108TH CONGRESS
2D SESSION

S. 2038

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 SENATE OF THE UNITED STATES

JANUARY 28, 2004

Mr. BAYH (for himself, Mr. CRAIG, Ms. LANDRIEU, and Mr. DURBIN) introduced the following bill; which was read twice and referred to the Committee on Finance

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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.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Flu Protection Act of 2004''.

TITLE I—FLU VACCINE AWARENESS CAMPAIGN

SEC. 101. AWARENESS CAMPAIGN AND EDUCATION AND OUTREACH EFFORTS.

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

''Subtitle 3—Influenza Vaccine

''AWARENESS CAMPAIGN AND EDUCATION AND OUTREACH EFFORTS

''SEC. 2141. (a) CAMPAIGN.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention (in this subtitle referred to as the 'Director'), shall conduct a public awareness campaign and education and outreach efforts each year during the time period preceding the influenza season on each of the following:

''(1) The importance of receiving the influenza vaccine.

''(2) Which populations the Director recommends to receive the influenza vaccine to prevent health complications associated with influenza, including health care workers and household contacts.

''(3) Professional medical education of physicians, nurses, pharmacists, and other health care

providers and such providers' associated organizations.

''(4) Information that emphasizes the safety, efficacy, and benefit of recommended vaccines for the public good.

''(b) OUTREACH TO MEDICARE RECIPIENTS.—

''(1) IN GENERAL.—The Administrator of the Centers for Medicare & Medicaid Services shall, at the earliest possible time in the influenza vaccine planning and production process, reach out to providers of medicare services, including managed care providers, nursing homes, hospitals, and physician offices to urge early and full preordering of the influenza vaccine so that production levels can accommodate the needs for the influenza vaccine.

''(2) RATES OF IMMUNIZATION AMONG MEDICARE RECIPIENTS.—The Director shall work with the Administrator of the Centers for Medicare & Medicaid Services to publish the rates of influenza immunization among individuals receiving assistance under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

''(c) STATE AND PUBLIC HEALTH ADULT IMMUNIZATION ACTIVITIES.—The Director shall support the development of State adult immunization programs that place

emphasis on improving influenza vaccine delivery to high-risk populations and the general population, including the exploration of improving access to the influenza vaccine.

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

''(e) EXISTING MODES OF COMMUNICATION.—In carrying out the public awareness campaign and education and outreach efforts under subsections (a) and (b), the Director may use existing websites or structures for communication.

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

TITLE II—ENCOURAGING VACCINE PRODUCTION CAPACITY

SEC. 201. INCENTIVES FOR THE CONSTRUCTION OF VACCINE MANUFACTURING FACILITIES.

(a) VACCINE MANUFACTURING FACILITIES INVESTMENT TAX CREDIT.—

(1) ALLOWANCE OF CREDIT.—Section 46 of the Internal Revenue Code of 1986 (relating to amount of investment credit) is amended by striking ''and'' at the end of paragraph (2), by striking the period at the end of paragraph (3) and inserting '', and'',

and by adding at the end the following new paragraph:

''(4) the vaccine manufacturing facilities investment credit.''.

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

''(c) VACCINE MANUFACTURING FACILITIES INVESTMENT CREDIT.—

''(1) IN GENERAL.—For purposes of section 46, the vaccine manufacturing facilities investment credit for any taxable year is an amount equal to 20 percent of the qualified investment for such taxable year.

''(2) QUALIFIED INVESTMENT.—For purposes of paragraph (1), the qualified investment for any taxable year is the basis of each vaccine manufacturing facilities property placed in service by the taxpayer during such taxable year.

''(3) VACCINE MANUFACTURING FACILITIES PROPERTY.—For purposes of this subsection, the term 'vaccine manufacturing facilities property' means real and tangible personal property—

''(A)(i) the original use of which commences with the taxpayer, or

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

''(B) which is depreciable under section 167,

''(C) which is used for the manufacture, distribution, or research and development of vaccines, and

''(D) which is in compliance with any standards and regulations which are promulgated by the Food and Drug Administration, the Occupational Safety and Health Administration, or the Environmental Protection Agency and which are applicable to such property.

''(4) CERTAIN PROGRESS EXPENDITURE RULES MADE APPLICABLE.—Rules similar to rules of subsections (c)(4) and (d) of section 46 (as in effect on the day before the date of the enactment of the Revenue Reconciliation Act of 1990) shall apply for purposes of this subsection.

''(5) TERMINATION.—This subsection shall not apply to any property placed in service after December 31, 2008.''.

(b) TECHNICAL AMENDMENTS.—

(1) Subparagraph (C) of section 49(a)(1) of such Code is amended by striking ''and'' at the end

of clause (ii), by striking the period at the end of clause (iii) and inserting ", and", and by adding at the end the following new clause:

"(iv) the basis of any vaccine manufacturing facilities property.".

(2) Subparagraph (E) of section 50(a)(2) of such Code is amended by inserting "or 48(c)(4)" before the period.

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

"SEC. 48. OTHER CREDITS.".

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

"Sec. 48. Other credits.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to property placed in service after December 31, 2003, under rules similar to the rules of section 48(m) of the Internal Revenue Code of 1986 (as in effect on the day before the date of enactment of the Revenue Reconciliation Act of 1990).

TITLE III—ENSURING SUFFICIENT FLU VACCINE SUPPLY

SEC. 301. VACCINE SUPPLY.

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

''VACCINE SUPPLY

''SEC. 2142. (a) REQUESTS FOR MORE DOSES.—

''(1) IN GENERAL.—Not later than March 15 of each year, the Director shall enter into a contract with manufacturer(s) to produce such additional doses of the influenza vaccine as determined necessary by the Director.

''(2) CONTENT OF CONTRACT.—The contract for additional doses shall provide that the manufacturer(s) will be compensated by the Director at an equitable rate negotiated by the Director and the manufacturer for any doses that—

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

''(B) were requested by the Director to be produced by such manufacturer(s).

''(3) WHEN SUCH VACCINE PURCHASES SHOULD TAKE PLACE.—The Director may purchase

from the manufacturer(s) the doses for which it has contracted at any time after which it is determined by the Director, in consultation with the manufacturer(s), that the doses will likely not be absorbed by the private market.

''(b) CONTINGENCY PLAN.—The Director shall encourage States to develop a contingency plan, in coordination with the Department of Health and Human Services, for maximizing influenza immunization for high-risk populations in the event of a delay or shortage of the influenza vaccine.

''(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary.''.

TITLE IV—PREPARING FOR A PANDEMIC OR EPIDEMIC

SEC. 401. PREPARATION FOR INFLUENZA PANDEMIC OR EPIDEMIC.

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

''PREPARATION FOR INFLUENZA PANDEMIC OR EPIDEMIC

''SEC. 2143. (a) ESTABLISHMENT OF A PROTOCOL.—The Secretary, acting through the Director, shall establish a protocol to attempt to prevent, prepare for, and respond

to an influenza pandemic or epidemic. Such protocol shall be updated as determined appropriate by the Director.

''(b) CONTENTS OF PROTOCOL.—The protocol established under subsection (a) shall—

''(1) address methods to coordinate dissemination of the influenza vaccine to key populations in the event of an influenza pandemic or epidemic;

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

''(3) improve upon the current influenza vaccines and production and dissemination methods;

''(4) address alternative ways to manufacture or produce the influenza vaccine;

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

''(6) address public awareness and education, and professional education on the need to receive an influenza vaccine;

''(7) address alternative methods to prevent the spread of, and complications associated with, influenza, including antiviral medications;

''(8) address a tracking method for publicly and privately sold doses of the influenza vaccine to enable the Director to determine, after consultation with manufacturers of the influenza vaccine, how much supply is in circulation in the case of an influenza pandemic or epidemic; and

''(9) address other issues determined by the Director to be appropriate.

''(c) COORDINATION; PREPARATION; PREVENTION.—In establishing the protocol under subsection (a), the Director shall—

''(1) coordinate with health care providers, manufacturers, research institutions, health care organizations, and other expert stakeholders;

''(2)(A) conduct international and national surveillance;

''(B) build State surveillance capacity;

''(C) collect influenza vaccine safety and efficacy data; and

''(D) engage in epidemiological studies and research on novel influenza viruses;

''(3) assist States with preparedness activities for a rapid State and local response to an influenza pandemic, including exploring methods of making the influenza vaccine more accessible to the general population; and

''(4) develop systems to routinely measure the impact of influenza on pediatric and high-risk populations.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $100,000,000 for each of fiscal years 2004 through 2008.''.

TITLE V—NOTICE OF INTENT TO WITHDRAW FROM THE MARKET

SEC. 501. MANUFACTURER WITHDRAWAL FROM THE MARKET.

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

''Subtitle 4—Notice of Intent To Withdraw From the Market

''MANUFACTURER WITHDRAWAL FROM THE MARKET

''SEC. 2151. Any manufacturer of a vaccine that receives authority under Federal law to distribute such vaccine shall provide advance notification to the Department

of Health and Human Services regarding such manufacturer's intent to stop the distribution of such vaccine into the marketplace.''.

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