

108TH CONGRESS
1ST SESSION

S. 371

To amend the Public Health Service Act to ensure an adequate supply
of vaccines.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 12, 2003

Mr. DEWINE (for himself, Mrs. CLINTON, and Mr. REED) introduced the fol-
lowing bill; which was read twice and referred to the Committee on
Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to ensure an
adequate supply of vaccines.

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. SUPPLY OF VACCINES.**

4 Title XXI of the Public Health Service Act (42
5 U.S.C. 300aa–1 et seq.) is amended by adding at the end
6 the following:

7 “Subtitle 3—Adequate Vaccine Supply

8 **“SEC. 2141. SUPPLY OF VACCINES.**

9 “(a) IN GENERAL.—

1 “(1) PLAN.—Not later than 6 months after the
2 date of enactment of this section, the Secretary, act-
3 ing through the Director of the Centers for Disease
4 Control and Prevention, shall develop a plan for the
5 purchase, storage, and rotation of a supply of vac-
6 cines sufficient to provide routinely recommended
7 vaccinations for a 6-month period for—

8 “(A) a national stockpile of vaccines for all
9 children as authorized under section 1928(d)(6)
10 of the Social Security Act (42 U.S.C.
11 1396s(d)(6)); and

12 “(B) adults.

13 “(2) SUPPLY.—The supply of vaccines under
14 paragraph (1) shall—

15 “(A) include all vaccines routinely rec-
16 ommended for children by the Advisory Com-
17 mittee on Immunization Practices; and

18 “(B) include all vaccines routinely rec-
19 ommended for adults by the Advisory Com-
20 mittee on Immunization Practices.

21 “(3) SUPPLY AUTHORITY.—The Secretary shall
22 carry out—

23 “(A) paragraph (2)(A) using the authority
24 provided for under section 1928(d)(6) of the

1 Social Security Act (42 U.S.C. 1396s(d)(6));
2 and

3 “(B) paragraph (2)(B) using—

4 “(i) the authority provided for under
5 section 317; and

6 “(ii) any other authority relating to
7 the vaccines described in such paragraph.

8 “(b) SUBMISSION OF PLAN.—

9 “(1) IN GENERAL.—Not later than 1 year after
10 the date of enactment of this section, the Secretary
11 shall submit the plan developed under subsection (a)
12 to—

13 “(A) the Committee on Health, Education,
14 Labor, and Pensions of the Senate;

15 “(B) the Committee on Finance of the
16 Senate; and

17 “(C) the Committee on Energy and Com-
18 merce of the House of Representatives.

19 “(2) INCLUSIONS.—The plan shall include a
20 discussion of the considerations that formed—

21 “(A) the basis for the plan; and

22 “(B) the prioritization of the schedule for
23 purchasing vaccines set forth in the plan.

1 “(c) IMPLEMENTATION OF THE PLAN.—Not later
2 than September 30, 2006, the Secretary shall fully imple-
3 ment the plan developed under subsection (a).

4 “(d) NOTICE.—

5 “(1) IN GENERAL.—For the purposes of main-
6 taining and administering the supply of vaccines de-
7 scribed under subsection (a), the Secretary shall re-
8 quire by contract that the manufacturer of a vaccine
9 included in such supply provide not less than 1 year
10 notice to the Secretary of a discontinuance of the
11 manufacture of the vaccine, or of other factors, that
12 may prevent the manufacturer from providing vac-
13 cines pursuant to an arrangement made to carry out
14 this section.

15 “(2) REDUCTION OF PERIOD OF NOTICE.—The
16 notification period required under paragraph (1)
17 may be reduced if the manufacturer certifies to the
18 Secretary that good cause exists for reduction, under
19 the conditions described in section 506C(b) of the
20 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
21 356c).

22 “(e) PROCEEDS.—Any proceeds received by the Sec-
23 retary from the sale of vaccines contained in the supply
24 maintained pursuant to this section, shall be available to
25 the Secretary for the purpose of purchasing additional

1 vaccines for the supply. Such proceeds shall remain avail-
2 able until expended.

3 “(f) ONGOING REPORTS.—

4 “(1) IN GENERAL.—Not later than 2 years
5 after submitting the plan pursuant to subsection (b),
6 and periodically thereafter, the Secretary shall sub-
7 mit a report to the Committees identified in sub-
8 section (b)(1) that—

9 “(A) details the progress made in imple-
10 menting the plan developed under subsection
11 (a); and

12 “(B) notes impediments, if any, to imple-
13 menting the plan developed under subsection
14 (a).

15 “(2) RECOMMENDATION.—The Secretary shall
16 include in the first of such reports required under
17 paragraph (1)—

18 “(A) a recommendation as to whether the
19 vaccine supply should be extended beyond the
20 6-month period provided in subsection (a); and

21 “(B) a discussion of the considerations
22 that formed the recommendation under sub-
23 paragraph (A).

24 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
25 are authorized to be appropriated to carry out this section

- 1 such sums as may be necessary for each of fiscal years
- 2 2004 through 2009.”.

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