act) specified by the Secretary.

Classified information.

(b) TO WHOM REPORTED.—The information required to be reported under sections 421, 422(a), and 423(b) shall be reported to the Secretary, or, in the Secretary's discretion, to an appropriate private or public agency which has made suitable arrangements with the Secretary with respect to receipt, storage, protection of confidentiality, and dissemination of the information under this part.

(c) REPORTING TO STATE LICENSING BOARDS.—

(1) MALPRACTICE PAYMENTS.—Information required to be reported under section 421 shall also be reported to the appropriate State licensing board (or boards) in the State in which the medical malpractice claim arose.

(2) REPORTING TO OTHER LICENSING BOARDS.—Information required to be reported under section 423(b) shall also be reported to the appropriate State licensing board in the State in which the health care entity is located if it is not otherwise reported to such board under subsection (b).

42 USC 11135.

SEC. 425. DUTY OF HOSPITALS TO OBTAIN INFORMATION.

(a) IN GENERAL.—It is the duty of each hospital to request from the Secretary (or the agency designated under section 424(b)), on and after the date information is first required to be reported under section 424(a))—

(1) at the time a physician or licensed health care practitioner applies to be on the medical staff (courtesy or otherwise) of, or for clinical privileges at, the hospital, information reported under this part concerning the physician or practitioner, and

(2) once every 2 years information reported under this part concerning any physician or such practitioner who is on the medical staff (courtesy or otherwise) of, or has been granted clinical privileges at, the hospital.

A hospital may request such information at other times.

(b) FAILURE TO OBTAIN INFORMATION.—With respect to a medical malpractice action, a hospital which does not request information respecting a physician or practitioner as required under subsection (a) is presumed to have knowledge of any information reported under this part to the Secretary with respect to the physician or practitioner.

(c) RELIANCE ON INFORMATION PROVIDED.—Each hospital may rely upon information provided to the hospital under this title and shall not be held liable for such reliance in the absence of the hospital's knowledge that the information provided was false.

SEC. 426. DISCLOSURE AND CORRECTION OF INFORMATION.

Regulations.
42 USC 11136.

With respect to the information reported to the Secretary (or the agency designated under section 424(b)) under this part respecting a physician or other licensed health care practitioner, the Secretary shall, by regulation, provide for—

(1) disclosure of the information, upon request, to the physician or practitioner, and

(2) procedures in the case of disputed accuracy of the information.

SEC. 427. MISCELLANEOUS PROVISIONS.

State and local governments.
42 USC 11137.
Health maintenance organizations.

(a) PROVIDING LICENSING BOARDS AND OTHER HEALTH CARE ENTITIES WITH ACCESS TO INFORMATION.—The Secretary (or the agency designated under section 424(b)) shall, upon request, provide information reported under this part with respect to a physician or other licensed health care practitioner to State licensing boards, to hospitals, and to other health care entities (including health maintenance organizations) that have entered (or may be entering) into an employment or affiliation relationship with the physician or practitioner or to which the physician or practitioner has applied for clinical privileges or appointment to the medical staff.

(b) CONFIDENTIALITY OF INFORMATION.—

(1) IN GENERAL.—Information reported under this part is considered confidential and shall not be disclosed (other than to the physician or practitioner involved) except with respect to professional review activity, with respect to medical malpractice actions, or in accordance with regulations of the Secretary promulgated pursuant to subsection (a). Nothing in this subsection shall prevent the disclosure of such information by a party which is otherwise authorized, under applicable State law, to make such disclosure.

(2) PENALTY FOR VIOLATIONS.—Any person who violates paragraph (1) shall be subject to a civil money penalty of not more than $10,000 for each such violation involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A of the

42 USC 1320a-7a.

Social Security Act are imposed and collected under that section.

(3) USE OF INFORMATION.—Subject to paragraph (1), information provided under section 425 and subsection (a) is intended to be used solely with respect to activities in the furtherance of the quality of health care.

(c) RELIEF FROM LIABILITY FOR REPORTING.—No person or entity shall be held liable in any civil action with respect to any report made under this part without knowledge of the falsity of the information contained in the report.

(d) INTERPRETATION OF INFORMATION.—In interpreting information reported under this part, a payment in settlement of a medical malpractice action or claim shall not be construed as creating a presumption that medical malpractice has occurred.

PART C—DEFINITIONS AND REPORTS

42 USC 11151.

SEC. 431. DEFINITIONS.

In this title:

(1) The term "adversely affecting" includes reducing, restricting, suspending, revoking, denying, or failing to renew clinical privileges or membership in a health care entity.

(2) The term "Board of Medical Examiners" includes a body comparable to such a Board (as determined by the State) with responsibility for the licensing of physicians and also includes a subdivision of such a Board or body.

(3) The term "clinical privileges" includes privileges, membership on the medical staff, and the other circumstances pertaining to the furnishing of medical care under which a physician or other licensed health care practitioner is permitted to furnish such care by a health care entity.

(4)(A) The term "health care entity" means—

(i) a hospital that is licensed to provide health care services by the State in which it is located,

(ii) an entity (including a health maintenance organization or group medical practice) that provides health care services and that follows a formal peer review process for the purpose of furthering quality health care (as determined under regulations of the Secretary), and

(iii) subject to subparagraph (B), a professional society (or committee thereof) of physicians or other licensed health care practitioners that follows a formal peer review process for the purpose of furthering quality health care (as determined under regulations of the Secretary).

(B) The term "health care entity" does not include a professional society (or committee thereof) if, within the previous 5 years, the society has been found by the Federal Trade Commission or any court to have engaged in any anti-competitive practice which had the effect of restricting the practice of licensed health care practitioners.

42 USC 1395x.

(5) The term "hospital" means an entity described in paragraphs (1) and (7) of section 1861(e) of the Social Security Act.

(6) The terms "licensed health care practitioner" and "practitioner" mean, with respect to a State, an individual (other than a physician) who is licensed or otherwise authorized by the State to provide health care services.

(7) The term "medical malpractice action or claim" means a written claim or demand for payment based on a health care provider's furnishing (or failure to furnish) health care services, and includes the filing of a cause of action, based on the law of tort, brought in any court of any State or the United States seeking monetary damages.

(8) The term "physician" means a doctor of medicine or osteopathy or a doctor of dental surgery or medical dentistry legally authorized to practice medicine and surgery or dentistry by a State (or any individual who, without authority holds himself or herself out to be so authorized).

(9) The term "professional review action" means an action or recommendation of a professional review body which is taken or made in the conduct of professional review activity, which is based on the competence or professional conduct of an individual physician (which conduct affects or could affect adversely the health or welfare of a patient or patients), and which affects (or may affect) adversely the clinical privileges, or membership in a professional society, of the physician. Such term includes a formal decision of a professional review body not to take an action or make a recommendation described in the previous sentence and also includes professional review activities relating to a professional review action. In this title, an action is not considered to be based on the competence or professional conduct of a physician if the action is primarily based on—

(A) the physician's association, or lack of association, with a professional society or association,

(B) the physician's fees or the physician's advertising or engaging in other competitive acts intended to solicit or retain business,

(C) the physician's participation in prepaid group health plans, salaried employment, or any other manner of delivering health services whether on a fee-for-service or other basis,

(D) a physician's association with, supervision of, delegation of authority to, support for, training of, or participation in a private group practice with, a member or members of a particular class of health care practitioner or professional, or

(E) any other matter that does not relate to the competence or professional conduct of a physician.

(10) The term "professional review activity" means an activity of a health care entity with respect to an individual physician—

(A) to determine whether the physician may have clinical privileges with respect to, or membership in, the entity,

(B) to determine the scope or conditions of such privileges or membership, or

(C) to change or modify such privileges or membership.

(11) The term "professional review body" means a health care entity and the governing body or any committee of a health care entity which conducts professional review activity, and includes any committee of the medical staff of such an entity when assisting the governing body in a professional review activity.

(12) The term "Secretary" means the Secretary of Health and Human Services.

(13) The term "State" means the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

(14) The term "State licensing board" means, with respect to a physician or health care provider in a State, the agency of the State which is primarily responsible for the licensing of the physician or provider to furnish health care services.

42 USC 11152.

SEC. 432. REPORTS AND MEMORANDA OF UNDERSTANDING.

(a) ANNUAL REPORTS TO CONGRESS.—The Secretary shall report to Congress, annually during the three years after the date of the enactment of this Act, on the implementation of this title.

(b) MEMORANDA OF UNDERSTANDING.—The Secretary of Health and Human Services shall seek to enter into memoranda of understanding with the Secretary of Defense and the Administrator of Veterans' Affairs to apply the provisions of part B of this title to hospitals and other facilities and health care providers under the jurisdiction of the Secretary or Administrator, respectively. The Secretary shall report to Congress, not later than two years after the date of the enactment of this Act, on any such memoranda and on the cooperation among such officials in establishing such memoranda.

Ante, p. 3788.

Drugs and drug abuse.

(c) MEMORANDUM OF UNDERSTANDING WITH DRUG ENFORCEMENT ADMINISTRATION.—The Secretary of Health and Human Services shall seek to enter into a memorandum of understanding with the Administrator of Drug Enforcement relating to providing for the reporting by the Administrator to the Secretary of information respecting physicians and other practitioners whose registration to dispense controlled substances has been suspended or revoked under section 304 of the Controlled Substances Act. The Secretary shall report to Congress, not later than two years after the date of the enactment of this Act, on any such memorandum and on the cooperation between the Secretary and the Administrator in establishing such a memorandum.

21 USC 824.

TITLE V—STATE COMPREHENSIVE MENTAL HEALTH SERVICES PLANS

State Comprehensive Mental Health Services Plan Act of 1986.
42 USC 201 note.

SEC. 501. SHORT TITLE.

This title may be cited as the "State Comprehensive Mental Health Services Plan Act of 1986".

SEC. 502. STATE COMPREHENSIVE MENTAL HEALTH SERVICES PLAN.

42 USC 300x.

Part B of title XIX of the Public Health Service Act is amended—

(1) by inserting before the heading for section 1911 the following:

"SUBPART 1—BLOCK GRANT"; and

(2) by adding at the end thereof the following:

"SUBPART 2—STATE COMPREHENSIVE MENTAL HEALTH SERVICES PLAN

"DEVELOPMENT GRANTS

"SEC. 1920B. (a) The Secretary shall make grants to States for the development of State comprehensive mental health services plans which comply with section 1920C. In order to receive a grant under this section, a State shall submit an application to the Secretary. Such application shall be in such form, and shall contain such information, as the Secretary may by regulation prescribe. Regulations. 42 USC 300x-10.

"(b)(1) Except as provided in paragraph (2), the amount of a grant to a State under this section for a fiscal year shall be the amount which bears the same ratio to the amount appropriated to carry out this section for such fiscal year as the population of the State bears to the total of the population of all States which submit applications under this section.

"(2) Notwithstanding paragraph (1), the amount of a grant to any State under this section shall not be less than $150,000.

"(c) To carry out this section, there are authorized to be appropriated $10,000,000 for each of the fiscal years 1988 and 1989. Appropriation authorization.

"STATE COMPREHENSIVE MENTAL HEALTH SERVICES PLANS

"SEC. 1920C. (a) For each fiscal year, beginning with fiscal year 1988, each State shall submit a State comprehensive mental health services plan (hereafter referred to in this subpart as the 'State plan') to the Secretary. 42 USC 300x-11.

"(b) A State plan shall, for the fiscal year for which the plan is submitted and each of the 2 succeeding fiscal years, meet the following requirements:

"(1) The State plan shall provide for the establishment and of implementation of an organized community-based system of care for chronically mentally ill individuals.

"(2) The State plan shall contain quantitative targets to be achieved in the implementation of such system, including numbers of chronically mentally ill individuals residing in the areas to be served under such system.

"(3) The State plan shall describe services to be provided to chronically mentally ill individuals to enable such individuals to gain access to mental health services, including access to treatment, prevention, and rehabilitation services.

"(4) The State plan shall describe rehabilitation services, employment services, housing services, medical and dental care, and other support services to be provided to chronically mentally ill individuals in order to enable such individuals to function outside of inpatient institutions to the maximum extent of their capabilities.

"(5) The State plan shall provide for activities to reduce the rate of hospitalization of chronically mentally ill individuals.

"(6) Except as provided in paragraph (7), the State plan shall require the provision of case management services to each chronically mentally ill individual in the State who receives substantial amounts of public funds or services. For purposes of this paragraph, the term 'chronically mentally ill individual' means a chronically mentally ill individual as defined under State laws and regulations.

"(7) The State plan may provide for the implementation of the requirements of paragraph (6) in a manner which—

"(A) phases in, beginning in fiscal year 1989, the provision to all chronically mentally ill individuals to which such paragraph applies the case management services required to be provided under such paragraph; and

"(B) provides for the substantial completion of the phasing in of the provision of such services by the end of fiscal year 1992.

Homeless persons.

"(8) The State plan shall provide for the establishment and implementation of a program of outreach to, and services for, chronically mentally ill individuals who are homeless.

"(c) In developing each State plan required under this section, the State shall consult with representatives of employees of State institutions and public and private nursing homes who care for chronically mentally ill individuals.

"(d) The Secretary shall provide technical assistance to States in the development and implementation of State plans which comply with this section. Such technical assistance shall include the development and publication by the Secretary of model elements for State plans and model data systems for the collection of data concerning the implementation of State plans.

"ENFORCEMENT

42 USC 300x-12.

"SEC. 1920D. (a) If the Secretary determines that a State has not, by the end of fiscal year 1989, developed the State plan required by section 1920C, the Secretary shall reduce the amount of the State's allotment under subpart 1 for fiscal year 1990 by the amount specified in subsection (d).

"(b) If the Secretary determines that a State has not, by the end of fiscal year 1990, developed and substantially implemented the State plan required by section 1920C, the Secretary shall reduce the amount of the State's allotment under subpart 1 for fiscal year 1991 by the amount specified in subsection (d).

Ante, p. 3794.

"(c) If the Secretary determines that a State has not, by the end of fiscal year 1991, developed and completely implemented the State plan required by section 1920C, the Secretary shall reduce the amount of the State's allotment under subpart 1 for fiscal year 1992 and each succeeding fiscal year by the amount specified in subsection (d). The Secretary shall discontinue the reduction under this subsection of a State's allotment under subpart 1 for a fiscal year if the Secretary determines that the State has, in the preceding fiscal year, developed and completely implemented the State plan required by section 1920C.

"(d) The amount referred to in subsections (a), (b), and (c) with respect to a State is the total amount expended by the State for administrative expenses for fiscal year 1986 from amounts paid to the State under subpart 1 for such fiscal year.

"(e) Notwithstanding any other provision of this subpart, the Secretary shall not require a State government, in carrying out a State plan submitted under this subpart, to expend an amount for mental health services for any fiscal year which exceeds the total amount that would have been expended for such services by such government for such fiscal year if such plan had not been implemented.

"MODEL STANDARDS FOR THE PROVISION OF CARE TO THE CHRONICALLY MENTALLY ILL

"SEC. 1920E. (a) Within one year after the date of enactment of this subpart, the Secretary shall develop and make available a model plan for a community-based system of care for chronically mentally ill individuals. Such plan shall be developed in consultation with State mental health directors, providers of mental health services, chronically mentally ill individuals, advocates for such individuals, and other interested parties.". 42 USC 300x-13.

SEC. 503. STATE MENTAL HEALTH SERVICES PLANNING COUNCILS.

Section 1916(f) of the Public Health Service Act is amended— 42 USC 300x-4.

(1) by striking out "With amounts available under section 1915(a), the chief executive officer of the State may" and inserting in lieu thereof "The chief executive officer of the State shall"; and 42 USC 300x-3.

(2) by adding at the end thereof the following new sentence: "The State may use amounts available under section 1915(a) to establish and operate such a council.".

SEC. 504. DEMONSTRATION PROJECTS FOR SERVICES FOR HOMELESS CHRONICALLY MENTALLY ILL INDIVIDUALS.

(a) DEMONSTRATION PROJECTS.—Section 504(f)(1) of the Public Health Service Act is amended by striking out "and elderly individuals" and inserting in lieu thereof "elderly individuals, and homeless chronically mentally ill individuals". Aged persons. 42 USC 290aa-3.

(b) AUTHORIZATION.—Section 504(f)(3) of such Act is amended by striking out "1985, 1986, and 1987" and inserting in lieu thereof "1985 and 1986, and $24,000,000 for fiscal year 1988".

(c) ADMINISTRATIVE EXPENSES.—Section 504(f) of such Act is further amended by adding at the end thereof the following new paragraph:

"(4)(A) Not more than 25 percent of the total amount of a grant for fiscal year 1988 made to a State under this subsection for a project for services for chronically mentally ill adults (other than a project for services for elderly individuals or a project for services for homeless chronically mentally ill individuals) may be used by the State for administrative expenses in carrying out such grant in such fiscal year. Grants.

"(B) Not more than 25 percent of the total amount of any grant made to a State under this subsection for services to chronically mentally ill adults for any fiscal year (beginning with fiscal year 1989) may be used by the State for administrative expenses in carrying out such grant in such fiscal year.".

TITLE VI—GERIATRIC TRAINING

SEC. 601. ESTABLISHMENT OF TRAINING PROGRAM.

(a) Section 788 of the Public Health Service Act is amended— 42 USC 295g-8.

(1) by redesignating subsections (e), (f), and (g) as subsections (f), (g), and (h), respectively; and

(2) by inserting after subsection (d) the following new subsection:

"(e)(1) The Secretary may make grants to, and enter into contracts with, schools of medicine, schools of osteopathy, teaching hospitals, Grants. Contracts. Schools and colleges. Education. Physicians. Dentists.

and graduate medical education programs, for the purpose of providing support for geriatric medicine training projects to train physicians and dentists who plan to teach geriatric medicine or geriatric dentistry.

"(2) Each project for which a grant or contract is made under this subsection shall—

"(A) be staffed by full-time teaching physicians who have experience or training in geriatric medicine;

"(B) be staffed by full-time or part-time teaching dentists who have experience or training in geriatric dentistry;

"(C) be based in a graduate medical education program in internal medicine or family medicine;

"(D) provide participants in the project with exposure to a diversified population of elderly individuals;

"(E) provide training in geriatrics and exposure to the physical and mental disabilities of elderly individuals through a variety of service rotations, such as geriatric consultation services, acute care services, dental services, geriatric psychiatry units, day and home care programs, rehabilitation services, extended care facilities, geriatric ambulatory care and comprehensive evaluation units, and community care programs for elderly mentally retarded individuals; and

"(F) provide training in geriatrics through one or both of the training options described in subparagraphs (A) and (B) of paragraph (3).

"(3) The training options referred to in subparagraph (F) of paragraph (2) are as follows:

"(A) A one-year retraining program in geriatrics for—

"(i) physicians who are faculty members in departments of internal medicine, family medicine, gynecology, and psychiatry at schools of medicine and osteopathy; and

"(ii) dentists who are faculty members at schools of dentistry or at hospital departments of dentistry.

Fellowships.

"(B) A one-year or two-year internal medicine or family medicine fellowship program providing emphasis in geriatrics, which shall be designed to provide training in clinical geriatrics and geriatrics research for—

"(i) physicians who have completed graduate medical education programs in internal medicine, family medicine, psychiatry, neurology, gynecology, or rehabilitation medicine; and

"(ii) dentists who have completed post-doctoral dental education programs.

"(4) For purposes of this subsection—

"(A) the term 'graduate medical education program' means a program sponsored by a school of medicine, a school of osteopathy, a hospital, or a public or private institution, which—

"(i) offers postgraduate medical training in the specialties and subspecialties of medicine; and

"(ii) has been accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association through its Committee on Postdoctoral Training; and

"(B) the term 'post-doctoral dental education program', means a program sponsored by a school of dentistry, a hospital, or a public or private institution, which—

"(i) offers post-doctoral training in the specialties of dentistry, advanced education in general dentistry, or a dental general practice residency; and

"(ii) has been accredited by the Commission on Dental Accreditation.".

(b) Section 788(d)(1)(D) of such Act is amended by inserting "(other than training and retraining of faculty for schools of medicine and osteopathy) before the semicolon. 42 USC 295g-8.

(c) Section 788(h) of such Act (as redesignated by subsection (a)(1) of this section) is amended—

(1) by striking out "$8,000,000" the third place it appears in the first sentence and inserting in lieu thereof "$12,000,000";

(2) by striking out "each of the fiscal years" in paragraph (2) and inserting in lieu thereof "the fiscal year";

(3) by inserting "25 percent of such amount for the fiscal year ending" before "September 30, 1988" in paragraph (2); and

(4) by adding at the end thereof the following: "One-third of the amounts appropriated to carry out this section for fiscal year 1988 shall be available to carry out subsection (e) for such fiscal year.".

TITLE VII—HEALTH PLANNING

SEC. 701. REPEAL OF TITLE XV.

(a) REPEAL.—Title XV of the Public Health Service Act is repealed effective January 1, 1987. Effective date. 42 USC 300k-1 *et seq.*

(b) FUNDS.—The repeal made by subsection (a) shall not affect any funds obligated for the purposes of title XV of the Public Health Service Act before January 1, 1987. 42 USC 300k-1 note.

TITLE VIII—HEALTH MAINTENANCE ORGANIZATIONS

Health Maintenance Organization Amendments of 1986.

SEC. 801. SHORT TITLE.

This title may be cited as the "Health Maintenance Organization Amendments of 1986". 42 USC 201 note.

SEC. 802. REFERENCE.

Whenever in this title an amendment or repeal is expressed in terms of an amendment to, or a repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Public Health Service Act. 42 USC 201 note.

SEC. 803. ELIMINATION OF AUTHORIZATION OF SUPPORT FOR FEASIBILITY SURVEYS, PLANNING, AND INITIAL DEVELOPMENT COSTS.

(a) Sections 1303, 1304, and 1307(c) (42 U.S.C. 300e-2, 300e-3, and 300e-6(c)) are repealed.

(b)(1) Section 1306 (42 U.S.C. 300e-5) is amended— Loans.

(A) by striking out "grant, contract, loan," each place it appears (except in subsection (b)(6)) and inserting in lieu thereof "loan",

(B) by striking out "in the case of an application for assistance under section 1303 or 1304, such application meets the applica-

tion requirements of such section and in the case of an application for a loan or loan guarantee," in subsection (b)(1),

(C) by striking out "1304," in subsection (b)(2), and

(D) by striking out "grants, contracts, loans," in subsection (c) and inserting in lieu thereof "loans".

Loans.

(2) Section 1307 (42 U.S.C. 300e–6) is amended—

(A) by striking out "grant, contract, loan," each place it appears and inserting in lieu thereof "loan",

(B) by striking out "grant, contract, or" in subsection (a)(1), and

(C) by striking out "such assistance" in subsection (a)(1) and inserting in lieu thereof "the loan".

(3) Section 1309(a) (42 U.S.C. 300e–8(a)) is amended—

(A) by striking out paragraph (1), and

(B) by striking out "(2)".

(4) The first sentence of section 1317(b) (42 U.S.C. 300e–16(b)) is amended—

(A) by striking out clause (1), and

(B) by redesignating clauses (2) and (3) as clauses (1) and (2), respectively.

Grants.
Contracts.
42 USC 300e–5 note.

(c) The amendments made by this section do not apply to any grant made or contract entered into under title XIII of the Public Health Service Act before October 1, 1985.

42 USC 300e *et seq.*

SEC. 804. LIMITATION ON LOANS AND LOAN GUARANTEES FOR INITIAL COSTS OF OPERATION.

Grants.
Contracts.

(a) The last sentence of section 1305(a) (42 U.S.C. 300e–4(a)) is amended by inserting before the period ", and unless the Secretary has made a grant or loan to, entered into a contract with, or guaranteed a loan for, the organization in fiscal year 1981, 1982, 1983, 1984, or 1985 under this section or section 1304(b) (as in effect before October 1, 1985)".

Ante, p. 3799.

42 USC 300e–4 note.

(b) The amendment made by subsection (a) does not apply to any loan or loan guarantee for the initial costs of operation of a health maintenance organization made under title XIII of the Public Health Service Act before October 1, 1985.

SEC. 805. ELIMINATION OF LOANS AND LOAN GUARANTEES FOR ACQUISITION AND CONSTRUCTION OF AMBULATORY CARE FACILITIES.

(a) Section 1305A (42 U.S.C. 300e–4a) is repealed.

(b) Section 1306(b)(2) (42 U.S.C. 300e–5(b)(2)) is amended by striking out "or 1305A,".

42 USC 300e–5 note.

(c) The amendments made by this section do not apply to any loan or loan guarantee made under section 1305A of the Public Health Service Act before October 1, 1985.

SEC. 806. REPEAL OF REQUIREMENT FOR HEALTH SYSTEMS AGENCY REVIEW.

Section 1306(b) (42 U.S.C. 300e–5(b)) is amended by striking out paragraph (5) and by redesignating paragraphs (6), (7), and (8) as paragraphs (5), (6), and (7), respectively.

SEC. 807. LIMITATION ON BORROWING BY LOAN GUARANTEE FUND.

The first sentence of section 1308(d)(2) (42 U.S.C. 300e–7(d)(2)) is amended by inserting "before October 1, 1986," after "guarantees issued by him".

SEC. 808. REPEAL OF REQUIREMENT FOR PERIODIC DEMONSTRATION OF COMPLIANCE.

Section 1310(d) (42 U.S.C. 300e-9(d)) is amended by striking out the last sentence.

SEC. 809. ANNUAL UPDATE OF STATE LAW DIGEST.

The first sentence of section 1311(c) (42 U.S.C. 300e-10(c)) is amended by striking out "quarterly" and inserting in lieu thereof "annually".

SEC. 810. ELIMINATION OF UNNECESSARY REPORT.

Section 1318(e) (42 U.S.C. 300e-17(e)) is repealed.

SEC. 811. AUTHORIZATION OF APPROPRIATIONS.

Section 1309(b) (42 U.S.C. 300e-8(b)) is amended to read as follows: Loans.
"(b) To meet the obligations of the loan fund established under section 1308(e) resulting from defaults on loans made from the fund and to meet the other obligations of the fund, there is authorized to be appropriated to the loan fund for fiscal years 1987, 1988, and 1989, such sums as may be necessary.".

SEC. 812. ORGAN TRANSPLANTS AS PART OF BASIC COVERAGE.

(a) Section 1302(1) (42 U.S.C. 300e-1(1)) is amended by inserting before the last sentence the following new sentence: "Such term includes a health service directly associated with an organ transplant only if such organ transplant was required to be included in basic health services on April 15, 1985.".

(b)(1) The amendment made by subsection (a) shall take effect on October 1, 1985, and shall cease to be in effect on April 1, 1988. Effective date. Termination date.

(2) After April 1, 1988, for purposes of title XIII of the Public Health Service Act, no health service directly associated with an organ transplant shall be considered to be a basic health service if such service would otherwise have been added as a basic health service between April 15, 1985, and April 1, 1988. 42 USC 300e-1 note. 42 USC 300e *et seq.*

SEC. 813. STUDY ON THE HEALTH MAINTENANCE ORGANIZATION PROGRAM.

(a) The Secretary of Health and Human Services shall provide for the conduct of a study to assess the operation and impact of the provisions of title XIII of the Public Health Service Act. The study shall— 42 USC 300e note.

(1) assess the attitudes of employers and employees toward prepaid health benefits plans, particularly health maintenance organization plans;

(2) examine the operation of the community rating approach and the impact of such approach on the membership composition and competitiveness of health maintenance organizations qualified under such title;

(3) analyze the effects of the dual choice option provided in section 1310 of such Act on health maintenance organizations and on other health benefits plans; 42 USC 300e-9.

(4) assess the approach used to add services no longer considered to be experimental to basic health services for health maintenance organizations qualified under such title, particularly with respect to the addition of organ transplants to such basic health services and the impact of such addition on the competitiveness of such health maintenance organizations; and

(5) examine the effect of minimum benefit requirements, underwriting restrictions, restrictions on cost sharing, and the requirement that services be provided without limitation as to time or cost on the competitiveness of health maintenance organizations qualified under such title.

Reports.

(b) Within 18 months after the date of enactment of this Act, the Secretary shall prepare and transmit to the Congress a report which describes the findings and conclusions of the study conducted under subsection (a) and contains such recommendations for legislative and regulatory action as the Secretary considers appropriate.

Contracts.

(c) Any contract entered into under this section shall be to such extent or in such amounts as are provided in appropriation Acts.

42 USC 300e-1.

SEC. 814. SERVICES OF PSYCHOLOGISTS.

(a) Paragraphs (1) and (2) of section 1302 of the Public Health Service Act are amended by inserting "psychologist," after "podiatrist," each place it appears.

(b) Paragraph (4) of such section is amended by striking out "and podiatrists" and inserting in lieu thereof "podiatrists, and psychologists".

(c) Paragraph (5) of such section is amended by inserting "psychology," after "optometry,".

42 USC 300e-1 note.

SEC. 815. EFFECTIVE DATE.

(a) Except as provided in subsection (b) and section 812(b), this title and the amendments made by this title shall take effect on October 1, 1985.

(b) Section 813 shall take effect on the date of enactment of this Act.

42 USC 300e-1 note.

SEC. 816. CONSTRUCTION.

The provisions of this title and of the amendments made by this title do not authorize the appropriation of any funds for fiscal year 1986.

Alzheimer's Disease and Related Dementias Services Research Act of 1986.

TITLE IX—ALZHEIMER'S DISEASE AND RELATED DEMENTIAS SERVICES RESEARCH

PART A—GENERAL PROVISIONS

SHORT TITLE

42 USC 11201 note.

SEC. 901. This title may be cited as the "Alzheimer's Disease and Related Dementias Services Research Act of 1986".

FINDINGS

42 USC 11201.

SEC. 902. The Congress finds that—

(1) best estimates indicate that between 2,000,000 and 3,000,000 Americans presently have Alzheimer's disease or related dementias;

(2) estimates of the number of individuals afflicted with Alzheimer's disease and related dementias are unreliable because current diagnostic procedures lack accuracy and sensitivity and because there is a need for epidemiological data on incidence and prevalence of such disease and dementias;

(3) studies estimate that between one-half and two-thirds of patients in nursing homes meet the clinical and mental status criteria for dementia;

(4) the care for individuals with Alzheimer's disease and related dementias falls primarily on their families, and such care is very often financially and emotionally devastating;

(5) the cost of caring for individuals with Alzheimer's disease and related dementias is great, and conservative estimates range between $38,000,000,000 and $42,000,000,000 per year solely for direct costs;

(6) although substantial progress has been made in recent years in identifying possible leads to the causes of Alzheimer's disease and related dementias and more progress can be expected in the near future, there is little likelihood of a breakthrough in the foreseeable future which would eliminate or substantially reduce the number of individuals with such disease and dementias or the difficulties of caring for such individuals;

(7) attempts to reduce the emotional and financial burden of caring for dementia patients is impeded by a lack of knowledge about such patients, how to care for such patients, the costs associated with such care, the effectiveness of various modes of care, the quality and type of care necessary at various stages of the disease, and other appropriate services that are needed to provide quality care;

(8) the results of the little research that has been undertaken concerning dementia has been inadequate or the results have not been widely disseminated;

(9) more knowledge is needed concerning—

(A) the epidemiology of, and the identification of risk factors for, Alzheimer's disease and related dementias;

(B) the development of methods for early diagnosis, functional assessment, and psychological evaluation of individuals with Alzheimer's disease for the purpose of monitoring the course of the disease and developing strategies for improving the quality of life for such individuals;

(C) the understanding of the optimal range and cost-effectiveness of community and institutional services for individuals with Alzheimer's disease and related dementias and their families, particularly with respect to the design, delivery, staffing, and mix of such services and the coordination of such services with other services, and with respect to the relationship of formal to informal support services;

(D) the understanding of optimal methods to combine formal support services provided by health care professionals with informal support services provided by family, friends, and neighbors of individuals with Alzheimer's disease, and the identification of ways family caregivers can be sustained through interventions to reduce psychological and social problems and physical problems induced by stress;

(E) existing data that are relevant to Alzheimer's disease and related dementias; and

(F) the costs incurred in caring for individuals with Alzheimer's disease and related dementias;

(10) it is imperative to provide appropriate coordination of the efforts of the Federal Government in the provision of services for individuals with Alzheimer's disease and related dementias;

(11) it is important to increase the understanding of Alzheimer's disease and related dementias by the diverse range of personnel involved in the care of individuals with such disease and dementias; and

(12) it is imperative that the Social Security Administration be provided information pertaining to Alzheimer's disease and related dementias, particularly for personnel in such Administration involved in the establishment and updating of criteria for determining whether an individual is under a disability for purposes of titles II and XVI of the Social Security Act.

42 USC 401 *et seq.*, 1381 *et seq.*

PART B—COUNCIL ON ALZHEIMER'S DISEASE

ESTABLISHMENT

42 USC 11211.

SEC. 911. (a) There is established in the Department of Health and Human Services (hereinafter referred to as the "Department") the Council on Alzheimer's Disease (hereinafter referred to as the "Council"). The Council shall be composed of—

(1) the Assistant Secretary for Health;

(2) the Surgeon General of the United States;

(3) the Assistant Secretary for Planning and Evaluation;

(4) the Director of the National Institute of Allergy and Infectious Diseases;

(5) the Director of the National Institute of Mental Health;

(6) the Director of the National Institute of Neurological and Communicative Diseases and Stroke;

(7) the Director of the National Institute on Aging;

(8) the Commissioner on Aging;

(9) the Administrator of the Health Care Financing Administration (or the designee of such Administrator);

(10) the Director of the National Center for Health Services Research and Health Care Technology Assessment;

(11) the Administrator of Veterans' Affairs (or the designee of such Administrator); and

(12) such additional members as the Secretary of Health and Human Services (hereinafter referred to as the "Secretary") considers appropriate.

(b) The Secretary shall select a Chairman for the Council from among its members.

(c) A majority of the members of the Council shall constitute a quorum, but a lesser number may hold hearings.

(d) The Council shall meet periodically at the call of the Chairman, but not less than twice each year.

(e) The Secretary shall appoint an Executive Secretary for the Council and shall provide the Council with such additional administrative staff and support as may be necessary to enable the Council to carry out its functions.

FUNCTIONS

42 USC 11212.

SEC. 912. (a) The Council shall—

(1) coordinate continuing research conducted by or through the Department on Alzheimer's disease and related dementias;

(2) establish a mechanism for the sharing of information among all officers and employees of the Department involved in carrying out programs serving elderly individuals; Aged persons.

(3) identify the most promising areas of research concerning Alzheimer's disease and related dementias;

(4) establish mechanisms to use the results of research concerning Alzheimer's disease and related dementias in the development of policies, programs, and means to improve the quality of life for older Americans; and Aged persons.

(5) assist the National Institute on Aging, the National Institute of Mental Health, and the National Center for Health Services Research and Health Care Technology Assessment in developing and coordinating the plans for research required under part E, and in making revisions in such plans. *Post*, p. 3808.

(b)(1) Not later than 9 months after the date of enactment of this Act, the Council shall transmit to the Congress and make available to the public a report detailing the plans for research prepared by the National Institute on Aging, the National Institute of Mental Health, and the National Center for Health Services Research and Health Care Technology Assessment under part E. Such report shall— Reports.

(A) describe, insofar as feasible, the activities to be carried out under such part during each of the fiscal years 1987, 1988, 1989, 1990, and 1991; and

(B) ensure that activities carried out under such part are coordinated with, and use, to the maximum extent feasible, the resources of, other Federal programs relating to Alzheimer's disease and related dementias, including centers supported under section 445 of the Public Health Service Act, centers supported by the National Institute of Mental Health on the psychopathology of the elderly, relevant activities of the Administration on Aging, other centers supported by Federal funds involved in research on Alzheimer's disease and related dementias, and other programs relating to Alzheimer's disease and related dementias which are planned or conducted by Federal agencies other than the Department, State or local agencies, community organizations, or private foundations. Aged persons. 42 USC 289h.

(2) Within 1 year after the date on which the report required by paragraph (1) is transmitted to the Congress, and annually thereafter, the Council shall transmit to the Congress, and make available to the public, a report on— Reports. Public information.

(A) the revisions made by the National Institute on Aging, the National Institute of Mental Health, and the National Center for Health Services Research and Health Care Technology Assessment in the plans for research required by part E;

(B) progress made by research sponsored by the Federal Government on Alzheimer's disease and related dementias; and

(C) new directions in research on Alzheimer's disease and related dementias which the Council considers potentially important.

PART C—ADVISORY PANEL ON ALZHEIMER'S DISEASE

ESTABLISHMENT OF PANEL

42 USC 11221.

SEC. 921. (a) There is established in the Department the Advisory Panel on Alzheimer's Disease (hereinafter referred to as the 'Panel'). The Panel shall be composed of—

(1) 15 voting members appointed by the Director of the Office of Technology Assessment, of which—

(A) 3 shall be individuals who are biomedical research scientists with demonstrated achievements in biomedical research relating to Alzheimer's disease, including at least one individual who is a researcher at a center supported under section 445 of the Public Health Service Act;

42 USC 289h.

(B) 3 shall be individuals with demonstrated achievements in research relevant to services for the care of individuals with Alzheimer's disease and related dementias;

(C) 3 shall be individuals who are providers of services, or administrators of organizations which provide services, for individuals with Alzheimer's disease and related dementias and their families;

(D) 3 shall be individuals who are experts in the financing of health care services and long-term care services, including one individual who is a representative of private health care services insurers; and

(E) 3 shall be representatives of national voluntary organizations which are concerned with the problems of individuals with Alzheimer's disease and related dementias and their families; and

(2) the Chairman of the Council, the Director of the National Institute on Aging, the Director of the National Institute of Mental Health, the Director of the National Center for Health Services Research and Health Care Technology Assessment, and the Commissioner on Aging, who shall be nonvoting ex officio members.

(b) The Director of the Office of Technology Assessment shall appoint members to the Panel under subsection (a)(1) within 90 days after the date of enactment of this Act.

(c) The Secretary shall appoint a Chairman of the Panel from among the members appointed under subsection (a)(1).

(d) Members of the Panel shall serve for the life of the Panel. A vacancy on the Panel shall be filled in the same manner as the original appointment was made. A vacancy on the Panel shall not affect its powers.

(e) A majority of the members of the Panel appointed under subsection (a)(1) shall constitute a quorum, but a lesser number may hold hearings. The Panel may establish such subcommittees as the Panel considers appropriate.

(f) The Panel shall meet at the call of the Chairman, but not less than twice per year.

(g) The Executive Secretary of the Council shall serve as Executive Secretary of the Panel. The Secretary shall provide the Panel with such additional administrative staff and support as may be necessary to enable the Panel to carry out its functions.

(h) Each member of the Panel appointed under subsection (a)(1) shall receive compensation at a rate of $100 per day for each day, including travel time, that such member is engaged in duties as a

member of the Panel. While away from their homes or regular places of business in the performance of duties as a member of the Panel, members of the Panel appointed under subsection (a)(1) shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under section 5702 of title 5, United States Code.

FUNCTIONS OF THE PANEL

SEC. 922. (a) The Panel shall assist the Secretary and the Council in the identification of priorities and emerging issues with respect to Alzheimer's disease and related dementias and the care of individuals with such disease and dementias. The Panel shall advise the Secretary and the Council with respect to the identification of— 42 USC 11222.

(1) emerging issues in, and promising areas of, biomedical research relating to Alzheimer's disease and related dementias;

(2) emerging issues in, and promising areas of, research relating to services for individuals with Alzheimer's disease and related dementias and their families;

(3) emerging issues and promising initiatives in home and community based services, and systems of such services, for individuals with Alzheimer's disease and related dementias and their families; and

(4) emerging issues in, and innovative financing mechanisms for, payment for health care services and social services for individuals with Alzheimer's disease and related dementias and their families, particularly financing mechanisms in the private sector.

(b) The Panel shall prepare and transmit to the Congress, the Secretary, and the Council, and make available to the public, an annual report. Such report shall contain such recommendations as the Panel considers appropriate for administrative and legislative actions to improve services for individuals with Alzheimer's disease and related dementias and their families and to provide for promising biomedical research relating to Alzheimer's disease and related dementias. Reports. Public information.

AUTHORIZATION OF APPROPRIATIONS

SEC. 923. To carry out this part, there are authorized to be appropriated $100,000 for each of the fiscal years 1988 through 1991. 42 USC 11223.

PART D—AWARDS FOR LEADERSHIP AND EXCELLENCE IN ALZHEIMER'S DISEASE AND RELATED DEMENTIAS

AWARDS AUTHORIZED

SEC. 931. (a) The Director of the National Institute on Aging shall make awards to senior researchers who have made distinguished achievements in biomedical research in areas relating to Alzheimer's disease and related dementias. Awards under this section shall be used by the recipients to support research in areas relating to such disease and dementias, and may be used by the recipients to train junior researchers who demonstrate exceptional promise to conduct research in such areas. Research and development. 42 USC 11231.

(b) The Director of the National Institute on Aging may make awards under this section to researchers at centers supported under

42 USC 289h.

section 445 of the Public Health Service Act and to researchers at other public and nonprofit private entities.

(c) The Director of the National Institute on Aging shall make awards under this section only to researchers who have been recommended for such awards by the National Advisory Council on Aging.

(d) The Director of the National Institute on Aging shall establish procedures for the selection of the recipients of awards under this section.

(e) Awards under this section shall be made for a one-year period, and may be renewed for not more than six additional consecutive one-year periods.

AUTHORIZATION OF APPROPRIATIONS

Research and development.
42 USC 11232.

SEC. 932. To carry out this part, there are authorized to be appropriated $5,000,000 for each of the fiscal years 1988 through 1991. Amounts authorized to be appropriated under this section are in addition to amounts authorized to be appropriated for biomedical research relating to Alzheimer's disease and related dementias under part E of this title and under other provisions of law.

PART E—RESEARCH RELATING TO SERVICES FOR INDIVIDUALS WITH ALZHEIMER'S DISEASE AND RELATED DEMENTIAS AND THEIR FAMILIES

SUBPART 1—RESPONSIBILITIES OF THE NATIONAL INSTITUTE ON AGING

RESEARCH PROGRAM AND PLAN

Grants.
42 USC 11241.

SEC. 941. (a) The Director of the National Institute on Aging shall conduct, or make grants for the conduct of, research relevant to appropriate services for individuals with Alzheimer's disease and related dementias and their families.

(b)(1) Within 6 months after the date of enactment of this Act, the Director of the National Institute on Aging shall prepare and transmit to the Chairman of the Council a plan for the research to be conducted under subsection (a). The plan shall—

(A) provide for research concerning—

(i) the epidemiology of, and the identification of risk factors for, Alzheimer's disease and related dementias; and

(ii) the development and evaluation of reliable and valid multidimensional diagnostic and assessment procedures and instruments; and

(B) ensure that research carried out under the plan is coordinated with, and uses, to the maximum extent feasible, resources of, other Federal programs relating to Alzheimer's disease and related dementias, including centers supported under section 445 of the Public Health Service Act, centers supported by the National Institute of Mental Health on the psychopathology of the elderly, relevant activities of the Administration on Aging, other programs and centers involved in research on Alzheimer's disease and related dementias supported by the Department, and other programs relating to Alzheimer's disease and related dementias which are planned or conducted by Federal agencies other than the Department, State or local agencies, community organizations, or private foundations.

(2) Within one year after transmitting the plan required under paragraph (1), and annually thereafter, the Director of the National Institute on Aging shall prepare and transmit to the Chairman of the Council such revisions of such plan as the Director considers appropriate.

(c) In preparing and revising the plan required by subsection (b), the Director of the National Institute on Aging shall consult with the Chairman of the Council and the heads of agencies within the Department.

DISSEMINATION

SEC. 942. The Director of the National Institute on Aging shall disseminate the results of research conducted under this subpart to appropriate professional entities and to the public.

Research and development.
42 USC 11242.

AUTHORIZATION OF APPROPRIATIONS

SEC. 943. To carry out this subpart, there are authorized to be appropriated $2,000,000 for each of fiscal years 1988 through 1991.

42 USC 11243.

Subpart 2—Responsibilities of the National Institute of Mental Health

RESEARCH PROGRAM AND PLAN

SEC. 944. (a) The Director of the National Institute of Mental Health shall conduct, or make grants for the conduct of, research relevant to appropriate services for individuals with Alzheimer's disease and related dementias and their families.

Grants.
42 USC 11251.

(b)(1) Within 6 months after the date of enactment of this Act, the Director of the National Institute of Mental Health shall prepare and transmit to the Chairman of the Council a plan for the research to be conducted under subsection (a). The plan shall—

(A) provide for research concerning—

(i) mental health services and treatment modalities relevant to the mental, behavioral, and psychological problems associated with Alzheimer's disease and related dementias;

(ii) the most effective methods for providing comprehensive multidimensional assessments to obtain information about the current functioning of, and needs for the care of, individuals with Alzheimer's disease and related dementias;

(iii) the optimal range and cost-effectiveness of community and institutional services for individuals with Alzheimer's disease and related dementias and their families, particularly with respect to the design of such services, appropriate staffing for the provision of such services, the timing of such services during the progression of such disease or dementias, and the appropriate mix and coordination of such services;

(iv) the efficacy of various special care units in the United States for individuals with Alzheimer's disease, including an assessment of the costs incurred in operating such units, appropriate standards to be used by such units, and the measurement of patient outcomes in such units;

(v) methods to combine formal support services provided by health care professionals for individuals with Alz-

heimer's disease and related dementias with informal support services provided for such individuals by their families, friends, and neighbors, including services such as day care services, respite care services, home care services, and nursing home services, and an evaluation of the services actually used for such individuals and the sources of payment for such services;

(vi) methods to sustain family members who provide care for individuals with Alzheimer's disease and related dementias through interventions to reduce psychological and social problems and physical problems induced by stress; and

(vii) improved methods to deliver services for individuals with Alzheimer's disease and related dementias and their families, including services such as outreach services, comprehensive assessment and care management services, outpatient treatment services, home care services, respite care services, adult day care services, partial hospitalization services, and nursing home services; and

(B) ensure that research carried out under the plan is coordinated with, and uses, to the maximum extent feasible, resources of, other Federal programs relating to Alzheimer's disease and dementia, including centers supported under section 445 of the Public Health Service Act, centers supported by the National Institute of Mental Health on the psychopathology of the elderly, relevant activities of the Administration on Aging, other programs and centers involved in research on Alzheimer's disease and related dementias supported by the Department, and other programs relating to Alzheimer's disease and related dementias which are planned or conducted by Federal agencies other than the Department, State or local agencies, community organizations, or private foundations.

42 USC 289h.

(2) Within one year after transmitting the plan required under paragraph (1), and annually thereafter, the Director of the National Institute of Mental Health shall prepare and transmit to the Chairman of the Council such revisions of such plan as the Director considers appropriate.

(c) In preparing and revising the plan required by subsection (b), the Director of the National Institute of Mental Health shall consult with the Chairman of the Council and the heads of agencies within the Department.

DISSEMINATION

Research and development.
42 USC 11252.

SEC. 945. The Director of the National Institute of Mental Health shall disseminate the results of research conducted under this subpart to appropriate professional entities and to the public.

AUTHORIZATION OF APPROPRIATIONS

42 USC 11253.

SEC. 946. To carry out this subpart, there are authorized to be appropriated $2,000,000 for each of fiscal years 1988 through 1991.

Subpart 3—Responsibilities of the National Center for Health Services Research and Health Care Technology Assessment

RESEARCH PROGRAM AND PLAN

SEC. 947. (a) The Director of the National Center for Health Services Research and Health Care Technology Assessment shall conduct, or make grants for the conduct of, research relevant to appropriate services for individuals with Alzheimer's disease and related dementias and their families. Grants. 42 USC 11261.

(b)(1) Within 6 months after the date of enactment of this Act, the Director of the National Center for Health Services Research and Health Care Technology Assessment shall prepare and transmit to the Chairman of the Council a plan for the research to be conducted under subsection (a). The plan shall—

(A) provide for the inventory and analysis of existing data and studies relevant to Alzheimer's disease and related dementias, including data and studies available through the Health Care Financing Administration, the Administration on Aging, the National Center for Health Statistics, the Office of Human Development Services, the Office of the Assistant Secretary for Planning and Evaluation, and the Veterans' Administration;

(B) provide for research concerning the costs incurred by individuals with Alzheimer's disease and related dementias in obtaining services, particularly services which are essential to such individuals and which are not needed by other patients under long-term care;

(C) provide for research on the costs of various interventions to provide services for individuals with Alzheimer's disease and related dementias and their families;

(D) provide for research on the cost-effectiveness of various service interventions for individuals with Alzheimer's disease and related dementias and their families; and

(E) ensure that research carried out under the plan is coordinated with, and uses, to the maximum extent feasible, resources of, other Federal programs relating to Alzheimer's disease and dementia, including centers supported under section 445 of the Public Health Service Act, centers supported by the National Institute of Mental Health on psychopathology of the elderly, relevant activities of the Administration on Aging, other programs and centers involved in research on Alzheimer's disease and related dementias supported by the Department, and other programs relating to Alzheimer's disease and related dementias which are planned or conducted by Federal agencies other than the Department, State or local agencies, community organizations, or private foundations. 42 USC 289h.

(2) Within one year after transmitting the plan required under paragraph (1), and annually thereafter, the Director of the National Center for Health Services Research and Health Care Technology Assessment shall prepare and transmit to the Chairman of the Council such revisions of such plan as the Director considers appropriate.

(c) In preparing and revising the plan required by subsection (b), the Director of the National Center for Health Services Research and Health Care Technology Assessment shall consult with the Chairman of the Council and the heads of agencies within the Department.

DISSEMINATION

Research and development.
42 USC 11262.

SEC. 948. The Director of the National Center for Health Services Research and Health Care Technology Assessment shall disseminate the results of research conducted under this subpart to appropriate professional entities and to the public.

AUTHORIZATION OF APPROPRIATIONS

42 USC 11263.

SEC. 949. To carry out this subpart, there are authorized to be appropriated $2,000,000 for each of fiscal years 1988 through 1991.

Subpart 4—Responsibilities of the Health Care Financing Administration

RESEARCH PROGRAM AND PLAN

Grants.
42 USC 11271.

SEC. 949A. (a) The Administrator of the National Health Care Financing Administration shall conduct, or make grants for the conduct of, research relevant to appropriate services for individuals with Alzheimer's disease and related dementias and their families.

(b)(1) Within 6 months after the date of enactment of this Act, the Administrator of the Health Care Financing Administration shall prepare and transmit to the Chairman of the Council a plan for research to be conducted under (a). The plan shall—

(A) provide for a determination of the types of services required by individuals with Alzheimer's disease and related dementias and their families to allow such individuals to remain living at home or in a community-based setting;

(B) provide for a determination of the costs of providing needed services to individuals with Alzheimer's disease and related dementias and their families, including the expenditures for institutional, home, and community-based services and the source of payment for such expenditures;

(C) provide for an assessment of the adequacy of benefits provided through the Medicare and Medicaid programs and through private health insurance for needed services for individuals with Alzheimer's disease and related dementias and their families; and

(D) provide for a determination of the costs to the Medicare and Medicaid programs and to private health insurers (if available) of providing covered benefits to individuals with Alzheimer's disease and related dementias and their families.

(2) Within one year after transmitting the plan required under paragraph (1), and annually thereafter, the Administrator of the Health Care Financing Administration shall prepare and transmit to the Chairman of the Council such revisions of such plan as the Administrator considers appropriate.

(c) In preparing and revising the plan required by subsection (b), the Administrator of the Health Care Financing Administration shall consult with the Chairman of the Council and the heads of agencies within the Department.

DISSEMINATION

42 USC 11272.

SEC. 949B. The Administrator of the Health Care Financing Administration shall disseminate the results of research conducted

under this subpart to appropriate professional entities and to the public.

AUTHORIZATIONS OF APPROPRIATIONS

SEC. 949C. To carry out this subpart, there are authorized to be appropriated $2,000,000 for each of fiscal years 1988 through 1991. 42 USC 11273.

PART F—DISSEMINATION

CLEARINGHOUSE ON ALZHEIMER'S DISEASE

SEC. 951. (a) The Director of the National Institute on Aging shall establish the Clearinghouse on Alzheimer's Disease (hereinafter referred to as the "Clearinghouse"). The purpose of the Clearinghouse is the dissemination of information concerning services available for individuals with Alzheimer's disease and related dementias and their families. The Clearinghouse shall— 42 USC 11281.

(1) compile, archive, and disseminate information concerning research, demonstration, evaluation, and training programs and projects concerning Alzheimer's disease and related dementias; and Research and development.

(2) annually publish a summary of the information compiled under paragraph (1) during the preceding 12-month period, and make such information available upon request to appropriate individuals and entities, including educational institutions, research entities, and Federal and public agencies. Research and development. Education.

(b) The Clearinghouse may charge an appropriate fee for information provided through the toll-free telephone line established under subsection (a)(3). Communications and telecommunications.

(c) The Director of the National Institute on Aging, the Director of the National Institute of Mental Health, and the Director of the National Center for Health Services Research and Health Care Technology Assessment shall provide to the Clearinghouse summaries of the findings of research conducted under part E. *Ante*, p. 3808.

DISSEMINATION PROJECT

SEC. 952. (a) The Director of the National Institute on Aging shall make a grant to, or enter into a contract with, a national organization representing individuals with Alzheimer's disease and related dementias for the conduct of the activities described in subsection (b). Grants. Contracts. 42 USC 11282.

(b) The organization receiving a grant or contract under this section shall—

(1) establish a central computerized information system to— Science and technology.

(A) compile and disseminate information concerning initiatives by State and local governments and private entities to provide programs and services for individuals with Alzheimer's disease and related dementias; and State and local governments.

(B) translate scientific and technical information concerning such initiatives into information readily understandable by the general public, and make such information available upon request; and

(2) establish a national toll-free telephone line to make available the information described in paragraph (1), and information concerning Federal programs, services, and benefits for Communications and telecommunications.

individuals with Alzheimer's disease and related dementias and their families.

(c) The organization receiving a grant or contract under this section may charge appropriate fees for information provided through the toll-free telephone line established under subsection (b)(2), and may make exceptions to such fees for individuals and organizations who are not financially able to pay such fees.

(d) In order to receive a grant or contract under this section, an organization shall submit an application to the Director of the National Institute on Aging. Such application shall contain—

(1) information demonstrating that such organization has a network of contacts which will enable such organization to receive information necessary to the operation of the central computerized information system described in subsection (b)(1);

(2) information demonstrating that, by the end of fiscal year 1991, such organization will be financially able to, and will, carry out the activities described in subsection (b) without a grant or contract from the Federal Government; and

(3) such other information as the Director may prescribe.

AUTHORIZATION OF APPROPRIATIONS

42 USC 11283.

SEC. 953. To carry out this part, there are authorized to be appropriated $300,000 for each of the fiscal years 1988 through 1991.

PART G—EDUCATIONAL ACTIVITIES

PROVIDING INFORMATION FOR PERSONNEL OF THE SOCIAL SECURITY ADMINISTRATION

42 USC 11291.

SEC. 961. (a) The Secretary shall develop a mechanism to ensure the prompt provision of the most current information concerning Alzheimer's disease and related dementias to the Commissioner of Social Security, particularly information which will increase the understanding of personnel of the Social Security Administration concerning such disease and dementias.

(b) The Commissioner of Social Security shall ensure that information received under subsection (a) is provided to personnel of the Social Security Administration, particularly personnel involved in the process of determining, for purposes of titles II and XVI of the Social Security Act, whether an individual is under a disability.

42 USC 401 *et seq*, 1381 *et seq.*

EDUCATION PROGRAMS FOR PROVIDERS OF CARE FOR INDIVIDUALS WITH ALZHEIMER'S DISEASE

Physicians.
Nurses.
Psychologists.
Social workers.
Therapists.
42 USC 11292.
42 USC 289h.

SEC. 962. The Director of the National Institute on Aging, through centers supported under section 445 of the Public Health Service Act, professional associations, and continuing education programs, shall conduct education and information dissemination activities concerning the special problems of individuals with Alzheimer's disease and their families. Such activities shall be designed to enhance the understanding of such problems by individuals who provide care for individuals with Alzheimer's disease and related dementias, including physicians, nurses, psychologists, social workers, occupational therapists, nursing home administrators, nurses, and health care aides.

EDUCATION PROGRAMS FOR SAFETY AND TRANSPORTATION PERSONNEL

SEC. 963. The Director of the National Institute on Aging, through centers supported under section 445 of the Public Health Service Act, training academies, and continuing education programs, shall conduct education and information dissemination activities concerning Alzheimer's disease and related dementias for personnel involved in ensuring the public safety and providing public transportation. Such activities shall be designed to enhance the ability of such personnel to respond appropriately to individuals with Alzheimer's disease and related dementias whom such personnel may encounter in the course of their employment. 42 USC 11293. 42 USC 289h.

AUTHORIZATION OF APPROPRIATIONS

SEC. 964. To carry out this part, there are authorized to be appropriated $1,000,000 for each of the fiscal years 1988 through 1991. 42 USC 11294.

Approved November 14, 1986.

LEGISLATIVE HISTORY—S. 1744:

SENATE REPORTS: No. 99-380 (Comm. on Labor and Human Resources).
CONGRESSIONAL RECORD, Vol. 132 (1986):
Aug. 12, considered and passed Senate.
Oct. 17, considered and passed House, amended.
Oct. 18, Senate concurred in House amendment.
WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 22 (1986):
Nov. 14, Presidential statement.