

109<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 628

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.

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 8, 2005

Mr. EMANUEL (for himself, Mr. SNYDER, Mr. REYES, Mr. ABERCROMBIE, Mr. GUTIERREZ, Mr. HINCHEY, Mrs. MALONEY, Mr. PAYNE, Ms. WOOLSEY, Mr. BERRY, Mr. KENNEDY of Rhode Island, Mr. ENGEL, and Ms. DELAURO) 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

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## 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 2005”.

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  
6           and benefit of recommended vaccines for the public  
7           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 2005 through 2009.”.

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

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

8 (2) AMOUNT OF CREDIT.—Subpart E of part  
9 IV of subchapter A of chapter 1 of such Code (relat-  
10 ing to rules for computing investment credit) is  
11 amended by inserting after section 48 the following  
12 new section:

13 **“SEC. 48A. VACCINE MANUFACTURING FACILITIES CREDIT.**

14 “(a) IN GENERAL.—For purposes of section 46, the  
15 vaccine manufacturing facilities investment credit for any  
16 taxable year is an amount equal to 20 percent of the quali-  
17 fied investment for such taxable year.

18 “(b) QUALIFIED INVESTMENT.—

19 “(1) IN GENERAL.—For purposes of subsection  
20 (a), the qualified investment for any taxable year is  
21 the basis of each vaccine manufacturing facilities  
22 property placed in service by the taxpayer during  
23 such taxable year.

24 “(2) VACCINE MANUFACTURING FACILITIES  
25 PROPERTY.—For purposes of this section, the term

1 ‘vaccine manufacturing facilities property’ means  
2 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 “(c) CERTAIN PROGRESS EXPENDITURE RULES  
19 MADE APPLICABLE.—Rules similar to rules of subsections  
20 (c)(4) and (d) of section 46 (as in effect on the day before  
21 the date of the enactment of the Revenue Reconciliation  
22 Act of 1990) shall apply for purposes of this subsection.

23 “(d) TERMINATION.—This subsection shall not apply  
24 to any property placed in service after December 31,  
25 2009.”.

1 (b) TECHNICAL AMENDMENTS.—

2 (1) Clause (iii) of section 49(a)(1)(C) of such  
3 Code is amended to read as follows:

4 “(iii) the basis of any vaccine manu-  
5 facturing facilities property.”.

6 (2) Subparagraph (E) of section 50(a)(2) of  
7 such Code is amended by inserting “or 48A(c)” be-  
8 fore the period.

9 (3) The table of sections for subpart E of part  
10 IV of subchapter A of chapter 1 of such Code is  
11 amended by inserting after the item relating to sec-  
12 tion 48 the following:

“Sec. 48A. Vaccine manufacturing facilities credit.”.

13 (c) EFFECTIVE DATE.—The amendments made by  
14 this section shall apply to property placed in service after  
15 December 31, 2004, under rules similar to the rules of  
16 section 48(m) of the Internal Revenue Code of 1986 (as  
17 in effect on the day before the date of enactment of the  
18 Revenue Reconciliation Act of 1990).

19 **TITLE III—ENSURING SUFFI-**  
20 **CIENT FLU VACCINE SUPPLY**

21 **SEC. 301. VACCINE SUPPLY.**

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

## 1 “VACCINE SUPPLY

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

3 “(1) IN GENERAL.—Not later than March 15 of  
4 each year, the Director shall enter into contracts  
5 with manufacturers to produce such additional doses  
6 of the influenza vaccine as determined necessary by  
7 the Director.8 “(2) CONTENT OF CONTRACT.—A contract for  
9 additional doses shall provide that the manufacturer  
10 will be compensated by the Director at an equitable  
11 rate negotiated by the Director and the manufac-  
12 turer for any doses that—13 “(A) were not sold by the manufacturer  
14 through routine market mechanisms at the end  
15 of the influenza season for that year; and16 “(B) were requested by the Director to be  
17 produced by such manufacturer.18 “(3) WHEN SUCH VACCINE PURCHASES  
19 SHOULD TAKE PLACE.—The Director may purchase  
20 from the manufacturer the doses for which it has  
21 contracted at any time after which it is determined  
22 by the Director, in consultation with the manufac-  
23 turer, that the doses will likely not be absorbed by  
24 the private market.

1       “(b) CONTINGENCY PLAN.—The Director shall en-  
2 courage States to develop a contingency plan, in coordina-  
3 tion with the Department of Health and Human Services,  
4 for maximizing influenza immunization for high-risk popu-  
5 lations in the event of a delay or shortage of the influenza  
6 vaccine.

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

## 10       **TITLE IV—PREPARING FOR A** 11       **PANDEMIC OR EPIDEMIC**

### 12       **SEC. 401. PREPARATION FOR INFLUENZA PANDEMIC OR** 13       **EPIDEMIC.**

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

17       “PREPARATION FOR INFLUENZA PANDEMIC OR EPIDEMIC

18       “SEC. 2143. (a) ESTABLISHMENT OF A PROTOCOL.—  
19 The Secretary, acting through the Director, shall continue  
20 progress on the pandemic preparedness plan and establish  
21 a protocol to attempt to prevent, prepare for, and respond  
22 to an influenza pandemic or epidemic. Such protocol shall  
23 be updated as determined appropriate by the Director.

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

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

4           “(2) address expansion of influenza vaccine  
5           manufacturing capacity (including making advance  
6           arrangements for ensuring the availability of raw  
7           materials) to respond to the needs of the United  
8           States during an influenza pandemic or epidemic;

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

11          “(4) address alternative ways to manufacture or  
12          produce the influenza vaccine;

13          “(5) address alternative methods to prevent the  
14          spread of, and complications associated with, influ-  
15          enza, including antiviral medications;

16          “(6) address a tracking method for publicly and  
17          privately sold doses of the influenza vaccine to en-  
18          able the Director to determine, after consultation  
19          with manufacturers of the influenza vaccine, how  
20          much supply is in circulation in the case of an influ-  
21          enza pandemic or epidemic; and

22          “(7) address other issues determined by the Di-  
23          rector to be appropriate.

1 “(c) COORDINATION; PREPARATION; PREVENTION.—  
2 In establishing the protocol under subsection (a), the Di-  
3 rector shall—

4 “(1) coordinate with health care providers,  
5 manufacturers, research institutions, health care or-  
6 ganizations, and other expert stakeholders; and

7 “(2) assist States with preparedness activities  
8 for a rapid State and local response to an influenza  
9 pandemic, including exploring methods of making  
10 the influenza vaccine more accessible to the general  
11 population.

12 “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
13 are authorized to be appropriated to carry out this section  
14 \$100,000,000 for each of fiscal years 2005 through  
15 2009.”.

16 **TITLE V—NOTICE OF INTENT TO**  
17 **WITHDRAW FROM THE MARKET**

18 **SEC. 501. MANUFACTURER WITHDRAWAL FROM THE MAR-**

19 **KET.**

20 Title XXI of the Public Health Service Act (42  
21 U.S.C. 300aa–1 et seq.), as amended by this Act, is fur-  
22 ther amended by adding at the end the following:

1 “Subtitle 4—Notice of Intent to Withdraw From the  
2 Market

3 “MANUFACTURER WITHDRAWAL FROM THE MARKET

4 “SEC. 2151.

5 Any manufacturer of a vaccine that receives authority  
6 under Federal law to distribute such vaccine shall provide  
7 advance notification to the Department of Health and  
8 Human Services regarding such manufacturer’s intent to  
9 stop the distribution of such vaccine into the market-  
10 place.”.

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