I

109TH CONGRESS
1ST SESSION

H. R. 4245

To provide for programs and activities with respect to pandemic influenza, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 7, 2005

Mr. LEWIS of California (for himself, Mr. REGULA, Mr. FRELINGHUYSEN, Mr. DREIER, Mrs. BONO, Mr. ISSA, and Mr. DOOLITTLE) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Resources and Agriculture, 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 provide for programs and activities with respect to pandemic influenza, 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; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Influenza Preparedness and Prevention Act of 2005''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—VACCINE AND ANTIVIRAL PURCHASING

Sec. 101. Influenza antivirals supply.
Sec. 102. Procurement of vaccines for the Strategic National Stockpile.
Sec. 103. Procurement of essential supplies.

TITLE II—VACCINE PRODUCTION CAPACITY

Sec. 201. Liability protections for pandemics, epidemics, and biodefense countermeasures.
Sec. 202. Vaccine buyback program.
Sec. 203. Approval of vaccines.
Sec. 204. Establishment of Office of Safety Evaluation and Pandemic Preparedness.

TITLE III—PANDEMIC PREPAREDNESS

Sec. 301. Public education on pandemic influenza and preparedness.
Sec. 302. Educational efforts and grants.
Sec. 303. Domestic surveillance of wild birds.
Sec. 304. Research at the National Institutes of Health.
Sec. 305. Research at the Centers for Disease Control and Prevention.
Sec. 306. Global surveillance.
Sec. 307. Proposal for international fund to support pandemic influenza control.
Sec. 308. Pandemic influenza and animal health.

TITLE IV—STATE AND LOCAL INFRASTRUCTURE

Sec. 401. State preparedness plan.

TITLE V—GENERAL PROVISIONS

Sec. 501. Authorization of appropriations.

TITLE I—VACCINE AND ANTIVIRAL PURCHASING

SEC. 101. INFLUENZA ANTIVIRALS SUPPLY.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this Act as the ''Secretary'') shall establish a stockpile of anti-virals to use for rapid response to an influenza outbreak.

(b) AMOUNT.—The stockpile established under subsection (a) shall be of sufficient quantity to treat not less than 25 percent of the population of the United States.

SEC. 102. PROCUREMENT OF VACCINES FOR THE STRATEGIC NATIONAL STOCKPILE.

Subject to development and testing of potential vaccines for pandemic influenza, including possible pandemic avian influenza, the Secretary shall determine the minimum number of doses of vaccines needed to prevent infection during at least the first wave of pandemic influenza for health professionals (including doctors, nurses, mental health professionals, pharmacists, veterinarians, laboratory personnel, epidemiologists, virologists, and public health practitioners), core public utility employees, and those persons expected to be at high risk for serious morbidity and mortality from pandemic influenza, and take immediate steps to procure this minimum number of doses for the Strategic National Stockpile.

SEC. 103. PROCUREMENT OF ESSENTIAL SUPPLIES.

The Secretary shall, as soon as is practicable, take action to procure for the Strategic National Stockpile essential supplies (including ventilators, syringes, respirators, surgical masks, and gloves) that may be needed in the event of a pandemic.

TITLE II—VACCINE PRODUCTION CAPACITY

SEC. 201. LIABILITY PROTECTIONS FOR PANDEMICS, EPIDEMICS, AND BIODEFENSE COUNTERMEASURES.

Part B of title III of the Public Health Service Act is amended by inserting after section 319F–2 (42 U.S.C. 247d–6b) the following:

"SEC. 319F–3. LIABILITY PROTECTIONS FOR PANDEMIC AND EPIDEMIC PRODUCTS AND SECURITY COUNTERMEASURES.

''(a) AUTHORITY.—As provided for in subsection (b), and subject to paragraph (1)(C) of such subsection, a manufacturer, distributor, administrator, or health care provider shall be immune, under Federal and State law, from suit or liability caused by or arising out of the covered application of a covered countermeasure pursuant to a declaration by the Secretary described in subsection (b)(2).

''(b) LITIGATION MANAGEMENT.—

''(1) LIMITATION ON CAUSE OF ACTION.—

''(A) NO CAUSE OF ACTION IN CERTAIN CASES.—

''(i) IN GENERAL.—No cause of action shall exist against a manufacturer, dis-

tributor, administrator, or a health care provider described in subsection (a) for claims of loss arising out of, relating to, or resulting from the covered application of a covered countermeasure that is deployed pursuant to a declaration by the Secretary described in paragraph (2).

''(ii) RULE OF CONSTRUCTION.—For purposes of this section, the term 'arising out of, relating to, or resulting from' shall not be construed to apply to a loss that has no causal relationship with the administration or use of a covered countermeasure.

''(B) RULE.—

''(i) SUBSEQUENT INJURY.—The protections provided for in subsection (a) and subparagraph (A) of this paragraph shall apply to a covered application of a covered countermeasure regardless of the date of alleged injury.

''(ii) PRIVATE DONATION OR SALE.—The protections provided for in subsection (a) and subparagraph (A) of this paragraph shall apply to a covered application

of a covered countermeasure regardless of whether the covered countermeasure is on the commercial market, so long as the covered countermeasure is deployed in a declaration described in paragraph (2) and the Secretary does not specifically prohibit such private donation or sale in such declaration.

''(C) POTENTIAL LIABILITY UPON DETERMINATION.—

''(i) IN GENERAL.—A manufacturer, distributor, or administrator of a covered countermeasure or a health care provider who administers a covered countermeasure shall not be immune under subsection (a) or exempted from a cause of action under subparagraph (A) if—

''(I) in the case of a manufacturer or distributor, the Secretary makes an affirmative determination under subparagraph (D)(ii) against such manufacturer or distributor; or

''(II) in the case of an administrator or health care provider, the administrator or health care provider

acts with willful misconduct as that term is defined in regulations promulgated by the Secretary and the Attorney General.

"(D) INVESTIGATION AND DETERMINATION BY SECRETARY CONCERNING ACTIONS AGAINST MANUFACTURERS, OR DISTRIBUTORS.—

"(i) INVESTIGATION BY SECRETARY.—A petitioner seeking a determination under clause (ii) may petition the Secretary to investigate allegations of willful misconduct against a manufacturer or distributor for a loss arising out of, relating to, or resulting from a covered application of a covered countermeasure as provided for in subparagraph (A). The petition shall demonstrate to the Secretary that such petitioner has suffered a loss as a direct result of the willful misconduct of a manufacturer or distributor. The decision whether or not to undertake the investigation shall be within the Secretary's discretion and shall not be subject to judicial review.

"(ii) DETERMINATION BY SECRETARY.—To make an affirmative determination under this subparagraph, the Secretary shall find, by clear and convincing evidence, that—

"(I) the manufacturer or distributor of a covered countermeasure violated a provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or this Act, and such violation is material to the loss alleged; and

"(II) in violating either such Act, such manufacturer or distributor acted with willful misconduct and such misconduct—

"(aa) caused the covered countermeasure to present a significant or unreasonable risk to human health; and

"(bb) proximately caused the injury alleged by the petitioner.

"(iii) NOTICE AND HEARING.—If the Secretary finds that an affirmative deter-

mination will likely be made under clause (ii), the Secretary shall undertake an action in accordance with section 556 of title 5, United States Code.

"(iv) EFFECT OF DETERMINATION.—Subject to subsection (c) and subparagraph (C) of this paragraph, the only exception to the immunity from suit and liability of manufacturers or distributors of a covered countermeasure provided for in subsection (a) and subparagraph (A) of this paragraph shall be for actions against a manufacturer or distributor as provided for in such subparagraph (A) that are subject to an affirmative determination under clause (ii).

"(v) JUDICIAL REVIEW.—

"(I) MANUFACTURERS OR DISTRIBUTORS.—At any time prior to the 90th day following an affirmative determination by the Secretary under subparagraph (D)(ii), any manufacturer or distributor subject to such an affirmative determination may file a petition with the United States Court

of Appeals for the District of Columbia, for a judicial review of such determination. The court's review under this subclause shall be limited in scope to a review of the record to determine whether the Secretary's actions were unsupported by substantial evidence or unwarranted by the facts. A copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by the Secretary for that purpose. The Secretary thereupon shall file in the court the record of the findings on which the Secretary based his or her determination. The filing of a petition under this clause shall automatically stay the Secretary's determination for the duration of the judicial proceeding.

''(II) PETITIONERS.—Any person who brought a petition to the Secretary under subparagraph (D)(i) may, at any time prior to the 90th day following a determination by the Secretary under subparagraph (D)(ii),

file a petition with the United States Court of Appeals for the District of Columbia Circuit, for a judicial review of such determination. Notwithstanding any other provision of law, the court's review under this subclause shall be limited in scope to a review of the record to determine whether the Secretary's actions were arbitrary, capricious, or an abuse of discretion.

''(vi) TOLLING OF STATUTE OF LIMITATIONS.—The computation of the statute of limitations for any action against a manufacturer or distributor described in this subparagraph shall not include any period of time that occurs prior to the time at which an affirmative determination by the Secretary under this subparagraph becomes final, and upon—

''(I) the expiration of the 90-day period following such determination if the aggrieved party does not seek judicial review of such determination under clause (ii); or

''(II) the conclusion of a judicial review proceeding under clause (ii), including any appeal.

''(vii) PROCEDURES FOR ACTIONS AGAINST MANUFACTURERS AND DISTRIBUTORS.—An action that is allowed under this paragraph shall be brought in the United States District Court. No jury trial shall be allowed. If the plaintiff prevails, the court may award only compensatory damages, and not punitive damages.

''(E) REGULATORY AUTHORITY.—Not later than 90 days after the date of enactment of this section, the Secretary, in consultation with the Attorney General, shall promulgate regulations to define what actions by a manufacturer, distributor, administrator, or health care provider of a covered countermeasure shall be deemed to constitute 'willful misconduct' for purposes of clause (i). In promulgating such regulations, the Secretary shall consider the nature of the actual or potential public health emergency, the timing and extent of any covered countermeasure program, and any other circumstances the Secretary determines to be

significant, so that any civil actions permitted under this subsection will not adversely affect public health. The Secretary may specify the period of time for which such regulations apply.

''(F) PROCEDURES FOR SUIT AGAINST ADMINISTRATORS AND HEALTH CARE PROVIDERS.—An action that is permitted under this subsection shall be brought in United States District Court. A plaintiff in such action shall specify in his or her complaint each action or omission that allegedly constitutes willful misconduct. No jury trial shall be allowed. No discovery will be allowed before the court rules on any motion to dismiss or a motion for summary judgment. If a plaintiff prevails, the court may award only compensatory damages, and not punitive damages.

''(G) SCOPE.—Subparagraph (C) shall apply regardless of whether the action or liability described in subsection (a) or the claim described in subparagraph (A) of this paragraph arises from the covered application by the Federal Government or by any person.

''(2) DECLARATION BY THE SECRETARY.—

"(A) IN GENERAL.—The Secretary may issue a declaration, pursuant to this paragraph, that an actual or potential public health emergency makes it advisable that a covered countermeasure be manufactured, tested, or deployed to a covered individual.

"(B) SECURITY COUNTERMEASURE OR QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT.—The Secretary shall specify in a declaration under subparagraph (A) the covered countermeasure to be sold by, purchased from, or donated by a manufacturer or drawn from the Strategic National Stockpile.

"(C) EFFECTIVE PERIOD.—The Secretary shall specify in a declaration under subparagraph (A) the beginning and the ending dates of the effective period of the declaration. The Secretary may subsequently amend such declaration to shorten or extend such effective period if the new ending date is after the date on which the declaration is amended.

"(D) PUBLICATION.—The Secretary shall promptly publish each declaration under subsection (a) and any amendments in the Federal Register.

''(c) ACTIONS BY AND AGAINST THE UNITED STATES.—

''(1) ACTIONS BY THE UNITED STATES.—Nothing in this section shall be construed to abrogate or limit any right, remedy, or authority that the United States or any agency thereof may possess under any other provision of law.

''(2) IMMUNITY.—The United States shall be immune from an action or liability caused by or arising out of the covered application of a covered countermeasure, described in subsection (b)(1)(A), to the same extent as a health care provider, a manufacturer, a distributor, or an administrator of a covered countermeasure.

''(d) SEVERABILITY.—If any provision of this section, or the application of such provision, to any person or circumstance is held to be unconstitutional, the remainder of this section and the application of such provisions to any person or circumstance shall not be affected thereby.

''(e) DEFINITIONS.—In this section:

''(1) ADMINISTRATOR.—The term 'administrator' includes a State or local government, a person employed by the State or local government, or other person, who supervised or administered a program with respect to the administration, dispensing,

distribution, or provision of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice assistance or provides a facility to administer or use a covered countermeasure in accordance with a designation under subsection (b)(2).

''(2) COVERED APPLICATION.—The term 'covered application' means design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of a qualified pandemic or epidemic product or a security countermeasure.

''(3) COVERED COUNTERMEASURE.—The term 'covered countermeasure' means a qualified pandemic or epidemic product or a security countermeasure.

''(4) COVERED INDIVIDUAL.—The term 'covered individual' means one or more categories of individuals who the Secretary has identified in a declaration under subsection (b)(2).

''(5) DEPLOYED.—The term 'deployed' means manufactured, tested, distributed, sold, purchased,

donated, dispensed, prescribed, administered, licensed, or used.

''(6) HEALTH CARE PROVIDER.—The term 'health care provider' means a person, including a volunteer, who is licensed or authorized under State law to distribute, prescribe, administer, or dispense, a security countermeasure or a qualified pandemic or epidemic product.

''(7) LOSS.—The term 'loss' means death, injury, illness, disability, condition, medical monitoring, or loss of or damage to property, including business interruption loss.

''(8) MANUFACTURER.—The term 'manufacturer' includes—

''(A) a contractor or subcontractor of a manufacturer;

''(B) a supplier or licensor of any product, intellectual property, service, research tool, or component of the qualified pandemic or epidemic product or security countermeasure; and

''(C) any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

''(9) QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT.—The term 'qualified pandemic or epidemic

product' means a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 351(i) of this Act), device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)), that is manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such pandemic or epidemic might otherwise cause or a serious or life-threatening disease or condition caused by such a product, that—

"(A)(i) is approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act;

"(ii) is authorized for emergency use in accordance with section 564 of the Federal Food, Drug, and Cosmetic Act;. or

"(iii) is the object of research for possible use to treat, identify, or prevent harm from pandemic flu; and

"(B) is specified in a declaration under subsection (b)(2).

''(10) PERSON.—The term 'person' includes an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department.

''(11) SECURITY COUNTERMEASURE.—The term 'security countermeasure' has the meaning given such term in section 319F–2(c)(1)(B).''.

SEC. 202. VACCINE BUYBACK PROGRAM.

(a) IN GENERAL.—The Secretary shall establish an influenza vaccine buyback protocol under which the Secretary may enter into buyback contracts with manufacturers of influenza vaccine to purchase such manufacturers' excess stocks of influenza vaccine so long as such vaccine has been manufactured in accordance with the recommendations of the Advisory Committee for the production of seasonal influenza vaccine.

(b) MANUFACTURERS.—The Secretary shall have the discretion to award buyback contracts under subsection (a) to several influenza vaccine manufacturers in a manner consistent with the goal of providing stability in the influenza vaccine market, as long as the Federal Government purchases not more than 50 percent of the excess influenza vaccine stock of any single manufacturer at market price.

SEC. 203. APPROVAL OF VACCINES.

(a) CRITERIA FOR FAST-TRACK APPROVAL.—Promptly after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall consult with potential manufacturers of vaccines against pandemic influenza to develop specific criteria for fast-track approval of such vaccines.

(b) PROVISIONS RELATING TO INFLUENZA VACCINE MANUFACTURERS.—Chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

"SEC. 909. PROVISIONS RELATING TO INFLUENZA VACCINE MANUFACTURERS.

"(a) ASSISTANCE AND TECHNICAL TRAINING BRANCH.—The Secretary shall expand and strengthen the activities of the Manufacturer Assistance and Technical Training Branch at the Center for Biologics Evaluation and Research of the Food and Drug Administration to provide for the dissemination of information, and to provide technical guidance, to entities seeking to comply with regulations of the Secretary relating to the production of biologic materials, particularly influenza vaccine.

"(b) PROVISIONS RELATED TO THE EMERGENCY ACQUISITION OF VACCINES.—

''(1) INCREASED COMMUNICATION.—The Food and Drug Administration shall carry out activities to increase communication between the agency and the scientific community regarding vaccine development and regulation, including participation in conferences on the science related to infectious diseases, influenza, biologic manufacturing, and other issues as determined appropriate by the Director of the Center for Biologics Evaluation and Research.

''(2) REGULATORY ROADMAP.—The Commissioner, in consultation with the Director of the Centers for Disease Control and Prevention, the Secretary, and other agencies or participants as determined appropriate by the Secretary, shall develop a regulatory roadmap to address the following issues surrounding emergency use authorization of influenza vaccine, as determined by the Secretary during a public health emergency involving an actual or imminent outbreak of naturally occurring or engineered seasonal influenza:

''(A) Policies for the emergency use authorization of influenza vaccine that is produced and sold in other countries so that such vaccine may be imported into the United States by the

United States government during a vaccine shortage.

''(B) Policies for the facilitation of the distribution of any such vaccine imported into the United States during a vaccine shortage, including the interstate transportation, allocation and equitable distribution of vaccine among high priority populations (as defined by the Advisory Committee on Immunization Practices and the Centers for Disease Control and Prevention) during an emergency use situation.

''(C) Policies for the communication and coordination of a response to an emergency use authorization with State and local health departments, including guidelines for notification of such entities in such situations.

''(D) Policies for the emergency use authorization of vaccines that are in clinical development in both the United States and other countries, including clarification of IND protocols for such vaccines, particularly those using new vaccine development technologies.

''(3) CONSULTATION.—In developing the roadmap under paragraph (2), the Commissioner shall solicit input from private and nonprofit stakeholders,

including State and local health officials, and such input shall include recommendations for developing emergency use authorization guidelines that maintain the scientific and regulatory standards of the Food and Drug Administration.''.

SEC. 204. ESTABLISHMENT OF OFFICE OF SAFETY EVALUATION AND PANDEMIC PREPAREDNESS.

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—Office of Safety Evaluation and Pandemic Preparedness

''SEC. 2141. ESTABLISHMENT; DEFINITIONS.

''(a) ESTABLISHMENT.—There is established in the Office of the Secretary the Office of Safety Evaluation and Pandemic Preparedness, to be headed by the Director of Safety Evaluation and Pandemic Preparedness.

''(b) DEFINITIONS.—In this subtitle:

''(1) The term 'Director' means the Director of Safety Evaluation and Pandemic Preparedness.

''(2) The term 'Office' means, unless otherwise specified, the Office of Safety Evaluation and Pandemic Preparedness.

''(3) The term 'qualified pandemic or epidemic product' has the meaning given to that term in section 4101 of title 28, United States Code.

''(4) The term 'security countermeasure' has the meaning given to that term in section 4101 of title 28, United States Code.

"SEC. 2142. AUTHORITIES.

''(a) IN GENERAL.—With respect to qualified pandemic or epidemic products and security countermeasures, the Director shall—

''(1) conduct or support safety research, including research on—

''(A) acute and chronic adverse reactions, including with respect to subpopulations;

''(B) components of such products and countermeasures, including additives, adjuvants, and preservatives; and

''(C) delivery mechanisms;

''(2) conduct or support long- and short-term monitoring, including with respect to new and altered products and countermeasures;

''(3) conduct or support research across a range of disciplines, including molecular genetics, toxicology, pharmacokinetics, cell biology, neurology, immunology, and epidemiology;

''(4) conduct or support research to address issues raised in claims of injury brought before the Secretary or the Attorney General of the United States;

''(5) develop and test hypotheses about potential adverse reactions;

''(6) evaluate, on a regular basis, the compliance of health care providers and the manufacturers of such products and countermeasures with Federal requirements for reporting adverse reactions related to such products and countermeasures;

''(7) conduct or support research to evaluate reports of injury following administration of such products and countermeasures for the purpose of developing tests to prescreen individuals and subpopulations at greater risk of injury; and

''(8) conduct or support research to evaluate biological mechanisms of injury for the purpose of eliminating or reducing the risk of such injury through better prescreening tools or through modification of such products and countermeasures.

''(b) PERSONNEL.—In carrying out this subtitle, the Director—

''(1) may not employ at management positions any individual—

''(A) who has been employed by the Centers for Disease Control and Prevention or the Food and Drug Administration to carry out any function relating to monitoring, or research on, adverse reactions related to a licensed vaccine; or

''(B) who has been employed by a vaccine manufacturer; and

''(2) shall ensure that all personnel assigned to carry out functions relating to monitoring, or research on, adverse reactions related to qualified pandemic or epidemic products or security countermeasures do not have any related professional, familial, or financial conflict of interest.

''(c) GRANT APPLICANTS.—In awarding any grant relating to research on adverse reactions related to qualified pandemic or epidemic products or security countermeasures, the Director—

''(1) shall ensure that the applicant for the grant does not have—

''(A) any financial conflict of interest that might compromise the research findings, such as holding a related patent or having a family member who holds a related patent; or

''(B) any conflict of interest resulting from the applicant's association with an entity with direct or indirect financial interest in the outcomes of the research, such as receiving money or an in-kind contribution from a manufacturer of such products or countermeasures; and

''(2) shall disqualify any applicant having any contractual relationship with, or receiving any funding from, any person with a direct or indirect interest in the outcomes of the research.''.

TITLE III—PANDEMIC PREPAREDNESS

SEC. 301. PUBLIC EDUCATION ON PANDEMIC INFLUENZA AND PREPAREDNESS.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, shall develop and implement a public education campaign about pandemic influenza and preparedness.

(b) CERTAIN REQUIREMENTS.—The education and outreach activities under subsection (a) shall include—

(1) efforts to distribute information concerning the potential need for general vaccination; education materials on personal precautionary measures;

(2) the development of a strategy with the business community to provide information about the economic disruptions that may arise during a pandemic period;

(3) consulting with State and local governments to inform the public on procedures that may be taken during a pandemic period, including with respect to vaccine and antiviral distributions and quarantines.

SEC. 302. EDUCATIONAL EFFORTS AND GRANTS.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 319B the following:

"SEC. 319B–1. IMMUNIZATION EDUCATIONAL EFFORTS AND GRANTS.

''(a) IN GENERAL.—The Director of the Centers for Disease Control and Prevention, in conjunction with State and local health departments, shall revise and expand the influenza-related educational materials to the Centers for Disease Control and Prevention, and facilitate the use of such materials by health care providers and patients. The Director is authorized to coordinate such educational efforts with nonprofit provider and patient advocacy groups.

''(b) INFLUENZA VACCINE EDUCATION AND OUTREACH.—

''(1) IN GENERAL.—In order to achieve an optimal balance in the influenza vaccine market, and to ensure that the recommendations of the Advisory Committee on Immunization Practices to the Centers for Disease Control and Prevention for vaccine administration are carried out to the maximum extent possible, the Director of the Centers for Disease Control and Prevention, in conjunction with State and local health departments, shall carry out influenza immunization education and outreach activities that target physicians and other health care providers, health insurance providers, health care institutions and patients, particularly those in high priority populations (as defined by the Advisory Committee on Immunization Practices and the Centers for Disease Control and Prevention) (referred to in this section as 'high priority populations').

''(2) TYPES OF ACTIVITIES.—The education and outreach activities under paragraph (1) shall include—

''(A) activities to encourage voluntary participation in influenza vaccination programs, with the goal of increasing overall influenza vaccination rates in the United States, achieving full influenza vaccination of all high priority

populations, and full use of each season's influenza vaccine supply;

''(B) the provision of information on influenza prevention;

''(C) activities to increase the number of healthcare providers who receive influenza vaccines each year; and

''(D) other influenza educational efforts determined appropriate by the Director.

''(c) GRANTS.—The Director of the Centers for Disease Control and Prevention may award grants to State and local health departments to carry out activities to encourage individuals, particularly those from high priority populations, to seek out influenza vaccinations.

''(d) COLLABORATION.—State and local health departments that receive grants under subsection (b) are encouraged to collaborate on projects with physicians and other health care providers, health insurance providers, health care institutions, and groups representing high priority populations.''.

SEC. 303. DOMESTIC SURVEILLANCE OF WILD BIRDS.

(a) IN GENERAL.— The United State Geological Survey, working in coordination with the United States Fish and Wildlife Service, the National Park Service, and other

relevant agencies, shall carry out an interagency effort to detect avian influenza in wild birds.

(b) TYPES OF ACTIVITIES.—The efforts under subsection (a) shall include—

(1) preparing standard guidelines for routine and systematic monitoring of wild birds;

(2) developing a uniform protocol for reporting mortality events; developing instructions for safe handling and shipping of specimens to diagnostic facilities;

(3) training for field personnel in procedures; and

(4) reporting on finding back to the field.

SEC. 304. RESEARCH AT THE NATIONAL INSTITUTES OF HEALTH.

The Director of the National Institutes of Health (referred to in this section as the ''Director of NIH''), in collaboration with the Director of the Centers for Disease Control and Prevention, and other relevant agencies, shall expand and intensify human and animal research, with respect to influenza, on—

(1) vaccine development and manufacture, including strategies to increase immunological response;

(2) effectiveness of inducing heterosubtypic immunity;

(3) antigen-sparing studies;

(4) antivirals, including minimal dose or course of treatment and timing to achieve prophylactic or therapeutic effect;

(5) side effects and drug safety of vaccines and antivirals in subpopulations;

(6) alternative routes of delivery of vaccines, antivirals, and other medications as appropriate;

(7) more efficient methods for testing and determining virus subtype;

(8) protective measures;

(9) modes of influenza transmission;

(10) effectiveness of masks, hand-washing, and other non-pharmaceutical measures in preventing transmission;

(11) improved diagnostic tools for influenza; and

(12) other areas determined appropriate by the Director of NIH.

SEC. 305. RESEARCH AT THE CENTERS FOR DISEASE CONTROL AND PREVENTION.

The Director of the Centers for Disease Control and Prevention, in collaboration with other relevant agencies,

shall expand and intensify research, with respect to influenza, on—

(1) historical research on prior pandemics to better understand pandemic epidemiology, transmission, protective measures, high-risk groups, and other lessons that may be applicable to future pandemic;

(2) communication strategies for the public during pandemic influenza, taking into consideration age, racial and ethnic background, health literacy, and risk status;

(3) changing and influencing human behavior as it relates to vaccination;

(4) population-based surveillance methods to estimate influenza infection rates and rates of outpatient illness;

(5) vaccine effectiveness;

(6) systems to monitor vaccination coverage levels and adverse events from vaccination; and

(7) other areas determined appropriate by the Director of the Centers for Disease Control and Prevention.

SEC. 306. GLOBAL SURVEILLANCE.

The Director of the Centers for Disease Control and Prevention, in collaboration with the Department of State

and other relevant agencies, shall expand and intensify the efforts of the Global Disease Detection Initiative. The Secretary shall increase the number of international public health sites and staff abroad in countries impacted by pandemic influenza to conduct disease identification and intervention activities, provide critical public health expertise to countries in need, train international collaborators to recognize and respond to influenza and other disease threats, and improve communication capabilities. The Director of the Centers for Disease Control and Prevention shall conduct a feasibility study and plan for the containment of a human pandemic flu outbreak abroad.

SEC. 307. PROPOSAL FOR INTERNATIONAL FUND TO SUPPORT PANDEMIC INFLUENZA CONTROL.

(a) IN GENERAL.—The Secretary should submit to the Director of the World Health Organization a proposal to study the feasibility of establishing a fund, (referred to in this section as the ''Pandemic Fund'') to support pandemic influenza control and relief activities conducted in countries affected by pandemic influenza, including pandemic avian influenza.

(b) CONTENT OF PROPOSAL.—The proposal submitted under subsection (a) shall describe, with respect to the Pandemic Fund—

(1) funding sources;

(2) administration;

(3) application process by which a country may apply to receive assistance from such Fund;

(4) factors used to make a determination regarding a submitted application, which may include—

(A) the gross domestic product of the applicant country;

(B) the burden of need, as determined by human morbidity and mortality and economic impact related to pandemic influenza and the existing capacity and resources of the applicant country to control the spread of the disease; and

(C) the willingness of the country to cooperate with other countries with respect to preventing and controlling the spread of the pandemic influenza; and

(5) any other information the Secretary determines necessary.

(c) USE OF FUNDS.—Funds from any Pandemic Fund established as provided for in this section shall be used to complement and augment ongoing bilateral programs and activities from the United States and other donor nations.

SEC. 308. PANDEMIC INFLUENZA AND ANIMAL HEALTH.

(a) IN GENERAL.—The Secretary of Agriculture shall expand and intensify efforts to prevent pandemic influenza, including possible pandemic avian influenza.

(b) REPORT.—Not later than 180 days after the date of enactment this Act, the Secretary of Agriculture shall submit to Congress a report that describes the anticipated impact of pandemic influenza on the United States agriculture industry.

(c) ASSISTANCE.—The Secretary of Agriculture, in consultation with the Secretary of Health and Human Services, the World Health Organization, and the World Organization for Animal Health, shall provide domestic and international assistance with respect to pandemic influenza preparedness to—

(1) support the eradication of infectious animal diseases and zoonosis;

(2) increase transparency in animal disease states;

(3) collect, analyze, and disseminate veterinary data;

(4) strengthen international coordination and cooperation in the control of animal diseases; and

(5) promote the safety of world trade in animals and animal products.

TITLE IV—STATE AND LOCAL INFRASTRUCTURE

SEC. 401. STATE PREPAREDNESS PLAN.

(a) IN GENERAL.—As a condition of receiving funds from the Centers for Disease Control and Prevention or the Health Resources and Services Administration related to bioterrorism, a State shall—

(1) designate an official or office as responsible for pandemic influenza preparedness;

(2) submit to the Director of the Centers for Disease Control and Prevention (referred to in this section as the ''Director'') a Pandemic Influenza Preparedness Plan described under subsection (b); and

(3) have such Preparedness Plan approved in accordance with this section.

(b) PREPAREDNESS PLAN.—

(1) IN GENERAL.—The Pandemic Influenza Preparedness Plan required under subsection (a) shall address—

(A) human and animal surveillance activities, including capacity for epidemiological analysis, isolation and subtyping of influenza viruses year-round, including for avian influenza

among domestic poultry, and reporting of information across human and veterinary sectors;

(B) methods to ensure surge capacity in hospitals, laboratories, outpatient healthcare provider offices, medical suppliers, and communication networks;

(C) assisting the recruitment and coordination of national and State volunteer banks of healthcare professionals;

(D) distribution of vaccines, antivirals, and other treatments to priority groups, and monitor effectiveness and adverse events;

(E) networks that provide alerts and other information for healthcare providers and organizations at the National, State, and regional level;

(F) communication with the public with respect to prevention and obtaining care during pandemic influenza;

(G) maintenance of core public functions, including public utilities, refuse disposal, mortuary services, transportation, police and firefighter services, and other critical services;

(H) provision of security for—

(i) first responders and other medical personnel and volunteers;

(ii) hospitals, treatment centers, and isolation and quarantine areas;

(iii) transport and delivery of resources, including vaccines, medications and other supplies; and

(iv) other persons or functions as determined appropriate by the Secretary;

(I) the acquisition of necessary legal authority for pandemic activities;

(J) integration with existing national, State, and regional bioterrorism preparedness activities or infrastructure;

(K) coordination among public and private health sectors with respect to healthcare delivery, including mass vaccination and treatment systems, during pandemic influenza; and

(L) coordination with Federal pandemic influenza preparedness activities.

(2) UNDERSERVED POPULATIONS.—The Pandemic Influenza Preparedness Plan required under subsection (a) shall include a specific focus on surveillance, prevention, and medical care for traditionally underserved populations, including low-income,

racial and ethnic minority, immigrant, and uninsured populations.

(c) APPROVAL OF STATE PLAN.—

(1) IN GENERAL.—The Director shall develop criteria to rate State Pandemic Influenza Preparedness Plans required under subsection (a) and determine the minimum rating needed for approval.

(2) TIMING OF APPROVAL.—Not later than 90 days after a State submits a State Pandemic Influenza Preparedness Plan as required under subsection (a), the Director shall make a determination regarding approval of such Plan.

(d) REPORTING OF STATE PLAN.—All Pandemic Influenza Preparedness Plans submitted and approved under this section shall be made available to Congress, State officials, and the public as determined appropriate by the Director.

(e) ASSISTANCE TO STATES.—The Centers for Disease Control and Prevention and the Health Resources and Services Administration may provide assistance to States in carrying out this section, or implementing an approved State Pandemic Influenza Preparedness Plan, which may include the detail of an officer to approved domestic pandemic sites or the purchase of equipment and supplies.

(f) WAIVER.—The Director may grant a temporary waiver of 1 or more of the requirements under this section.

TITLE V—GENERAL PROVISIONS

SEC. 501. AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this Act and the amendments made by this Act, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2006 through 2010.

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