Public Law 101-502 101st Congress

An Act

To amend the Public Health Service Act to extend various programs with respect to vaccine-preventable diseases.

Nov. 3, 1990 [H.R. 4238]

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

Vaccine and Immunization Amendments

SECTION 1. SHORT TITLE.

This Act may be cited as the "Vaccine and Immunization Amend- 42 USC 201 note. ments of 1990".

SEC. 2. GRANTS FOR IMMUNIZATIONS.

(a) Extension of General Program.—Section 317(j)(1) of the Public Health Service Act (42 U.S.C. 247B(j)(1)) is amended—

(1) in subparagraph (A), by striking "there are authorized" and all that follows in the first sentence and inserting the following: "there are authorized to be appropriated \$205,000,000 for fiscal year 1991, and such sums as may be necessary for each

of the fiscal years 1992 through 1995.";
(2) in subparagraph (B), by striking "after the date" and all that follows and inserting the following: "after October 1, 1990, there are authorized to be appropriated such sums as may be

necessary."; and

(3) by striking subparagraph (C).

(b) DEMONSTRATION PROJECTS FOR OUTREACH PROGRAMS.—

(1) In General.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control, may make grants to public and nonprofit private entities for the purpose of carrying out demonstration projects-

(A) to provide, without charge, immunizations against vaccine-preventable diseases to children not more than 2 years of age who reside in communities whose population includes a significant number of low-income individuals; and

(B) to provide outreach services to identify such children and to inform the parents (or other guardians) of the children of the availability from the entities of the immuniza-

tions specified in subparagraph (A).

(2) Authorization of appropriations.—For the purpose of carrying out paragraph (1), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 1993.

SEC. 3. SUPPLY OF VACCINES.

(a) In General.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control, shall acquire and maintain a supply of vaccines sufficient to provide vaccinations throughout a 6-month period. Any proceeds received by the Secretary from the sale of vaccines from such supply shall be available to the Secretary for the purpose of purchasing vaccines for

Appropriation authorization. 42 USC 247b.

Infants and children. 42 USC 300aa-2 note.

42 USC 300aa-2 note

the supply. Such proceeds shall remain available for such purpose

until expended.

(b) Authorization of Appropriations.—For the purpose of carrying out subsection (a), there are authorized to be appropriated \$5,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995.

Appropriation authorization.

SEC. 4. EXTENSION OF NATIONAL VACCINE PROGRAM.

Section 2106 of the Public Health Service Act (42 U.S.C. 300aa-6) is amended—

(1) in subsection (a), by striking "there are authorized" and all that follows and inserting the following: "there are authorized to be appropriated \$4,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995."; and

(2) in subsection (b), by striking "there are authorized" and all that follows and inserting the following: "there are authorized to be appropriated \$30,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995.".

Claims. Courts.

SEC. 5. TECHNICAL AMENDMENTS.

(a) Section 2111.—Section 2111 of the Public Health Service Act (42 U.S.C. 300aa-11) is amended—

(1) in subsection (a)(2)(A), by striking "unless" and all that

follows in that subsection and inserting the following: "unless a petition has been filed, in accordance with section 2116, for

compensation under the Program for such injury or death and—
"(i)(I) the United States Claims Court has issued a judgment

under section 2112 on such petition, and

"(II) such person elects under section 2121(a) to file such an

action, or

"(ii) such person elects to withdraw such petition under section 2121(b) or such petition is considered withdrawn under such section.",

(2) in subsection (a)(5)(A), by striking "without prejudice" the

second time it occurs,

(3) in subsection (a)(5)(B), by striking "plaintiff who" and inserting "plaintiff",

(4) in subsection (d), by striking "(d) except as provided in paragraph (3)," before "(d) Additional Information", and

(5) in subsection (e), by striking "(e)" before "(e) SCHEDULE".

(b) Section 2112.—

(1) SUSPENSION OF PROCEEDINGS.—Section 2112(d)(3) of the Public Health Service Act (42 U.S.C. 300aa-12(d)(3)) is amended

by adding at the end the following:

"(D) If, in reviewing proceedings on petitions for vaccine-related injuries or deaths associated with the administration of vaccines before the effective date of this part, the chief special master determines that the number of filings and resultant workload place an undue burden on the parties or the special master involved in such proceedings, the chief special master may, in the interest of justice, suspend proceedings on any petition for up to 180 days in addition to the suspension time under subparagraph (C)."

(2) Notice.—Section 2112 of the Public Health Service Act (42 U.S.C. 300aa-12) is amended by adding at the end the following:

"(g) Notice.- If-

"(1) a special master fails to make a decision on a petition within the 240 days prescribed by subsection (d)(3)(A)(ii) (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D), and (B) any days the petition is before a special master

as a result of a remand under subsection (e)(2)(C)), or

"(2) the United States Claims Court fails to enter a judgment under this section on a petition within 420 days (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D), and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C)) after the date on which the petition was filed,

the special master or court shall notify the petitioner under such petition that the petitioner may withdraw the petition under section 2121(b) and the petition will be considered withdrawn under such section if the petitioner, the special master, or the court do not take

certain actions."

(c) Section 2113.—Section 2113(c) of the Public Health Service Act (42 U.S.C. 300aa-13(c)) is amended by inserting "the" after "special masters of".

(d) Section 2115.—Section 2115 of the Public Health Service Act

(42 U.S.C. 300aa-15) is amended-

(1) in subsection (e)(2), by striking "the Program," the second time it occurs and all that follows through "limited to the costs" and inserting the following: "the Program, in awarding compensation on such petition the special master or court may include an amount of compensation limited to the costs",

(2) in subsection (f)-

(A) in the second sentence of paragraph (2), by striking "section 2121(b)" and inserting "section 2121(a)", and
(B) in the last sentence of paragraph (4)(B), by striking "subsection (i)" and inserting "subsection (j)" and by striking ing "section 2111(a)" and inserting "the limitation on civil actions prescribed by section 2121(a)", and

(3) in the first sentence of subsection (i), by inserting before the period ", and \$80,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection

(f)(4)(B)"

(e) Section 2116.—Section 2116 of the Public Health Service Act (42 U.S.C. 300aa-16) is amended-

(1) in subsection (a)(1)-

(A) by striking "24 months" and inserting "28 months",

and

(B) by inserting before the comma at the end the following: "and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months after the date

of administration of the vaccine", and
(2) in subsection (c), by striking "and ending on the date a final judgment is entered on the petition" and inserting "and ending on the date (1) an election is made under section 2121(a) to file the civil action, (2) an election is made under section 2121(b) to withdraw the petition, or (3) the petition is considered withdrawn under section 2121(b)".

(f) SECTION 2121.-

(1) LIMITATION ON ACTIONS.—Section 2121(a) of the Public Health Service Act (42 U.S.C. 300aa-21(a)) is amended—

(A) by inserting before the last sentence the following: "If a person elects to receive compensation under a judgment of the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part or is deemed to have accepted the judgment of the court in such an action, such person may not bring or maintain a civil action for damages against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered.", and

(B) by inserting after "actions" in the last sentence the following: "for vaccine-related injuries or deaths associated with the administration of a vaccine after the effective date

of this part".

(2) WITHDRAWAL OF PETITION.—Section 2121(b) of the Public Health Service Act (42 U.S.C. 300aa-21(b)) is amended to read as follows:

"(b) WITHDRAWAL OF PETITION.-

"(1) A petitioner under a petition filed under section 2111 may submit to the United States Claims Court a notice in writing

withdrawing the petition if-

"(A) a special master fails to make a decision on such petition within the 240 days prescribed by section 2112(d)(3)(A)(ii) (excluding (i) any period of suspension under section 2112(d)(3)(C) or 2112(d)(3)(D), and (ii) any days the petition is before a special master as a result of a remand under section 2112(e)(2)(C)), or

"(B) the court fails to enter a judgment under section 2112 on the petition within 420 days (excluding (i) any period of suspension under section 2112(d)(3)(C) or 2112(d)(3)(D), and (ii) any days the petition is before a special master as a result of a remand under section

2112(e)(2)(C)) after the date on which the petition was filed. Such a notice shall be filed within 30 days of the provision of the notice required by section 2112(g). If such a notice is not filed before the expiration of such 30 days, the petition with respect to which the notice was to be filed shall be considered withdrawn under this paragraph.

"(2) If a special master or the court does not enter a decision or make a judgment on a petition filed under section 2111 within 30 days of the provision of the notice in accordance with section 2112(g), the special master or court shall no longer have jurisdiction over such petition and such petition shall be consid-

ered as withdrawn under paragraph (1).".
(g) Section 322.—Section 322 of the National Childhood Vaccine

Injury Act of 1986 (42 U.S.C. 300aa-1 note) is amended—

in subsection (a)-

(A) by striking "of title XXI" and inserting "part A or B of subtitle 2 of title XXI", and

(B) by striking "such title XXI" and inserting "both such

parts", and
(2) by adding at the end the following:

"(c) REVIEW UNDER SECTION 2112(f).—If the review authorized by section 2112(f) is held invalid because the judgment of the United States Claims Court being reviewed did not arise from a case or controversy under Article III of the Constitution, such judgment shall be reviewed by a 3-judge panel of the United States Claims

42 USC 300aa-12 note

Court. Such panel shall not include the judge who participated in

such judgment."

(h) Effective Date.—The amendments made by subsections (f)(1) and (g) shall take effect as of November 14, 1986, and the amendments made by subsections (a) through (e) and subsection (f)(2) shall take effect as of September 30, 1990.

42 USC 300aa-11

(i) AUTHORIZATION OF APPROPRIATIONS.—Section 6601(r) of the Omnibus Reconciliation Act of 1989 (Public Law 101-239) is

103 Stat. 2292.

amended-(1) in paragraph (1), by striking "\$1,500,000 for each of the fiscal years 1990 and 1991", and inserting "\$2,500,000 for each

of the fiscal years 1991 and 1992",

(2) in paragraph (2), by striking "\$1,500,000 for each of the fiscal years 1990 and 1991", and inserting "\$2,500,000 for each of the fiscal years 1991 and 1992", and

(3) in paragraph (3), by striking "\$1,500,000 for each of the fiscal years 1990 and 1991", and inserting "\$2,500,000 for each

of the fiscal years 1991 and 1992".

(j) RECORDS AND REPORTS.—Section 301(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)) is amended by striking out "or (j)" and inserting in lieu thereof "or (k)".

(k) COMMISSIONED CORPS.—

(1) Appointment of commissioned officer.—Section 206(a) of the Public Health Service Act (42 U.S.C. 207(a)) is amended by inserting after the first sentence the following new sentence: "During the period of appointment to the position of Assistant Secretary for Health, a commissioned officer of the Public Health Service shall have the grade corresponding to the grade of General of the Army.".

(2) Conforming amendment.—Section 201(a) of title 37, United States Code, is amended by inserting "Assistant Secretary for Health." in the fourth column of the table cor-

responding with pay grade O-10.

(3) Effective date.—The amendments made by paragraphs 37 USC 201 note.
(1) and (2) shall take effect on the first day of the month immediately following the month in which this Act was enacted.

SEC. 6. TECHNICAL AMENDENTS IN CERTAIN PROGRAMS PROVIDING SERVICES REGARDING ACQUIRED IMMUNE DEFICIENCY SYN-

(a) Formula for Emergency Relief Grants.—Section 2603(a)(3) of the Public Health Service Act, as added by section 101(3) of Public Law 101-381, is amended to read as follows:

42 USC 300ff-13.

"(3) Amount of grant.—

"(A) In general.-

"(i) Subject to the extent of amounts made available in appropriations Acts, a grant made for purposes of this paragraph to an eligible area shall be made in an amount equal to the product of-

"(I) an amount equal to the amount available for distribution under paragraph (2) for the fiscal year

involved; and

"(II) the percentage constituted by the ratio of the distribution factor for the eligible area to the sum of the respective distribution factors for all eligible areas.

42 USC 300ff-49.

"(ii) For purposes of clause (i)(II), the term 'distribution factor' means the sum of-

"(I) an amount equal to the product of 3 and the amount determined under subparagraph (B) for

the eligible area involved; and

"(II) an amount equal to the product of the amount determined under subparagraph (B) for the eligible area and the amount determined under subparagraph (C) for the area.

Amount relating to cumulative number of CASES.—The amount determined in this subparagraph is an

amount equal to the ratio of-

"(i) an amount equal to the cumulative number of cases of acquired immune deficiency syndrome in the eligible area involved, as indicated by the number of such cases reported to and confirmed by the Director of the Centers for Disease Control by the applicable date specified in section 2601(a); to

"(ii) an amount equal to the sum of the respective amounts determined under clause (i) for each eligible area for which an application for a grant for purposes

of this paragraph has been approved.

"(C) Amount relating to per capita incidence of CASES.—The amount determined in this subparagraph is an

amount equal to the ratio of-

"(i) the per capita incidence of cumulative cases of acquired immune deficiency syndrome in the eligible area involved (computed on the basis of the most recently available data on the population of the area); to "(ii) the per capita incidence of cumulative such cases in all eligible areas for which applications for grants for purposes of this paragraph have been approved

(computed on the basis of the most recently available data on the population of the areas)."

(b) Set-Aside Regarding Categorical Grants to Certain Enti-TIES FOR EARLY INTERVENTION SERVICES.—Section 2649(c) of the Public Health Service Act, as added by section 301(a) of Public Law 101-381, is amended-

(1) by striking "(c) CERTAIN ALLOCATIONS" and all that follows through "After determining" and inserting the following:

"(c) CERTAIN ALLOCATIONS BY SECRETARY. —

"(1) DISCRETIONARY GRANTS TO CERTAIN STATES.—After determining"; and

(2) by adding at the end the following new paragraph: "(2) Grants to certain political subdivisions.—

"(A)(i) In the case of a State containing any political subdivision described in clause (ii), the Secretary shall, subject to subparagraph (B), make a reduction in the amount of the allotment under subsection (a) for the State for each fiscal year in an amount necessary for carrying out subparagraphs (B) and (C) with respect to the political subdivision. Any such reduction shall be in addition to the reduction required in paragraph (1) for the fiscal year involved.

"(ii) The political subdivision referred to in clause (i) is any political subdivision that received a cooperative agreement from the Secretary, acting through the Director of the

Centers for Disease Control, for fiscal year 1990 for programs to provide counseling and testing with respect to

acquired immune deficiency syndrome.

(B) In the case of a State described in subparagraph (A), the Secretary shall, from the amounts made available as a result of reductions under such subparagraph, make a grant each fiscal year to each political subdivision described in such subparagraph that exists in the State if the political subdivision involved agrees that the provisions of subparts II and III will apply to the political subdivision to the same extent and in the same manner as such subparts apply to entities receiving grants under section 2651(a).

"(C) Grants under subparagraph (B) for a fiscal year for a political subdivision shall be provided in an amount equal to the amount received by the political subdivision in fiscal year 1990 under the cooperative agreement described in

subparagraph (A).".

(c) Miscellaneous Amendment.—Section 2647(c) of the Public Health Service Act, as added by section 301(a) of Public Law 101-381, is amended-

(1) in the first sentence, by striking "are adequate" and inserting the following: "certifies to the Secretary that the laws of the State are adequate"; and

(2) in the second sentence, by striking "subsection (a)" and

inserting "subsection (a),".

Approved November 3, 1990.

LEGISLATIVE HISTORY-H.R. 4238 (S. 2629):

HOUSE REPORTS: No. 101-611 (Comm. on Energy and Commerce). SENATE REPORTS: No. 101-390 accompanying S. 2629 (Comm. on Labor and Human Resources).

CONGRESSIONAL RECORD, Vol. 136 (1990):
July 23, considered and passed House.
Oct. 12, considered and passed Senate, amended. Oct. 15, House concurred in Senate amendments. 42 USC 300ff-47.