

108TH CONGRESS
2D SESSION

H. R. 3758

To amend the Public Health Service Act to provide for an influenza vaccine awareness campaign, ensure a sufficient influenza vaccine supply, and prepare for an influenza pandemic or epidemic, to amend the Internal Revenue Code of 1986 to encourage vaccine production capacity, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 3, 2004

Mr. EMANUEL (for himself, Mr. SHIMKUS, Ms. DEGETTE, and Mr. ENGEL) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Public Health Service Act to provide for an influenza vaccine awareness campaign, ensure a sufficient influenza vaccine supply, and prepare for an influenza pandemic or epidemic, to amend the Internal Revenue Code of 1986 to encourage vaccine production capacity, 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Flu Protection Act
3 of 2004”.

4 **TITLE I—FLU VACCINE**
5 **AWARENESS CAMPAIGN**

6 **SEC. 101. AWARENESS CAMPAIGN AND EDUCATION AND**
7 **OUTREACH EFFORTS.**

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

11 “Subtitle 3—Influenza Vaccine
12 “AWARENESS CAMPAIGN AND EDUCATION AND OUTREACH
13 EFFORTS

14 “SEC. 2141. (a) CAMPAIGN.—The Secretary, acting
15 through the Director of the Centers for Disease Control
16 and Prevention (in this subtitle referred to as the ‘Direc-
17 tor’), shall conduct a public awareness campaign and edu-
18 cation and outreach efforts each year during the time pe-
19 riod preceding the influenza season on each of the fol-
20 lowing:

21 “(1) The importance of receiving the influenza
22 vaccine.

23 “(2) Which populations the Director rec-
24 ommends to receive the influenza vaccine to prevent
25 health complications associated with influenza, in-
26 cluding health care workers and household contacts.

1 “(3) Professional medical education of physi-
2 cians, nurses, pharmacists, and other health care
3 providers and such providers’ associated organiza-
4 tions.

5 “(4) Information that emphasizes the safety, ef-
6 ficacy, and benefit of recommended vaccines for the
7 public good.

8 “(b) OUTREACH TO MEDICARE RECIPIENTS.—

9 “(1) IN GENERAL.—The Administrator of the
10 Centers for Medicare & Medicaid Services shall, at
11 the earliest possible time in the influenza vaccine
12 planning and production process, reach out to pro-
13 viders of medicare services, including managed care
14 providers, nursing homes, hospitals, and physician
15 offices to urge early and full preordering of the in-
16 fluenza vaccine so that production levels can accom-
17 modate the needs for the influenza vaccine.

18 “(2) RATES OF IMMUNIZATION AMONG MEDI-
19 CARE RECIPIENTS.—The Director shall work with
20 the Administrator of the Centers for Medicare &
21 Medicaid Services to publish the rates of influenza
22 immunization among individuals receiving assistance
23 under the medicare program under title XVIII of the
24 Social Security Act (42 U.S.C. 1395 et seq.).

1 “(c) STATE AND PUBLIC HEALTH ADULT IMMUNIZA-
 2 TION ACTIVITIES.—The Director shall support the devel-
 3 opment of State adult immunization programs that place
 4 emphasis on improving influenza vaccine delivery to high-
 5 risk populations and the general population, including the
 6 exploration of improving access to the influenza vaccine.

7 “(d) EFFICACY OF VACCINE.—The Director shall
 8 work with appropriate agencies in conducting a study to
 9 assess the efficacy of the influenza vaccine.

10 “(e) EXISTING MODES OF COMMUNICATION.—In car-
 11 rying out the public awareness campaign and education
 12 and outreach efforts under subsections (a) and (b), the
 13 Director may use existing websites or structures for com-
 14 munication.

15 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
 16 are authorized to be appropriated to carry out this section
 17 \$10,000,000 for each of fiscal years 2004 through 2008.”.

18 **TITLE II—ENCOURAGING VAC-** 19 **CINE PRODUCTION CAPACITY**

20 **SEC. 201. INCENTIVES FOR THE CONSTRUCTION OF VAC-** 21 **CINE MANUFACTURING FACILITIES.**

22 (a) VACCINE MANUFACTURING FACILITIES INVEST-
 23 MENT TAX CREDIT.—

24 (1) ALLOWANCE OF CREDIT.—Section 46 of the
 25 Internal Revenue Code of 1986 (relating to amount

1 of investment credit) is amended by striking “and”
2 at the end of paragraph (2), by striking the period
3 at the end of paragraph (3) and inserting “, and”,
4 and by adding at the end the following new para-
5 graph:

6 “(4) the vaccine manufacturing facilities invest-
7 ment credit.”.

8 (2) AMOUNT OF CREDIT.—Section 48 of such
9 Code is amended by adding at the end the following
10 new subsection:

11 “(c) VACCINE MANUFACTURING FACILITIES INVEST-
12 MENT CREDIT.—

13 “(1) IN GENERAL.—For purposes of section 46,
14 the vaccine manufacturing facilities investment cred-
15 it for any taxable year is an amount equal to 20 per-
16 cent of the qualified investment for such taxable
17 year.

18 “(2) QUALIFIED INVESTMENT.—For purposes
19 of paragraph (1), the qualified investment for any
20 taxable year is the basis of each vaccine manufac-
21 turing facilities property placed in service by the tax-
22 payer during such taxable year.

23 “(3) VACCINE MANUFACTURING FACILITIES
24 PROPERTY.—For purposes of this subsection, the

1 term ‘vaccine manufacturing facilities property’
2 means real and tangible personal property—

3 “(A)(i) the original use of which com-
4 mences with the taxpayer, or

5 “(ii) which is acquired through purchase
6 (as defined by section 179(d)(2)),

7 “(B) which is depreciable under section
8 167,

9 “(C) which is used for the manufacture,
10 distribution, or research and development of
11 vaccines, and

12 “(D) which is in compliance with any
13 standards and regulations which are promul-
14 gated by the Food and Drug Administration,
15 the Occupational Safety and Health Adminis-
16 tration, or the Environmental Protection Agen-
17 cy and which are applicable to such property.

18 “(4) CERTAIN PROGRESS EXPENDITURE RULES
19 MADE APPLICABLE.—Rules similar to rules of sub-
20 sections (c)(4) and (d) of section 46 (as in effect on
21 the day before the date of the enactment of the Rev-
22 enue Reconciliation Act of 1990) shall apply for pur-
23 poses of this subsection.

1 “(5) TERMINATION.—This subsection shall not
2 apply to any property placed in service after Decem-
3 ber 31, 2008.”.

4 (b) TECHNICAL AMENDMENTS.—

5 (1) Subparagraph (C) of section 49(a)(1) of
6 such Code is amended by striking “and” at the end
7 of clause (ii), by striking the period at the end of
8 clause (iii) and inserting “, and”, and by adding at
9 the end the following new clause:

10 “(iv) the basis of any vaccine manu-
11 facturing facilities property.”.

12 (2) Subparagraph (E) of section 50(a)(2) of
13 such Code is amended by inserting “or 48(c)(4)” be-
14 fore the period.

15 (3)(A) The section heading for section 48 of
16 such Code is amended to read as follows:

17 **“SEC. 48. OTHER CREDITS.”.**

18 (B) The table of sections for subpart E of part
19 IV of subchapter A of chapter 1 of such Code is
20 amended by striking the item relating to section 48
21 and inserting the following:

 “Sec. 48. Other credits.”.

22 (c) EFFECTIVE DATE.—The amendments made by
23 this section shall apply to property placed in service after
24 December 31, 2003, under rules similar to the rules of
25 section 48(m) of the Internal Revenue Code of 1986 (as

1 in effect on the day before the date of the enactment of
 2 the Revenue Reconciliation Act of 1990).

3 **TITLE III—ENSURING SUFFI-**
 4 **CIENT FLU VACCINE SUPPLY**

5 **SEC. 301. VACCINE SUPPLY.**

6 Subtitle 3 of title XXI of the Public Health Service
 7 Act, as added by section 101, is amended by adding at
 8 the end the following:

9 “VACCINE SUPPLY

10 “SEC. 2142. (a) REQUESTS FOR MORE DOSES.—

11 “(1) IN GENERAL.—Not later than March 15 of
 12 each year, the Director shall enter into a contract
 13 with one or more manufacturers to produce such ad-
 14 ditional doses of the influenza vaccine as determined
 15 necessary by the Director.

16 “(2) CONTENT OF CONTRACT.—A contract for
 17 additional doses shall provide that the manufacturer
 18 will be compensated by the Director at an equitable
 19 rate negotiated by the Director and the manufac-
 20 turer for any doses that—

21 “(A) were not sold by the manufacturer
 22 through routine market mechanisms at the end
 23 of the influenza season for that year; and

24 “(B) were requested by the Director to be
 25 produced by such manufacturer.

1 “(3) WHEN SUCH VACCINE PURCHASES
2 SHOULD TAKE PLACE.—The Director may purchase
3 from a manufacturer the doses for which it has con-
4 tracted at any time after which it is determined by
5 the Director, in consultation with the manufacturer,
6 that the doses will likely not be absorbed by the pri-
7 vate market.

8 “(b) CONTINGENCY PLAN.—The Director shall en-
9 courage States to develop a contingency plan, in coordina-
10 tion with the Department of Health and Human Services,
11 for maximizing influenza immunization for high-risk popu-
12 lations in the event of a delay or shortage of the influenza
13 vaccine.

14 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
15 are authorized to be appropriated to carry out this section
16 such sums as may be necessary.”.

17 **TITLE IV—PREPARING FOR A** 18 **PANDEMIC OR EPIDEMIC**

19 **SEC. 401. PREPARATION FOR INFLUENZA PANDEMIC OR** 20 **EPIDEMIC.**

21 Subtitle 3 of title XXI of the Public Health Service
22 Act, as added by section 101 and amended by section 301,
23 is further amended by adding at the end the following:

24 “PREPARATION FOR INFLUENZA PANDEMIC OR EPIDEMIC

25 “SEC. 2143. (a) ESTABLISHMENT OF A PROTOCOL.—
26 The Secretary, acting through the Director, shall establish

1 a protocol to attempt to prevent, prepare for, and respond
2 to an influenza pandemic or epidemic. Such protocol shall
3 be updated as determined appropriate by the Director.

4 “(b) CONTENTS OF PROTOCOL.—The protocol estab-
5 lished under subsection (a) shall—

6 “(1) address methods to coordinate dissemina-
7 tion of the influenza vaccine to key populations in
8 the event of an influenza pandemic or epidemic;

9 “(2) address expansion of influenza vaccine
10 manufacturing capacity (including making advance
11 arrangements for ensuring the availability of raw
12 materials) to respond to the needs of the United
13 States during an influenza pandemic or epidemic;

14 “(3) improve upon the current influenza vac-
15 cines and production and dissemination methods;

16 “(4) address alternative ways to manufacture or
17 produce the influenza vaccine;

18 “(5) address how many doses of the influenza
19 vaccine should be produced on an annual basis and
20 which strains of influenza should be covered by such
21 vaccine in a particular year;

22 “(6) address public awareness and education,
23 and professional education on the need to receive an
24 influenza vaccine;

1 “(7) address alternative methods to prevent the
2 spread of, and complications associated with, influ-
3 enza, including antiviral medications;

4 “(8) address a tracking method for publicly and
5 privately sold doses of the influenza vaccine to en-
6 able the Director to determine, after consultation
7 with manufacturers of the influenza vaccine, how
8 much supply is in circulation in the case of an influ-
9 enza pandemic or epidemic; and

10 “(9) address other issues determined by the Di-
11 rector to be appropriate.

12 “(c) COORDINATION; PREPARATION; PREVENTION.—
13 In establishing the protocol under subsection (a), the Di-
14 rector shall—

15 “(1) coordinate with health care providers,
16 manufacturers, research institutions, health care or-
17 ganizations, and other expert stakeholders;

18 “(2)(A) conduct international and national sur-
19 veillance;

20 “(B) build State surveillance capacity;

21 “(C) collect influenza vaccine safety and effi-
22 cacy data; and

23 “(D) engage in epidemiological studies and re-
24 search on novel influenza viruses;

9 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
10 are authorized to be appropriated to carry out this section
11 \$100,000,000 for each of fiscal years 2004 through
12 2008.”.

15 SEC. 501. MANUFACTURER WITHDRAWAL FROM THE MAR-
16 KET.

20 “Subtitle 4—Notice of Intent to Withdraw From the
21 Market

23 “SEC. 2151. Any manufacturer of a vaccine that re-
24 ceives authority under Federal law to distribute such vac-
25 cine shall provide advance notification to the Department

1 of Health and Human Services regarding such manufac-
2 turer's intent to stop the distribution of such vaccine into
3 the marketplace.”.

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