AN ACT

TO PROVIDE FOR THE IMMUNIZATION OF ALL CHILDREN IN THE UNITED STATES AGAINST VACCINE-PREVENTABLE DISEASES, AND FOR OTHER PURPOSES.
AN ACT

To provide for the immunization of all children in the United States against vaccine-preventable diseases, and for other purposes.

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

SECTION 1. SHORT TITLE, REFERENCES AND PURPOSE.
(a) SHORT TITLE.—This Act may be cited as the “Comprehensive Child Immunization Act of 1993”.

S. 732

103d CONGRESS 1st Session
(b) REFERENCES.—Except as otherwise expressly provided, whenever in this Act 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 made to a section or other provision of the Public Health Service Act (42 U.S.C. 201 et seq.).

(c) PURPOSE.—It is the purpose of this Act to ensure that children in the United States are appropriately immunized against vaccine preventable infectious diseases at the earliest appropriate age.

SEC. 2. MONITORING OF CHILDHOOD IMMUNIZATIONS.

Title XXI of the Public Health Service Act (42 U.S.C. 300aa-1 et seq.) is amended by adding at the end thereof the following new subtitle:

"Subtitle 3—Improved Immunization Delivery and Monitoring Systems

"Part A—List of Vaccines and Administration

"SEC. 2141. LIST OF PEDIATRIC VACCINES; SCHEDULE FOR ADMINISTRATION.

"(a) RECOMMENDED PEDIATRIC VACCINES.—

"(1) IN GENERAL.—The Secretary shall establish a list of the vaccines that the Secretary recommends for administration to all children for the purpose of immunizing the children, subject to such
contraindications for particular medical categories of children as the Secretary may establish under subsection (b)(1)(D). The Secretary shall periodically review the list, and shall revise the list as appropriate.

"(2) Rule of Construction.—

"(A) The list of vaccines specified in subparagraph (B) is deemed to be the list of vaccines maintained under paragraph (1).

"(B) The list of vaccines specified in this subparagraph is the list of vaccines that, for purposes of paragraph (1), is established (and periodically reviewed and as appropriate revised) by the Advisory Committee on Immunization Practices, an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention.

"(b) Recommended Schedule for Administration.—

"(1) In General.—Subject to paragraph (2), in the case of a pediatric vaccine, the Secretary shall establish (and periodically review and as appropriate revise) a schedule of nonbinding recommendations for the following:
“(A) The number of immunizations with the vaccine that children should receive.

“(B) The ages at which children should receive the immunizations.

“(C) The dose of vaccine that should be administered in the immunizations.

“(D) Any contraindications regarding administration of the vaccine.

“(E) Such other guidelines as the Secretary determines to be appropriate with respect to administering the vaccine to children.

“(2) Variations in Medical Practice.—In establishing and revising a schedule under paragraph (1), the Secretary shall ensure that, in the case of the pediatric vaccine involved, the schedule provides for the full range of variations in medical judgment regarding the administration of the vaccine, subject to remaining within medical norms.

“(3) Rule of Construction.—

“(A) The schedule specified in subparagraph (B) is deemed to be the schedule maintained under paragraph (1).

“(B) The schedule specified in this subparagraph is the schedule that, for purposes of paragraph (1), is established (and periodically
reviewed and as appropriate revised) by the ad-
visory committee specified in subsection
(a)(2)(B).

"(c) Generally Applicable Rules of Construc-
tion.—This section does not supersede any State law or
requirements with respect to receiving immunizations (in-
cluding any such law relating to religious exemptions or
other exemptions under such State laws).

"(d) Issuance of List and Schedules.—Not
later than 180 days after the date of the enactment of
this section, the Secretary shall establish the initial list
required in subsection (a) and the schedule required in
subsection (b).

"Part B—State Registry System for Immunization
Information

"SEC. 2145. PURPOSE.

"It is the purpose of this part to authorize the Sec-
retary, in consultation with State public health officials,
to establish State registry systems to monitor the immuni-
ization status of all children.

"SEC. 2146. GRANTS FOR IMMUNIZATION REGISTRIES.

"(a) In General.—For the purpose described in
section 2145, the Secretary, acting through the Director
of the Centers for Disease Control and Prevention, shall
make an allotment each fiscal year for each State in an
amount determined in accordance with section 2151. The Secretary shall make a grant to the State of the allotment made for the State for the fiscal year if the State submits to the Secretary an application in accordance with section 2150 on behalf of the chief executive officer of such State.

"(b) Design of State Registries.—To carry out the purpose described in section 2145, a State registry established under this part shall be designed to—

“(1) provide accurate and up to date surveillance data regarding immunization rates at the State and local levels;

“(2) assist in identifying localities with inadequate immunization rates to target for necessary remedial assistance;

“(3) assist in the effective administration and management of immunization programs at State and local levels by providing data to guide immunization program efforts;

“(4) assist the State in providing and receiving information on the immunization status of children who move across geographic boundaries that are covered by different State or local registries; and

“(5) facilitate the linkage of vaccine dosage information to adverse events reported to the Centers for Disease Control and Prevention under section
2125(b) and disease outbreak patterns, for the purpose of monitoring vaccine safety and effectiveness.

“(c) Eligible Use of Funds.—The Secretary may make a grant under subsection (a) only if the State agrees to expend the grant for the purpose of—

“(1) collecting the data described in section 2147;

“(2) operating registries to maintain the data (and establishing such registries, in the case of a State that is not operating such a registry);

“(3) utilizing the data to monitor the extent to which children have received immunizations in accordance with the schedule established under section 2141;

“(4) notifying parents, as appropriate, if children have not received immunizations in accordance with such schedule;

“(5) coordinating and exchanging information with other State registries to allow the monitoring of the immunization status of children changing State of residence; and

“(6) such other activities as the Secretary may authorize with respect to achieving the objectives established by the Secretary for the year 2000 for the
immunization status of children in the United States.

“(d) REQUIREMENT REGARDING STATE LAW.—

“(1) IN GENERAL.— The Secretary may make a grant under subsection (a) only if the State involved—

“(A) provides assurances satisfactory to the Secretary that, not later than October 1, 1996, the State will be operating a registry in accordance with this part, including having in effect such laws and regulations as may be necessary to so operate such a registry;

“(B) agrees that, prior to such date, the State will make such efforts to operate a registry in accordance with this part as may be authorized in the law and regulations of the State; and

“(C) has in effect such laws and regulations as may be necessary to ensure the following safeguards for the rights of parents:

“(i) An exemption for the parent, upon the request of the parent, from the requirements established by the State, pursuant to this part, for the collection of data described in subsections (b) and (c) of
section 2147, or the collection of any other data regarding any child of the parent that the State may require for incorporation in the State immunization registry.

"(ii) Restrictions ensuring that no information relating to a child or to the parent or guardian of a child that is collected or maintained by the State immunization registry pursuant to this part, or the national immunization surveillance program established under section 2153, will be used as a basis for the criminal prosecution or the commencement of a criminal investigation of a parent or guardian.

"(2) Rules of construction.—

"(A) With respect to the agreements made by a State under this part, other than paragraph (1)(B), the Secretary may require compliance with the agreements only to the extent consistent with such paragraph.

"(B) The provisions of this part do not authorize the Secretary, as a condition of the receipt of a grant under subsection (a) by a State, to prohibit the State from providing any parent, upon the request of the parent, with an
exemption from the requirements established by
the State pursuant to this part for the collec-
tion of data regarding any child of the parent.

“SEC. 2147. REGISTRY DATA.

“(a) In General.—For purposes of section
2146(c)(1), the data described in this section are the data
described in subsection (b) and the data described in sub-
section (c).

“(b) Data Regarding Birth of Child.—With re-
spect to the birth of a child, the data described in this
subsection is as follows:

“(1) The name of each child born in the State
involved after the date of the implementation of the
registry (in no event shall such date be later than
October 1, 1996).

“(2) Demographic data on the child.

“(3) The name of one or both of the parents of
the child. If the child has been given up for adop-
tion, any information regarding the identity of the
birth parent or parents of the child may not be en-
tered into the registry, or if entered, shall be deleted.

“(4) The address, as of the date of the birth of
the child, of each parent whose name is received in
the registry pursuant to paragraph (3).
(c) Data Regarding Individual Immunizations.—With respect to a child to whom a pediatric vaccine is administered in the State involved, the data described in this subsection is as follows:

“(1) The name, age, and address of the child.

“(2) The date on which the vaccine was administered to the child.

“(3) The name and business address of the health care provider that administered the vaccine.

“(4) The address of the facility at which the vaccine was administered.

“(5) The name and address of one or both parents of the child as of the date on which the vaccine was administered, if such information is available to the health care provider.

“(6) The type of vaccine.

“(7) The lot number or other information identifying the particular manufacturing batch of the vaccine.

“(8) The dose of vaccine that was administered.

“(9) A notation of the presence of any adverse medical reactions that the child experienced in relation to the vaccine and of which the health care provider is aware, in accordance with section 2125.
“(10) The presence of contraindications noted by the health care provider with respect to administration of the vaccine to the child.

“(11) Such other data regarding immunizations for the child, including identifying data, as the Secretary, in consultation with State public health officials, may require consistent with applicable law (including social security account numbers furnished pursuant to section 205(c)(2)(E) of the Social Security Act).

“(d) LIMITATION.—The Secretary may not establish information reporting requirements in addition to those described in subsection (c) if such requirements are unduly burdensome.

“(e) DATE CERTAIN FOR SUBMISSION TO REGISTRY.—The Secretary may make a grant under section 2146 only if the State involved agrees to ensure that, with respect to a child—

“(1) the data described in subsection (b) are submitted to the registry under such section as soon as possible but in no event later than 8 weeks after the date on which the child is born; and

“(2) the data described in subsection (c) with respect to a vaccine are submitted to such registry as soon as possible but in no event later than 4
weeks after the date on which the vaccine is administered to the child.

“(f) Uniformity in Methodologies.—The Secretary shall, in consultation with State public health officials, establish standards regarding the methodologies used in establishing and operating registries under section 2146, and may make a grant under such section only if the State agrees to comply with the standards. The Secretary shall provide maximum flexibility to the States while also retaining a reasonable degree of uniformity among the States in such methodologies for the purpose of ensuring the utility, comparability, and exchange of the data maintained in such registries.

“(g) Coordination Among States.—The Secretary may make a grant under section 2146 to a State only if, with respect to the operation of the registry of the State under such section, the State agrees to transfer that information contained in the State registry pursuant to section 2146 to other States upon the request of such States for such information.

“SEC. 2148. FEDERAL STANDARDS ON CONFIDENTIALITY.

“(a) Establishment.—

“(1) In general.—The Secretary, in consultation with the States, shall by regulation establish standards providing for maintaining the confidential-
ity of the identity of individuals with respect to whom data are maintained in registries under section 2146. Such standards shall, with respect to a State, provide that the State is to have in effect laws or regulations regarding such confidentiality, including appropriate penalties for violation of the laws. The Secretary may make a grant under such section only if the State involved agrees to comply with the standards.

"(2) USE OF DISCLOSURE.—

"(A) No personally identifiable information relating to a child or to the parent or guardian of such child that is collected or maintained by the State registry may be used or disclosed by any holder of such information except as permitted for—

"(i) the monitoring of a child’s immunization status;

"(ii) oversight, audit, and evaluation of the immunization delivery and registry systems;

"(iii) activities relating to establishing and maintaining a safe and effective supply of recommended childhood vaccine;
“(iv) processing of insurance claims for payment for vaccine administration (but only to the extent necessary for processing claims); and

“(v) administration of the National Vaccine Injury Compensation Program under subtitle 2.

“(B) Information regarding immunizations provided as described in subparagraph (A)(i) may be used or disclosed only with the written authorization of the individual to whom it refers or to the parent with custody of such individual.

“(b) USE OF SOCIAL SECURITY ACCOUNT NUMBERS.—Any usage or disclosure of data in registries under section 2146 that consists of social security account numbers and related information which is otherwise permitted under this part may be exercised only to the extent permitted under section 205(c)(2)(E) of the Social Security Act. For purposes of the preceding sentence, the term ‘related information’ has the meaning given such term in clause (iv)(II) of such section.

“SEC. 2149. PROVIDER PARTICIPATION.

“(a) IN GENERAL.—The State shall monitor and enforce compliance by health care providers with the requirements of sections 2147 and 2148 and section 2155(b) for
all doses of pediatric vaccine administered in the State. The State shall establish procedures satisfactory to the Secretary for discontinuing the distribution of federally purchased or State purchased vaccine for any health care provider who fails to comply with the requirements of section 2147 and for reinstating such vaccine supply to such provider upon receiving from such provider—

“(1) the reports necessary to make current and complete the information that would have been furnished to the State registry between the dates of the provider’s termination and reinstatement; and

“(2) satisfactory assurances regarding the provider’s future compliance.

“(b) REPORTS TO SECRETARY.—The Secretary may make a grant under section 2146 only if the State involved agrees to submit to the Secretary such reports as the Secretary determines to be appropriate with respect to the activities of the State under this part.

"SEC. 2150. APPLICATION FOR GRANT.

"An application by a State for a grant under section 2146 is in accordance with this section if the application—

“(1) is submitted not later than the date specified by the Secretary;

“(2) contains each agreement required in this part;
“(3) contains any information required in this part to be submitted to the Secretary; and
“(4) is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

“SEC. 2151. DETERMINATION OF AMOUNT OF ALLOTMENT.
“The Secretary shall determine the amount of the allotments required in section 2146 for States for a fiscal year in accordance with a formula established by the Secretary that allots the amounts appropriated under section 2152 for the fiscal year on the basis of the costs of the States in establishing and operating registries under section 2146.

“SEC. 2152. AUTHORIZATION OF APPROPRIATIONS.
“For the purpose of carrying out this part, other than section 2153, there are authorized to be appropriated $152,000,000 for fiscal year 1994, $125,000,000 for fiscal year 1995, and $35,000,000 for each of the fiscal years 1996 through 1999.

“SEC. 2153. NATIONAL IMMUNIZATION SURVEILLANCE PROGRAM.
“(a) In General.—The Secretary shall establish a national immunization surveillance program for the purpose of assessing the effects of the programs and activities
provided for in this subtitle towards appropriately immunizing children and facilitating State immunization registries. The national immunization surveillance program shall—

“(1) provide technical assistance to States for the development of vaccination registries and monitoring systems; and

“(2) receive aggregate epidemiologic data (that is in a format that is not person specific) collected by States as provided for in section 2147 at intervals determined appropriate by the Secretary for the purpose of—

“(A) compiling accurate and up-to-date surveillance data regarding immunization rates at the State level in order to assess the progress made towards achieving nationally established immunization goals;

“(B) assisting in the effective administration and management of immunization programs at the State level by providing technical assistance to guide immunization program efforts at the request of the State;

“(C) providing technical assistance to States and localities to facilitate monitoring the immunization status of children who move
across geographic boundaries that are covered by different State or local registries at the request of such States or localities; and

“(D) monitoring the safety and effectiveness of vaccines by linking vaccine dosage information with adverse events reporting under section 2125(b) and disease outbreak patterns.

“(b) Rule of Construction.—Nothing in this sub-title shall be construed to authorize the release of person specific information to the Secretary for the purpose of immunization surveillance.

“(c) Authorization of Appropriations.—There are authorized to be appropriated such sums as may be necessary to carry out this section in each of the fiscal years 1994 through 1999.

“SEC. 2154. REPORT.

“Not later than January 1, 1995, and biennially thereafter, the Secretary shall prepare and submit to the appropriate committees of Congress a report concerning the planning, development, operation and effectiveness of the national immunization surveillance program and the State immunization registries.
“Part C—Distribution of Vaccines, Public Outreach and Education

“SEC. 2155. DISTRIBUTION OF VACCINES.

“(a) IN GENERAL.—

“(1) HEALTH CARE PROVIDERS.—The Secretary shall provide for the distribution, without charge, of recommended pediatric vaccines (in accordance with section 2141) purchased by the Secretary to health care providers who serve children and who—

“(A) are members of a uniformed service, or are officers or employees of the United States;

“(B) are health centers (as defined in section 2162(2)); or

“(C) provide services under section 503 of the Indian Health Care Improvement Act or pursuant to a contract under section 102 of the Indian Self Determination Act.

“(2) STATES.—The Secretary shall provide for the distribution, without charge, of those recommended pediatric vaccines that are purchased by the Secretary and provided to States for the purposes of immunizing medicaid-eligible children, and additional vaccines that may be purchased by the Secretary for children within those States.
“(b) DUTIES OF HEALTH CARE PROVIDERS.—

“(1) FREE PROVISION TO CHILDREN.— A health care provider or entity receiving vaccine under this section may use such vaccine only for administration to children and may not impose a charge for such vaccine. A provider or health care entity may impose a fee that reflects actual regional costs as determined by the Secretary for the administration of such vaccine, except that a provider may not deny a child a vaccination due to the inability of the child’s parent to pay an administration fee.

“(2) REPORTING REQUIREMENTS.— A health care provider receiving vaccine under this section shall report the information required under section 2147 to the applicable State registry operated pursuant to a grant under section 2146 if such State registry exists. The provider shall additionally report to such State registry any occurrence reported to the Secretary pursuant to section 2125(b). The provider shall also provide regular and periodic estimates to the State of the provider’s future dosage needs for recommended childhood vaccines distributed under this section. All reports shall be made with such frequency and in such detail as the Secretary, in con-
consultation with State public health officials, may pre-
scribe.

"SEC. 2156. IMPROVED IMMUNIZATION DELIVERY, OUT-
REACH AND EDUCATION.

“(a) FEDERAL EFFORTS.—The Secretary, acting
through the Centers for Disease Control and Prevention
and in conjunction with State health officials and other
appropriate public and private organizations, shall conduct
the following activities to improve Federal, State and local
vaccine delivery systems and immunization outreach and
education efforts:

“(1) NATIONAL PUBLIC AWARENESS CAM-
PAIGN.—

“(A) IN GENERAL.—The Secretary, in con-
junction with State health officials and other
appropriate public and private organizations,
shall develop and implement a National Immu-
nization Public Awareness Campaign to assist
families (through bilingual means if necessary)
of children under the age of 2 years, and ex-
pectant parents, in obtaining knowledge con-
cerning the importance of having their children
immunized and in identifying the vaccines,
schedules for immunization, and vaccine pro-
vider locations, appropriate with respect to their children.

“(B) IMPLEMENTATION.—In implementing the Campaign under subparagraph (A), the Secretary shall ensure that—

“(i) new and innovative methods are developed and utilized to publicly advertise the need to have children immunized in a timely manner;

“(ii) print, radio and television media are utilized to convey immunization information to the public; and

“(iii) with respect to immunization information, efforts are made to target pregnant women and the parents of children under the age of 2.

“(2) INTERAGENCY COMMITTEE ON IMMUNIZATION.—The Secretary, in conjunction with the Secretary of Agriculture, the Secretary of Housing and Urban Development, and the Secretary of Education, shall carry out activities through the Interagency Committee on Immunization to incorporate immunization status assessments and referral services as an integral part of the process by which individuals apply for assistance under—
“(A) the food stamp program under the Food Stamp Act of 1977;
“(B) section 17 of the Child Nutrition Act of 1966;
“(C) the Head Start Act;
“(D) part A of title IV of the Social Security Act;
“(E) title XIX of the Social Security Act;
“(F) any of the housing assistance laws of the United States; and
“(G) other programs determined appropriate by any of the Secretaries described in this paragraph.
“(3) EXPANDED OPPORTUNITY FOR NATIONAL SERVICE.—The Secretary, in conjunction with the Commission on National and Community Service and other independent agencies, is encouraged to develop opportunities for participants in national and community service programs to contribute to local initiatives for the improvement of immunization services, including public outreach and education efforts.
“(b) GRANTS TO STATES.—
“(1) IN GENERAL.—
“(A) The Secretary may award grants to States to enable such State to develop, revise and implement immunization improvement plans as described in paragraph (2).

“(B) To be eligible to receive a grant under subparagraph (A), a State shall prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

“(2) Design.—A State immunization improvement plan shall be designed to improve immunization delivery, outreach, education and coordination within the State. Such plan shall provide for the creation of—

“(A) a vaccine provider education campaign and the distribution of any other materials determined to be appropriate by State health officials—

“(i) to enable such providers to make the best use of vaccination opportunities; and

“(ii) to educate such providers concerning their obligation to report immunization information with respect to their patients to State registries;
“(B) expanded capacity for the delivery of immunizations through—

“(i) increasing the number or type of facilities through which vaccines may be made available and the capacity of such facilities to immunize more children;

“(ii) developing alternative methods of delivering vaccines, such as mobile health clinics;

“(iii) increasing the number of hours during which vaccines are made available by providers within the State; or

“(iv) coordinating with federally qualified health centers to reach and immunize underserved children through education, outreach, tracking, and the provision of services;

except that, the Secretary may waive any specific requirement of this subparagraph if the Secretary determines that State immunization delivery efforts are sufficient without the imposition of such requirement;

“(C) population-based assessment criteria through which the State is able to assess the effectiveness of immunization activities in the
State, which may be fulfilled through the implementation of a State immunization registry under section 2146;

“(D) a public awareness campaign, in conjunction with the National Campaign established under subsection (a)(1), to provide parents with information about the importance of immunization, the types and schedules for the administration of vaccines, and the locations of vaccines providers;

“(E) coordinated community outreach activities among public or private health programs, including local health departments and health centers, and other public or private entities, to encourage and facilitate the ability of parents to obtain immunization services for their children; and

“(F) other activities that are not inconsistent with the purposes of this subtitle, subject to the approval of the Secretary.

“(3) IMMUNIZATION IMPROVEMENT PLAN APPROVAL.—

“(A) GOALS.—As part of the immunization improvement plan of a State, the State shall es-
establish immunization rate goals for children residing within the State.

“(B) Approval.—The immunization improvement plan developed by a State under this subsection shall be submitted to the Secretary for approval prior to the distribution of grant funds to the States under this subsection. The Secretary shall periodically review the progress that the State has made under such plan in achieving the goals established under subparagraph (A).

“(C) Distribution of Grants.—In awarding grants under this section, the Secretary shall ensure that grant awards will be equitably distributed between rural and urban areas. In determining such distribution, the Secretary shall take into account the added costs of supporting the health care delivery infrastructure in sparsely populated areas. The Secretary shall give special consideration to those States that have low childhood immunization rates and that submit plans that demonstrate the State’s substantial effort and commitment to improving such rates.
“(D) Reporting.—A State shall annually prepare and submit to the Director of the Centers for Disease Control and Prevention a report concerning the implementation of the State immunization improvement plan.

“(c) Authorization of Appropriations.—There are authorized to be appropriated to carry out this section, $250,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1999.

“Sec. 2157. Performance Based Grant Program.

“(a) Annual Report.—Not later than July 1 of each year, a State shall prepare and submit to the Director of the Centers for Disease Control and Prevention a report that contains an estimate (based on a base population sample) of the percentage of 2 year old residents of the State who have been fully immunized as described in subsection (c).

“(b) Payments to States.—

“(1) In general.—Subject to the availability of appropriations, the Secretary shall provide to a State that has submitted an annual report under subsection (a) that demonstrates that the State has fully immunized at least 50 percent of the 2 year old residents of that State, with respect to the year for
which the report was prepared, a payment in an amount equal to—

“(A) with respect to a State that has demonstrated the full immunization of at least 50 and less than 64 percent of all 2 year old residents of the State, $50 multiplied by the number of fully immunized 2 year old resident children in excess of the number of children equaling such 50 percent amount;

“(B) with respect to a State that has demonstrated the full immunization of at least 65 and less than 70 percent of all 2 year old residents of the State, $75 multiplied by the number of fully immunized 2 year old resident children in excess of the number of children equaling such 65 percent amount; and

“(C) with respect to a State that has demonstrated the full immunization of at least 70 and less than 91 percent of all 2 year old residents of the State, $100 multiplied by the number of fully immunized 2 year old resident children in excess of the number of children equaling such 70 percent amount.

“(2) Use of funds.—
"(A) CONDITION.—As a condition of receiving amounts under this section a State that uses a combination of Federal and State funds in achieving the immunization goals described in paragraph (1) shall agree to reinvest, in activities related to improving immunization services, that percentage of the payments to the State under paragraph (1) that is equal to the amount of Federal contributions to immunization services in the State as compared to the amount of the State contributions to such services.

"(B) DISCRETIONARY USE.—A State that has demonstrated that the use of State-only funds was responsible for the increase in the immunization rate which qualified such State for payments under paragraph (1), may use amounts awarded under this section for other purposes, at the discretion of the State.

"(3) VERIFICATION.—Prior to making a payment to a State under this subsection, the Secretary shall, in collaboration with the Centers for Disease Control and Prevention, verify the accuracy of the State report involved.
(c) Definition.— For purposes of this section, the term ‘fully immunized’ means a 2 year old child that has received four doses of DTP vaccine (diphtheria, tetanus, pertussis), three doses of polio vaccine, and one dose of MMR (measles, mumps, rubella) vaccine.

“Part D—General Provisions

SEC. 2161. REPORT.

‘Not later than October 1, 1995, and biennially thereafter, the Secretary shall prepare and submit to the appropriate committees of Congress a report concerning the costs, efficiency, and effectiveness of procedures established to deliver vaccine to health care providers.

SEC. 2162. NATIONAL VACCINE PROGRAM.

‘The Secretary shall authorize a report to be prepared by the National Academy of Sciences concerning the role of the National Vaccine Program established under this title in achieving progress towards the nationally established immunization goals for the year 2000, and recommendations with respect to the changes in such Program that would facilitate greater progress towards achieving such goals.

SEC. 2163. DEFINITIONS.

‘For purposes of this subtitle—

“(1) HEALTH CARE PROVIDER.—The term ‘health care provider’, with respect to the adminis-
Administration of vaccines to children, means an entity that is licensed or otherwise authorized for such administration under the law of the State in which the entity administers the vaccine, subject to section 333(e).

"(2) Health center.—The term ‘health center’ means—

"(A) a federally qualified health center, as defined in section 1905(l)(2) of the Social Security Act; or

"(B) a public or nonprofit private entity receiving Federal funds under—

"(i) section 329, 330 or 340;

"(ii) section 340A (relating to grants for health services for residents of public housing); or

"(iii) section 501(a)(2) of the Social Security Act (relating to special projects of regional and national significance).

"(3) Immunization.—The term ‘immunization’ means an immunization against a vaccine-preventable disease.

"(4) Parent.—The term ‘parent’, with respect to a child, means a legal guardian of the child.
“(5) **PEDIATRIC VACCINE.**—The term ‘pediatric vaccine’ means a vaccine included on the list established under section 2141.

“(6) **STATE.**—The term ‘State’ means the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the U.S. Virgin Islands, the Republic of the Marshall Islands, Micronesia, the Northern Mariana Islands, and Palau.”

**SEC. 3. NATIONAL VACCINE INJURY COMPENSATION PROGRAM AMENDMENTS.**

(a) **Amendment of Vaccine Injury Table.**—

(1) **Addition of Vaccines.**—Section 2114 (42 U.S.C. 300aa-14) is amended by adding at the end thereof the following new subsection:

“‘(f) **Addition of Vaccines to Table.**—

“(1) **In general.**—The Vaccine Injury table contained in subsection (a) shall also include any recommended childhood vaccine included in the list promulgated by the Secretary under section 2141.

“(2) **Review of information and revision.**—Not later than 2 years after the addition of a new vaccine to the table contained in subsection (a), and on a regular basis thereafter, the Secretary shall review information obtained under sections
2125 and part B of subtitle 3, and based on such review (and other relevant information) shall, as appropriate, develop with respect to such new vaccine—

“(A) revisions with respect to illnesses, disabilities, injuries or conditions covered by such table;

“(B) appropriate specifications of the time period for the first symptom or manifestation of onset or of significant aggravation of such illnesses, disabilities, injuries or condition after vaccine administration, for purposes of receiving compensation under the Program; and

“(C) recommendations as to the amount of tax that should be imposed under section 4131 of the Internal Revenue Code of 1986 for each dose of vaccine.

“(3) LIMITATION.—The Secretary may modify the table contained in subsection (a) pursuant to paragraphs (1) and (2) only in accordance with subsection (c).

“(4) REVISION.—For purposes of section 2116(b), the addition of vaccine to the table contained in subsection (a) by operation of this subsection shall constitute a revision of the table.”.
(2) Attorneys’ Fees.—Section 2115(e) (42 U.S.C. 300aa-15(e)) is amended by adding at the end thereof the following new paragraph:

“(4) The special master may award reasonable attorneys’ fees whether or not an election has been made under section 2121(a) to file a civil action concerning such petition.”.

(3) Consent for Annuity.—Subparagraphs (A) and (B) of section 2115(f)(4) are amended by striking “, with the consent of the petitioner,” each place that such appears.

(4) Time Periods for Fees and Costs.—

(A) In General.—Section 2115(e) (42 U.S.C. 300aa-15(e)) (as amended by paragraph (3)) is further amended by adding at the end thereof the following new paragraph:

“(5) With respect to a petitioners’ application for attorneys’ fees and costs—

“(A) if the respondent enters no objection to such application within 21 days of the date on which the application was filed (unless such time period is extended by the special master with the consent of the petitioner) the special master shall enter a decision on such application within 30 days of such filing;
“(B) if the respondent files an objection to such application and the special master does not enter a decision with respect to the application within 60 days after the date on which the objection is filed, the special master involved shall, upon the written request of the petitioner, enter a decision within 15 days after the filing of such request; and

“(C) if the respondent files an objection to such application and the petitioner moves to reduce costs and fees as provided for in the objection, the special master shall enter a decision within 5 days after the receipt of the petitioner’s motion.

The chief special master, upon the request of a special master, may waive the time limitations applicable to the special master under this paragraph if the special master demonstrates that complicating factors exist with respect to the issues involved to which the time limitation applies.’’.

(B) APPLICATION.—The amendment made by subparagraph (A) shall apply to all petitioners’ applications for attorneys’ fees and costs filed under section 2115(e) of the Public Health
Service Act which are pending on the date of enactment of this Act.

(5) Authorization of Appropriations.—Section 2115(j) (42 U.S.C. 300aa-15(j)) is amended by striking "$80,000,000 for each succeeding fiscal year" and inserting in lieu thereof "$110,000,000 for each succeeding fiscal year".

(6) Limitation of Actions.—Section 2116(b) (42 U.S.C. 300aa-16(b)) is amended by striking "such person may file" and inserting "or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding section 2111(b)(2), file".

(b) Extension of Time for Decision.—

(1) Jurisdiction.—Section 2112(d)(3)(D) (42 U.S.C. 300aa-12(d)(3)(D)) is amended by striking "540 days" and inserting "30 months (but for not more than 6 months at a time)".

(2) Report on Collections.—Section 2117 (42 U.S.C. 300aa-17) is amended by adding at the end thereof the following new subsection:

"(c) Report.—The Attorney General shall, on January 1 of each year, prepare and submit to the appropriate committees of Congress a report concerning amounts collected under this section.".
(3) INCREASED RESPONSIBILITIES OF COMMISSION.—Section 2119(f) (42 U.S.C. 300aa-19(f)) is amended—

   (A) by striking “and” at the end of paragraph (4);

   (B) by striking the period at the end of paragraph (5) and inserting “, and”; and

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

   “(6) monitor the balance of the Vaccine Injury Trust Fund established by section 9510 of the Internal Revenue Code and, as appropriate, recommend changes in the tax per dose of vaccine imposed under section 4131 of such Code.”.

(c) SIMPLIFICATION OF VACCINE INFORMATION MATERIALS.—

   (1) INFORMATION.—Section 2126(b) (42 U.S.C. 300aa-26(b)) is amended—

   (A) by striking “by rule” in the matter preceding paragraph (1);

   (B) in paragraph (1), by striking “90” and inserting “30”; and

   (C) in paragraph (2), by striking “, appropriate health care providers and parent organizations”.

S 732 ES
(2) Requirements.—Section 2126(c) (42 U.S.C. 300aa–26(c)) is amended—

(A) in the matter preceding paragraph (1), by inserting “shall be based on available data and information,” after “such materials”; and

(B) by striking out paragraphs (1) through (10) and inserting in lieu thereof the following new paragraphs:

“(1) a concise description of the benefits of the vaccine;

“(2) a concise description of the risks associated with the vaccine;

“(3) a statement of the availability of the National Vaccine Injury Compensation Program;

“(4) a statement of the availability from the Secretary of more detailed written information concerning the information required under paragraphs (1), (2), and (3), that shall be made available to the parent, legal guardian, or other responsible person upon request; and

“(5) such other relevant information as determined appropriate by the Secretary.”.

(3) Other individuals.—Subsections (a) and (d) of section 2126 (42 U.S.C. 300aa–26 (a) and (d)) are amended by inserting “or to any other indi-
individual” immediately after “to the legal representative of any child” each place that such occurs.

(4) PROVIDER DUTIES.—Subsection (d) of section 2126 (42 U.S.C. 300aa–26(d)) is amended—

(A) by striking all after “subsection (a),” the second place it appears in the first sentence and inserting “supplemented with visual presentations or oral explanations, in appropriate cases.”; and

(B) by striking “or other information” in the last sentence.

(d) AUTHORIZATION OF APPROPRIATIONS.—Part A of subtitle 2 of title XXI (42 U.S.C. 300aa–10 et seq.) is amended by adding at the end thereof the following new section:

“AUTHORIZATION OF APPROPRIATIONS

“SEC. 2120. (a) SECRETARY.—For purposes of administering this part, there are authorized to be appropriated from the Vaccine Injury Compensation Trust Fund established under section 9510(c) of the Internal Revenue Code of 1986, to the Secretary, $3,000,000 for each of the fiscal years 1994, 1995, and 1996.

“(b) ATTORNEY GENERAL.—For purposes of administering this part, there are authorized to be appropriated from the Vaccine Injury Compensation Trust Fund described in subsection (a), to the Attorney General,
$3,000,000 for each of the fiscal years 1994, 1995, and 1996.

“(c) Court of Federal Claims.—For purposes of administering this part, there are authorized to be appropriated from the Vaccine Injury Compensation Trust Fund described in subsection (a), to the Court of Federal Claims, $3,000,000 for each of the fiscal years 1994, 1995, and 1996.”

SEC. 4. MISCELLANEOUS PROVISIONS.

Section 317(k) (42 U.S.C. 247b(k)) is amended—

(1) by striking out paragraph (1); and

(2) by redesignating paragraphs (2) through (5) as paragraphs (1) and (4), respectively.


(a) Clarification of Coverage of Officers and Employees of Clinics.—The first sentence of section 224(g)(1) of the Public Health Service Act (42 U.S.C. 233(g)(1)) is amended by striking “officer, employee, or contractor” and inserting the following: “officer or employee of such an entity, and any contractor”.

(b) Coverage for Services Furnished to Individuals Other Than Patients of Clinic.—Section 224(g) of such Act (42 U.S.C. 233(g)(1)), as amended by paragraph (1), is further amended—
(1) in the first sentence of paragraph (1), by inserting after “Service” the following: “with respect to services provided to patients of the entity and (subject to paragraph (7)) to certain other individuals’’; and
(2) by adding at the end the following new paragraph:

“(7) For purposes of paragraph (1), an officer, employee, or contractor described in such paragraph may be deemed to be an employee of the Public Health Service with respect to services provided to individuals who are not patients of an entity described in paragraph (4) only if the Secretary determines—

“(A) that the provision of the services to such individuals benefits health center patients and general populations that could be served by the health center through community-wide intervention efforts within the communities served by such health center, and facilitates the provision of services to health center patients; or

“(B) that such services are otherwise required to be provided to such individuals under an employment contract (or other similar arrangement) between the individual and the entity.”.
(c) Determining Compliance of Entity with Requirements for Coverage.—

(1) In general.—Section 224(h) of such Act (42 U.S.C. 233(h)), as added by section 2(b) of the Federally Supported Health Centers Assistance Act of 1992, is amended by striking “the entity—” and inserting the following: “the Secretary, after receiving such assurances and conducting such investigation as the Secretary considers necessary, finds that the entity—”.

(2) Finding.—Section 224 of such Act (42 U.S.C. 233) is amended by adding at the end thereof the following new subsection:

“(l) With respect to subsection (h), the finding of the Secretary that an entity meets all of the requirements under such subsection shall apply for the period specified by the Secretary, and shall be binding for all parties unless the Secretary reverses such finding for good cause shown at a later date.”.

(d) Payment of Judgments.—Section 224(k)(2) of such Act (42 U.S.C. 233(k)(2)), as added by section 4 of the Federally Supported Health Centers Assistance Act of 1992, is amended by adding at the end thereof the following new sentence: “Appropriations for purposes of this
paragraph shall be made separate from appropriations made for purposes of sections 329, 330, 340 and 340A.’’.

(d) Effective Date.—The amendments made by this section shall take effect as if included in the enactment of the Federally Supported Health Centers Assistance Act of 1992.

Passed the Senate November 4 (legislative day, November 2), 1993.

Attest:

Secretary.