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THE GLOBAL PATHOGEN SURVEILLANCE ACT OF 2002

JULY 15, 2002.—Ordered to be printed

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

REPORT

[To accompany S. 2487]

The Committee on Foreign Relations, to which was referred the bill S. 2487, to provide for global pathogen surveillance and response, having considered the same, reports favorably thereon and recommends that the bill do pass.

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I. COMMITTEE ACTION

The Committee held a hearing on September 5, 2001 on “The Threat of Bioterrorism and the Spread of Infectious Diseases.” At that hearing, the Committee heard testimony supporting the development of a global pathogen surveillance and monitoring network. S. 2487 was introduced on May 9, 2002 by Senators Biden, Helms, Kennedy, and Frist. On May 23, 2002, the Committee ordered the bill reported by voice vote with a favorable recommendation.

II. BACKGROUND AND PURPOSES OF THE BILL

The anthrax attacks in the United States in the fall of 2001 underscored the need to address the growing threat of bioterrorism to our nation. While the anthrax attacks were delivered through the U.S. postal system, the next biological attack against the United States could in fact originate in a foreign country. It could also be

developed or tested overseas, or be derived from a new disease or strain that first appears overseas. Limited capabilities exist to identify and contain a biological weapons attack or a naturally occurring infectious disease outbreak, especially in developing countries. Accordingly, an essential building block in any effort to combat bioterrorism—a global pathogen surveillance and monitoring network—is hampered by serious gaps in developing countries.

Even prior to the anthrax attacks, the threat of biological terrorism was receiving increasing public attention from health officials, security experts, and government officials. In January 2000, the National Intelligence Council released a National Intelligence Estimate (NIE) entitled, *The Global Infectious Disease Threat and Its Implications for the United States*. According to the NIE, the probability of a bioterrorist attack against U.S. civilians and military personnel will continue to grow as states and terrorist groups develop a biological warfare capability. Moreover, the NIE warned that emerging and re-emerging infectious diseases overseas could threaten U.S. national security by causing high mortality rates for Americans in the event of an epidemic or by infecting U.S. military personnel participating in humanitarian and peacekeeping operations in developing countries.

In January 2001, the National Intelligence Council released a NIE entitled, *The Biological Warfare Threat*. The 2001 NIE not only points to the growing biological warfare capabilities of state and nonstate actors but, more importantly, validates 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 versus a natural disease outbreak. Furthermore, both are potentially devastating to human, animal, and plant life, as well as economically costly. Accordingly, epidemiologists and public health experts rely on similar tools to help prevent, detect, and contain both intentional and naturally occurring disease outbreaks.

The Committee held a hearing to examine the threat of bioterrorism and the spread of infectious diseases on September 5, 2001. The Committee heard from a range of experts including former Senator Sam Nunn, former Director of Central Intelligence R. James Woolsey, Jr., and Dr. Donald A. Henderson, who led the World Health Organization's smallpox eradication campaign. The witnesses presented the potentially grim consequences of a bioterrorist attack or a naturally occurring disease epidemic, consequences that, in their opinions, would likely be exacerbated by delays in the recognition of an epidemic and identification of the specific pathogen involved. According to Dr. Henderson, "In cooperation with WHO and other countries, we need to strengthen greatly our intelligence gathering capability. A focus on international surveillance and on scientist-to-scientist communication will be necessary if we are to have an early warning about the possible development and production of biological weapons by rogue nations or groups." Dr. David L. Heymann, Executive Director for Communicable Diseases at the World Health Organization, asserted, "National surveillance systems need to be in place well in advance of a possible attack, as adequate data on the prevalence of background diseases are needed to aid recognition of an unusual and possibly deliberately caused disease. Moreover, the epidemio-

logical techniques needed to investigate deliberate and natural outbreaks are the same.” Finally, Frank Cilluffo, then with the Center for Strategic and International Studies, declared, “Core public health functions, disease surveillance and lab capability will be the foundation of detection, investigation and response for bioterrorist attacks.”

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 alone in an age of unprecedented air travel and international trade, as infectious pathogens are transported across borders each day. 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. Thus, the United States must enhance its participation in combating global infectious disease threats.

Developing nations represent one of the weak links in a comprehensive global surveillance and monitoring network. According to an August 2001 report by the General Accounting Office on “Challenges in Improving Infectious Disease Surveillance Systems”,

Surveillance in developing countries is often impaired by shortages of human and material resources. Key positions in laboratories and clinics often are filled by people who do not possess the necessary qualifications. According to WHO, staff in over 90 percent of developing country laboratories are not familiar with quality assurance principles, and more than 60 percent of laboratory equipment is outdated or not functioning . . . In addition, poor roads and communications make it difficult for health care workers to alert higher authorities about outbreaks or quickly transport specimens to laboratories . . . These weaknesses limit the effectiveness of even the most widely supported international disease control programs.¹

Naturally occurring disease outbreaks are most likely to occur in the developing world, 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, where there is documented interest in biological agents.

Accordingly, the Global Pathogen Surveillance Act of 2002 seeks to identify and 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. Several provisions are intended to address shortfalls in public health education and training, including in laboratory techniques and syndrome surveillance, for eligible nationals from developing countries. We must enable public health officials to better detect, diagnose, and contain infectious disease outbreaks. The Global Pathogen Surveillance Act of 2002 includes sections that authorize

¹ General Accounting Office. “Global Health: Challenges in Improving Infectious Disease Surveillance Systems.” P. 3. August 2001.

the President to provide assistance for the purchase of laboratory and communications equipment. The President is authorized to provide assistance for the purpose of enhancing the surveillance and reporting capabilities for the World Health Organization and existing regional health networks. The heads of appropriate Federal agencies are authorized to make available greater numbers of United States Government public health personnel to international health organizations, regional health networks, and United States diplomatic missions where appropriate.

The Committee's intent in approving the Global Pathogen Surveillance Act of 2002 is to improve the world's anti-terrorism capabilities, and the training that is provided pursuant to this bill must include information on pathogens that have been identified as possible biological warfare agents. Witnesses at the Committee's September 5, 2001, hearing made clear, however, that the training and equipment needed to meet anti-terrorism concerns will also assist in the detection, identification and containment of naturally occurring disease outbreaks.

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

III. SECTION-BY-SECTION ANALYSIS

Section 1. Short Title.

This Act is called the "Global Pathogen Surveillance Act of 2002."

Section 2. Findings; Purpose.

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

Section 3. Definitions.

This section defines five terms of art and sets forth two routine definitions.

Section 4. Priority for Certain Countries.

According to the previously cited 2000 NIE, "disease incidence in developing countries, in particular, is either unreported or under-reported due to a lack of adequate medical and administrative personnel, the stigma associated with many diseases, or the reluctance of countries to incur the trade, tourism, and other losses that such revelations might produce." This reporting gap is of particular concern in a world where an unreported disease could become, or even be caused by, a novel biological warfare agent.

Section 4 therefore requires that priority in allocating assistance under the provisions of this bill be given 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. In particular, the Committee expects that recipient nations will adhere to the terms of the International Health Regulations regarding prompt notification of disease outbreaks, cooperation with WHO investigations, and speedy implementation of contain-

ment strategies. Such adherence will serve the interests of public health and anti-terrorism alike.

Section 5. Restriction.

Access to biological agents should be carefully regulated and appropriate accounting procedures should be followed when handling potentially deadly pathogens. Accordingly, section 5 restricts access that foreign nationals participating in programs authorized under this Act may gain to select agents that may be used as, or in, a biological weapon, except in a supervised and controlled setting. The Committee believes that there is no compelling reason for participants to have unlimited access to such select agents. 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.

Section 6. Fellowship Program.

A major obstacle to effective global pathogen surveillance and response will continue to be a lack of adequately trained public health officials in developing countries who can properly identify and diagnose an infectious disease outbreak. Many developing countries not only have a paucity of properly trained public health personnel, but also lack the capacity to train these individuals. The Committee believes that public health officials, properly trained in epidemiology and in diagnosing possible bioterrorism agents, are essential to the implementation of a strong and effective global surveillance system.

To this end, Section 6 authorizes the Secretary of State to award fellowships to eligible nationals of developing countries to pursue a master of public health degree or advanced public health training in epidemiology. 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. So that this education and training pays dividends in global pathogen surveillance efforts and, in particular, benefits public health and surveillance efforts in developing countries, the Secretary of State shall require the recipient to enter into an agreement under which the recipient, upon completing said education or training, will return to the recipient's 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 nongovernmental, not-for-profit entity in that country. If the recipient is unable to meet these requirements, the recipient will be required to reimburse the U.S. government for the value of the assistance provided. The Secretary of State is authorized to enter into an agreement with any eligible developing country in order to establish the procedures for implementing the program.

While the fellowship program is intended to benefit eligible nationals from eligible developing countries to receive education and training, subsection (e) allows for the participation of United States citizens, on a case-by-case basis, if the Secretary determines that it is in the national interest of the United States to do so. 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 the World Health Organization.

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

Global pathogen disease surveillance requires a comprehensive strategy, including both laboratory-based and clinic-based surveillance efforts. Laboratory-based surveillance is critical to accurate diagnoses. Section 7 supports short-term training courses, outside the United States, in laboratory techniques for laboratory technicians and public health officials. Such training courses offer the opportunity for public health personnel to train in their indigenous environment, utilizing the available technology. Subsection 7(a) complements the assistance authorized in Section 8 for the purchase and maintenance of public health laboratory equipment.

While traditional disease surveillance and identification methods are irreplaceable, the need for rapid surveillance that does not depend on confirmed laboratory diagnosis is growing. Infectious disease outbreaks, particularly those perpetrated by biological terrorism, often present themselves as ill-defined or unexplained syndromes and/or deaths. While there can be no substitute for laboratory identification of pathogens, and astute diagnosis of disease by public health officials, it is possible to recognize suspicious patterns at the local level before individual patient data (signs and symptoms) raise alarm and/or are sent to a laboratory for diagnosis.

Subsection 7(b) supports training in syndrome surveillance techniques. Syndrome surveillance systems provide the means for early detection and recognition, limit infection and mortality rates, and help to more efficiently focus limited public health resources. Utilizing simple desktop computer technology, a syndrome surveillance system at the fingertips of doctors and clinicians can transmit and track information in real-time using simple geographic locators to detect suspicious patterns of disease outbreak and to alert regional, national or international public health agencies. During a March 19, 2002 hearing before the Senate Foreign Relations Committee, Dr. Alan P. Zelicoff, Senior Scientist, Sandia National Laboratories testified that the most critical aspect of our bioterrorism prevention efforts is “enhanced disease surveillance accomplished through an inexpensive, international, secure, Internet-based system located in primary care clinics and some hospital emergency wards. . . .”

The Committee does not intend that this program will take away from any existing programs or authorities. Rather, it is intended to be a very specific addition to the surveillance tool kit.

Sections 8 and 9. Assistance for the Purchase and Maintenance of Public Health Laboratory Equipment and Assistance for Improved Communication of Public Health Information.

Equipment shortages are widespread in developing countries and severely impair pathogen surveillance efforts. The WHO reports that more than sixty percent of laboratory equipment in developing countries is outdated or defunct. According to the previously cited GAO report, “The ability of developing country health officials to provide accurate disease information is further compromised by

their frequent lack of clear and accurate diagnostic tests that they can perform themselves or ready access to functioning laboratories.”

At the same time, in order to establish a truly global surveillance systems, local and regional health networks must have the ability to communicate with one another, both intra-state and inter-state. In doing so, the Committee recognizes the need to strengthen the telecommunications capacities of different networks and to employ common software tools and compatible reporting requirements. Without modern and interoperable communications equipment and information technology, developing countries cannot employ effective disease surveillance and reporting systems. The Committee believes that improved communications equipment will result in the more timely and accurate dissemination of information throughout regional health networks, in circumstances in which time can mean the difference between low or high rates of infection or mortality from disease outbreaks.

Sections 8 and 9 authorizes the President to provide assistance, subject to the availability of appropriations, to eligible developing countries to purchase and maintain (1) public health laboratory equipment necessary for the collection, analysis, and identification of pathogens which may cause disease outbreaks or be used as biological weapons and (2) communications equipment and information technology, along with supporting equipment, necessary to effectively collect, analyze, and transmit public health information. The equipment should be appropriate for ready use in the intended geographical area and compatible with general standards established by the WHO and, as appropriate, the CDC to ensure interoperability with regional and international networks. Recipient countries are expected to commit the necessary resources, infrastructure, and other assets to maintain and support use of this equipment.

Subsections (c) and (d) in both sections reflect the Committee’s belief that equipment purchased with assistance provided under these sections should be in compliance with the Export Administration Act of 1979 and that no funds should be made available for the purchase from a foreign country of equipment that, if made in the United States, would be subject to the Arms Export Control Act. Subsection (e) in both sections reflects the Committee’s preference that equipment purchased with this assistance be of U.S. manufacture and that the amounts appropriated to carry out this section shall be subject to section 604 of the Foreign Assistance Act of 1961.

The Committee favors standardizing the reporting of public health information between and among developing countries and international health organizations. Standardized reporting requirements will enable information to be more easily transmitted and understood. Thus, the President is authorized under subsection (f) of Section 9 to provide assistance for this purpose.

It is the belief of this Committee that financial assistance must be accompanied by a requisite commitment, on the part of the recipient country, to the overall goals of global pathogen surveillance. The United States cannot undertake full support for the establishment of surveillance systems in developing countries. Thus, in order to make use of this assistance, Sections 8 and 9 direct that

the recipient country must agree to provide the resources, infrastructure, and other assets required to house, support, maintain, secure, and maximize use of this equipment and appropriate technical personnel.

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. These details, intended to be flexible in nature, should be for the purpose of enhancing disease and pathogen surveillance efforts in developing countries. The Secretary of State must concur with any such detail. This section also provides for the appropriate reimbursement of the home department or agency for the loss of personnel, subject to the availability of appropriations.

The Committee envisions use of this provision, among other examples, to enable the posting of Epidemiological Intelligence Service Officers at U.S. embassies and consulates overseas and the detail of additional U.S. personnel to the WHO.

Section 11. Laboratory-to-Laboratory Exchange Program.

An important element of training for personnel from developing countries involves educational exchanges. Such types of exchanges allow U.S. personnel to spend time in developing countries and foreign personnel to observe disease surveillance techniques in U.S. laboratories.

Section 11 authorizes the head of a federal department or agency, with the concurrence of the Secretary of State, to provide for such exchanges, subject to the availability of appropriations. The section defines “approved public health and research laboratories” as those overseas non-U.S. government laboratories which are well-established and have a demonstrated record of excellence, as determined by the Secretary.

The Committee intends that such exchanges provide U.S. personnel the opportunity to share their knowledge and skills with public health officials in developing countries and, in doing so, contribute to the development of a robust global surveillance system. Similarly, foreign public health personnel are provided the opportunity to work alongside distinguished public health practitioners and to hone their skills on state-of-the-art equipment.

Section 12. Expansion of Certain United States Governmental Laboratories Abroad.

Section 12, subject to the availability of appropriations, authorizes the expansion of the overseas laboratories and other related facilities of the Centers for Disease Control and the Department of Defense, as appropriate, to further the goals of global pathogen surveillance and monitoring. This expansion applies to both numbers of personnel and the scope of operations.

Overseas CDC and DoD facilities, working with host governments, play a crucial role in enhancing the capability of developing countries to monitor disease outbreaks and suspected biological weapons attacks. For example, the Pentagon administers the Glob-

al Emerging Infections Surveillance and Response System (GEIS), a program established in 1997 to address the challenges of identifying, reporting, and responding to emerging infectious disease threats. The continued success of the GEIS program is predicated upon the availability of resources at overseas laboratories. Recently, this program received positive marks in a study by the Institute of Medicine. The Committee believes expanded funding will allow the GEIS program and overseas CDC facilities to foster greater international efforts on pathogen surveillance.

Section 13. Assistance for Regional Health Networks and Expansion of Foreign Epidemiology Training Programs.

The Committee notes the invaluable contributions of the World Health Organization to the development of a global pathogen surveillance system. The World Health Organization, responsible for initiating the Global Alert and Response Network in April 2000, has been at the forefront of the creation of a global surveillance system, engineering links between a series of local, regional, and national health networks. Furthermore, the Committee believes that by making a commitment to expand the number, geographic scope, and quality of regional health networks, we move closer to our goal of a truly global pathogen surveillance system. A global surveillance system will not materialize overnight nor will it become a reality without a series of interconnected regional and disease specific surveillance networks.

The Committee believes that still more can and should be done to increase the capacities of the World Health Organization and regional health networks to ensure early warning of potential bioterrorist attacks and emerging or reemerging infectious disease threats. Section 13 therefore authorizes the President to provide assistance for the purposes of enhancing the surveillance and reporting capabilities of the World Health Organization and existing regional networks. The President is also authorized to provide funding for the development of new regional health networks, as a means of continuing to expand the reach of a global surveillance network.

Additionally, subsection (b) authorizes the Secretary of Health and Human Services to establish new country or regional Foreign Epidemiology Training Programs in eligible developing countries. The FETP program offers 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 in approximately twenty countries.

Section 14. Authorization of Appropriations.

Section 14 authorizes appropriations for carrying out the provisions of this bill for Fiscal Years 2003 and 2004. The section authorizes \$150 million in total, \$70 million for FY 2003 and \$80 million for FY 2004. Of these amounts, \$50 million is authorized each year to carry out Sections 6, 7, 8, and 9; \$5 million each year to carry out Section 10; \$2 million each year to carry out Section 11; \$8 million in FY 2003 and \$18 million in FY 2004 to carry out Section 12; and \$5 million each year to carry out Section 13. All of these authorization levels are subject to the availability of appropriations.

In providing the training and tools for developing countries to establish an indigenous capability to participate in a global disease surveillance network, the Committee recognizes that the level of required assistance will be modest in comparison to other foreign assistance efforts. Targeted U.S. assistance can leverage other international assistance and, more importantly, establish benchmarks for public health programs in developing countries to strive for in sustaining and expanding pathogen surveillance efforts. Global surveillance does not command large-scale investments nor does it require high-tech equipment. Simple desktop computers or even telephone lines can serve as effective reporting mechanisms depending upon the particular geographic circumstances. However, the Committee does expect developing countries receiving assistance under this Act to make an unwavering commitment to improving their pathogen surveillance and monitoring efforts.

The Committee hopes that U.S. allies and partners will contribute a proportionate share in funding these types of efforts to develop a comprehensive global surveillance network. The absence of authorized funding beyond FY 2005 does not indicate the need for a re-authorization of these programs.

IV. EVALUATION OF REGULATORY IMPACT

In accordance with Rule XXVI, paragraph 11(b) of the Standing Rules of the Senate, the Committee has concluded that there is no regulatory impact from this legislation.

V. COST ESTIMATE

In accordance with Rule XXVI, paragraph 11(a) of the Standing Rules of the Senate, the Committee provides the following estimate of the cost of this legislation prepared by the Congressional Budget Office:

CONGRESSIONAL BUDGET OFFICE,
U.S. Congress, Washington, DC.
June 11, 2002.

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. 2487, the Global Pathogen Surveillance Act of 2002.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Sunita D'Monte.

Sincerely,

DAN L. CRIPPEN,
Director.

Enclosure:

cc: HON. JESSE HELMS, *Ranking Minority Member.*

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

S. 2487—GLOBAL PATHOGEN SURVEILLANCE ACT OF 2002

Summary

S. 2487 would authorize appropriations of \$70 million in 2003 and \$80 million in 2004 to establish a worldwide monitoring and response system against bioterrorism and outbreaks of infectious disease. CBO estimates that implementing S. 2487 would cost \$20 million in 2003 and \$145 million over the 2003–2007 period, assuming appropriation of the authorized amounts. Because the bill would not affect direct spending or receipts, pay-as-you-go procedures would not apply.

S. 2487 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would not affect the budgets of state, local, or tribal governments.

Estimated Cost to the Federal Government

The estimated budgetary impact of S. 2487 is shown in the following table. This estimate assumes that the amounts authorized will be appropriated by the start of each fiscal year and that outlays would follow historical spending patterns. The costs of this legislation fall within budget functions 050 (defense), 150 (international affairs), and 550 (health).

Spending for Global Pathogen Surveillance Under S. 2487

(By Fiscal Year, in Millions of Dollars—Changes in Spending Subject to Appropriation)

	2003	2004	2005	2006	2007
Authorization Level	70	80	0	0	0
Estimated Outlays	20	56	46	16	7

Basis of Estimate

S. 2487 would establish a worldwide monitoring and response system against bioterrorism and outbreaks of infectious disease. It would authorize appropriations of \$70 million in 2003 and \$80 million in 2004 for the U.S. Agency for International Development, the Department of State, the Centers for Disease Control and Prevention, the Department of Defense, and other federal agencies. Assuming appropriation of the authorized amounts, CBO estimates that implementing the bill would cost \$20 million in 2003 and \$145 million over the 2003–2007 period.

Some of the specific programs authorized by the bill include:

- Educational exchange programs;
- Fellowships and training courses for health personnel in developing countries;
- Development assistance for developing countries to purchase and maintain laboratory equipment, information technology, and communications equipment;
- Assigning public health personnel to U.S. missions and international organizations;

- Expansion of personnel, operations, and training activities of U.S. government laboratories abroad;
- Development assistance to improve the surveillance and reporting mechanisms of the World Health Organization and regional health networks; and
- Establishing and expanding epidemiology training programs in developing countries.

Pay-As-You-Go Considerations

None.

Intergovernmental and Private-Sector Impact

S. 2487 contains no intergovernmental or private-sector mandates as defined in UMRA and would not affect the budgets of state, local, or tribal governments.

Estimate Prepared By

Federal Costs:

Education and Exchange Programs: Sunita D'Monte.

Foreign Assistance: Joseph C. Whitehill.

Department of Defense: Sam Papenfuss.

Centers for Disease Control and Prevention: Jeanne De Sa.

Impact on State, Local, and Tribal Governments: Elyse Goldman.

Impact on the Private Sector: Paige Piper/Bach.

Estimate Approved By

Peter H. Fontaine, *Deputy Assistant Director for Budget Analysis*.

VI. 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 are made by this bill.