

103^D CONGRESS
1ST SESSION

H. R. 1640

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

IN THE HOUSE OF REPRESENTATIVES

APRIL 1, 1993

Mr. WAXMAN (for himself, Mr. DINGELL, Ms. SLAUGHTER, Mrs. CLAYTON, Mr. SYNAR, Mr. RICHARDSON, Mr. ROWLAND, Mr. SLATTERY, Mr. WASHINGTON, Mr. BROWN of Ohio, Mr. KREIDLER, Ms. PELOSI, Mr. McDERMOTT, and Mr. WYDEN) introduced the following bill; which was referred jointly to the Committees on Energy and Commerce and Ways and Means

MAY 13, 1993

Additional sponsors: Mr. KLEIN, Mr. STUDDS, Mr. SWIFT, and Mr. RANGEL

OCTOBER 21, 1993

Additional sponsors: Mr. GUTIERREZ, Mr. BERMAN, and Mr. BISHOP

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE AND REFERENCES IN THE ACT.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Comprehensive Child Immunization Act of 1993”.

1 (b) REFERENCES IN ACT.—The amendments in this
2 Act apply to the Public Health Service Act unless other-
3 wise specifically stated.

4 **SEC. 2. PURPOSE OF THE ACT.**

5 The purpose of this Act is to ensure that all children
6 in the United States are protected against vaccine prevent-
7 able infectious diseases at the earliest appropriate age; to
8 establish a program to purchase vaccines and to distribute
9 them to all willing health care providers; to establish a
10 tracking program to monitor which children need to be
11 immunized and the results of immunizing children; and
12 to extend the National Childhood Vaccine Injury Com-
13 pensation Program.

14 **SEC. 3. FINDINGS OF THE CONGRESS.**

15 (a) CURRENT CIRCUMSTANCES.—The Congress
16 makes the following findings as to current circumstances:

17 (1) Immunizations are among the most cost-ef-
18 fective means of preventing disease.

19 (2) Although Federal support for childhood im-
20 munizations has been in existence since 1962, the
21 full potential of immunizations remains to be
22 achieved. Enactment and enforcement of school im-
23 munization requirements have resulted in excellent
24 immunization levels (96 percent or greater) in school
25 children. However, approximately 80 percent of vac-

1 cine doses should be received before the second
2 birthday in order to protect children during their
3 most vulnerable periods. Many children do not re-
4 ceive their basic immunizations by that time, and in
5 some inner cities as few as 10 percent of 2-year olds
6 have received a complete series. This low level of im-
7 munizations has been reflected in recent years by
8 outbreaks of measles among inadequately immunized
9 pre-school children.

10 (3) The “infrastructure” to immunize children
11 is both public and private. There is considerable evi-
12 dence to suggest that the “private” infrastructure
13 has been damaged over the past decade as a result
14 of the significantly increased cost of privately pur-
15 chased vaccine.

16 (4) In some cases costs have risen over a ten-
17 year period by nearly 1400 percent, with private
18 rates exceeding the rates paid for like vaccines in
19 some other industrialized nations by over 2500 per-
20 cent.

21 (5) High costs, coupled with the growing num-
22 ber of uninsured and underinsured families, mean
23 that private physicians are increasingly referring
24 their private patients to overburdened public clinics
25 for vaccinations.

1 (6) Eleven States now have programs that pro-
2 vide vaccines without charge to both public and pri-
3 vate health care providers. Some of these programs
4 have been in place for more than 20 years, with vir-
5 tually no burden or controversy. Other States that
6 have sought to establish such programs have been
7 denied additional discounted vaccines by manufac-
8 turers.

9 (7) There is no evidence to suggest that a nego-
10 tiated price that takes into account the reasonable
11 cost of production, marketing, research and develop-
12 ment, and distribution will not fairly compensate
13 vaccine manufacturers. Indeed, a recent report by
14 the Congressional Office of Technology Assessment
15 supports the proposition that negotiated rates can
16 assure fair compensation while holding down costs.

17 (8) The Secretary of Health and Human Serv-
18 ices has experience negotiating vaccine purchase
19 through the Federal contract system.

20 (9) The National Vaccine Injury Compensation
21 Program is an essential element in a comprehensive
22 immunization program and should be strengthened
23 and applied to additional vaccines recommended for
24 universal use in children.

1 (b) NEEDED ACTIONS.—The Congress makes the fol-
2 lowing findings as to actions needed to ensure the full im-
3 munization of children at the earliest appropriate age:

4 (1) The Federal Government should purchase
5 and provide free of charge to health care providers
6 vaccines recommended for universal use in children.
7 This action will not only remove financial barriers to
8 immunization that impede children from being vac-
9 cinated at the appropriate time, but will also facili-
10 tate development of an immunization tracking sys-
11 tem.

12 (2) The Federal Government and the States
13 should develop linked registries to track the immuni-
14 zation status of the Nation's children. The registries
15 should have the capability to notify parents of inad-
16 equately immunized children of the need to protect
17 their children with specific vaccines.

18 (2) The coordinated national information and
19 education outreach initiative inaugurated by the De-
20 partment of Health and Human Services in 1993
21 should be continued. This program brings needed in-
22 formation to parents and health care providers and
23 focuses their attention on the importance of achiev-
24 ing the full immunization of children at the earliest
25 appropriate age.

1 (4) Private and public health insurers should be
2 encouraged to provide adequate reimbursement for
3 the administration of childhood vaccines.

4 (5) Volunteer community activities to promote
5 the full immunization of children at the earliest ap-
6 propriate age should be encouraged.

7 (6) The National Vaccine Injury Compensation
8 Program should be extended and improved. Vaccine
9 information materials should be simplified to ensure
10 that parents can understand the benefits and risks
11 of vaccines.

12 **SEC. 4. FEDERAL PURCHASE AND TRACKING OF CHILD-**
13 **HOOD VACCINES.**

14 (a) IN GENERAL.—Title XXI of the Public Health
15 Service Act is amended by adding at the end a new Sub-
16 title 3 as follows:

17 **“Subtitle 3—Federal Purchase and Tracking of**
18 **Childhood Vaccines.**

19 **“SEC. 2141. PURCHASE BY THE SECRETARY.**

20 **“(a) RECOMMENDED CHILDHOOD VACCINES.—**The
21 Secretary shall promulgate not later than October 1, 1994
22 (and periodically thereafter as the Secretary determines
23 appropriate in view of advances in scientific understanding
24 in the areas of immunization and disease control), a list
25 of vaccines that provide immunization against naturally

1 occurring infectious diseases and are recommended for
2 universal use in children. The Secretary shall concurrently
3 promulgate recommendations regarding the appropriate
4 dosage for each vaccine and the age or ages of children
5 at which each vaccine should be administered.

6 “(b) CONSULTATION.—The Secretary shall, in order
7 to determine the amounts of vaccines to be purchased
8 under subsection (c), consult with Federal agencies in-
9 volved in research regarding, or the regulation, procure-
10 ment, or distribution of, recommended childhood vaccines.
11 The consultation may be effected through the establish-
12 ment of a Vaccine Requirements Panel, composed entirely
13 of representatives of the relevant Federal agencies, or
14 through such other means as the Secretary finds appro-
15 priate.

16 “(c) PURCHASE OF VACCINE.—

17 “(1) IN GENERAL.—The Secretary shall peri-
18 odically purchase recommended childhood vaccines in
19 amounts necessary for—

20 “(A) distribution under section 2142 to
21 meet anticipated needs for the routine and
22 catch-up immunization of children in the Unit-
23 ed States in accordance with the recommenda-
24 tions promulgated under subsection (a) and
25 foreseeable outbreak control activities, and

1 “(B) maintenance of a reserve supply suf-
2 ficient for a six-month period.

3 The Secretary shall negotiate a reasonable price for
4 such vaccine that takes fairly into account the var-
5 ious costs described in paragraph (3).

6 “(2) PRE-PROCUREMENT CONSULTATIONS.—
7 The Secretary may consult with representatives of
8 State governments, experts in vaccine delivery,
9 health care providers, and others with expertise in
10 purchasing and pricing pharmaceutical products
11 prior to soliciting bids or offers for recommended
12 childhood vaccines under this subtitle.

13 “(3) COST OR PRICING DATA.—A manufacturer
14 of recommended childhood vaccine shall provide cost
15 or pricing data in support of its proposed price at
16 the time it responds to a procurement instituted by
17 the Secretary under this section. A manufacturer
18 shall also provide such data upon the request of the
19 Secretary whenever the Secretary determines that
20 contract modifications are necessary. This informa-
21 tion shall include data related to the research and
22 development costs of the vaccine, production costs,
23 handling, shipping, and other costs associated with
24 delivering vaccine to health care providers and
25 States in accordance with the distribution plan of

1 the Secretary (or a State, as the case may be) under
2 section 2142, marketing costs, profit levels sufficient
3 to encourage future investments in research and de-
4 velopment of new or improved vaccines, the cost of
5 maintaining adequate capacity for outbreak control,
6 and any other data the Secretary determines are
7 relevant.

8 “(4)(A) CONFIDENTIALITY OF DATA.—Informa-
9 tion provided to the Secretary under paragraph (3)
10 shall be treated as trade secret or confidential infor-
11 mation subject to section 552(b)(4) of title 5, United
12 States Code and section 1905 of title 18, United
13 States Code and shall not be revealed to any person
14 other than those authorized by the Secretary in con-
15 nection with carrying out official duties under this
16 section.

17 “(B) Subparagraph (A) does not authorize the
18 withholding of information provided under para-
19 graph (3) from any duly authorized subcommittee or
20 committee of the Congress. If the Secretary provides
21 such information to any subcommittee or committee,
22 the Secretary shall give written notice of this fact to
23 the manufacturer that provided the information.

1 “(C) The Secretary shall establish written pro-
2 cedures to ensure the confidentiality of information
3 provided under paragraph (3).

4 “(5) PROHIBITION ON ADDITIONAL SHIPPING
5 OR HANDLING CHARGES.—Each contract for the
6 purchase of recommended childhood vaccine under
7 this section shall contain a provision by which the
8 manufacturer agrees to ship or otherwise arrange
9 for the delivery of such vaccine in accordance with
10 the distribution plan of the Secretary (or a State, as
11 the case may be) without imposing any additional
12 charge for shipping, handling, or any other cost on
13 the health care provider or State to which the
14 vaccine is shipped or delivered.

15 “(6) MULTIPLE SUPPLIERS.—To ensure a reli-
16 able and adequate supply of vaccine, the Secretary
17 may enter into contracts with multiple manufactur-
18 ers of the same recommended childhood vaccine,
19 under such terms and conditions and utilizing such
20 procurement processes as the Secretary deems ap-
21 propriate.

22 “(7) REPORTING REQUIREMENTS.—Each con-
23 tract for the purchase of recommended childhood
24 vaccine under this section shall require the manufac-
25 turer to report to the Secretary or the Secretary’s

1 designee, at intervals determined by the Secretary,
2 data regarding the destination of vaccine by lot
3 number, and any other information the Secretary
4 may require.

5 **“SEC. 2142. DISTRIBUTION OF VACCINES.**

6 “(a) IN GENERAL.—The Secretary shall provide for
7 the distribution without charge of recommended childhood
8 vaccines purchased under this subtitle to health care pro-
9 viders who serve children and who (1) are members of a
10 uniformed service, or are officers or employees of the Unit-
11 ed States, (2) are health centers (as defined in section
12 2144(2)), (3) provide services under section 503 of the
13 Indian Health Care Improvement Act or pursuant to a
14 contract under section 102 of the Indian Self-Determina-
15 tion Act, or (4) are located in a State receiving a grant
16 under section 2143(b). The Secretary may provide for
17 such distribution through any State that receives a grant
18 under section 2143(b).

19 “(b) DUTIES OF HEALTH CARE PROVIDERS.—

20 “(1) FREE PROVISION TO CHILDREN.—A health
21 care provider receiving vaccine under this section
22 may use such vaccine only for administration to chil-
23 dren and may not impose a charge for such vaccine.
24 A provider may impose a fee for the administration
25 of such vaccine, except that a provider may not deny

1 a child a vaccination due to inability of the child's
2 parent or guardian to pay an administration fee.

3 “(2) REPORTING REQUIREMENTS.—A health
4 care provider receiving vaccine under this section
5 shall report to the applicable State registry operated
6 pursuant to a grant under section 2143(b) (or to the
7 Secretary if there is no such State registry) the data
8 described in section 2143(b)(1) for each dose of vac-
9 cine administered to a child. The provider shall addi-
10 tionally report to such State registry any occurrence
11 reported to the Secretary pursuant to section
12 2125(b). The provider shall also provide periodic es-
13 timates of the provider's future dosage needs for rec-
14 ommended childhood vaccine distributed under this
15 section. All reports shall be made with such fre-
16 quency and in such detail as the Secretary may
17 prescribe.

18 **“SEC. 2143. TRACKING OF CHILDHOOD IMMUNIZATIONS.**

19 “(a) NATIONAL TRACKING SYSTEM.—The Secretary
20 shall establish a national system to track the immuniza-
21 tion status of children. The system shall be designed to
22 obtain timely information about the immunization status
23 of individual children and to monitor immunization rates
24 at the State and local levels. In addition, the system shall
25 be designed to monitor the safety and efficacy of vaccines,

1 and to provide for the coordination of vaccine administra-
2 tion information with the information on adverse events
3 reported under section 2125(b). In addition, the Secretary
4 is authorized, in the case of inadequately immunized chil-
5 dren in States not receiving grants under subsection (b),
6 to notify the parents or guardians of those children of the
7 need to protect their children with specific vaccine.

8 “(b) STATE REGISTRY GRANTS.—

9 “(1) IN GENERAL.—The Secretary may make
10 grants to States to establish and operate State im-
11 munization tracking registries. A State receiving a
12 grant under this section shall maintain a registry
13 that includes the following information for each child
14 living within the State:

15 “(A) type and lot number of each rec-
16 ommended childhood vaccine administered after
17 September 30, 1996,

18 “(B) identification of the health care pro-
19 vider administering such vaccine,

20 “(C) address and other demographic data
21 needed to find the child,

22 “(D) notations of any adverse events asso-
23 ciated with each immunization, and

24 “(E) such other information as the Sec-
25 retary may prescribe.

1 “(2) GRANT CONDITIONS.—A State, as a condi-
2 tion of receiving a grant under this subsection, shall
3 comply with the following requirements:

4 “(A) The State registry shall provide for
5 entry of the birth of each infant within the
6 State within six weeks following the birth, and
7 for timely entry thereafter of all information re-
8 ceived from health care providers pursuant to
9 section 2142(b)(2).

10 “(B) The State shall provide for the shar-
11 ing of appropriate information from the State’s
12 registry, including immunization status and re-
13 ports of adverse reactions, with health care pro-
14 viders who offer immunizations, for the purpose
15 of achieving the full immunization of all chil-
16 dren in accordance with the recommendations
17 of the Secretary under section 2141(a).

18 “(C) The State shall provide for notifica-
19 tion to the parents or guardian of an inad-
20 equately immunized child of the need to protect
21 the child with specific vaccine.

22 “(D) The State shall provide for the co-
23 ordination and exchange of information with
24 other State registries to allow the tracking of

1 the immunization status of children changing
2 state of residence.

3 “(E) The State shall periodically furnish to
4 the Secretary, at such times and in such form
5 as the Secretary may prescribe, information
6 contained in the State registry.

7 “(F) In designing its registry, the State
8 shall adhere to tracking models and systems
9 specifications prescribed by the Secretary for
10 the purpose of ensuring the mutual compatibil-
11 ity of the data systems and electronic informa-
12 tion technology utilized by the Secretary and
13 the various States in carrying out activities
14 under this subtitle.

15 “(G) The State shall monitor and enforce
16 compliance by health care providers with the re-
17 quirements of section 2142(b). The State shall
18 establishes procedures satisfactory to the Sec-
19 retary for terminating from participation in the
20 recommended childhood vaccine distribution
21 program any health care provider who fails to
22 comply with the requirements of section
23 2142(b), and for reinstating such provider to
24 program participation upon receiving from such
25 provider (i) the reports necessary to make cur-

1 rent and complete the information that would
2 have been furnished to the State registry be-
3 tween the dates of the provider’s termination
4 and reinstatement, and (ii) satisfactory assur-
5 ances regarding the provider’s future compli-
6 ance.

7 “(H) If a State distributes recommended
8 childhood vaccines within the State on behalf of
9 the Secretary pursuant to section 2142(a), the
10 State shall compile data, including lot numbers,
11 on the vaccines distributed to each health care
12 provider, and shall furnish such data to the
13 Secretary in such form and at such intervals as
14 the Secretary may prescribe.

15 “(3) APPLICATIONS.—A State shall submit an
16 application for a grant under subsection (b) in such
17 form and containing such information as the Sec-
18 retary may prescribe. The application shall include a
19 description of the methods by which the State will
20 comply with the requirements of paragraph (2). The
21 application shall also include the assurances required
22 by paragraph (4) and a description of the expenses
23 that the State will incur in carrying out its respon-
24 sibilities under the grant.

1 “(4) A State submitting an application for a
2 grant under this section shall provide assurances
3 satisfactory to the Secretary that—

4 “(A) the State’s tracking registry will be
5 fully operational not later than October 1,
6 1996;

7 “(B) the State’s tracking registry will ad-
8 here to any tracking models and systems speci-
9 fications prescribed by the Secretary pursuant
10 to paragraph (2)(F); and

11 “(C) as appropriate, the State is making
12 satisfactory and timely progress toward achiev-
13 ing the conditions described in subparagraphs
14 (A) and (B).

15 “(5) ALLOWABLE USES OF GRANT FUNDS.—A
16 State may use funds from a grant awarded under
17 this subsection for reasonable costs associated with
18 the development and operation of its registry, includ-
19 ing computer needs, technical assistance and train-
20 ing, education of health care providers, personnel
21 costs, travel expenses, and other appropriate activi-
22 ties.

23 “(6) STATE REPORTS TO THE SECRETARY.—A
24 State shall submit periodic reports to the Secretary
25 on the operation of the State’s registry and other ac-

1 activities under this subtitle. The reports shall be in
2 such form, contain such information, and be submit-
3 ted at such intervals as the Secretary may prescribe.

4 “(c) USE AND DISCLOSURE OF PERSONAL INFORMA-
5 TION.—

6 “(1) Notwithstanding any other provision of
7 this subtitle, no personally-identifiable information
8 relating to a child who receives recommended child-
9 hood vaccine under this subtitle or to the parent or
10 guardian of such a child that is collected or main-
11 tained by the National Tracking System established
12 under subsection (a), or a State immunization track-
13 ing registry established under subsection (b), may be
14 used or disclosed by any holder of such information
15 except as permitted by this subsection.

16 “(2) Information described in paragraph (1)
17 may be used or disclosed, without the consent of the
18 individual to whom it refers, or of the parent or
19 guardian of such individual, for—

20 “(A) the tracking of children’s immuniza-
21 tion status, and other purposes directly related
22 to the health of the children being tracked and
23 of their families;

24 “(B) oversight, audit, and evaluation of
25 the immunization delivery and tracking activi-

1 ties, and the enforcement of the provisions of
2 this subtitle;

3 “(C) activities relating to establishing and
4 maintaining a safe and effective supply of rec-
5 ommended childhood vaccine (including activi-
6 ties to carry out part C of subtitle 2);

7 “(D) processing of insurance claims for
8 payment for vaccine administration (but only to
9 the extent necessary to process a claim);

10 “(E) administration of the National Vac-
11 cine Injury Compensation Program under sub-
12 title 2; or

13 “(F) health research, including research on
14 the delivery and financing of health services.

15 “(3) Information described in paragraph (1)
16 may be used or disclosed with the written authoriza-
17 tion of the individual to whom it refers, or the par-
18 ent or guardian of such individual, and must, upon
19 the request of such individual, or parent or guard-
20 ian, be provided in writing to the individual.

21 “(4) The Secretary is authorized to issue regu-
22 lations governing the use, maintenance, and disclo-
23 sure, by any holder of information described in para-
24 graph (1), including appropriate administrative,

1 technical and physical safeguards to ensure that only
2 authorized persons have access to the information.

3 “(5) ANY PERSON WHO KNOWINGLY—

4 “(A) uses or discloses information in viola-
5 tion of this subsection, or

6 “(B) requests or obtains any information
7 in violation of this subsection, and offers or
8 provides anything of value in exchange for the
9 provision of the information,

10 shall be fined as prescribed by title 18, United
11 States Code, or imprisoned not more than 3 years,
12 or both.”

13 “(d) AUTHORITY TO USE SOCIAL SECURITY NUM-
14 BERS.—

15 “(1) IN GENERAL.—Notwithstanding section
16 205 of the Social Security Act or any other provision
17 of law, the Secretary and States receiving grants
18 under subsection (b) may utilize the social security
19 number of a child or of a parent or guardian of the
20 child for purposes of identification of a child in any
21 registry established under this section, and may re-
22 quire a child’s parent or guardian to furnish such
23 number (in any case where such a number has been
24 assigned by the Social Security Administration) as a

1 condition of the child receiving recommended child-
2 hood vaccine under this subtitle.

3 “(2) AUTHORITY TO REDISCLOSE.—Notwith-
4 standing section 205(c)(2)(C)(vii)(I) of the Social
5 Security Act, a social security number obtained in
6 connection with activities under this subtitle may be
7 redisclosed if such redisclosure is otherwise in ac-
8 cordance with subsection (c) of this section.

9 “(e) REPORTS BY SECRETARY TO THE CONGRESS.—
10 The Secretary shall submit a report to Congress not later
11 than January 1, 1996, and biennially thereafter on the
12 operation of the national tracking system and the State
13 registries.

14 **“SEC. 2144. DEFINITIONS.**

15 “For purposes of this subtitle—

16 “(1) The term ‘recommended childhood vaccine’
17 is a vaccine on the list promulgated by the Secretary
18 pursuant to section 2141(a).

19 “(2) The term ‘health center’ means—

20 “(A) a federally qualified health center, as
21 defined in section 1905(l)(2) of the Social Secu-
22 rity Act; or

23 “(B) a public or nonprofit private entity
24 receiving Federal funds under—

1 “(i) section 340A (relating to grants
2 for health services for residents of public
3 housing), or

4 “(ii) section 501(a)(2) of the Social
5 Security Act (relating to special projects of
6 regional and national significance).

7 **“SEC. 2145. APPROPRIATIONS AND AUTHORIZATION.**

8 “(a) VACCINE PURCHASES.—There shall be made
9 available for expenditure by the Secretary, out of the Com-
10 prehensive Child Immunization Account in the Treasury
11 established pursuant to section 6 of the Comprehensive
12 Child Immunization Act of 1993, such amounts as are re-
13 quired to carry out subsections (b) and (c) of section 2141
14 for fiscal year 1995 and for each fiscal year thereafter
15 during which such subsections remain in effect.

16 “(b) OTHER ACTIVITIES.—For carrying out this sub-
17 title other than subsections (b) and (c) of section 2141,
18 there are authorized to be appropriated \$152,000,000 for
19 fiscal year 1995, \$125,000,000 for fiscal year 1996, and
20 \$35,000,000 for each of fiscal years 1997, 1998, and
21 1999.

22 “(c) In addition to other amounts available for carry-
23 ing out title III and subtitle 1 of title XXI, there are au-
24 thorized to be appropriated for fiscal years 1993 and 1994
25 such additional sums as may be necessary for activities

1 related to and preparatory to implementation of this sub-
2 title, including infrastructure improvements, information
3 and education, surveillance and response, and vaccine
4 safety.”.

5 (b) REQUIREMENTS CONCERNING IMMUNIZATIONS
6 OF CHILDREN UNDER STATE MEDICAID PROGRAMS.—

7 (1) Coverage of immunizations under early and
8 periodic screening, diagnosis, and testing
9 (EPSDT).—Section 1905(r)(1)(B)(iii) of the Social
10 Security Act is amended to read as follows:

11 “(iii) appropriate immunizations ac-
12 cording to the recommendations of the
13 Secretary promulgated under section
14 2141(a) of the Public Health Service Act,
15 taking into account the health history of
16 the individual.”.

17 (2) REIMBURSEMENT RATES FOR IMMUNIZA-
18 TIONS WITH RECOMMENDED CHILDHOOD VAC-
19 CINES.—Section 1902(a)(13) of the Social Security
20 Act is amended—

21 (A) by striking “and” and the end of sub-
22 paragraph (E),

23 (B) by inserting “and” at the end of sub-
24 paragraph (F), and

1 (C) by adding at the end the following new
2 subparagraph:

3 “(G) that payments to providers shall in-
4 clude amounts, as appropriate, as reimburse-
5 ment for administration of recommended child-
6 hood vaccines (as defined in section 2144 of the
7 Public Health Service Act) in accordance with
8 section 1905(r)(i)(B)(iii);”.

9 (3) EFFECTIVE DATE.—(A) IN GENERAL.—Ex-
10 cept as provided in subparagraph (B), the amend-
11 ments made by this subsection shall be effective with
12 respect to calendar quarters beginning on or after
13 October 1, 1994.

14 (B) EXTENSION FOR STATE LAW AMEND-
15 MENT.—In the case of a State plan under title XIX
16 of the Social Security Act which the Secretary of
17 Health and Human Services determines requires
18 State legislation in order for the plan to meet the
19 additional requirements imposed by the amendments
20 made by paragraph (2), the State plan shall not be
21 regarded as failing to comply with the requirements
22 of such title solely on the basis of its failure to meet
23 these additional requirements before the first day of
24 the first calendar quarter beginning after the close
25 of the first regular session of the State legislature

1 that begins after the date of enactment of this Act.
2 For purposes of the previous sentence, in the case
3 of a State that has a two-year legislative session,
4 each year of such session shall be deemed to be a
5 separate regular session of the State legislature.

6 (c) TERMINATION OF PURCHASE PROGRAM.—Sub-
7 sections (b) and (c) of section 2141 of the Public Health
8 Service Act (as added by subsection (a) of this section)
9 shall cease to be in effect beginning on such date as may
10 be prescribed in Federal law providing for immunization
11 services for all children as part of a broad-based reform
12 of the national health care system.

13 **SEC. 5. NATIONAL VACCINE INJURY COMPENSATION PRO-**
14 **GRAM AMENDMENTS.**

15 (a) USE OF VACCINE INJURY COMPENSATION TRUST
16 FUND.—

17 (1) Section 9510(c)(1) of the Internal Revenue
18 Code of 1986 is amended by striking out “, and be-
19 fore October 1, 1992,”.

20 (2) Section 6601(r) of the Omnibus Budget
21 Reconciliation Act of 1989 is amended by striking
22 out “\$2,500,000 for each of fiscal years 1991 and
23 1992” each place it appears and inserting in lieu
24 thereof “\$3,000,000 for fiscal year 1994 and each
25 fiscal year thereafter” (in three places).

1 (b) PERMANENT EXTENSION OF AUTHORITY TO IM-
2 POSE TAXES FOR THE VACCINE INJURY COMPENSATION
3 TRUST FUND.—

4 (1) PERMANENT EXTENSION OF TAX.—Section
5 4131(c) of the Internal Revenue Code of 1986 is re-
6 pealed.

7 (2) REINSTATEMENT OF TAX.—The tax im-
8 posed by section 4131 of the Internal Revenue Code
9 of 1986 is hereby reinstated effective April 1, 1993.

10 (c) AMENDMENT OF VACCINE INJURY TABLE.—(1)
11 Section 2114 is amended by adding at the end thereof the
12 following new subsection:

13 “(f) ADDITION OF VACCINES TO TABLE.—The Vac-
14 cine Injury Table set out in subsection (a) also includes
15 any recommended childhood vaccine included in the list
16 promulgated by the Secretary under section 2141(a). The
17 Secretary may modify the Table with respect to any vac-
18 cine added by operation of the preceding sentence only in
19 accordance with subsection (c). For purposes of section
20 2116(b), the addition of a vaccine to the Table by oper-
21 ation of the subsection shall constitute a revision of this
22 Table.”.

23 (2) Section 2116(b) is amended by striking out “such
24 person may file” and inserting in lieu thereof “or to sig-
25 nificantly increase the likelihood of obtaining compensa-

1 tion, such person may, notwithstanding section
2 2111(b)(2), file”.

3 (d) EXTENSION OF TIME FOR DECISION.—Section
4 2112(d)(3)(D) is amended by striking out “540 days” and
5 inserting in lieu thereof “30 months (but for no more than
6 6 months at a time)”.

7 (e) SIMPLIFICATION OF VACCINE INFORMATION MA-
8 TERIALS.—

9 (1) Section 2126 (b) is amended—

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

12 (B) by striking out, in paragraph (1), “,
13 opportunity for a public hearing, and 90” and
14 inserting in lieu thereof “and 30”; and

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

18 (2) Section 2126(c) is amended—

19 (A) by inserting “shall be based on avail-
20 able data and information,” immediately after
21 “such materials” in the matter preceding para-
22 graph (1), and

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

1 “(1) a concise description of the bene-
2 fits of the vaccine,

3 “(2) a concise description of the risks
4 associated with the vaccine, and

5 “(3) a statement of the availability of
6 the National Vaccine Injury Compensation
7 Program.”.

8 (3) Subsections (a) and (d) of section 2126 are
9 each amended by inserting “or to any other individ-
10 ual” immediately after “to the legal representative
11 of any child”.

12 (4) Subsection (d) of section 2126 is amend-
13 ed—

14 (A) by striking out all after “subsection
15 (a),” the second place it appears in the first
16 sentence and inserting in lieu thereof “supple-
17 mented with visual presentations or oral expla-
18 nations, in appropriate cases.”, and

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

21 **SEC. 6. FUNDING FOR CHILD IMMUNIZATION PROGRAM.**

22 (a) MAINTENANCE OF SEPARATELY IDENTIFIABLE
23 ACCOUNT.—There shall be established in the Treasury of
24 the United States the Comprehensive Child Immunization
25 Account for the purpose of funding activities under sub-

1 sections (b) and (c) of section 2141 of the Public Health
2 Service Act.

3 (b) SOURCE OF RECEIPTS.—Receipts shall be cred-
4 ited to the Account established under subsection (a) as
5 may be provided in Federal law.

○

HR 1640 SC2—2

HR 1640 SC2—3