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REPORT
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COMPREHENSIVE TUBERCULOSIS ELIMINATION ACT OF 2007

APRIL 22, 2008.—Ordered to be printed

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

R E P O R T

[To accompany S. 1551]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 1551) 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.

CONTENTS

I. PURPOSE AND SUMMARY

The Comprehensive Tuberculosis Elimination Act of 2007 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).

69–010

The act enhances research, education, training, and international efforts to eliminate TB through the CDC and expands basic research through the NIH. The act includes the following provisions:

1. 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. Additionally, the CDC will conduct demonstration projects; education and training of health care professionals; and public education projects. These grants are authorized at $300 million in fiscal year 2008 and such sums as may be necessary in fiscal years 2009 through 2012.

2. The legislation mandates the creation of a national strategy.

The Advisory Council for the Elimination of Tuberculosis (ACET) will develop a national strategy 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 counsel on U.S. involvement in global TB-control activities.

3. The act calls for the development of new tools for the elimination of tuberculosis.

The Secretary may expand, intensify, and coordinate research for the development of new tools for the elimination of tuberculosis, including drugs, diagnostics, vaccines, and public health interventions, such as directly observed therapy and non-pharmaceutical interventions. The Federal Tuberculosis Task Force will make recommendations on the development of a comprehensive plan for the creation of new tools. These efforts are authorized at $100 million in fiscal year 2008, and such sums as may be necessary in fiscal years 2009 through 2012.

4. The act calls for the evaluation of public health authorities related to tuberculosis.

The Secretary will submit a report to Congress that evaluates and provides recommendations on Federal and State disease-containment challenges, including an evaluation of the effectiveness of policies to detain patients with active tuberculosis, an evaluation of whether Federal policies should be strengthened to address the movement of infected individuals, and any other legislative recommendations for changes to Federal laws. The Secretary must also promulgate regulations within 8 months to update interstate and foreign quarantine regulations.

5. The act calls for increased basic and clinical research regarding TB at the National Institutes of Health.

The Director of the National Institutes of Health will enhance basic and clinical research and development related to tuberculosis.

II. Background and Need for Legislation

Tuberculosis (TB) is a preventable and treatable disease that continues to infect thousands of Americans each year. Recent cases

of drug-resistant TB have served as timely warnings that TB, particularly drug-resistant TB, is a real and present public health threat to the United States. It is critical to recognize that drug-resistant TB is a human-made disaster caused by the world's failure to properly treat the disease and develop new, more effective tools to fight TB. Although drugs, diagnostics and vaccines for TB exist, these technologies are 40–100 years old and are increasingly inadequate for controlling the global epidemic.

The widespread global utilization of the BCG vaccine and antibiotics, in addition to generally improved public health, led to a dramatic reduction in the global TB deaths and disease burden between 1940 and 1980. But the short-term success of these tools led to complacency and a lessening interest on the part of governments and pharmaceutical companies in TB research and development.

What resulted in the late 1980s in the United States, 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.

Commissioned by the CDC, 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 United States 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.

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

Today, the United States faces four significant challenges to the elimination of TB. First, our progress in reducing the TB case rate in the United States has stalled. Between 1993 and 2000, the Nation's TB rate fell by 7.3 percent, but from 2000 to 2006, the rate of decline slowed to 3.8 percent. Although the number of TB cases in the United States continues to fall, with 13,779 cases reported

in 2006, our progress against the disease should be measured by annual decreases of at least 7 percent in the number of active TB cases. This is occurring at a time when domestic TB control categorical funding has been stagnant for a decade. As we have learned from the history of TB in this country, complacency and neglect of TB control programs can lead to costly resurgences of the disease.

Second, the emergence of multidrug-resistant, and extensively drug-resistant strains of TB poses a major challenge to current methods of treating TB. Twenty-seven States reported cases of multidrug-resistant TB in 2006. Treatment failure with any of these cases could lead to the development of extensively drug-resistant strains. Multidrug-resistant TB requires treatment with toxic, expensive, and less effective drugs and even then, is often fatal. The number of multidrug-resistant TB cases among the foreign-born population in the United States has increased significantly since the early 1990s from approximately 26 percent of multidrug-resistant cases in 1993 to approximately 76 percent of cases between 1999 and 2006.

Extensively drug-resistant TB is characterized by very high, and among immunocompromised persons, very rapid fatality rates. According to the CDC, about 30 percent of extensively drug-resistant TB patients can be cured, but more than half will die within 5 years of diagnosis. Between 1993 and 2006, there were 49 cases of extensively drug-resistant TB in the United States.

Third, 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 about 1.6 million people die of the disease every year. If current trends continue, by 2020, nearly 1 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 57 percent of all cases in 2006. To eliminate TB from the United States, targeted efforts are needed to prevent and treat TB among foreign-born individuals residing in the United States.

Finally, TB will never be defeated without new and more effective tools for preventing the disease in people of all ages. The most commonly used TB diagnostic in the world, sputum microscopy, is more than 100 years old and lacks sensitivity to detect TB in most HIV/AIDS patients and in children. The standard TB skin test, developed over a century ago, needs to be replaced by promising single-visit blood tests but extensive field testing will be needed to ensure the proper use and interpretation of these newer tests. The TB vaccine, Baccillus Calmette-Guerin (BCG), provides some protection against TB to infants and children but it has little or no efficacy in preventing pulmonary TB in adolescents and adults.

Improved testing for drug susceptibility is critical to combating the spread of drug-resistant TB. Current drug susceptibility tests take at least 1 month to complete. Faster drug susceptibility tests must be developed to stop the spread of drug-resistant TB.

There is an urgent need for new anti-TB drugs, particularly for a shorter regimen. The current TB drug regimen requires 6 to 9 months of treatment and patients with multidrug-resistant TB require treatment for 18–24 months, creating difficulties in com-

pleting therapy, further promoting the development of drug-resistant strains of TB. A shorter drug regimen with new classes of drugs active against susceptible and drug-resistant strains would increase compliance and prevent the development of more extensive drug resistance. There is also a critical need for drugs that can safely be taken concurrently with antiretroviral therapy for HIV.

By unanimously supporting this legislation, the committee recognizes that, given the rising threat of drug-resistant TB and the expertise of public health officials and promise of new tools to more effectively fight TB, we now have a historic opportunity 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 TB 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. 1551 was introduced on June 5, 2007 by Senator Sherrod Brown for himself, Senator Hutchison, Senator Kennedy, Senator Clinton and Senator Murray. The bill is cosponsored by Senator Bingaman, Senator Boxer, Senator Cantwell, Senator Feinstein, Senator Harkin, Senator Landrieu, Senator Menendez, Senator Murkowski, Senator Sanders, Senator Lautenberg, and Senator Johnson. S. 1551 was referred to the Committee on Health, Education, Labor, and Pensions. On November 14, 2007 the Senate Committee on Health, Education, Labor, and Pensions held an executive session to consider a substitute for S. 1551 in the nature of an amendment. S. 1551 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 and new investment into new diagnostic, treatment and prevention tools are needed to eradicate TB from the United States.

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

TITLE I—DEPARTMENT OF HEALTH AND HUMAN SERVICES IN COORDINATION WITH THE CENTERS FOR DISEASE CONTROL AND PREVENTION AND OTHER APPROPRIATE AGENCIES

The Department of Health and Human Services including the Centers for Disease Control and Prevention currently supports research, demonstration projects, education, and training related to the prevention, control, and elimination of TB. The scientific community, including Stop TB USA, has estimated that $528 million is needed annually to implement strategies that will advance us toward the goal of TB elimination, such as those outlined in the IOM report. The act increases the authorization level for grants to $300

million in fiscal year 2008 and such sums as may be necessary for fiscal years 2009 through 2012.

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 with HIV, foreign-born persons from high incidence countries, minority populations with high TB rates, homeless persons, intravenous drug users, and incarcerated persons. The committee also understands the necessity for developing improved methods of diagnosing and treating drug-resistant TB and 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 reauthorizes the Department's (including the Centers for Disease Control and Prevention and the National Institutes of Health) priority research on TB including clinical trials to evaluate the safety and effectiveness of new drugs, diagnostics and vaccines for latent and active TB, including drug-resistant TB, through the Tuberculosis Trials Consortium, epidemiological studies through the Tuberculosis Epidemiologic Studies Consortium and field studies to evaluate the effectiveness of new drugs, diagnostics, and vaccines and assess the prevalence of drug-resistant TB.

The act amends current authority to provide four new examples of demonstration projects that may be funded. 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-effective and efficient manner and to ensure the presence of sufficient public health staff to educate health care providers and to identify an outbreak or emergency situation.

In new subsection 317E(b)(2)(B), the committee authorizes the Secretary, acting through the Director of the Centers for Disease Control and Prevention, to fund demonstration project activities to reduce health disparities in the incidence of TB. The committee understands that disparities among racial and ethnic minorities, including African-Americans, Hispanic-Americans, and Asian-Americans, persists and that additional targeted efforts are needed to eliminate these disparities.

This act recommends the expansion of programs to identify immigrants with latent and active 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 Immigration and Customs Enforcement (ICE) 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 ICE to develop targeted screening programs that are effective in screen-

ing and treating latent TB without endangering the rights of all immigrants and refugees in the United States.

In new subsection 317E(b)(2)(C), the committee authorizes the CDC to fund demonstration project activities for the intensification of efforts to control TB along the United States-Mexico border and among binational populations, including expanding the scope and number of programs to detect and treat binational cases of TB and high risk cases referred from Mexican health departments.

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)(2)(D), the committee authorizes the CDC to fund demonstration project activities for the intensification of efforts to prevent, detect, and treat TB among foreign-born persons who are in the United States.

In new subsection 317E(b)(2)(E), the committee authorizes the CDC to fund demonstration project activities for the intensification of efforts to prevent, detect, and treat TB among high-risk populations and settings documented as having a high risk for TB.

In new subsection 317E(b)(2)(F), the committee authorizes the CDC to fund demonstration project activities for TB detection, control and prevention. This additional prioritization is granted to facilitate CDC's capacity for enhanced TB detection, control and prevention in general.

The act reauthorizes CDC's authority 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 2004–2008 as a joint project of the National Tuberculosis Centers and the Centers for Disease Control and Prevention's Division of TB Elimination (DTBE). The plan provides a blueprint for creating a strong, coordinated, and effective system for TB training and education.

In subsection 317E(b)(5), the committee does not intend to limit support of "Centers" to the four Regional Training and Medical Consultation Centers that are currently in operation in New York City, San Francisco, CA, and San Antonio, TX, and Gainesville, FL. Rather, the committee intends that support for these continue and that the development of additional centers, particularly in areas of high incidence, commences.

The committee further understands that the elimination of TB from the United States cannot be achieved without cooperation be-

tween the United States and Mexico and collaboration with international organizations. In 2006, Mexico was the country of origin for 25 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.

In new subsection 317E(b)(7), the committee authorizes the CDC to fund activities to develop, enhance, and expand TB control surveillance and database management systems with cross-jurisdictional capabilities, which shall conform to the standards and implementation specifications for information technologies as recommended by the Secretary.

In new subsection 317(E)(d)(3), the committee authorizes the Secretary to give highest priority to grant applicants that provide non-Federal funds, which may be provided directly or through donations from public or private entities and may be cash or in kind, including equipment or services. Amounts provided by the government or services assisted or subsidized to any significant extent by the Federal Government may not be included in determining the amount of non-Federal contributions.

Subtitle B—Interagency collaboration

The ACET works closely with the 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 22 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 over 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 United States-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.

In new subsection 317E(f)(2)(B), the committee authorizes ACET to provide the Secretary and other appropriate Federal officials advice on responding rapidly and effectively to emerging issues in TB.

In new subsection 317E(f)(3)(B), the committee authorizes ACET to consult with appropriate public and private entities, subject to the discretion of the Secretary that may include scientists, physicians, laboratorians, and other health professionals who represent the disciplines relevant to TB elimination; members of public-private partnerships established to address the elimination of TB; members of national and international nongovernmental organizations established to address TB elimination; and members of the general public who are knowledgeable with respect to TB elimination including individuals who have or have had TB.

In new subsection 317E(f)(4)(A), the committee charges ACET to submit an annual report to the Secretary on the activities carried under this section. The annual report will also include the opinion of the Council on the extent to which its recommendations regarding the elimination of TB have been implemented. In new subsection 317E(f)(4)(B), the committee authorizes the Secretary to make ACET's annual report public.

In new subsection 317E(f)(5)(B), the committee authorizes the composition of ACET to include State and local TB control and public health officials; individuals who are scientists, physicians, laboratorians, and other health professionals who represent disciplines relevant to TB elimination; members of national and international nongovernmental organizations established to address the elimination of TB; and members from the general public who are knowledgeable with respect to the elimination of TB, including individuals who have or have had TB.

In new subsection 317E(b) Rule of Construction Regarding Current Membership—the amendments made to the act may not be construed as terminating the membership on ACET of any individual serving as such a member as of the day before the date of the enactment of the act.

Subtitle C—New tools for tuberculosis elimination

The act creates a new authorization through the Secretary of the Department of Health and Human Services to fund grants, cooperative agreements and contracts for research and development on drugs, diagnostics, vaccines and public health interventions for the elimination of TB. The act authorizes $100 million in fiscal year 2008 and such sums as necessary for fiscal years 2009 through 2012.

The act will provide a first step in providing the U.S. contribution toward an urgently needed global reinvestment into new TB diagnostic, treatment and prevention tools research. The committee recognizes that the clinical trials and field studies needed to bring new TB diagnostics, drugs and vaccines into practice are ongoing through the CDC's DTBE, including the multisite TB Trials Consortium, the TB Epidemiologic Studies Consortium; and this research is often derived from research conducted by the National Institute of Allergy and Infectious Disease's Division of Microbiology and Infectious Diseases, Division of AIDS and the Division of Intramural Research. The committee recommends that these activities be expanded and intensified and encourages collaboration between the CDC and the NIH in the area of TB research.

New subsection 317E(g)(1) authorizes the Secretary to expand, intensify and coordinate research and development and related activities to develop new TB elimination tools, including drugs, diagnostics, vaccines and public health interventions, including methods to enhance detection and response to outbreaks of drug resistant TB.

New subsection 317E(g)(2) authorizes the Federal TB Task Force. The Federal TB Task Force works closely with the CDC's DTBE and the NIH in developing a comprehensive plan for the creation of new tools for the elimination of tuberculosis, including drugs, diagnostics, vaccines and public health interventions. The committee intends for the Task Force to continuously modify the plan for new TB tools development as new research or technology become available.

The Task Force currently is composed of representatives from diverse Federal and non-Federal agencies, public health departments, and local groups that are concerned with TB research.

In new subsection 317E(g)(2)(C), the committee authorizes the Task Force to consult with appropriate public and private entities that may include scientists, physicians, laboratorians, and other health professionals who represent the disciplines relevant to TB research; members of public-private partnerships engaged in TB research; members of national and international nongovernmental organizations established to address TB elimination; members of the general public who are knowledgeable with respect to TB elimination including individuals who have or have had TB; and health professionals from other countries with a substantial incidence of TB, and who represent the specialties and disciplines relevant to TB research.

In new subsection 317E(g)(3), the committee authorizes the Secretary to award grants, cooperative agreements and contracts to public and private entities for the provision of the research activities described in section 317E(g)(1).

New subtitle D—Evaluation of public health authorities

In new subsection 131, the committee requests that the Secretary submit a report to the appropriate congressional committees that evaluates the effectiveness of Federal and State public health authorities to address disease containment challenges and provides recommendations for improvement, including: an evaluation of the effectiveness of policies to detain patients with active TB; an evaluation of the need for Federal laws to be strengthened to address

the movement of infected individuals; and specific legislative recommendations for Federal law changes. This section also requires the Secretary to promulgate regulations within 8 months to update interstate and foreign quarantine regulations

TITLE III—NATIONAL INSTITUTES OF HEALTH

The committee recommends that the National Institutes of Health expand and intensify its TB research and development activities including basic and clinical research on TB. Given the global health emergency of drug-resistant TB and the strong co-occurrence between TB and HIV, the committee would emphasize that special priority be given to research concerning drug-resistant TB and the relationship between TB and HIV.

V. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, April 17, 2008.

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. 1551, the Comprehensive Tuberculosis Elimination Act of 2007.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Tim Gronniger and Sarah Evans.

Sincerely,

ROBERT A. SUNSHINE
(For Peter R. Orszag, Director).

Enclosure.

S. 1551—Comprehensive Tuberculosis Elimination Act of 2007

Summary: S. 1551 would amend the Public Health Service Act to authorize funding for grants to States and local governments, research on treatment and prevention, and other activities intended to eliminate tuberculosis in the United States. CBO estimates that implementing S. 1551 would cost $11 million in 2008 and $2.2 billion over the 2009–2013 period, assuming appropriation of the authorized amounts.

S. 1551 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA), and would have no effect on direct spending or revenues of the Federal Government.

Estimated cost to the Federal Government: The estimated budgetary impact of S. 1551 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2008	2009	2010	2011	2012	2013
SPENDING SUBJECT TO APPROPRIATION						
Spending Under Current Law:						
CDC:						
Budget Authority [1]	140	0	0	0	0	0

	By fiscal year, in millions of dollars—					
	2008	2009	2010	2011	2012	2013
Estimated Outlays	135	86	50	5	1	0
NIH:						
Budget Authority[2]	165	0	0	0	0	0
Estimated Outlays	159	118	40	15	5	0
Total Spending:						
Budget Authority	305	0	0	0	0	0
Estimated Outlays	294	204	90	20	6	0
Proposed Changes:						
CDC:						
Estimated Authorization Level	290	440	448	457	468	0
Estimated Outlays	11	343	460	438	453	288
NIH:						
Estimated Authorization Level	0	168	0	0	0	0
Estimated Outlays	0	44	79	26	10	5
Total Changes:						
Estimated Authorization Level	290	608	448	457	468	0
Estimated Outlays	11	387	539	464	463	293
Spending Under S. 1551:						
CDC:						
Estimated Authorization Level	430	440	448	457	468	0
Estimated Outlays	146	429	510	443	454	288
NIH:						
Estimated Authorization Level	165	168	0	0	0	0
Estimated Outlays	159	162	119	41	15	5
Total Spending Under S. 1551:						
Estimated Authorization Level	595	608	448	457	468	0
Estimated Outlays	305	591	629	484	469	293

[1] The 2008 level is the amount appropriated for that year for tuberculosis control activities at CDC.
[2] The 2008 level is the amount appropriated for that year for tuberculosis research at NIH.

Note: CDC = Centers for Disease Control and Prevention, NIH = National Institutes of Health.

Basis of estimate: S. 1551 would modify the Public Health Service Act to authorize programs to detect, prevent, and treat tuberculosis. The bill also would authorize research on new vaccines, treatment interventions, tests, and other tools to help eliminate tuberculosis in the United States. Those activities would be administered by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). CDC's activities would be authorized for fiscal years 2008 through 2012, and NIH's activities would be authorized for fiscal years 2008 and 2009. This estimate assumes that the authorized amounts would be provided in a supplemental appropriation for 2008 and near the start of subsequent fiscal years, and that outlays would follow historical patterns for similar activities. CBO estimates that implementing S. 1551 would cost $11 million in 2008 and $2.2 billion over the 2009–2013 period.

CDC's Activities. The bill would authorize CDC to administer grant programs, research and demonstration programs, and research activities related to tuberculosis. Based on information provided by CDC, CBO estimates that the agency will spend $135 million of its 2008 appropriation for activities specified by the bill. In total, CBO estimates that the additional cost for CDC to implement S. 1551 would amount to $11 million in fiscal year 2008 and $2.0 billion over the 2008–2013 period.

The bill would authorize the appropriation of $300 million for 2008 and such sums as may be necessary for the 2009–2012 period to provide grants to States, local governments, and other public entities for the prevention, control, and elimination of tuberculosis in the United States. CBO estimates that implementing that provi-

sion would cost $8 million in 2008 and $1.4 billion over the 2008–2013 period, assuming appropriation of the authorized amounts.

In addition, S. 1551 would authorize the appropriation of such sums as are necessary for research and demonstration programs that promote the elimination of tuberculosis in the United States. CBO estimates that the CDC would require the appropriation of an additional $7 million for such activities in 2008 and $134 million over the 2008–2012 period. Assuming the appropriation of the necessary amounts, CBO estimates that implementing that provision would cost less than $500,000 in 2008 and $126 million over the 2008–2013 period.

The bill also would authorize appropriation of $100 million for 2008 and such sums as are necessary for the 2009–2012 period for research on new tools to help eliminate tuberculosis in the United States. The tools include vaccines, treatment, interventions, and diagnostic tests. That authorization would apply only for years in which the appropriated amount for other activities relating to the elimination of tuberculosis in the United States exceeds its level in 2007. (For 2008, the amount appropriated for those activities was $6 million more than the amount appropriated for 2007.) Assuming that the 2007 level continues to be surpassed for those other activities, CBO estimates that implementing that provision would cost $3 million in 2008 and $467 million over the 2009–2013 period.

NIH Activities. NIH estimates that it will spend $159 million on tuberculosis research in fiscal year 2008. S. 1551 would modify Title IV of the Public Health Service Act to direct the Director of the NIH to conduct research on tuberculosis, particularly with regard to drug-resistant tuberculosis and the relationship between tuberculosis and the human immunodeficiency virus. Activities under title IV are authorized through fiscal year 2009, so this estimate reflects an authorization of funding only for that year. Based on information provided by NIH, CBO expects that implementing S. 1551 would not have a significant effect on tuberculosis-related research or spending at NIH in fiscal year 2008, and would cost $164 million over the 2009–2013 period.

Intergovernmental and private-sector impact: S. 1551 contains no intergovernmental or private-sector mandates as defined in the UMRA.

Estimate prepared by: Federal Costs: Sarah Evans, Tim Gronniger; Impact on State, Local, and Tribal Governments: Lisa Ramirez-Branum; Impact on the Private Sector: Patrick Bernhardt.

Estimate approved by: Keith J. Fontenot, Deputy Assistant Director for Health and Human Resources, Budget Analysis Division.

VI. Regulatory Impact Statement

The committee has determined that there is no legislative impact.

VII. Application of Law to the Legislative Branch

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;

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

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

"Task Force" means the Federal Tuberculosis Task Force;

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

Section 1. Short title

This legislation is titled the "Comprehensive Tuberculosis Elimination Act of 2007."

TITLE I—DEPARTMENT OF HEALTH AND HUMAN SERVICES IN COORDINATION WITH THE CENTERS FOR DISEASE CONTROL AND PREVENTION AND OTHER APPROPRIATE AGENCIES

Subtitle A—Section 101, National Strategy for Combating and Eliminating Tuberculosis, amends Section 317E of the PHSA

The heading for the section is changed to the "National Strategy for Combating and Eliminating Tuberculosis."

Section 317E(b)(2) is amended to refocus the activities of regional capabilities on the prevention of multidrug-resistant and extensively drug-resistant strains of TB in addition to the prevention, control and elimination of TB.

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 reduce health disparities in the incidence of TB.

Section 317E(b)(2)(C) 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 intensification of efforts to control TB along the United States-Mexico border and among binational populations, including expanding the scope and number of programs to detect and treat binational cases of TB and high risk cases referred from Mexican health departments.

Section 317E(b)(2)(D) is added to provide an example of a demonstration project that would be appropriate for the CDC to conduct under this section to intensify efforts to prevent, detect, and treat TB among foreign-born persons who are in the United States.

Section 317E(b)(2)(E) is added to provide an example of a demonstration project that would be appropriate for the CDC to conduct under this section to intensify efforts to prevent, detect, and treat TB among high-risk populations and settings documented as having a high risk for TB.

Section 317E(b)(2)(F) is added to clarify that TB detection, control and prevention activities are appropriate demonstration project activities.

Section 317E(b)(7) is added to clarify that support should be provided for the development, enhancement and expansion of TB con-

trol surveillance and database management systems with cross-jurisdictional capabilities, and to clarify that such systems should conform to the standards and implementation specifications for information technologies as recommended by the Secretary.

Section 317E(3)(A)(B) is amended such to allow priority to be given grant applicants that contribute non-Federal contributions to carry out activities under this section, which may be provided directly or through donations from public or private entities and may be in cash or in kind, including equipment or services.

Section 317E(3)(A)(B), is added to allow grant applicants to provide non-Federal funds, which may be provided directly or through donations from public or private entities and may be cash or in kind, including equipment or services. (B) is added to clarify that amounts or services assisted or subsidized to any significant extent by the Federal Government may not be included in determining the amount of non-Federal contributions.

Subtitle B—Interagency Collaboration

Section 111—Advisory Council for the Elimination of Tuberculosis

Section 317E(f)(2)(B) is amended to direct ACET to provide the Secretary and other appropriate Federal officials advice on responding rapidly and effectively to emerging issues in TB.

Section 317E(f)(3)(B) is amended to direct ACET to consult with appropriate public and private entities, subject to the discretion of the Secretary, that may include: scientists, physicians, laboratorians, and other health professionals who represent the disciplines relevant to TB elimination; members of public-private partnerships established to address the elimination of TB; members of national and international nongovernmental organizations established to address TB elimination; and members of the general public who are knowledgeable with respect to TB elimination including individuals who have or have had TB.

Section 317E(f)(4)(A), is amended to require ACET to submit a bienniel report to the Secretary on the activities carried under this section. The report will also include the opinion of the Council on the extent to which its recommendations regarding the elimination of TB have been implemented.

Section 317E(f)(4)(B) is amended to require the Secretary to make ACET's annual report public.

Section 317E(f)(5)(B) is revised to specify that ACET shall include in its composition State and local TB control and public health officials; individuals who are scientists, physicians, laboratorians, and other health professionals who represent disciplines relevant to TB elimination; members of national and international nongovernmental organizations established to address the elimination of TB; and members from the general public who are knowledgeable with respect to the elimination of TB, including individuals who have or have had TB.

Section 317E(b) is added to specify that the amendments to this section should not be construed as terminating the membership on ACET of any individual serving as such a member as of the day before the date of the enactment of the act.

New Subtitle C—New tools for tuberculosis elimination

Section 317E(g)(1) authorizes the Secretary to expand, intensify and coordinate research and development and related activities to develop new TB elimination tools including drugs, diagnostics, vaccines and public health interventions, as well as methods to enhance detection and response to outbreaks of drug resistant TB.

Section 317E(g)(2) establishes a Federal TB Task Force to advise the Secretary and other Federal officials on the development of new TB elimination tools including drugs, diagnostics, vaccines and public health interventions.

Section 317E(g)(B) is added to direct the Task Force to make recommendations on the development of a comprehensive plan for the elimination of TB. Section 317E(g)(2)(C) is added to direct the Task Force to consult with appropriate public and private entities that may include: scientists, physicians, laboratorians, and other health professionals who represent the disciplines relevant to TB research; members of public-private partnerships engaged in TB research; members of national and international nongovernmental organizations established to address TB elimination; members of the general public who are knowledgeable with respect to TB elimination including individuals who have or have had TB; and health professionals from other countries with a substantial incidence of TB, and who represent the specialties and disciplines relevant to TB research.

Section 317E(g)(3) is added to authorize the Secretary to award grants, cooperative agreements, and contracts to public and private entities for the provision of the research activities described in section 317E(g)(1).

New Subtitle D—Evaluation of public health authorities

Section 131 is added to direct the Secretary to submit a report to the appropriate congressional committees that evaluates the effectiveness of Federal and State public health authorities to address disease containment challenges and provides recommendations for improvement, including an evaluation of the effectiveness of policies to detain patients with active TB; an evaluation of the need for Federal laws to be strengthened to address the movement of infected individuals; and specific legislative recommendations for Federal law changes. This section also requires the Secretary to promulgate regulations within 8 months to update interstate and foreign quarantine regulations.

Subtitle E—Authorization of appropriations

Section 317E(h)(1)(A) authorizes $300 million in fiscal year 2008 and such sums as may be necessary for fiscal years 2009 through 2012 for a National Strategy for Combating and Eliminating Tuberculosis under Title I.

Section 317E(h)(1)(B) is added to direct the Secretary to reserve no more than 25 percent of funds for emergency grants for geographic areas, States, political subdivisions of States or other public entities under the National Strategy for Combating and Eliminating Tuberculosis under Title 1.

Section 317E(h)(1)(C) is added to authorize such sums as necessary for fiscal years 2008 through 2012 for research, education

and training activities under the National Strategy for Combating and Eliminating Tuberculosis under Title I.

Section 317E(h)(1)(D) is added to direct the Secretary to distribute grants under section 317E(h)(1)(B) on the basis of a formula that takes into account the level of TB morbidity and case complexity in respective geographic areas and consideration of other factors. This section also clarifies that the Secretary may use the existing formula from fiscal year 2007.

Section 317E(h)(2) authorizes $100 million for fiscal year 2008 and such sums as necessary for fiscal years 2009 through 2012 for new tools for tuberculosis elimination, section 317E(g).

TITLE III—NATIONAL INSTITUTES OF HEALTH

Section 201 amends subpart 2 of part C of title IV of the PHSA by adding section 424C after section 424B.

Section 424C authorizes the Director of the National Institute of Health to expand and intensify its TB research and development activities, including basic and clinical research on TB. Given the global health emergency of drug-resistant TB and the strong co-occurrence between TB and HIV, the committee would emphasize that special priority be given to research concerning drug-resistant TB and the relationship between TB and HIV.

IX. 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

* * * * * * *

[PREVENTIVE HEALTH SERVICES REGARDING TUBERCULOSIS] *NATIONAL STRATEGY FOR COMBATING AND ELIMINATING TUBERCULOSIS*

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

* * * * * * *

[(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 certain 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 AND DEVELOPMENT; DEMONSTRATION PROJECTS; EDUCATION AND TRAINING.—With respect to the prevention, treatment, 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 and development concerning latent tuberculosis infection, strains of tuberculosis resistant to drugs, and research concerning cases of tuberculosis that affect certain populations at risk for tuberculosis.

(2) Demonstration projects for—

(A) the development of regional capabilities to prevent, control and eliminate tuberculosis and prevent multidrug resistant and extensively drug resistant strains of tuberculosis;

(B) the intensification of efforts to reduce health disparities in the incidence of tuberculosis;

(C) the intensification of efforts to control tuberculosis along the United States-Mexico border and among United States-Mexico binational populations, including through expansion of the scope and number of programs that—

(i) detect and treat binational cases of tuberculosis; and

(ii) treat high-risk cases of tuberculosis referred from Mexican health departments;

(D) the intensification of efforts to prevent, detect, and treat tuberculosis among foreign-born persons who are in the United States;

(E) the intensification of efforts to prevent, detect, and treat tuberculosis among populations and settings documented as having a high risk for tuberculosis; and

(F) tuberculosis detection, control, and prevention.

(3) Public information and education activities.

(4) Education, training, clinical skills improvement activities, and workplace exposure prevention 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.

(7) Develop, enhance, and expand information technologies that support tuberculosis control including surveillance and database management systems with cross-jurisdictional capabilities, which shall conform to the standards and implementation specifications for such information technologies as recommended by the Secretary.

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(d) APPLICATION FOR GRANT.—

(1) IN GENERAL.—* * *

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(3) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTIONS.—

(A) PRIORITY.—In awarding grants under subsection (a) or (b), the Secretary shall give highest priority to an applicant that provides assurances that the applicant will contribute non-Federal funds to carry out activities under this section, which may be provided directly or through donations from public or private entities and may be in cash or in kind, including equipment or services.

(B) FEDERAL AMOUNTS NOT TO BE INCLUDED AS CONTRIBUTIONS.—Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of non-Federal contributions as described in subparagraph (A).

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(f) ADVISORY COUNCIL.—

(1) IN GENERAL.—* * *

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[(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.—The Council shall provide advice and recommendations regarding the elimination of tuberculosis to the Secretary. In addition, the Council shall, with respect to eliminating such disease, provide to the Secretary and other appropriate Federal officials advice on—

(A) coordinating the activities of the Department of Health and Human Services and other Federal agencies that relate to the disease, including activities under subsection (b);

(B) responding rapidly and effectively to emerging issues in tuberculosis; and

(C) efficiently utilizing the Federal resources involved.

(3) COMPREHENSIVE PLAN.—

(A) IN GENERAL.—In carrying out paragraph (2), the Council shall make or update recommendations on the development, revision, and implementation of a comprehensive plan to eliminate tuberculosis in the United States.

(B) CONSULTATION.—In carrying out subparagraph (A), the Council may consult with appropriate public and private entities, which may, subject to the direction or discretion of the Secretary, include—

(i) individuals who are scientists, physicians, laboratorians, and other health professionals, who are not officers or employees of the Federal Government and who represent the disciplines relevant to tuberculosis elimination;

(ii) members of public-private partnerships or private entities established to address the elimination of tuberculosis;

(iii) members of national and international nongovernmental organizations whose purpose is to eliminate tuberculosis; and

(iv) members from the general public who are knowledgeable with respect to tuberculosis elimination including individuals who have or have had tuberculosis.

(C) CERTAIN COMPONENTS OF PLAN.—In carrying out subparagraph (A), the Council shall, subject to the direction or discretion of the Secretary—

(i) consider recommendations for the involvement of the United States in continuing global and cross-border tuberculosis control activities in countries where a high incidence of tuberculosis directly affects the United States; and

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

(4) BIENNIAL REPORT.—

(A) IN GENERAL.—The Council shall submit a biennial report to the Secretary, as determined necessary by the Secretary, on the activities carried under this section, other than subsection (g). Each such report shall include the opinion of the Council on the extent to which its recommendations regarding the elimination of tuberculosis have been implemented, including with respect to—

(i) activities under subsection (b); and

(ii) the national plan referred to in paragraph (3).

(B) PUBLIC.—The Secretary shall make a report submitted under subparagraph (A) public.

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

(A) ex officio representatives from the Centers for Disease Control and Prevention, the National Institutes of Health, the United States Agency for International Development, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the United States-Mexico Border Health Commission, and other Federal departments and agencies that carry out significant activities related to tuberculosis;

(B) State and local tuberculosis control and public health officials;

(C) individuals who are scientists, physicians, laboratorians, and other health professionals who represent disciplines relevant to tuberculosis elimination; and

(D) members of national and international nongovernmental organizations established to address the elimination of tuberculosis.

[(5)] *(6)* STAFF, INFORMATION, AND OTHER ASSISTANCE.—
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(g) NEW TOOLS FOR ELIMINATION OF TUBERCULOSIS.—

(1) RESEARCH AND DEVELOPMENT ON DRUGS, DIAGNOSTICS, VACCINES, AND PUBLIC HEALTH INTERVENTIONS.—The Secretary may expand, intensify, and coordinate research and development and related activities to develop new tools for the elimination of tuberculosis, including drugs, diagnostics, vaccines, and public health interventions, such, as directly observed therapy and non-pharmaceutical intervention, and methods to enhance detection and response to outbreaks of tuberculosis, including multidrug resistant tuberculosis. The Secretary shall give priority to programmatically relevant research so that new tools can be utilized in public health practice.

(2) FEDERAL TUBERCULOSIS TASK FORCE.—

(A) DUTIES.—The Federal Tuberculosis Task Force (in this subsection referred to as the Task Force) shall provide to the Secretary and other appropriate Federal officials advice on the implementation of paragraph (1), including advice regarding the efficient utilization of the Federal resources involved.

(B) COMPREHENSIVE PLAN FOR NEW TOOLS DEVELOPMENT.—In carrying out paragraph (1), the Task Force shall make recommendations on the development of a comprehensive plan for the creation of new tools for the elimination of tuberculosis, including drugs, diagnostics, and vaccines.

(C) CONSULTATION.—In developing the comprehensive plan under paragraph (1), the Task Force shall consult with external parties including representatives from groups such as—

(i) scientists, physicians, laboratorians, and other health professionals who represent the specialties and disciplines relevant to the research under consideration;

(ii) members from public-private partnerships, private entities, or foundations (or both) engaged in activities relevant to research under consideration;

(iii) members of national and international nongovernmental organizations established to address tuberculosis elimination;

(iv) members from the general public who are knowledgeable with respect to tuberculosis including individuals who have or have had tuberculosis; and

(v) scientists, physicians, laboratorians, and other health professionals who reside in a foreign country with a substantial incidence or prevalence of tuberculosis, and who represent the specialties and disciplines relevant to the research under consideration.

(3) GRANTS AND CONTRACTS.—The Secretary may carry out paragraph (1) directly and through awards of grants, cooperative agreements, and contracts to public and private entities, including—

(A) public-private partnerships;

(B) academic institutions, including institutions of higher education;

(C) research institutions; and

(D) nonprofit entities established and dedicated to tuberculosis vaccine and treatment product development.

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[(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.]

(h) AUTHORIZATION OF APPROPRIATIONS.—

(1) GENERAL PROGRAM.—

(A) IN GENERAL.—For the purpose of carrying out this section, other than subsections (b) and (g), there are authorized to be appropriated $300,000,000 for fiscal year 2008, and such sums as may be necessary for each of the fiscal years 2009 through 2012.

(B) RESERVATION FOR EMERGENCY GRANTS.—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, State, political subdivision of a State, or other public entity in which there is, relative to other areas, a substantial number of cases of tuberculosis, multidrug resistant tuberculosis, or extensively drug resistant tuberculosis or a substantial rate of increase in such cases.

(C) 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 fiscal years 2008 through 2012.

(D) PRIORITY.—In allocating amounts appropriated under subparagraph (A) and not reserved under subparagraph (B), the Secretary shall give priority to allocating such amounts for grants under subsection (a).

(E) ALLOCATION OF FUNDS.—

(i) REQUIREMENT OF FORMULA.—Of the amounts appropriated under subparagraph (A), not reserved under subparagraph (B), and allocated by the Secretary for grants under subsection (a), the Secretary shall distribute a portion of such amounts to grantees under subsection (a) on the basis of a formula.

(ii) RELEVANT FACTORS.—The formula developed by the Secretary under clause (i) shall take into account the level of tuberculosis morbidity and case complexity in the respective geographic area and may consider other factors relevant to tuberculosis in such area.

(iii) NO CHANGE TO FORMULA REQUIRED.—This subparagraph does not require the Secretary to modify the formula that was used by the Secretary to distribute funds to grantees under subsection (a) for fiscal year 2007.

(2) NEW TOOLS.—

(A) IN GENERAL.—For the purpose of carrying out subsection (g), there are authorized to be appropriated $100,000,000 for fiscal year 2008, and such sums as may be necessary for each of the fiscal years 2009 through 2012.

(B) LIMITATION.—The authorization of appropriations established in subparagraph (A) for a fiscal year is effective only if the amount appropriated under paragraph (1) for such year equals or exceeds the amount appropriated to carry out this section for fiscal year 2007.

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TITLE IV—NATIONAL RESEARCH INSTITUTES

PART A—NATIONAL INSTITUTES OF HEALTH

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PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

Subpart 1—National Cancer Institute

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Subpart 2—National Heart, Lung, and Blood Institute

PURPOSE OF THE INSTITUTE

SEC. 418. [285b] * * *

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COORDINATION OF FEDERAL ASTHMA ACTIVITIES

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

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SEC. 424C. TUBERCULOSIS.

(a) IN GENERAL.—The Director of the National Institutes of Health may expand, intensify, and coordinate research and development and related activities of the Institute with respect to tuberculosis including activities toward the goal of eliminating such disease.

(b) CERTAIN ACTIVITIES.—Activities under subsection (a) may include—

(1) enhancing basic and clinical research on tuberculosis, including drug resistant tuberculosis; and

(2) expanding research on the relationship between such disease and the human immunodeficiency virus.

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