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GLOBAL PATHOGEN SURVEILLANCE ACT OF 2007

SEPTEMBER 11, 2007.—Ordered to be printed

Mr. BIDEN, from the Committee on Foreign Relations,
submitted the following

REPORT

[To accompany S. 1687]

The Committee on Foreign Relations, having had under consideration a bill (S. 1687), to provide for global pathogen surveillance and response, reports favorably thereon and recommends that the bill do pass.

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I. PURPOSE

This legislation is designed to enhance the capability of the international community to detect, identify, and contain infectious disease outbreaks, whether the cause of those outbreaks is intentional or natural in origin. This bill targets U.S. assistance to developing nations in the following areas:

- Training of public health personnel in epidemiology, including diagnosis and containment of likely bioterrorism agents;
- Acquisition of laboratory and diagnostic equipment;
- Acquisition of communications technology to quickly transmit data on disease patterns and pathogen diagnoses to national public health authorities and to international institutions such as the World Health Organization (WHO);
- Expansion of overseas Centers for Disease Control and Prevention (CDC) and Department of Defense laboratories engaged in infectious disease research and disease surveillance, through the establishment of additional laboratories, enlargement of existing facilities, increases in the number of personnel, and/or expanding the scope of their activities; and

- Expanded assistance to the WHO and regional international disease surveillance efforts, including expansion of U.S.-administered Field Epidemiology Training Programs.

II. LEGISLATIVE HISTORY AND COMMITTEE ACTION

S. 1687 was introduced by Senator Biden on June 25, 2007. It is cosponsored by Senators Hagel, Kennedy and Casey. On June 27, 2007, the committee ordered the bill reported favorably by voice vote.

III. DISCUSSION

In January 2000, the National Intelligence Council released a National Intelligence Estimate entitled, *The Global Infectious Disease Threat and Its Implications for the United States*. The key judgments in that report were sobering:

New and reemerging infectious diseases will pose a rising global health threat and will complicate US and global security over the next 20 years. These diseases will endanger US citizens at home and abroad, threaten US armed forces deployed overseas, and exacerbate social and political instability in key countries and regions in which the United States has significant interests.¹

Development of an effective global surveillance and response system probably is at least a decade or more away, owing to inadequate coordination and funding at the international level and lack of capacity, funds, and commitment in many developing and former communist states.²

The probability of a bioterrorist attack against US civilian and military personnel overseas or in the United States also is likely to grow as more states and groups develop a biological warfare capability. Although there is no evidence that the recent West Nile virus outbreak in New York City was caused by foreign state or nonstate actors, the scare and several earlier instances of suspected bioterrorism showed the confusion and fear they can sow regardless of whether or not they are validated.³

The Estimate went on to elaborate regarding the challenges to maintaining an effective world-wide disease surveillance system:

A major obstacle to effective global surveillance and control of infectious diseases will continue to be poor or inaccurate national health statistical reporting by many developing countries and lack of both capacity and will to properly direct aid . . . and to follow WHO and other recommended health care practices. Those areas of the world most susceptible to infectious disease problems are least able to develop and maintain the sophisticated and costly communications equipment needed for effective disease surveillance and reporting. In addition to the barriers dictated by low levels of development, revealing an outbreak of a dreaded disease may harm national prestige, commerce, and tourism.⁴

In January 2001, the National Intelligence Council released another National Intelligence Estimate, entitled, *The Biological Warfare Threat*. The report pointed to the growing biological warfare capabilities of state and nonstate actors and, more importantly, highlighted the similar patterns and symptoms of a deliberately initiated disease outbreak and a naturally occurring outbreak. Once an outbreak is detected and begins to spread, it is very difficult to distinguish between a deliberate and a natural disease outbreak. Both are potentially devastating to human, animal, and plant life, moreover, as well as economically costly. Epidemiologists

¹National Intelligence Council, "The Global Infectious Disease Threat and Its Implications for the United States," National Intelligence Estimate NIE 99-17D (January 2000), p. 5.

²Ibid., p. 8.

³Ibid., p. 11.

⁴Ibid., p. 34.

and public health experts rely on similar tools to help prevent, detect, and contain both intentional and naturally occurring disease outbreaks.

According to an August 2001 report by the U.S. General Accounting Office (GAO, now known as the U.S. Government Accountability Office), WHO officials said that more than 60 percent of laboratory equipment in developing countries was either outdated or non-functioning, and that the vast majority of national personnel were not familiar with quality assurance principles for handling and analyzing biological samples. Deficiencies in training and equipment meant that many public health units in Africa and Asia were simply unable to perform accurate and timely disease surveillance.⁵

On September 5, 2001, the Senate Foreign Relations Committee held a hearing regarding the threat of bioterrorism and the spread of infectious diseases. Witnesses included former Senator Sam Nunn, Dr. Donald A. Henderson of Johns Hopkins University (later a scientific advisor to the White House and the Department of Health and Human Services), and Dr. David L. Heymann, then Executive Director for Communicable Diseases at the WHO. After the appearance, later in September 2001, of letters containing anthrax spores, which left 5 dead and caused major disruptions in the U.S. Senate and elsewhere, the committee held a March 19, 2002, hearing on the chemical and biological weapons threat. At that hearing, Dr. Alan P. Zelicoff, Senior Scientist at Sandia National Laboratories, testified on the role of syndromic surveillance in bioterrorism prevention.

The committee believes that the threat of bioterrorism poses significant challenges not only for the United States, but for the entire world. It is difficult to protect our nation's health without international cooperation in an age of unprecedented air travel and international trade, as infectious pathogens are transported across borders each day. The global outbreak of severe acute respiratory syndrome, or SARS, was an unfortunate reminder of this vulnerability. More recently, a man thought at the time to have extensively drug-resistant tuberculosis flew across an ocean—twice—and drove across several national borders, reminding us how readily a disease can be spread in the modern world. Fortunately, although extensively drug-resistant TB is especially difficult to treat, it does not spread as readily as influenza or some other diseases. Authorities knew who the disease vector was, moreover, and they knew (more or less) what he had. The risk with H5N1 avian influenza or a bioterrorism attack is heightened by the likelihood that the disease will spread before its presence is even evident.

Infectious disease outbreaks are transnational threats and the defense of our homeland is not an isolated activity. Rather it requires a comprehensive strategy, including a critical international component. Whether intentional or natural, infectious diseases do not recognize the boundaries set by national borders.

Developing nations represent one of the weak links in a comprehensive global surveillance and monitoring network. For example, even though the world has made substantial efforts to combat

⁵ United States General Accounting Office, "Global Health: Challenges in Improving Infectious Disease Surveillance Systems," GAO-01-722 (August 2001), p.3.

and prepare for the possibility of a global avian influenza pandemic, a recent GAO report suggests that the surveillance capabilities of many countries—even when focused on a single disease—remain dangerously inadequate. The report cites a senior WHO official as saying that numerous “disease blind spots” around the world hamper the organization’s ability to identify H5N1 outbreaks. It goes on to say that studies conducted in 2006 by the UN System Influenza Coordinator, in collaboration with the World Bank, found that about one-third of the countries surveyed lacked the capacity to diagnose avian influenza in humans.⁶ Unfortunately, naturally occurring disease outbreaks are most likely to occur in these areas where poor sanitary conditions, poverty, and a weak medical infrastructure combine to offer ideal breeding grounds for pathogens. In addition, some developing countries border rogue states or states that offer sanctuaries for international terrorist groups, which have a documented interest in biological agents.

In 2005, two sets of researchers reported in the journals *Nature* and *Science* that, based on computer simulations, if an outbreak of human-to-human-transmitted avian flu were to occur in a rural part of Southeast Asia, it might be possible to stem that dangerous epidemic by using anti-viral drugs to treat the tens of thousands of people who might have been exposed in the initial outbreak. One key requirement, however, was that the outbreak would have to be discovered, identified and reported very quickly; in one study, the assumption was that countermeasures were instituted when only 30 people had observable symptoms.⁷ These simulations underscore both the challenge of disease surveillance and the potential benefits if effective and timely surveillance can be made available where it is most needed.

So it is vital to give these countries the capability to track epidemics and to feed that information into international surveillance networks. Disease surveillance is a systematic approach that requires trained public health personnel, proper diagnostic equipment to identify viruses and pathogens, and prompt transmission of data from the doctor or clinic level all the way to national governments and the WHO.

The Global Pathogen Surveillance Act will offer such help to those countries that agree to give the United States and the WHO prompt access to disease outbreaks, so that we can help determine their origin. Recipients of this training will also be able to learn to spot diseases that might be used in a bioterrorist attack.

The Global Pathogen Surveillance Act was first introduced in 2002. The Senate Foreign Relations Committee reported this bill, either separately or as a title of a larger bill, on several occasions since 2002, and the Senate passed the bill in 2002 and 2005. The original bill was drafted in consultation with the WHO, the CDC, the Department of Defense and others, and later versions benefited

⁶United States Government Accountability Office, “Influenza Pandemic: Efforts to Forestall Onset Are Under Way: Identifying Countries at Greatest Risk Entails Challenges,” GAO-07-604 (June 2007), pp. 16n and 18-19.

⁷Neil M. Ferguson, Derek A.T. Cummings, Simon Cauchemez, Christophe Fraser, Steven Riley, Aronrag Meeyai, Sapon Iamsirithaworn and Donald S. Burke, “Strategies for containing an emerging influenza pandemic in Southeast Asia,” *Nature*, August 3, 2005. See also I.M. Longini Jr., A. Nizam, S. Xu, K. Ungchusak, W. Hanshaoworakul, D.A. Cummings, and M.E. Halloran, “Containing pandemic influenza at the source,” *Science*, August 3, 2005.

from suggestions from the State Department and, in 2005, from staff of the Senate Health, Education, Labor, and Pensions Committee.

The primary authority for implementation of the bill's provisions is vested in the Department of State. The committee expects that the Department of Health and Human Services will also play a critical role, however, including being consulted to the greatest extent possible.

Two years ago the Secretary of State, Dr. Condoleezza Rice, expressed her strong backing for this legislation in an answer for the record:

We believe that the Global Pathogen Surveillance Act will indeed help strengthen developing countries' abilities to identify and track pathogens that could be indicators of dangerous disease outbreaks—either naturally-occurring or deliberately released. Improved disease surveillance and communication among nations are critical defenses against both bioterrorism and natural outbreaks. We look forward to working with you in support of the Global Pathogen Surveillance Act. . . .

One of the true “nightmare” scenarios—of a bioterrorist attack or a naturally occurring disease—involves a contagious biological agent moving swiftly through a crowded urban area of a densely populated developing nation. Thus, we believe that it is critical to increase efforts to strengthen the public health and scientific infrastructure necessary to identify and quickly respond to infectious disease outbreaks—and that the Global Pathogen Surveillance Act will provide valuable support in these efforts.⁸

The WHO also shares the committee's concern. During the SARS epidemic, Dr. Michael Heymann, who was the highest-ranking American in the WHO, stated at a press conference: “it is clear that the best defense against the spread of emerging infections such as SARS is strong national public health—national disease detection and response capacities that can identify new diseases and contain them before they spread internationally.” He went on to highlight the important role that disease surveillance plays in combating both natural and terrorist outbreaks:

Global partnerships to combat global microbial threats make good sense as a defense strategy that brings immediate benefits in terms of strengthened public health and surveillance systems. The resulting infectious disease intelligence brings dual benefits in terms of protecting populations against both naturally occurring and potentially deliberately caused outbreaks. As SARS has so vividly demonstrated, the need is urgent and of critical importance to the health of economies as well as populations.

Support to developing countries such as proposed in the Global Pathogen Surveillance Act . . . will help strengthen capacity of public health professionals and epidemiologists, laboratory and other disease detection systems, and outbreak response mechanisms for naturally occurring infectious diseases such as SARS. This in turn will strengthen WHO and the world's safety net for outbreak detection and response, of which the United States is a major partner. And finally, strengthening this global safety net to detect and contain naturally occurring infectious diseases will strengthen the world's capacity to detect and respond to infectious diseases that may be deliberately caused.

IV. SECTION-BY-SECTION ANALYSIS

Section 1. Short Title

This Act is called the “Global Pathogen Surveillance Act of 2007.”

⁸“The Nomination of Dr. Condoleezza Rice to be Secretary of State,” Hearings before the Committee on Foreign Relations, U.S. Senate, January 18 and 19, 2005, S. Hrg. 109– 151, pp. 253–254.

Section 2. Findings; Purpose

This section lays out the findings and purposes of this Act.

Section 3. Definitions

This section defines five terms of art and sets forth one routine definition. The definition of “International Health Organization” in definition (3) is meant to be illustrative, rather than exclusive; additional organizations to those cited in the definition may also qualify as international health organizations under the Act.

Section 4. Eligibility for Assistance

Section 4 requires, in general, that assistance under the provisions of this Act be given only to those eligible developing countries that permit personnel from the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) to investigate infectious disease outbreaks on their territory and that provide pathogen surveillance data derived from such assistance to appropriate U.S. departments and agencies in addition to international health organizations. The committee intends that this requirement be met in a manner that does not reveal any classified information to persons not authorized to receive such information. Subsection (b) authorizes the Secretary of State to waive the limitation in subsection (a) if the Secretary determines that it is in the national interest of the United States to provide such a waiver.

Section 5. Restriction

Section 5 restricts access by foreign nationals participating in programs authorized under this title to select agents that may be used as, or in, a biological weapon, except in a supervised and controlled setting. The committee does not believe that such a restriction will constrain foreign nationals from fully participating in various training and educational programs under this Act. Subsection (b) makes clear that this restriction may not be construed to limit the ability of the Secretary of Health and Human Services to prescribe, through regulation, standards for the handling of a select agent or toxin or an overlap select agent or toxin.

Section 6. Fellowship Program

Section 6 authorizes the Secretary of State to award fellowships to eligible nationals of eligible developing countries to pursue a master of public health degree or advanced public health training in epidemiology within the United States. Each fellow may also take courses of study at the CDC or at an equivalent facility on diagnosis and containment of likely bioterrorism agents. The committee believes that carefully chosen programs of this sort should be encouraged as they not only impart technical skills utilizing state-of-the-art technology, but also help cultivate the management and organizational skills of future leaders for developing country public health programs.

Subsection (c) requires that fellows enter into an agreement with the Secretary of State under which the fellow will maintain satisfactory academic performance and, upon completing the education or training, will return to his or her country of nationality or last habitual residence (so long as it is an eligible developing country) and complete at least four years of employment in a public health

position in the government or a non-governmental, not-for-profit entity in that country. Alternatively, with the Secretary's consent, the fellow can complete part or all of this four-year requirement with an international health organization. If the fellow is unable to meet these requirements, he or she will be required to reimburse the U.S. government for the value of the assistance provided; the Secretary may waive the limitation in this subsection if the Secretary determines that it is in the national interest of the United States to provide such a waiver.

Subsection (d) authorizes the Secretary of State, in consultation with the Secretary of Health and Human Services, to enter into an agreement with any eligible developing country to establish the procedures for implementing the program.

Subsection (e) allows for the participation of U.S. citizens on a case-by-case basis, if the Secretary of State determines that it is in the national interest of the United States to provide for such participation. Such participants would be required, upon completion of education or training, to complete at least five years of employment in a public health position in an eligible developing country or at an international health organization.

Subsection (f) allows the Secretary, with the concurrence of the Secretary of Health and Human Services (HHS), to use existing HHS programs to provide the education and training described in this section, if the requirements of subsections (b), (c) and (d) will be substantially met under such existing programs.

Section 7. In-Country Training in Laboratory Techniques and Disease and Syndrome Surveillance

Section 7 authorizes the provision of short-term training courses outside the United States for laboratory technicians and public health officials in laboratory techniques relating to the identification, diagnosis, and tracking of pathogens responsible for infectious disease outbreaks. This training may take place in overseas facilities of the CDC or the Overseas Medical Research Units of the Department of Defense, as appropriate. Any such training shall be coordinated with existing programs and activities of international health organizations. Such training courses offer the opportunity for public health personnel to train in their indigenous environment, utilizing the available technology.

Subsection (b) authorizes short training courses, which shall be conducted either via the Internet or in appropriate facilities located in a foreign country, on disease and syndrome surveillance techniques. Using disease and syndrome surveillance, the emergence of a disease in a population is monitored based on geographic patterns of clinician-reported patient complaints and signs derived from physical examination and laboratory data.

Section 8. Assistance for the Purchase and Maintenance of Public Health Laboratory Equipment and Supplies

Section 8 authorizes the President to furnish assistance to eligible developing countries to purchase and maintain public health laboratory equipment and supplies that are needed to collect, analyze, and identify expeditiously a broad array of pathogens, including mutant strains, which may cause disease outbreaks or be used in a biological weapon. The equipment and supplies are to be ap-

propriate for use in the intended geographic area and compatible with general standards set forth by the WHO and, as appropriate, the CDC. They must not be defense articles or articles that would be subject to the Arms Export Control Act or likely be barred or subject to special conditions under the Export Administration Act of 1979 if purchased in the United States. This section does not exempt the exporting of goods or technology from compliance with applicable provisions of the Export Administration Act of 1979 (as in effect pursuant to the International Emergency Economic Powers Act, 50 U.S.C. 1701 et seq.).

Subsection (e) provides that preference should be given to the purchase of equipment and supplies of U.S. manufacture. Subsection (f) requires that the eligible developing country agree to properly house, maintain, support, secure, and maximize the use of equipment and supplies provided under this section.

Section 9. Assistance for Improved Communication of Public Health Information

Section 9 authorizes the President to provide assistance to eligible developing countries to purchase and maintain communications equipment and information technology to effectively and quickly collect, analyze, and transmit public health information within and among developing countries and to and from international health organizations. The requirements and limitations applied to assistance in section 8 are also applied to section 9. In addition, subsection (f) authorizes the President to provide assistance to international health organizations to facilitate standardization in the reporting of public health information.

Section 10. Assignment of Public Health Personnel to United States Missions and International Organizations

Section 10 authorizes the heads of Executive branch departments and agencies to assign public health personnel to U.S. diplomatic missions and international health organizations when requested, with the concurrence of the Secretary of State and of the employee concerned, for the purpose of enhancing disease and pathogen surveillance efforts in developing countries. The Department of State is authorized, under certain circumstances, to reimburse an agency or department for the costs incurred by reason of the detail of such personnel.

Section 11. Expansion of Certain United States Government Laboratories Abroad

Section 11 mandates the expansion of the overseas laboratories and other related facilities of the CDC and the Department of Defense, subject to the availability of appropriations. This expansion applies to both numbers of personnel and the scope of operations. The intent of this provision is to further the goals of global pathogen surveillance and monitoring. Overseas CDC and Department of Defense facilities, working with host governments, play a crucial role in enhancing the capability of developing countries to monitor disease outbreaks and possible biological weapons attacks. The committee intends that the expansion of CDC and Department of Defense overseas laboratory activities be undertaken in close co-

operation with host countries, to benefit their well-being and national security as well as that of the United States.

Subsection (b) provides that the expansion be carried out in such a manner as to foster cooperation and avoid duplication between and among laboratories. Subsection (c) provides that the expansion may not detract from the established core missions of the laboratories or compromise the security of those laboratories.

Section 12. Assistance for International Health Networks and Expansion of Field Epidemiology Training Programs

Section 12 authorizes the President to provide assistance for the purposes of enhancing the surveillance and reporting capabilities of the WHO and existing international regional and international health networks and for developing new international regional and international health networks, as a means of continuing to expand the reach of a global surveillance network.

Subsection (b) authorizes the Secretary of Health and Human Services to establish new country or regional international Field Epidemiology Training Programs in eligible developing countries. These programs offer two years of intense training for health professionals in entry- or mid-level positions to help build up indigenous capacity in epidemiology and public health.

Section 13. Reports

Section 13 requires the Secretary of State to submit a report to the Senate Foreign Relations Committee and the House Foreign Affairs Committee, not later than 90 days after the date of enactment of this Act, on the implementation of programs under this Act, including an estimate of the level of funding required to carry out such programs at a sufficient level.

Section 14. Authorization of Appropriations

This section authorizes appropriations for carrying out provisions of this title for Fiscal Years 2008 and 2009. The section authorizes \$115 million in total. Of this amount, \$40 million is authorized for Fiscal Year 2008 and \$75 million for Fiscal Year 2009. Subsection (b) provides that the amounts appropriated pursuant to subsection (a) are authorized to remain available until expended. Subsection (c) provides that not more than 10 percent of the amount appropriated for Fiscal Year 2008 may be obligated before the date on which a report is submitted, or required to be submitted, whichever first occurs, under section 13.

V. COST ESTIMATE

In accordance with Rule XXVI, paragraph 11(a) of the Standing Rules of the Senate, the committee provides this estimate of the costs of this legislation prepared by the Congressional Budget Office.

UNITED STATES CONGRESS,
 CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 20, 2007.

Hon. JOSEPH R. BIDEN, JR.,
Chairman, Committee on Foreign Relations,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 1687, the Global Pathogen Surveillance Act of 2007.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Sam Papenfuss.

Sincerely,

PETER R. ORSZAG.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

July 20, 2007.

S. 1687

Global Pathogen Surveillance Act of 2007

AS ORDERED REPORTED BY THE SENATE COMMITTEE ON FOREIGN
 RELATIONS ON JUNE 27, 2007

S. 1687 would authorize the appropriation of \$40 million in 2008 and \$75 million in 2009 for the following activities:

- Establish a fellowship program that would allow certain foreign nationals to pursue public health education or training in the United States;
- Expand operations at laboratories of the Department of Defense and the Centers for Disease Control and Prevention that are located in developing countries, and provide assistance to local individuals for training in laboratory techniques related to infectious diseases;
- Provide assistance to developing countries to purchase and maintain public health laboratory equipment and supplies and to purchase communications equipment and technology to effectively collect, analyze, and transmit public health information; and
- Provide assistance to the World Health Organization and establish new training programs in field epidemiology.

Based on historical spending patterns for similar activities, CBO estimates that implementing S. 1687 would cost \$8 million in 2008 and \$108 million over the 2008–2012 period, assuming appropriation of the authorized amounts. Enacting the bill would not affect direct spending or receipts.

S. 1687 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would not affect the budgets of state, local, or tribal governments.

The CBO staff contact for this estimate is Sam Papenfuss. This estimate was approved by Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

VI. EVALUATION OF REGULATORY IMPACT

Pursuant to Rule XXVI, paragraph 11(b) of the Standing Rules of the Senate, the committee has determined that there is no regulatory impact as a result of this legislation.

VII. CHANGES IN EXISTING LAW

In compliance with paragraph 12 of Rule XXVI of the Standing Rules of the Senate, the committee notes that no changes to existing law are made by this bill.

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