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SENATE

REPORT
107–227

COMPREHENSIVE TUBERCULOSIS ELIMINATION ACT OF 2001

JULY 26, 2002.—Ordered to be printed

Mr. KENNEDY, from the Committee on Health, Education, Labor, and Pensions, submitted the following

REPORT

together with

ADDITIONAL VIEWS

[To accompany S. 1115]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 1115) to amend the Public Health Service Act with respect to making progress toward the goal of eliminating tuberculosis, and for other purposes, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill (as amended) do pass.

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99–010

I. PURPOSE AND SUMMARY

The Comprehensive Tuberculosis Elimination Act of 2001 addresses the role of the Department of Health and Human Services in the development and implementation of a national strategy to eliminate tuberculosis (TB) in the United States. In order to attain this goal, the act mandates expansion, intensification, and coordination of the ongoing activities of the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). The act enhances research, education, training, and international efforts to eliminate TB through the CDC and expands basic research, clinical training, and vaccine-related research through the NIH. The act includes the following provisions:

1. The legislation mandates the creation of a national plan.

The Advisory Council for the Elimination of Tuberculosis (ACET) will develop a national plan to eliminate tuberculosis from the United States. While constructing the national plan, ACET will review the recommendations of the Institute of Medicine (IOM) report Ending Neglect: The Elimination of Tuberculosis in the United States. Not only will ACET's recommendations guide U.S. domestic TB programs, but they will provide council on U.S. involvement in global TB-control activities.

2. The legislation calls for expanding and intensifying the CDC's TB prevention, control, and elimination activities.

The CDC will award grants to public or nonprofit entities for the purposes of prevention, control, and elimination of TB, under section 317. The agency will support State public health activities including TB case finding, prevention and treatment utilizing directly observed therapy; research into the diagnosis and treatment of latent TB, drug-resistant TB, and cases of TB in high-risk populations; and clinical trials. Additionally, the CDC will conduct demonstration projects; education and training of health care professionals; and public education projects. These grants are authorized at $235 million in fiscal year 2003 and such sums as may be necessary in fiscal years 2004 through 2007.

3. The act calls for increased basic and clinical research regarding TB, its diagnosis and its treatment.

The activities of the National Heart, Lung, and Blood Institute at NIH are reauthorized with an enhanced emphasis on basic and clinical research into TB as well as its relationship to the human immunodeficiency virus (HIV). The Institute will grant TB Academic Awards in order to enable institutions to improve the clinical training of health care professionals in the prevention and management of tuberculosis. The Institute will grant TB/Pulmonary Infection Awards to support basic research into the biological processes involved in TB, as well as new diagnostic techniques and treatments.

4. The act calls for renewed focus on the development of a safe and effective TB vaccine.

The National Institute of Allergy and Infectious Diseases (NIAID) at NIH, under section 447, will pursue development of a vaccine to be used in the efforts to eliminate TB. In the process of establishing a vaccine development strategy, NIAID shall take into consideration the Blueprint for Tuberculosis Vaccine Development, published by NIH in 1998. These efforts are authorized at $136

million in FY 2003, $162 million in FY 2004, and such sums as may be necessary in fiscal years 2004 through 2007.

5. The legislation highlights the role of the Fogarty Center in global TB control efforts.

The John E. Fogarty International Center for Advanced Study in the Health Sciences (Fogarty Center) at NIH promotes international cooperation and collaboration in the life sciences. In such a capacity, the Fogarty Center has a crucial role in expanding and intensifying global TB activities. This legislation clarifies the function that the Fogarty Center serves in providing international training programs and support for clinical, operational, and health services research.

II. Background and Need for Legislation

Tuberculosis (TB) is a preventable and treatable disease that continues to infect thousands of Americans each year. After years of fighting TB, the Institute of Medicine (IOM) has determined that the incidence of TB has declined to the point where it is feasible to mobilize the expertise and the resources of the Federal, State, and local government and the public health community to fully eradicate the disease from the United States.

TB has been a public health threat in the United States for centuries. In the nineteenth century, the rise in European immigration to American cities led to overcrowded living conditions and unhealthy workplaces. TB became one of the leading causes of death in America. Early in the twentieth century, however, TB rates began to decline as social and economic conditions and our scientific knowledge of infectious diseases improved. Under these conditions, experts gradually began to consider the possibility of eliminating TB from the United States. In the 1950's, the first effective antimicrobials to treat TB were introduced, followed by the closing of many TB hospitals and sanatoriums in the 1960s. The elimination of TB appeared to be close at hand.

Unfortunately, our country failed to seize upon the opportunity to mount an aggressive campaign to eliminate the disease. Instead, the declining incidence of TB resulted in complacency and neglect. Federal categorical funding for TB control and prevention was discontinued from 1972 to 1981, and control efforts broke down in many parts of the country.

What resulted in the late 1980's, spurred by the spread of HIV and the increases in homelessness, incarceration, and injection drug use, was a 20 percent increase in TB case rates and the emergence of drug-resistant strains of TB. The TB outbreaks were difficult to control and extremely costly, given that the health infrastructure for dealing with the infection had been allowed to deteriorate due to a lack of funding. In New York City alone, more than $1 billion were needed to regain control of TB.

The Advisory Council for the Elimination of Tuberculosis was established in 1987 to provide recommendations regarding the elimination of TB to the Secretary and Assistant Secretary of Health and Human Services and the Director of the Centers for Disease Control and Prevention (CDC). In 1989, ACET and the CDC issued A Strategic Plan for the Elimination of TB in the United States, which described actions necessary to eliminate TB by 2010.

In 1991, a Federal TB Task Force was created to combat the resurgence of TB. The Task Force estimated that a Federal TB budget of $610 million, with $484 million allocated to CDC, was needed to adequately fight TB. Federal funding increased, but not to the level that was required. The public health community successfully mobilized to control the resurgence and in 1999, ACET reassessed its plans in light of the changed nature of the disease and the public health environment in the U.S. and issued a new report entitled, TB Elimination Revisited: Obstacles, Opportunities, and a Renewed Commitment.

The Institute of Medicine (IOM) released a report in 2000, entitled, "Ending Neglect: the Elimination of Tuberculosis in the United States." This report reviewed the current status of TB prevention and control in the U.S. and outlined a comprehensive framework for a national campaign to eliminate TB. The committee recognizes the value of the expert recommendations contained within the IOM report and believes that these recommendations should be carefully evaluated in planning our efforts to eliminate TB from the United States.

Today, the United States faces three significant challenges to the elimination of TB. First, the global TB epidemic endangers TB control efforts in the United States. Approximately one-third of the world's population is infected with latent TB, and 100 million people have active cases. If current trends continue, by 2020, nearly one billion more people will become infected, and 35 million people will die from TB. TB case rates in the United States reflect the global situation. The proportion of TB cases in foreign-born people has increased steadily in the last decade, from 27 percent of all cases in 1992 to 50 percent of all cases in 2001. To eliminate TB from the United States, targeted efforts are needed to prevent and treat TB among foreign-born individuals resident in the United States.

Second, the emergence of multidrug-resistant strains of TB poses a major challenge to current methods of treating TB. Cases involving variants of TB that are resistant to all major anti-TB drugs have been documented in 45 States and the District of Columbia. Multidrug-resistant strains often result from inconsistent or partial treatment-patients who do not take their required drugs or health care workers who prescribe ineffective treatments. Multidrug-resistant TB requires treatment with toxic, expensive, and less effective drugs and even then, is often fatal.

Finally, TB has retreated into high-risk populations and isolated communities across the United States. These populations include those co-infected with the human immunodeficiency virus (HIV), minorities, inmates and staff of correctional facilities, and those born in foreign countries, as previously discussed. For instance, in 2000, TB was eight times as prevalent among African Americans compared to Caucasians. Greater staffing, outreach, education, and follow-up are urgently needed in order to effectively prevent and treat TB in these populations.

By unanimously supporting this legislation, the committee shares a determination with the public health community to prevent the mistakes of the past from recurring. The committee believes that now, given the low incidence of TB and the expertise and awareness of public health officials, we have a historic oppor-

tunity to eradicate TB from the United States. At this critical time, with the expert recommendations of the IOM in hand, the Committee is committed to effectively targeting and eliminating tuberculosis from our country through renewed and expanded efforts in research, vaccine development, TB case finding, prevention, and treatment via directly observed therapy, education, and international collaboration.

III. Legislative History and Committee Action

S. 1115 was introduced on June 27, 2001 by Senator Edward M. Kennedy for himself, Senator Stevens, Senator Inouye, and Senator Hutchison. The bill is cosponsored by Senator Bingaman, Senator Corzine, Senator Murray, and Senator Torricelli. S. 1115 was referred to the Committee on Health, Education, Labor, and Pensions. On June 19, 2002, the Senate Committee on Health, Education, Labor, and Pensions held an executive session to consider a substitute for S. 1115 in the nature of an amendment. S. 1115 was ordered reported favorably by a unanimous voice vote.

IV. Committee Views

The committee recognizes that tuberculosis (TB), a preventable and treatable disease that continues to claim thousands of American lives, can be eliminated from the United States with the proper level of commitment and resources. The act also builds on a longstanding recognition by the public health community that an aggressive, sustained commitment is needed to eradicate TB from the U.S.

The committee further wishes to clarify its views regarding the act.

TITLE I—PREVENTIVE HEALTH SERVICES

The ACET works closely with the Centers for Disease Control and Prevention Division of TB Elimination (DTBE) in developing and evaluating guidelines for prevention, control, and treatment and addressing issues related to TB elimination in the United States.

The committee recognizes the value of ACET's expertise in advising and evaluating Federal, State, and local efforts to eliminate TB. With this legislation, the Committee authorizes ACET to create or update a national plan for the elimination of TB from the United States. In developing this plan, ACET should carefully evaluate and incorporate, as appropriate, the recommendations of the Institute of Medicine. The committee also intends for ACET to continuously modify this plan as new insights, data, or technology become available.

The committee understands that TB case rates in the United States are heavily impacted by the global TB burden and that elimination of TB from the United States is difficult, if not impossible, without addressing TB control in foreign countries. ACET should expand its scope of interest and provide recommendations to guide U.S. involvement in fighting the global TB epidemic. The World Health Organization (WHO) has identified a total of 23 high incidence countries that account for 80 percent of all new cases worldwide. ACET's recommendations should be concerned with

countries where the high incidence of TB may contribute to TB case rates in the United States. For instance, Mexico, the Philippines, Vietnam and India are the countries of origin for half the foreign-born residents of the United States infected with TB. ACET should specify goals and strategies for how the United States can assist these countries in reducing their TB rates and focus on implementing proven control measures, such as the WHO's directly observed treatment, short course strategy (DOTS).

ACET currently is composed of representatives from diverse Federal and non-federal agencies, public health departments, and local groups that are concerned with TB. The U.S.-Mexico Border Health Commission should also be represented on the Council, given the high TB case rates and difficulty controlling TB in communities near the U.S.-Mexico border. The expertise of the Health Resources and Services Administration (HRSA) and the Agency for Healthcare Research and Quality (AHRQ) should also be included in ACET because of the agencies' work with professionals in rural areas and on quality of care respectively. The committee reaffirms a commitment to address TB prevention, control, and treatment issues in this high-risk region.

TITLE II—CENTERS FOR DISEASE CONTROL AND PREVENTION

The CDC is currently authorized $200 million for fiscal year 2002 to support research, demonstration projects, education, and training related to the prevention, control, and elimination of TB. The scientific community, including the National Coalition for the Elimination of Tuberculosis, has estimated that $528 million will be needed annually to implement strategies that will advance us toward the goal of TB elimination, such as those outlined in the IOM report. The committee intends that the CDC reach the goal of $528 million annually for TB elimination as quickly as possible, but recognizes the value of an incremental expansion of TB prevention and control efforts. Thus, the Act increases CDC's authorization for grants to $235 million in FY 2003 and such sums as may be necessary for fiscal years 2004 through 2007.

Given the prevalence of TB in certain high risk and often isolated populations, the committee would emphasize that special priority be given to research concerning TB in these populations, including individuals infected by the HIV/AIDS, foreign-born persons from high incidence countries, minority populations with high TB rates compared to the general population, intravenous drug users, and incarcerated persons. The committee also understands the necessity for developing improved methods of diagnosing and treating latent TB that would increase screening and patient compliance with therapy, when therapy is indicated, and encourages the CDC to award grants for research in this area.

The act amends current authority to provide two examples of demonstration projects that may be funded through the CDC. The committee does not intend for funding to be limited to these specific demonstration projects.

Based on the IOM report, this act recommends evaluating the possible regionalization of TB elimination activities on a multistate level in areas of the country with a low incidence of TB. Projects in these low incidence regions should aim to maintain access to clinical, epidemiological, and other TB services in a cost ef-

fective and efficient manner and to ensure the presence of sufficient public health staff to education health care providers and to identify an outbreak or emergency situation.

This act also recommends investigation into the applicability of programs to identify immigrants with latent TB infection and offer treatment, when indicated. The committee intends to encourage increased screening and treatment, when appropriate, of immigrants from countries with a high incidence of TB. These activities may benefit from collaboration with the INS whose expertise in immigration policy and the feasibility of altering current practices will be useful in determining the best approach to the high incidence of TB among immigrants. It should be noted that the committee does not necessarily endorse mandated latent TB testing for immigrant visa and permanent residency applicants. The committee encourages the CDC to work with the INS to develop targeted screening programs that are effective in screening and treating latent TB without endangering the rights of all immigrants and refugees in the United States.

The committee understands that foreign-born individuals comprise an increasing proportion of TB cases in the United States and encourages the funding of immigrant outreach programs to increase the effectiveness of TB screening and prevention services among new refugees and immigrants. In King County, Washington, for example, two-thirds of TB cases occur among foreign-born individuals. A pilot program in this county utilizing bilingual-bicultural community members, interviews, and focus groups in a culturally sensitive manner, achieved a 96 percent completion rate for those being treated for TB, far exceeding the 70 percent completion rates obtained by other programs. The success of this pilot demonstrates the effectiveness of culturally and linguistically sensitive programs to eliminate TB among high risk foreign born populations, and is a commendable model for future demonstration projects and public outreach efforts.

In new subsection 317E(b)(1) the committee authorizes the CDC to prioritize funding for research concerning the diagnosis and treatment of latent TB infection, TB associated with the human immunodeficiency virus (HIV), and for clinical trials, especially those conducted through the Tuberculosis Trials Consortium; and, to prioritize funding for research concerning TB epidemiology, behavioral science, infection control, and field testing of laboratory methods, including those studies conducted through the Tuberculosis Epidemiologic Studies Consortium.

In new subsection 317E(b)(4), the committee authorizes the CDC to award grants for education, training, and clinical skills improvement activities for health professionals. The agency's implementation of these education and training programs should take into consideration appropriate recommendations in the Strategic Plan for TB Training and Education released in January 1999 as a joint project of the National Tuberculosis Centers and DTBE. The plan provides a blueprint for creating a strong, coordinated, and effective system for TB training and education.

In new subsection 317E(b)(5), the committee does not want to limit support of "model centers" to the three Model Tuberculosis Centers that are currently in operation in New York City, Newark, NJ, and San Francisco, CA. Rather, the committee intends that

support for these continue and that the development of additional centers, particularly in areas of high incidence, commences.

Section 317E(b)(6) is amended to specify that to properly address TB elimination in the United States, the CDC, in coordination with USAID, should support collaboration with international organizations and foreign countries, including Mexico, the Philippines, Vietnam, other WHO-designated high TB burden countries; countries with high burden multidrug resistant TB; and countries with high rates of HIV.

The committee further understands that the elimination of TB from the United States cannot be achieved without cooperation between the U.S. and Mexico. In 1999, Mexico was the country of origin for 23 percent of all foreign-born persons infected with TB. Of TB cases among Mexican-born persons living in the United States, three-fourths were reported by the four States bordering Mexico. The CDC should support the development of coordinated binational TB control projects at the national, state, and local levels in coordination with the United States Agency for International Development. Programs should aim to reduce the racial and ethnic disparities of TB by preventing, diagnosing, and treating infected persons along both sides of the U.S.-Mexico border.

On a biennial basis, the committee requests that the Secretary report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on activities regarding the act. Within that report, the Secretary will evaluate the effectiveness of the programs, areas for improvement and plans for appropriate changes, and the extent to which the recommendations of both the IOM and ACET have been addressed.

TITLE III—NATIONAL INSTITUTES OF HEALTH

The act authorizes the Tuberculosis Academic Awards currently administered through the National Heart, Lung, and Blood Institute (NHLBI) at the National Institutes of Health.

The act also authorizes Tuberculosis/Pulmonary Infection Awards to fund basic science and clinical research through the NHLBI on the processes of active and latent TB infection as they occur in the lung and other organ systems. The awards may also support research into the development of more efficient and effective treatments and diagnostic techniques.

The committee intends for the National Institute of Allergy and Infectious Diseases to intensify its TB research efforts and to focus on the development of a safe and effective TB vaccine. The scientific community has estimated, based on the development process outlined in the Blueprint for TB Vaccine Development, that $240 million annually will be required to develop an effective TB vaccine. The Act authorizes $136 million for FY 2003, $162 million for FY 2004, and such sums for fiscal years 2005 through 2007, with the goal of reaching $240 million and developing a TB vaccine as quickly as possible.

The NIAID should carefully consider the recommendations contained in the Blueprint for TB Vaccine Development, but not to the exclusion of evolving scientific discoveries that may enhance progress toward a TB vaccine, or of subsequent, similarly com-

prehensive planning by the NIAID and relevant stakeholders to achieve this important public health goal.

The John E. Fogarty Center has specialized expertise in the development and implementation of international training and research programs. The committee requests that they incorporate TB programs into their activities, as appropriate, in order to enhance and support global TB initiatives carried out by the United States Government.

V. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 23, 2002.

Hon. EDWARD M. KENNEDY,
Chairman, Committee on Health, Education, Labor, and Pensions, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 1115, the Comprehensive Tuberculosis Elimination Act of 2002.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Jeanne De Sa, Hallie Torrell, and Christopher Topoleski.

Sincerely,

STEVEN M. LIEBERMAN
(For Dan L. Crippen, Director).

Enclosure.

S. 1115—Comprehensive Tuberculosis Elimination Act of 2002

Summary: S. 1115 would amend the Public Health Service Act to increase the Department of Health and Human Services' responsibilities in the area of tuberculosis elimination. The bill would broaden the role of the department's Advisory Council for the Elimination of Tuberculosis. The bill also would expand the role at the Centers for Disease Control and Prevention (CDC) in the implementation of a national plan to eliminate tuberculosis.

Additionally, S. 1115 would require the National Institutes of Health (NIH) to award funds to educational institutions for education and training programs, and for research on pulmonary infection. The bill would authorize appropriations for the development of a tuberculosis vaccine and direct the John E. Fogarty International Center for Advanced Study in the Health Sciences at the NIH to carry out an international training program regarding tuberculosis.

Assuming the appropriation of necessary amounts (including annual adjustments for anticipated inflation), CBO estimates that implementing S. 1115 would cost $117 million in 2003 and $1.6 billion over the 2003–2007 period. The legislation would not affect direct spending or receipts; therefore, pay-as-you-go procedures would not apply.

S. 1115 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

Estimated cost to the Federal Government: The estimated budgetary impact of S. 1115 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—				
	2003	2004	2005	2006	2007
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
Estimated authorization level:					
Centers for Disease Control and Prevention [1]	235	241	246	252	258
National Institutes of Health [2]	146	172	176	180	184
Total	381	413	422	432	442
Estimated outlays:					
Centers for Disease Control and Prevention	82	190	227	240	252
National Institutes of Health	35	117	149	164	175
Total	117	307	377	404	427

[1] The 2003 level for the Centers for Disease Control and Prevention is the amount authorized for that year under the bill. The 2004 through 2007 levels reflect adjustments for anticipated inflation.

[2] The 2003 level for the National Institutes of Health is the combined amount the bill would authorize for the National Heart, Lung, and Blood Institute and the National Institute of Allergy and Infectious Diseases in 2003. The 2004 level is the amount authorized for the National Institute of Allergy and Infectious Diseases in 2004 and anticipated inflation for proposed activities in the National Heart, Lung, and Blood Institute. The 2005 through 2007 levels reflect adjustments for anticipated inflation.

Basis of estimate

CBO estimates that S. 1115 would authorize the appropriation of $381 million in 2003 and approximately $2.1 billion over the 2003–2007 period. CBO estimates that outlays would total $117 million in fiscal year 2003 and approximately $1.6 billion over the 2003–2007 period, assuming that the necessary amounts are appropriated.

Title I—Preventive Health Services

The bill would require the Advisory Council for the Elimination of Tuberculosis to make recommendations for developing, revising, and implementing a national plan to eliminate tuberculosis and global plans to control tuberculosis. S. 1115 does not specify an authorization of appropriations for those activities, but based on discussions with officials at the Department of Health and Human Services, CBO estimates that this proposal would not have significant costs.

Title II—Centers for Disease Control and Prevention

S. 1115 would authorize the creation of the National Program for Tuberculosis Elimination at the CDC, which would include current CDC efforts aimed at eliminating tuberculosis. (In fiscal year 2002, $134 million was appropriated for those activities.) The program also would include a broadened set of responsibilities related to research, demonstration projects, and collaboration with international organizations and foreign countries on tuberculosis elimination and control efforts.

The bill would authorize the appropriation of $235 million in fiscal year 2003 for the continuation and expansion of CDC tuberculosis elimination activities and such sums as necessary for the 2004–2007 period. Assuming that the 2003 level is increased annually to reflect anticipated inflation, CBO estimates that implementing this title would require the appropriation of $1,232 million over the 2003–2007 period. Based on historical spending patterns

for similar activities, CBO estimates that outlays would total $82 million in fiscal year 2003 and $991 million over the 2003–2007 period, assuming that the necessary amounts are appropriated.

Title III—National Institutes of Health

S. 1115 would authorize the Director of the National Heart, Lung, and Blood Institute to award grants to educational institutions to educate and train clinicians and medical, nursing, or osteopathic students about preventing, managing, and controlling tuberculosis and to support pulmonary infection research. To support those purposes, the bill would authorize the appropriation of $10 million in fiscal year 2003 and such sums as may be necessary for 2004 through 2007.

The bill would authorize the appropriation of $136 million for fiscal year 2003, $162 million for 2004, and such sums as may be necessary for 2005 through 2007 for the National Institute of Allergy and Infectious Diseases of NIH to develop a tuberculosis vaccine. The bill also would create statutory authority for an existing international training program regarding tuberculosis at the John E. Fogarty International Center for Advanced Study in the Health Sciences of the NIH. (Hence, that provision would have no significant impact on spending.)

CBO estimates that implementing title III would require the appropriation of $146 million for fiscal year 2003 and $858 million over the 2003–2007 period. Based on historical spending patterns for similar activities, CBO estimates that outlays would total $35 million in 2003 and $640 million over the 2003–2007 period, assuming that the necessary amounts are appropriated.

Pay-as-you-go consideration: None.

Intergovernmental and private-sector impact: S. 1115 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

Estimate prepared by: Federal costs: Jeanne De Sa, Hallie Torrell, and Christopher Topoleski; impact on state, local, and tribal governments: Leo Lex; impact on the private sector: Jennifer Bowman.

Estimate approved by: Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

VI. Application of Law to the Legislative Branch

The committee finds that the legislation has no application to the legislative branch.

VII. Regulatory Impact Statement

The committee has determined that there will be minimal increases in the regulatory burden imposed by this bill.

VIII. Section-by-Section Analysis

Note on References: Except as otherwise specified, as used in the summary—

"The Act" means the Public Health Service Act (PHSA), and references to provisions of law are provisions of the PHSA;

"ACET" means the Advisory Council for the Elimination of Tuberculosis;

"CDC" means the Centers for Disease Control and Prevention;

"Secretary" means the Secretary of Health and Human Services.

Section 1. Short title

This legislation is titled the "Comprehensive Tuberculosis Elimination Act of 2001."

TITLE I—PREVENTIVE HEALTH SERVICES

Section 101, Advisory Council for the Elimination of Tuberculosis, amends section 317E(f) of the PHSA

Section 317E(f)(2) is amended to direct ACET to advise the Secretary and other Federal officials on how best to coordinate the activities of the Public Health Service and other Federal agencies and how to efficiently utilize Federal resources in order to eliminate tuberculosis.

Section 317E(f)(3) is amended to require ACET to develop and update a national plan to eliminate TB in the U.S., taking into consideration the recommendations of the Institute of Medicine.

Section 317E(f)(4) is amended to require ACET to make recommendations for U.S. participation in global and cross border TB control activities.

Section 317E(f)(5) is redesignated as Section 317E(f)(6).

Section 317E(f)(5) is revised to specify that ACET shall include among its membership, representatives from the CDC, National Institutes of Health, Agency for Healthcare Research and Quality, Health Resources and Services Administration, the U.S.-Mexico Border Health Commission, and any other Federal departments or agencies active in TB activities, as well as individuals who are officers or employees of the Federal Government.

TITLE II—CENTERS FOR DISEASE CONTROL AND PREVENTION

Section 201, National Program for TB Elimination, amends Section 317E of the PHSA

The heading for Section 317E is changed to the "National Program for Tuberculosis Elimination."

Section 317E(b)(1) is amended to refocus activities within the scope of the CDC's research program, on research concerning the diagnosis and treatment of latent TB infection; drug-resistant TB; cases of TB that affect certain high-risk populations; and clinical trials, especially those conducted through the Tuberculosis Trials Consortium.

Section 317E(b)(2)(A) is added to provide an example of a demonstration project that would be appropriate for the CDC to conduct under this section. It calls for the development of regional, multi-state capabilities for TB prevention, control, and treatment in low incidence areas of the United States.

Section 317E(b)(2)(B) is added to provide an example of a demonstration project that would be appropriate for the CDC to conduct under this section to improve screening and treatment, when necessary, of high risk immigrant groups.

Section 317E(b)(5) is amended to clarify that support should go to model centers to implement tuberculosis activities outlined under paragraphs (2) through (4).

Section 317E(b)(6) is amended to specify the need for collaboration with Mexico, in particular, the necessity for coordination with the United States Agency for International Development, and the role of ACET.

Section 317E(g) is amended to require the Secretary to prepare a biennial report regarding the activities described under section 317E and submit it to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives. The report shall include the opinion of the Council on the extent to which its recommendations under section 317E(f)(3) have been implemented.

Section 317E(h) authorizes $235 million for fiscal year 2003, and such sums as may be necessary for fiscal years 2004 through 2007, for the Secretary to award grants as described in this section.

TITLE III—NATIONAL INSTITUTES OF HEALTH

Section 301 amends subpart 2 of part C of title IV of the PHSA by adding section 424C after section 424B

Section 424C(a) authorizes the Director of the National Heart, Lung, and Blood Institute to expand, intensify, and coordinate basic and clinical research regarding TB prevention, diagnosis, and treatment, and the relationship between tuberculosis and the human immunodeficiency virus.

Section 424C(b)(1) establishes the Tuberculosis Academic Awards for the development and support of clinical curricular programs in TB prevention, management, and control in patients for health professionals in training.

Section 424C(b)(2) establishes the Tuberculosis/Pulmonary Infection Awards to support basic science research into the pathophysiology of TB infection, as well as research in the development of new diagnostic techniques and treatments.

Section 424C(b)(3) authorizes $10 million for fiscal year 2003 and such sums as may be necessary for fiscal years 2004 through 2007 for the TB Academic Awards and the TB/Pulmonary Infection Awards.

Section 302, Activities of the National Institute of Allergy and Infectious Diseases, amends section 447A of the PHS Act

Section 447A(b) is redesignated Section 447A(c).

Section 447A(b) is amended to include specific reference to the development of a TB vaccine, taking into consideration the recommendations contained in the Blueprint for TB Vaccine Development.

Section 447A(c) is amended to increase the authorization for the Institute to pursue the activities described in Section 447A(a)–(b) to $136 million for fiscal year 2003, $162 million for fiscal year 2004, and such sums as may be necessary for fiscal years 2005 through 2007.

Section 303, John E. Fogarty International Center for Advanced Study in the Health Sciences, does not amend the PHS Act

This section authorizes the Center to expand, intensify, and coordinate international activities for research and training on tuberculosis. The Center will provide support for clinical, operational, and health services research and training. The Center shall model these activities on the international HIV training program currently administered by the Center.

IX. ADDITIONAL VIEWS

Tuberculosis in the U.S., unlike some other health conditions, responds quite well to careful and adequately-funded prevention and control programs. When neglect of these programs occurred in the past, particularly at the State and local levels, tuberculosis rates increased. When State and local Governments, in partnership with the Federal Government, invested appropriately in tuberculosis prevention and control, incidence of latent and active disease decreased. Accordingly, we support on-going, appropriate investments in TB prevention and control efforts.

We believe that report language should accurately reflect the content of the reported bill. In describing the committee views on authorization levels for CDC and NIH, the majority views appear to deviate from this principle. Though the report implies otherwise, the bill authorizes $235 million at CDC for FY 2003 and $136 million at NIH for FY 2003 and $162 million for FY 2005 for efforts at TB prevention and control. The bill, as reported, can not be interpreted to authorize more than the authorized amounts for 2003 and 2004 and such sums thereafter. The committee is, of course, aware of the recommendation by some members of the public health advocacy community (the National Coalition for the Elimination of Tuberculosis) that certain levels of funding are needed at CDC ($528 million) and NIH ($240 million) in order to eliminate TB. But the express intention of the committee for authorizations at CDC and NIH from FYS 2003–2007 is reflected in what is explicitly stated in the bill language itself.

JUDD GREGG.

X. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * * * *

Section 1.* * *

* * * * * * *

[PREVENTIVE HEALTH SERVICES REGARDING TUBERCULOSIS]

NATIONAL PROGRAM FOR TUBERCULOSIS ELIMINATION

* * * * * * *

SEC. 317E. [247b–6] (a) IN GENERAL.—* * *

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[(b) RESEARCH DEMONSTRATION PROJECTS, EDUCATION, AND TRAINING.—With respect to the prevention, control, and elimination of tuberculosis, the Secretary may, directly or through grants to public or nonprofit private entities, carry out the following:

[(1) Research, with priority given to research concerning strains of tuberculosis resistant to drugs and research concerning cases of tuberculosis that affect detain populations.

[(2) Demonstration projects.

[(3) Public information and education programs.

[(4) Education, training, and clinical skills improvement activities for health professionals, including allied health personnel and emergency response employees.

[(5) Support of centers to carry out activities under paragraphs (1) through (4).

[(6) Collaboration with international organizations and foreign countries in carrying out such activities.]

(b) RESEARCH, DEMONSTRATION PROJECTS, EDUCATION, AND TRAINING.—With respect to the prevention, control, and elimination of tuberculosis, the Secretary may, directly or through grants to public or nonprofit private entities, carry out the following:

(1) Research, with priority given to research concerning—

(A) diagnosis and treatment of latent infection of tuberculosis;

(B) strains of tuberculosis resistant to drugs.

(C) cases of tuberculosis that affect certain high-risk populations; and

(D) clinical trials, including those conducted through the Tuberculosis Trails Consortium.

(2) Demonstration projects, including for—

(A) the development of regional capabilities for the prevention control, and elimination of tuberculosis particularly in low-incidence regions; and

(B) collaboration with the Immigration and Naturalization Service to identify and treat immigrants with active or latent tuberculosis infection.

(3) Public information and education programs.

(4) Education, training and clinical skills improvement activities for health professionals, including allied health personnel.

(5) Support of model centers to carry out activities under paragraphs (2) through (4).

(6) Collaboration with international organizations and foreign countries, including Mexico, in coordination with the United States Agency for International Development, in carrying out such activities, including coordinating activities through the Advisory Council for the Elimination of Tuberculosis.

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(f) ADVISORY COUNCIL.—

(1) IN GENERAL.—The Secretary shall establish an advisory council to be known as the Advisory Council for the Elimination of Tuberculosis (in this subsection referred to as the "Council").

[(2) GENERAL DUTIES.—The Council shall provide advice and recommendations regarding the elimination of tuberculosis to the Secretary, the Assistant Secretary for Health, and the Director of the Centers for Disease Control and Prevention.

[(3) CERTAIN ACTIVITIES.—With respect to the elimination of tuberculosis, the Council shall—

[(A) in making recommendations under paragraph (2) make recommendations regarding policies, strategies, objectives, and priorities;

[(B) address the development and application of new technologies; and

[(C) review the extent to which progress has been made toward eliminating tuberculosis.

[(4) COMPOSITION.—The Secretary shall determine the size and composition of the Council, and the frequency and scope of official meetings of the Council.]

(2) DUTIES.—For the purpose of making progress toward the goal of eliminating tuberculosis from the United States, the Council shall provide to the Secretary and other appropriate Federal officials advice on coordinating the activities of the Public Health Service and other Federal agencies tat relate to such disease and on efficiently utilizing the Federal resources involved.

(3) NATIONAL PLAN.—In carrying out paragraph (2), the Council, in consultation with appropriate public and private entities, shall make recommendations on the development, revision, and implementation of a national plan to eliminate tuber-

culosis in the United States. In carrying out this paragraph, the Council shall—

(A) consider the recommendations of the Institute of Medicine regarding the elimination of tuberculosis;

(B) address the development and application of new technologies; and

(C) review the extent to which progress has been made toward eliminating tuberculosis.

(4) GLOBAL ACTIVITIES.—In carrying out paragraph (2), the Council, in consultation with appropriate public and private entities, shall make recommendations for the development and implementation of a plan to guide the involvement of the United States in global and cross border tuberculosis-control activities, including recommendations regarding policies, strategies, objectives, and priorities. Such recommendations for the plan shall have a focus on countries where a high incidence of tuberculosis directly affects the United States, such as Mexico, and on access to a comprehensive package of tuberculosis control measurers, as defined by the World Health Organization directly observed treatment, short course strategy (commonly known as DOTS).

(5) COMPOSITION.—The Council shall be composed of—

(A) representatives from the Centers for Disease Control and Prevention, the National Institutes of Health, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the U.S.-Mexico Border Health Commission, and other Federal departments and agencies that carry out significant activities relating to tuberculosis; and

(B) members appointed from among individuals who are not officers or employees of the Federal Government.

[5]*(6)* STAFF, INFORMATION AND OTHER ASSISTANCE.—The Secretary shall provide to the Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.

[(g) FUNDING.—

[(1) IN GENERAL; ALLOCATION FOR EMERGENCY GRANTS.—

[(A) For the purpose of making grants under subsection (a), there are authorized to be appropriated $200,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2002.

[(B) Of the amounts appropriated under subparagraph (A) for a fiscal year, the Secretary may reserve not more than 25 percent for emergency grants under subsection (a) for any geographic area in which there is, relative to other areas, a substantial number of cases of tuberculosis or a substantial rate of increase in such cases.

[(2) RESEARCH, DEMONSTRATION PROJECTS, EDUCATION, AND TRAINING.—For the purpose of carrying out subsection (b), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 2002.]

(g) REPORTS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Advisory Council for the Elimination of Tuberculosis, shall biennially prepare and submit to the Committee on Health, Edu-

cation, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the activities carried out under this section. Each report shall include the opinion of the Council on the extent to which its recommendations under section 317E(f)(3) regarding tuberculosis have been implemented.

(h) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $235,000,000 for fiscal year 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2007.

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SEC. 424B **[**285b–7b**]** (a) IN GENERAL.— * * *

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TUBERCULOSIS

SEC. 424C. (a) IN GENERAL.—The Director of the Institute shall expand, intensify, and coordinate research and related activities of the Institute with respect to the treatment, diagnosis, and prevention of tuberculosis, including—

(1) basic and clinical research on tuberculosis; and

(2) research on the relationship between tuberculosis and the human immunodeficiency virus.

(b) RESEARCH EDUCATION.—

(1) TUBERCULOSIS ACADEMIC AWARDS.—The Director of the Institute may award grants to institutions for the development and support of programs of core curricula for training clinical investigators, including medical, nursing, or osteopathic students, in the principles and practices of preventing, managing, and controlling tuberculosis in patients.

(2) TUBERCULOSIS/PULMONARY INFECTION AWARDS.—The Director of the Institute may provide awards to support the research of trained professionals into the basic biological processes and mechanisms involved in tuberculosis, as well as research into the development of new diagnostic techniques and treatments.

(3) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated $10,000,000 for fiscal year 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2007.

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SEC. 447A. **[**285f–2**]** (a) * * *

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(b) Activities under subsection (a) may include activities to develop a tuberculosis vaccine. The recommendations contained within the Blueprint for Tuberculosis Vaccine Development, described in the report prepared pursuant to the workshop convened in March 1998 by the Director of the Institute, shall be taken into consideration.

[(b)**]** *(c)* For the purpose of carrying out subsection (a), there are authorized to be appropriated $50,000,000 for fiscal year 1994, such sums as may be necessary for each of the fiscal years 1995 through 1998, *$136,000,000 for fiscal year 2003, $162,000,000 for*

fiscal year 2004, and such sums as may be necessary for each of the fiscal years 2005 through 2007. Such authorization is in addition to any other authorization of appropriations that is available for such purpose.

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