SMITH) and the Senator from Arizona (Mr. McCain) were added as cosponsors of S. 494, a bill to endorse further enlargement of the North Atlantic Treaty Organization (NATO) and to facilitate the timely admission of new members to NATO, and for other purposes.

S. 507

At the request of Mr. CONRAD, the name of the Senator from Washington (Mrs. MURRAY) was added as a cosponsor of S. 507, a bill to amend title XVIII of the Social Security Act to provide for reimbursement of certified midwife services and to provide for more equitable reimbursement rates for certified nurse-midwife services.

S. 509

At the request of Mr. INOUYE, the name of the Senator from Texas (Mrs. HUTCHISON) was added as a cosponsor of S. 509, a bill to provide improved aviation security, and for other purposes.

S. 536

At the request of Mr. Kohl, the name of the Senator from Wisconsin (Mr. Feingold) was added as a cosponsor of S. 536, a bill to amend the Organic Foods Production Act of 1990 to prohibit the labeling of cloned livestock and products derived from cloned livestock as organic.

S. 543

At the request of Mr. Nelson of Nebraska, the name of the Senator from Georgia (Mr. Isakson) was added as a cosponsor of S. 543, a bill to improve Medicare beneficiary access by extending the 60 percent compliance threshold used to determine whether a hospital or unit of a hospital is an inpatient rehabilitation facility under the Medicare program.

S. 558

At the request of Mr. Kennedy, the names of the Senator from Hawaii (Mr. Inouye), the Senator from New York (Mrs. Clinton), the Senator from North Dakota (Mr. Conrad), the Senator from Illinois (Mr. Durbin), the Senator from Minnesota (Ms. Klobuchar) and the Senator from Iowa (Mr. Harkin) were added as cosponsors of S. 558, a bill to provide parity between health insurance coverage of mental health benefits and benefits for medical and surgical services.

S. 561

At the request of Mr. Bunning, the name of the Senator from Florida (Mr. MARTINEZ) was added as a cosponsor of S. 561, a bill to repeal the sunset of the Economic Growth and Tax Relief Reconciliation Act of 2001 with respect to the expansion of the adoption credit and adoption assistance programs.

S. 574

At the request of Mr. Reid, the name of the Senator from Nebraska (Mr. Nelson) was added as a cosponsor of S. 574, a bill to express the sense of Congress on Iraq.

S. 578

At the request of Mr. Kennedy, the name of the Senator from Ohio (Mr. Brown) was added as a cosponsor of S.

578, a bill to amend title XIX of the Social Security Act to improve requirements under the Medicaid program for items and services furnished in or through an educational program or setting to children, including children with developmental, physical, or mental health needs, and for other purposes.

S. 579

At the request of Mr. Reid, the names of the Senator from Florida (Mr. NELSON), the Senator from Rhode Island (Mr. Whitehouse), the Senator from California (Mrs. FEINSTEIN), the Senator from Indiana (Mr. BAYH), the Senator from Washington (Mrs. Mur-RAY), the Senator from Wisconsin (Mr. KOHL) and the Senator from California (Mrs. Boxer) were added as cosponsors of S. 579, a bill to amend the Public Health Service Act to authorize the Director of the National Institute of Environmental Health Sciences to make grants for the development and operation of research centers regarding environmental factors that may be related to the etiology of breast cancer.

At the request of Mr. HATCH, the names of the Senator from New Hampshire (Mr. SUNUNU) and the Senator from Ohio (Mr. VOINOVICH) were added as cosponsors of S. 579, supra.

S. 597

At the request of Mrs. Feinstein, the names of the Senator from North Carolina (Mrs. Dole), the Senator from Missouri (Mr. Bond), the Senator from Utah (Mr. Hatch), the Senator from Arkansas (Mrs. Lincoln) and the Senator from Kentucky (Mr. Bunning) were added as cosponsors of S. 597, a bill to extend the special postage stamp for breast cancer research for 2 years.

S. 601

At the request of Mr. BAYH, the name of the Senator from New Mexico (Mr. BINGAMAN) was added as a cosponsor of S. 601, a bill to amend the Internal Revenue Code of 1986 to require broker reporting of customer's basis in securities transactions, and for other purposes.

# STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. PRYOR:

S. 602. A bill to develop the next generation of parental control technology; to the Committee on Commerce, Science, and Transportation.

Mr. PRYOR. Mr. President, I wish to introduce two communications bills. First, I am introducing the Child Safe Viewing Act, a bill to develop the next generation of parental control technology. Last year, following several hearings and forums on decency, I concluded that the V-Chip is not an adequate solution for parents to prevent their children from viewing adult content, especially in a world of 500 channels and video streaming.

During the 1996 Telecommunications Act debate, President Clinton urged inclusion of a mandatory V-Chip device, and in collaboration with Congress, the FCC, and the entertainment industry, the V-Chip was born. The V-Chip was an important beginning to control child access to adult material. Over a decade has passed since the 1996 act, and the world of communications has changed. However, the issues that inspired the V-Chip continue to exist today for not only television but for the Internet and other video streaming devices.

The Child Safe Viewing Act is a pragmatic approach to addressing the pitfalls of video content not intended for kids, and it acts on current law. It simply directs the Federal Communications Commission to begin a proceeding on the requirements in section 551 of the V-Chip law. Section 551 states that the Commission shall take action on alternative blocking technology as it is developed. This mandate is clear and the time has come. We must engage in this issue now to ensure that families have the tools to keep inappropriate and sometimes dangerous material out of their children's view.

I am also introducing ED 1.0, a bill to advance online higher education opportunities for minorities. Last Congress, Senator Allen and I introduced a bill that would establish a digital and wireless network technology program for minority-serving institutions, and it was reported favorably by the Commerce Committee. Regrettably, I am concerned that the cost of the bill will prohibit it from moving in this Congress. But the needs to this Nation's minorities are not standing still.

ED 1.0 would allow some of our goals to move forward now by creating a pilot online degree program at four minority-serving institutions. African-American, Hispanic, and tribal serving colleges and universities in socially and economically disadvantaged areas would be eligible to participate in this program to help define what works in ensuring that minorities are obtaining higher education degrees.

With the high costs of networks and limited availability of resources, the program would provide a national "lessons learned" about how to develop and implement flexible degree programs in fields such as health or education, which are currently underserved in the disadvantaged community. The goals of ED 1.0 will make education a reality for thousands of Americans, and I hope this bill will have the support of my colleagues.

By Mr. LAUTENBERG (for himself, Mr. HAGEL, Mr. KERRY, and Mrs. LINCOLN):

S. 604. A bill to amend title 10, United States Code, to limit increases in the certain costs of health care services under the health care programs of the Department of Defense, and for the purposes; to the Committee on Armed Services.

Mr. LAUTENBERG. Mr. President, I rise to introduce the Military Health

Care Protection Act along with my colleagues, Senators HAGEL, KERRY, and LINCOLN.

This important legislation will keep the Pentagon from dramatically raising health care fees on active duty military personnel, National Guard, Reserves, retirees and their families.

Our bill will limit increases to TRICARE military health insurance enrollment fees, deductibles, and pharmacy co-payments for those military retirees who are enrolled in TRICARE. Under this legislation, increases in these health care fees cannot exceed the rate of growth in uniformed services beneficiaries' military compensation, thereby protecting beneficiaries from an undue financial burden.

Our bill will also cap increases to TRICARE military health insurance pharmacy co-payments at current levels for those active duty military personnel, National Guard, Reserves members, and their families. Under this legislation, increases in such fees also cannot exceed the rate of growth in uniformed services beneficiaries' military compensation.

Just last week, the Department of Defense (DOD) submitted its Fiscal Year 2008 budget to Congress. Within that budget, a cut of \$1.86 billion was made to TRICARE out of the Defense Health Program budget. Such a cut would require a doubling of fees on senior enlisted retirees and a tripling of such fees for officer retirees. This would mean increases of up to \$1,000 annually for some military retirees. While the Department of Defense temporarily halted plans to raise fees last year at the direction of Congress, we are again faced with this challenge. We must pass legislation now that limits the amount of any health care increase and protects beneficiaries from extreme health care fee increases in the future.

With this bill, Senator HAGEL and I reiterate our commitment to our troops and future veterans by assuring them that just as they protected us, we will take care of them when their service ends.

Last year, Congress rejected the same increases that the Pentagon is proposing again for this year. I ask the support of my colleagues to pass this legislation this year to prevent these significant increases permanently.

I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

### S. 604

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

### SECTION 1. SHORT TITLE.

This Act may be cited as the "Military Health Care Protection Act".

### SEC. 2. FINDINGS AND SENSE OF CONGRESS.

- (a) FINDINGS.—Congress makes the following findings:
- (1) Career members of the uniformed services and their families endure unique and ex-

- traordinary demands, and make extraordinary sacrifices, over the course of 20-year to 30-year careers in protecting freedom for all Americans.
- (2) The nature and extent of these demands and sacrifices are never so evident as in wartime, not only during the current Global War on Terrorism, but also during the wars of the last 60 years when current retired members of the Armed Forces were on continuous call to go in harm's way when and as needed.
- (3) The demands and sacrifices are such that few Americans are willing to bear or accept them for a multi-decade career.
- (4) A primary benefit of enduring the extraordinary sacrifices inherent in a military career is a range of extraordinary retirement benefits that a grateful Nation provides for those who choose to subordinate much of their personal life to the national interest for so many years.
- (5) Many private sector firms are curtailing health benefits and shifting significantly higher costs to their employees, and one effect of such curtailment is that retired members of the uniformed services are turning for health care services to the Department of Defense, and its TRICARE program, for the health care benefits in retirement that they earned by their service in uniform.
- (6) In some cases, civilian employers establish financial incentives for employees who are also eligible for participation in the TRICARE program to receive health care benefits under that program rather than under the health care benefits programs of such employers.
- (7) While the Department of Defense has made some efforts to contain increases in the cost of the TRICARE program, a large part of those efforts has been devoted to shifting a larger share of the costs of benefits under that program to retired members of the uniformed services.
- (8) The cumulative increase in enrollment fees, deductibles, and copayments being proposed by the Department of Defense for health care benefits under the TRICARE program far exceeds the 33-percent increase in military retired pay since such fees, deductibles, and copayments were first required on the part of retired members of the uniformed services 11 years ago.
- (9) Proposals of the Department of Defense for increases in the enrollment fees, deductibles, and copayments of retired members of the uniformed services who are participants in the TRICARE program fail to recognize adequately that such members paid the equivalent of enormous in-kind premiums for health care in retirement through their extended sacrifices by service in uniform
- (10) Some of the Nation's health care providers refuse to accept participants in the TRICARE program as patients because that program pays them significantly less than commercial insurance programs, and imposes unique administrative requirements, for health care services.
- (11) The Department of Defense has chosen to count the accrual deposit to the Department of Defense Military Retiree Health Care Fund against the budget of the Department of Defense, contrary to the requirements of section 1116 of title 10, United States Code.
- (12) Senior officials of the Department of Defense leaders have reported to Congress that counting such deposits against the budget of the Department of Defense is impinging on other readiness needs of the Armed Forces, including weapons programs, an inappropriate situation which section 1116 of title 10, United States Code, was intended expressly to prevent.
- (b) SENSE OF CONGRESS.—It is the sense of Congress that—

- (1) the Department of Defense and the Nation have a committed obligation to provide health care benefits to retired members of the uniformed services that exceeds the obligation of corporate employers to provide health care benefits to their employees;
- (2) the Department of Defense has many additional options to constrain the growth of health care spending in ways that do not disadvantage retired members of the uniformed services who participate or seek to participate in the TRICARE program, and should pursue any and all such options rather than seeking large increases for enrollment fees, deductibles, and copayments for such retirees, and their families or survivors, who do participate in that program:
- (3) any percentage increase in fees, deductibles, and copayments that may be considered under the TRICARE program for retired members of the uniformed services and their families or survivors should not in any case exceed the percentage increase in military retired pay: and
- (4) any percentage increase in fees, deductibles, and copayments under the TRICARE program that may be considered for members of the uniformed services who are currently serving on active duty or in the Selected Reserve, and for the families of such members, should not exceed the percentage increase in basic pay for such members.

# SEC. 3. LIMITATIONS ON CERTAIN INCREASES IN HEALTH CARE COSTS FOR MEMBERS OF THE UNIFORMED SERVICES.

- (a) PHARMACY BENEFITS PROGRAM.—Section 1074g(a)(6) of title 10, United Stated Code, is amended by adding at the end the following new subparagraph:
- "(C) The amount of any cost sharing requirements under this paragraph may not be increased in any year by a percentage that exceeds the percentage increase of the most recent increase in retired pay for members of the armed forces under section 1401a(b)(2) of this title. To the extent that such increase for any year is less than one dollar, the accumulated increase may be carried over from year to year, rounded to the nearest dollar."
- (b) PREMIUMS FOR TRICARE STANDARD FOR RESERVE COMPONENT MEMBERS WHO COMMIT TO SERVICE IN THE SELECTED RESERVE.—Section 1076d(d)(3) of such title is amended—
- (1) by striking "The monthly amount" and inserting "(A) Subject to subparagraph (B), the monthly amount"; and
- (2) by adding at the end the following new subparagraph:
- "(B) Effective as of October 1, 2007, the percentage increase in the amount of the premium in effect for a month for TRICARE Standard coverage under this section may not exceed a percentage equal to the percentage of the most recent increase in the rate of basic pay authorized for members of the uniformed services for a year."
- (c) COPAYMENTS UNDER CHAMPUS.—Paragraph (3) of section 1086(b) of such title is amended in the first sentence by striking "during the period beginning on April 1, 2006, and ending on September 30, 2007." and inserting "after March 31, 2006"
- (d) PROHIBITION ON ENROLLMENT FEES FOR CERTAIN PERSONS UNDER CHAMPUS.—Section 1086(b) of such title is further amended by adding at the end the following new paragraph:
- "(5) A person covered by subsection (c) may not be charged an enrollment fee for coverage under this section.".
- (e) AUTOMATIC ENROLLMENT FOR CERTAIN PERSONS UNDER CHAMPUS.—Section 1086(b) of such title is further amended by adding at the end the following new paragraph:
- "(6) A person covered by subsection (c) shall not be subject to denial of claims for

coverage under this section for failure to enroll for such coverage. To the extent enrollment may be required, enrollment shall be automatic for any such person filing a claim under this section.".

(f) PREMIUMS AND OTHER CHARGES UNDER TRICARE.—Section 1097(e) of such title is amended-

(1) by inserting "(1)" before "The Secretary of Defense"; and

(2) by adding at the end the following new

paragraph:

"(2) Effective as of October 1, 2007, the percentage increase in the amount of any premium, deductible, copayment or other charge prescribed by the Secretary under this subsection may not exceed the percentage increase of the most recent increase in retired pay for members and former members of the armed forces under section 1041a(b)(2) of this title.".

> By Ms. CANTWELL (for herself, Mr. BINGAMAN, Mrs. BOXER, Mr. KENNEDY, Ms. LANDRIEU, Mr. LIEBERMAN, Mrs. LINCOLN, Ms. MIKULSKI, and Mrs. MURRAY):

S. 605. A bill to amend the Public Health Service Act to promote and improve the allied health professions; to the Committee on Health, Education, Labor, and Pensions.

Ms. CANTWELL. Mr. President. early in the 109th Congress I introduced a bill to address the troubling shortage of allied health professionals in our country. Sadly, we were unable to act on this bill despite continuing deficiencies in the health care workforce. That is why, today, I am reintroducing the Allied Health Reinvestment Act, along with my good colleagues, Senators BINGAMAN, BOXER, KENNEDY, LANDRIEU, LIEBERMAN, LINCOLN, MIKUL-SKI, and MURRAY.

Allied health professionals constitute roughly one third of the American healthcare workforce. These individuals take x-rays, perform lab tests, and provide emergency services. They help rehabilitate the injured, manage health records, and ensure patients are eating right. Allied health professionals are responsible for a critical and diverse array of functions, working with doctors and nurses to keep patients healthy.

The allied health professions recognized in this bill include professionals in the areas of: dental hygiene, dietetics/nutrition, emergency medical services, health information management, clinical laboratory sciences/medical technology, cytotechnology, occupational therapy, physical therapy, radiologic technology, nuclear medical technology, rehabilitation counseling, respiratory therapy, and speech language-pathology/audiology. This is by no means a complete list of allied health professions, which is why the Secretary of Health and Human Services will have the authority to determine additional professions that can benefit.

Today, many allied health professions suffer from existing workforce shortages. The American Hospital Association (AHA) reports vacancy rates of 18 percent for radiology technicians, 15.3 percent for imaging technicians,

and 12.7 percent for pharmacy technicians. In my State alone, the Washington State Hospital Association reports vacancy rates of 14.3 percent for ultrasound technologists, 11.3 percent for radiology technicians, and 10.9 percent for nuclear medicine technologists.

These shortages have real consequences for patients, often extending wait times for important test results or routine examinations. Every time I meet with hospital officials in my State, I always learn how patient care is hurt by the lack of available healthcare workers.

Enrollment figures in allied health education programs suggest we will not have the individuals available to meet the challenges created by existing shortages. The Association of Schools of Allied Health Professionals (ASAHP) reports in a 2006 survey of 87 member institutions that enrollment for a number of allied health programs have not reached capacity for the seventh straight year. The Institutional Profile Survey, which the ASAHP conducts every year, shows under-enrollment by 55 percent in dietetics, 54 percent in health administration, 49 percent in rehabilitation counseling, 43 percent in health information management, 38 percent in speech language pathology/ audiology, 33 percent in emergency medical sciences, 26 percent in nuclear medicine technology, 25 percent in clinical laboratory sciences/medical technology, and 20 percent in cytotechnology.

These rates cannot continue. On top of existing workforce shortages, our health system faces a growing senior population, a group that typically requires more care. The U.S. Census Bureau reports that the section of our population age 65 and over will begin to rapidly increase in 2011 when the first of the baby boom generation reaches age 65. This increase will create greater demand on all sectors of the healthcare

The bill my colleagues and I introduce today, like the Nurse Reinvestment Act in the 107th Congress, intends to provide incentives for individuals to seek and complete high-quality allied health education and training.

The bill offers allied health education, practice, and retention grants. Education grants will be used to expand enrollment in allied health education programs, especially by underrepresented racial and ethnic minority students, and provide educational opportunities through new technologies and methods, including distance-learning. Practice grants will establish or expand allied health practice arrangements in non-institutional settings to demonstrate methods that will improve access to primary health care in rural areas and other medically underserved communities. Retention grants will promote career advancement for allied health personnel.

Grants will also be made available for health care facilities to enable

them to carry out demonstrations of models and best practices in allied health for the purpose of developing innovative strategies or approaches for retention of allied health professionals. These grants will be awarded in a variety of geographic regions to a range of different types of facilities, including those in rural, urban, and suburban areas.

Furthermore, this bill will give the Secretary of HHS, acting through the Administrator of HRSA, the authority to enter into an agreement with any institution that offers an eligible allied health education program to establish and operate a faculty loan fund to increase the number of qualified allied health faculty. Loans may be granted to faculty pursuing a full-time course of study or, at the discretion of the Secretary, a part-time course of study in an advanced degree program.

Finally, the Allied Health Reinvestment Act will establish a scholarship program modeled after the National Health Service Corps that provides scholarships to individuals seeking allied health education in exchange for service by those individuals in rural and other medically underserved areas.

The Allied Health Reinvestment Act represents a serious commitment on our part to confront a problem that will only grow more serious in the future. Our system of care cannot operate without the dedicated allied health professionals working today, and we must take the actions necessary to ensure that there is a strong workforce that can serve in the future.

I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

### S. 605

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled

### SECTION 1. SHORT TITLE.

This Act may be cited as the "Allied Health Reinvestment Act".

### SEC. 2. FINDINGS AND PURPOSE.

- (a) FINDINGS.—Congress makes the following findings:
- (1) The United States Census Bureau and other reports highlight the increased demand for acute and chronic health care services among both the general population and a rapidly growing aging portion of the population.
- (2) The calls for reduction in medical errors, increased patient safety, and quality of care have resulted in an amplified call for allied health professionals to provide health care services.
- (3) Several allied health professions are characterized by workforce shortages, declining enrollments in allied health education programs, or a combination of both factors, and hospital officials have reported vacancy rates in positions occupied by allied health professionals.
- (4) Many allied health education programs are facing significant economic pressure that could force their closure due to an insufficient number of students.
- (b) PURPOSE.—It is the purpose of this Act to provide incentives for individuals to seek

and complete high quality allied health education and training and provide additional funding to ensure that such education and training can be provided to allied health students so that the United States health care industry with have a supply of allied health professionals needed to support the health care system of the United States in this decade and beyond.

#### SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

Title VII of the Public Health Service Act (42 U.S.C. 292 et seq.) is amended by adding at the end the following:

#### "PART G-ALLIED HEALTH **PROFESSIONALS**

#### "SEC. 799C. DEFINITIONS.

- "In this part:
- "(1) Allied health education program.— The term 'allied health education program' means any postsecondary educational program offered by an institution accredited by an agency or commission recognized by the Department of Education, or leading to a State certificate or license or any other educational program approved by the Secretary. Such term includes colleges, universities, or schools of allied health and equivalent entities that include programs leading to a certificate, associate, baccalaureate, or graduate level degree in an allied health profes-
- ALLIED HEALTH PROFESSIONS.—The term 'allied health professions' includes professions in the following areas at the certificate, associate, baccalaureate, or graduate level:
  - "(A) Dental hygiene.
  - "(B) Dietetics or nutrition.
  - "(C) Emergency medical services.
  - "(D) Health information management.
- "(E) Clinical laboratory sciences and medical technology.
  - "(F) Cytotechnology.
  - "(G) Occupational therapy.
- "(H) Physical therapy.
- "(I) Radiologic technology.
- "(J) Nuclear medical technology.
- "(K) Rehabilitation counseling.
- "(L) Respiratory therapy.
- "(M) Speech-language pathology and audiology.
- "(N) Any other profession determined appropriate by the Secretary.
- (3) HEALTH CARE FACILITY.—The term 'health care facility' means an outpatient health care facility, hospital, nursing home, home health care agency, hospice, federally qualified health center, nurse managed health center, rural health clinic, public health clinic, or any similar health care facility or practice that employs allied health professionals.

#### "SEC. 799C-1. PUBLIC SERVICE ANNOUNCE-MENTS.

- "The Secretary shall develop and issue public service announcements that shall-
- "(1) advertise and promote the allied health professions;
- "(2) highlight the advantages and rewards of the allied health professions; and
- '(3) encourage individuals from diverse communities and backgrounds to enter the allied health professions.

### "SEC. 799C-2, STATE AND LOCAL PUBLIC SERVICE ANNOUNCEMENTS.

- "(a) IN GENERAL.—The Secretary shall award grants to designated eligible entities to support State and local advertising campaigns that are conducted through appropriate media outlets (as determined by the Secretary) to-
- "(1) promote the allied health professions;
- "(2) highlight the advantages and rewards of the allied health professions; and
- "(3) encourage individuals from disadvantaged communities and backgrounds to enter the allied health professions.

- "(b) ELIGIBLE ENTITY.—To be eligible to receive a grant under subsection (a), an entity shall-
- "(1) be a professional, national, or State allied health association, State health care provider, or association of one or more health care facilities, allied health education programs, or other entities that provides similar services or serves a like function:
- "(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

## "SEC. 799C-3. ALLIED HEALTH RECRUITMENT GRANT PROGRAM.

- "(a) PROGRAM AUTHORIZED.—The Secretary shall award grants to eligible entities to increase allied health professions education opportunities.
- "(b) ELIGIBLE ENTITY.—To be eligible to receive a grant under subsection (a), an entity shall-
- "(1) be a professional, national, or State allied health association, State health care provider, or association of one or more health care facilities, allied health education programs, or other eligible entities that provides similar services or serves a like function: and
- "(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.
- '(c) USE OF FUNDS .- An entity shall use amounts received under a grant under subsection (a) to-
- '(1) support outreach programs at elementary and secondary schools that inform guidance counselors and students of education opportunities regarding the allied health professions:
- '(2) carry out special projects to increase allied health education opportunities for individuals who are from disadvantaged backgrounds (including racial and ethnic minorities that are underrepresented among the allied health professions) by providing student scholarships or stipends, pre-entry preparation, and retention activities;
- "(3) provide assistance to public and nonprofit private educational institutions to support remedial education programs for allied health students who require assistance with math, science, English, and medical ter-
- "(4) meet the costs of child care and transportation for individuals who are taking part in an allied health education program at any level: and
- "(5) support community-based partnerships seeking to recruit allied health professionals in rural communities and medically underserved urban communities, and other communities experiencing an allied health professions shortage.

#### "SEC. 799C-4. GRANTS FOR HEALTH CAREER ACADEMIES.

- "(a) IN GENERAL.—The Secretary shall award grants to eligible entities to assist such entities in collaborating to carry out programs that form education pipelines to facilitate the entry of students of secondary educational institutions, especially underrepresented racial and ethnic minorities, into careers in the allied health professions.
- "(b) ELIGIBLE ENTITY.—To be eligible to receive a grant under subsection (a), an entity
- "(1) be an institution that offers allied health education programs, a health care facility, or a secondary educational institution: and
- "(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

## "SEC. 799C-5. ALLIED HEALTH EDUCATION, PRACTICE, AND RETENTION GRANTS.

- "(a) EDUCATION PRIORITY AREAS.—The Secretary may award grants to or enter into contracts with eligible entities to-
- "(1) expand the enrollment of individuals in allied health education programs, especially the enrollment of underrepresented racial and ethnic minority students; and
- "(2) provide education through new technologies and methods, including distancelearning methodologies.
- "(b) PRACTICE PRIORITY AREAS.—The Secretary may award grants to or enter into contracts with eligible entities to-
- "(1) establish or expand allied health practice arrangements in noninstitutional settings to demonstrate methods to improve access to primary health care in rural areas and other medically underserved communities:
- "(2) provide care for underserved populations and other high-risk groups such as the elderly, individuals with HIV/AIDS, substance abusers, the homeless, and victims of domestic violence;
- "(3) provide managed care, information management, quality improvement, and other skills needed to practice in existing and emerging organized health care systems;
- "(4) develop generational and cultural competencies among allied health professionals.
  - (c) Retention Priority Areas.-
- "(1) IN GENERAL.—The Secretary may award grants to and enter into contracts with eligible entities to enhance the allied health professions workforce by initiating and maintaining allied health retention programs described in paragraph (2) or (3).
- "(2) Grants for career ladder pro-GRAMS.—The Secretary may award grants to and enter into contracts with eligible entities for programs-
- "(A) to promote career advancement for allied health personnel in a variety of training settings, cross training or specialty training among diverse population groups, and the advancement of individuals; and
- "(B) to assist individuals in obtaining the education and training required to enter the allied health professions and advance within such professions, such as by providing career counseling and mentoring.
- "(3) ENHANCING PATIENT CARE DELIVERY SYSTEMS.
- "(A) GRANTS.—The Secretary may award grants to eligible entities to improve the retention of allied health professionals and to enhance patient care that is directly related to allied health activities by enhancing collaboration and communication among allied health professionals and other health care professionals, and by promoting allied health involvement in the organizational and clinical decision-making processes of a health care facility.
- "(B) PREFERENCE.—In making awards of grants under this paragraph, the Secretary shall give preferences to applicants that have not previously received an award under this paragraph and to applicants from rural, underserved areas.
- "(C) CONTINUATION OF AN AWARD.—The Secretary shall make continuation of any award under this paragraph beyond the second year of such award contingent on the recipient of such award having demonstrated to the Secretary measurable and substantive improvement in allied health personnel retention or patient care.
- "(d) ELIGIBLE ENTITY.—To be eligible to receive a grant under this section, an entity shall-
- "(1) be a health care facility, or any partnership or coalition containing a health care

facility or allied health education program; and

"(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

## "SEC. 799C-6. DEVELOPING MODELS AND BEST PRACTICES PROGRAM.

"(a) AUTHORIZED.—The Secretary shall award grants to eligible entities to enable such entities to carry out demonstration programs using models and best practices in allied health for the purpose of developing innovative strategies or approaches for the retention of allied health professionals.

"(b) ELIGIBLE ENTITY.—To be eligible to receive a grant under this section, an entity shall—

"(1) be a health care facility, or any partnership or coalition containing a health care facility or allied health education program; and

"(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

"(c) DISTRIBUTION OF GRANTS.—In awarding grants under this section, the Secretary shall ensure that grantees represent a variety of geographic regions and a range of different types and sizes of facilities, including facilities located in rural, urban, and suburban areas.

"(d) USE OF FUNDS.—An entity shall use amounts received under a grant under this section to carry out demonstration programs of models and best practices in allied health for the purpose of—

"(1) promoting retention and satisfaction of allied health professionals;

"(2) promoting opportunities for allied health professionals to pursue education, career advancement, and organizational recognition; and

"(3) developing continuing education programs that instruct allied health professionals in how to use emerging medical technologies and how to address current and future health care needs

"(e) AREA HEALTH EDUCATION CENTERS.— The Secretary shall award grants to area health education centers to enable such centers to enter into contracts with allied health education programs to expand the operation of area health education centers to work in communities to develop models of excellence for allied health professionals or to expand any junior and senior high school mentoring programs to include an allied health professions mentoring program.

#### "SEC. 799C-7. ALLIED HEALTH FACULTY LOAN PROGRAM.

"(a) ESTABLISHMENT.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may enter into an agreement with any institution offering an eligible allied health education program for the establishment and operation of a faculty loan fund in accordance with this section (referred to in this section as the 'loan fund'), to increase the number of qualified allied health faculty.

"(b) AGREEMENTS.—Each agreement entered into under this section shall—

"(1) provide for the establishment of a loan fund by the institution offering the allied health education program involved;

"(2) provide for deposit in the loan fund of—

"(A) the Federal capital contributions to the fund;

"(B) an amount provided by the institution involved which shall be equal to not less than one-ninth of the amount of the Federal capital contribution under subparagraph (A);

"(C) any collections of principal and interest on loans made from the fund; and

"(D) any other earnings of the fund;

"(3) provide that the loan fund will be used only for the provision of loans to faculty of the allied health education program in accordance with subsection (c) and for the costs of the collection of such loans and the interest thereon;

"(4) provide that loans may be made from such fund only to faculty who are pursuing a full-time course of study or, at the discretion of the Secretary, a part-time course of study in an advanced degree program; and

"(5) contain such other provisions determined appropriate by the Secretary to protect the financial interests of the United States.

"(c) LOAN PROVISIONS.—Loans from any faculty loan fund established pursuant to an agreement under this section shall be made to an individual on such terms and conditions as the allied health education program may determine, except that—

"(1) such terms and conditions are subject to any conditions, limitations, and requirements prescribed by the Secretary;

"(2) in the case of any individual, the total of the loans for any academic year made by an allied health education program from loan funds established pursuant to agreements under this section may not exceed \$30,000, plus any amount determined by the Secretary on an annual basis to reflect inflation;

"(3) upon completion by the individual of each of the first, second, and third year of full-time employment, as required under the loan agreement, as a faculty member in an allied health education program, the program shall cancel 20 percent of the principal and interest due on the amount of the unpaid portion of the loan on the first day of such employment;

"(4) upon completion by the individual of the fourth year of full-time employment, as required under the loan agreement, as a faculty member in an allied health education program, the program shall cancel 25 percent of the principal and interest due on the amount of the unpaid portion of the loan on the first day of such employment;

"(5) the loan may be used to pay the cost of tuition, fees, books, laboratory expenses, and other reasonable education expenses;

"(6) the loan shall be repayable in equal or graduated periodic installments (with the right of the borrower to accelerate repayment) over the 10-year period that begins 9 months after the individual ceases to pursue a course of study in an allied health education program; and

"(7) such loan shall—

"(A) beginning on the date that is 3 months after the individual ceases to pursue a course of study in an allied health education program, bear interest on the unpaid balance of the loan at the rate of 3 percent per year; or

"(B) subject to subsection (e), if the allied health education program determines that the individual will not complete such course of study or serve as a faculty member as required under the loan agreement under this subsection, bear interest on the unpaid balance of the loan at the prevailing market rate.

"(d) PAYMENT OF PROPORTIONATE SHARE.— Where all or any part of a loan (including interest thereon) is canceled under this section, the Secretary shall pay to the allied health education program involved an amount equal to the program's proportionate share of the canceled portion, as determined by the Secretary.

"(e) REVIEW BY SECRETARY.—At the request of the individual involved, the Secretary may review any determination by an allied health education program under this section.

#### "SEC. 799C-8. SCHOLARSHIP PROGRAM FOR SERVICE IN RURAL AND OTHER MEDICALLY UNDERSERVED AREAS.

"(a) Program Authorized.—The Secretary shall establish a scholarship program (referred to in this section as the 'program') to provide scholarships to individuals seeking allied health education who agree to provide service in rural and other medically underserved areas with allied health personnel shortages.

"(b) Preference.—In awarding scholarships under this section, the Secretary shall give preference to—

"(1) applicants who demonstrate the greatest financial need:

"(2) applicants who agree to serve in health care facilities experiencing allied health shortages in rural and other medically underserved areas;

"(3) applicants who are currently working in a health care facility who agree to serve the period of obligated service at such facility:

"(4) minority applicants; and

"(5) applicants with an interest in a practice area of allied health that has unmet needs.

"(c) Program Requirements.—

"(1) CONTRACTS.—Under the program, the Secretary shall enter into contracts with eligible individuals under which such individuals agree to serve as allied health professionals for a period of not less than 2 years at a health care facility with a critical shortage of allied health professionals in consideration of the Federal Government agreeing to provide to the individuals scholarships for attendance in an allied health education program.

"(2) ELIGIBLE INDIVIDUALS.—In this subsection, the term 'eligible individual' means an individual who is enrolled or accepted for enrollment as a full-time or part-time student in an allied health education program.

"(3) SERVICE REQUIREMENT.-

"(A) IN GENERAL.—The Secretary may not enter into a contract with an eligible individual under this section unless the individual agrees to serve as an allied health professional at a health care facility with a critical shortage of allied health professionals for a period of full-time service of not less than 2 years, or for a period of part-time service in accordance with subparagraph (B).

"(B) PART-TIME SERVICE.—An individual may complete the period of service described in subparagraph (A) on a part-time basis if the individual has a written agreement that—

"(i) is entered into by the facility and the individual and is approved by the Secretary;

"(ii) provides that the period of obligated service will be extended so that the aggregate amount of service performed will equal the amount of service that would be performed through a period of full-time service of not less than 2 years.

"(d) REPORTS.—Not later than 18 months after the date of enactment of this part, and annually thereafter, the Secretary shall prepare and submit to the appropriate committees of Congress a report describing the program carried out under this section, including statements regarding—

"(1) the number of enrollees by specialty or discipline, scholarships, and grant recipients:

"(2) the number of graduates;

"(3) the amount of scholarship payments made;

"(4) which educational institution the recipients attended;

"(5) the number and placement location of the scholarship recipients at health care facilities with a critical shortage of allied health professionals;

- "(6) the default rate and actions required; "(7) the amount of outstanding default funds of the scholarship program;
- "(8) to the extent that it can be determined, the reason for the default;
- "(9) the demographics of the individuals participating in the scholarship program; and
- "(10) an evaluation of the overall costs and benefits of the program.

#### "SEC. 799C-9. GRANTS FOR CLINICAL EDU-CATION, INTERNSHIP, AND RESI-DENCY PROGRAMS.

"(a) PROGRAM AUTHORIZED.—The Secretary shall award grants to eligible entities to develop clinical education, internship, and residency programs that encourage mentoring and the development of specialties.

"(b) ELIGIBLE ENTITIES.—To be eligible for a grant under this section an entity shall—

- "(1) be a partnership of an allied health education program and a health care facility; and
- "(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.
- "(c) USE OF FUNDS.—An eligible entity shall use amounts received under a grant under this section to—
- "(1) develop clinical education, internship, and residency programs and curriculum and training programs for graduates of an allied health education program:
- "(2) provide support for faculty and mentors; and
- "(3) provide support for allied health professionals participating in clinical education, internship, and residency programs on both a full-time and part-time basis.

### "SEC. 799C-10. GRANTS FOR PARTNERSHIPS.

- "(a) IN GENERAL.—The Secretary shall award grants to eligible entities to enable such entities to form partnerships to carry out the activities described in this section.
- "(b) ELIGIBLE ENTITY.—To be eligible to receive a grant under this section, and entity shall—
- $\lq\lq(1)$  be a partnership between an allied health education program and a health care facility; and
- "(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.
- "(c) USE of FUNDS.—An eligible entity shall use amounts received under a grant under this section to—
- "(1) provide employees of the health care facility that is a member of the partnership involved advanced training and education in a allied health education program;
- "(2) establish or expand allied health practice arrangements in non-institutional settings to demonstrate methods to improve access to health care in rural and other medically underserved communities:
- "(3) purchase distance learning technology to extend general education and training programs to rural areas, and to extend specialty education and training programs to all areas; and
- "(4) establish or expand mentoring, clinical education, and internship programs for training in specialty care areas.

#### "SEC. 799C-11. ALLIED HEALTH PROFESSIONS TRAINING FOR DIVERSITY.

"The Secretary, acting in conjunction with allied health professional associations, shall develop a system for collecting and analyzing allied health workforce data gathered by the Bureau of Labor Statistics, the Health Resources and Services Administration, other entities within the Department of Health and Human Services, the Department of Veterans Affairs, the Centers for Medicare & Medicaid Services, the Department of De-

fense, allied health professional associations, and regional centers for health workforce studies to determine educational pipeline and practitioner shortages, and project future needs for such a workforce.

## "SEC. 799C-12. ALLIED HEALTH PROFESSIONS TRAINING FOR DIVERSITY.

"The Secretary shall include schools of allied health among the health professions schools that are eligible to receive grants under this part for the purpose of assisting such schools in supporting Centers of Excellence in health professions education for under-represented minority individuals.

## "SEC. 799C-13. REPORTS BY GENERAL ACCOUNTING OFFICE.

"Not later than 4 years after the date of enactment of this part, the Comptroller General of the United States shall conduct an evaluation of whether the programs carried out under this part have demonstrably increased the number of applicants to allied health education programs and prepare and submit to the appropriate committees of Congress a report concerning the results of such evaluation.

## "SEC. 799C-14. AUTHORIZATION OF APPROPRIATIONS.

"There is authorized to be appropriated to carry out this part, such sums as may be necessary for each of fiscal years 2008 through 2013.".

By Mr. DORGAN (for himself, Mr. BAYH, Mr. BINGAMAN, Mrs. BOXER, Mr. BROWN, Mrs. CLINTON, Mr. CONRAD, Mr. DURBIN, Mr. FEINGOLD, Mrs. FEINSTEIN, Mr. HARKIN, Mr. KENNEDY, Mr. KERRY, Ms. LANDRIEU, Mr. LAUTENBERG, Mr. LEAHY, Mr. MENENDEZ, Ms. MIKULSKI, Mr. NELSON of Florida, Mr. OBAMA, Mr. PRYOR, Mr. REID, and Mr. WYDEN):

S. 606. A bill to improve Federal contracting and procurement by eliminating fraud and abuse and improving competition in contracting and procurement and by enhancing administration of Federal contracting personnel, and for other purposes; to the Committee on Homeland Security and Governmental Affairs.

Mr. LEAHY. I am proud to cosponsor this bill, which will create new and better tools to combat fraud, waste, and abuse in government contracting. I commend our chief sponsor, Senator BYRON DORGAN, for his leadership on this.

Waste, fraud, and abuse in the name of defense is destructive and offensive, and it should never be tolerated. It saps critical resources needed by our troops, and it plays the taxpayers for fools, all the while hiding under the cover of national defense.

Within the last few weeks, the Special Inspector General for Iraq Reconstruction has reported that the problems of waste, fraud, and abuse continue to plague our reconstruction efforts in Iraq, and billions of dollars are unaccounted for, and possibly lost, to fraud and waste. So far, the Inspector General has initiated more than 100 investigations into this fraud and abuse, but to date the Department of Justice has prosecuted just a few individuals for wrongdoing. The Department has

yet to prosecute any of the contracting companies or their senior officials for fraud

This legislative reform package establishes new criminal penalties for war profiteers and cheats who, for illgotten gain, would exploit the chaos of war. I recently introduced the War Profiteering Prevention Act of 2007, and I am pleased that Senator DORGAN has included this legislation in the Honest Leadership and Accountability in Contracting Act.

This legislation also promotes openness and fairness in contracting, and it includes safeguards to end cronyism and eliminate conflicts of interest in contracting decisions. It also strengthens the Federal protections afforded to whistleblowers who alert the public to contract fraud and misconduct.

We have introduced antiwar profiteering legislation in the past, but the Republican-led Congress has repeatedly refused to pass it. While Congress has waited to act, we have learned that private contractors have stolen and defrauded, by some estimates, hundreds of millions of dollars from money that should have supported our troops in Iraq and Afghanistan. The time to stop these shameful acts is now, and Congress should act swiftly to enact this vital legislation.

I will continue my efforts on this issue as chairman of the Judiciary Committee. In particular, I plan to hold a hearing next month on the war profiteering bill.

Every penny of our taxpayers' money must be protected from waste, and Federal contracts—which are paid for with taxpayer funds—should be open and transparent. This is an accountability bill, and taxpayers deserve this to be one of our highest priorities.

By Mrs. FEINSTEIN (for herself, Mr. Cornyn, Mrs. Boxer, Mrs. HUTCHISON, Mr. LAUTENBERG, Mr. SCHUMER, Mrs. CLINTON, Mr. MENENDEZ, and Mr. OBAMA):

S. 608. A bill to improve the allocation of grants through the Department of Homeland Security, and for other purposes; to the Committee on Homeland Security and Governmental Affairs.

Mrs. FEINSTEIN. Mr. President, I rise today to introduce legislation that ensures our Nation's homeland security grant resources are allocated in the most effective manner possible. I am pleased to be joined by my colleague from Texas, Senator John Cornyn, as well as Senators Boxer, Hutchison, Lautenberg, Schumer, Clinton, Menendez, and Obama.

Simply put, the current system for allocating homeland security grants to States is fundamentally flawed. Proportionate funding is not allotted to regions which face the highest risk of a terrorist attack, and adequate assessment of threats is not calculated.

The "Risk-Based Homeland Security Grants Act of 2007" addresses these concerns with a common-sense approach that responsibly directs tax-payer dollars to protect our Nation's vital interests.

The methodology is straightforward and spelled out in the language at the beginning of the bill:

The Secretary of Homeland Security shall ensure that homeland security grants are allocated based on an assessment of threat, vulnerability, and consequence to the maximum extent practicable.

This direction would apply to the four major first-responder grant programs administered by the Department of Homeland Security: the State Homeland Security Grant Program; the Urban Area Security Initiative; the Law Enforcement Terrorism Prevention Program; and the Citizens Corps Program.

The primary objective of the legislation is accomplished by reducing the amount of funding that each State is guaranteed. Current practice requires a "small state minimum," giving each State at least 0.75 percent of much of the grant funding.

The result is that roughly 38 percent of the funds are marked for distribution before any substantive risk analysis has been performed. That sends disproportionate money to low-risk, rural areas and territories.

For most, this outcome is not acceptable. Funding to bolster the security of our country should go to where the threat is greatest—such as seaports, airports, and national landmarks.

This bill lowers the "small state minimum" to 0.25 percent per State. A Homeland Security Grants Board, comprised of seven top Department of Homeland Security officials, including the Secretary of Homeland Security and the Undersecretary of Information Analysis and Infrastructure Protection, is established to rank grant applications based upon risk. Three factors guide this evaluation: threat, vulnerability, and consequence.

The current system, by contrast, allocates a significant amount of funding to states based upon their population.

To ensure that grant funds are properly accounted for, and utilized within an integrated framework to enhance domestic security, grants must be designed to meet "essential" capabilities.

"Essential capabilities" refers to the ability of regions to address risks by reducing vulnerability to attacks and diminishing the consequences of such attacks by effective response.

This legislation assures that States must demonstrate that they have a detailed, prioritized plan for emergency preparedness and resource allocation, so that Federal funds are assigned to the most effective uses.

States must then quickly distribute the Federal funds to regions and localities.

The notion of risk-based allocation of homeland security grants is not novel. This is a bipartisan approach advocated by both the Bush Administration and the 9/11 Commission.

The 9/11 Commission report said: "Homeland security assistance should be based strictly on an assessment of risks and vulnerabilities."

Four years ago, President Bush signed Homeland Security Presidential Directive 8, which required the Department of Homeland Security to allocate grant funding "based on national priorities."

In April 2005, Representatives Cox and TURNER, the Chair and Ranking Member of the House Homeland Security Committee at the time, offered similar legislation to reform the grant process by reducing State minimums and allocating funds based upon risk assessments.

That effort, the "Faster and Smarter Funding for First Responders Act of 2005," passed the House of Representatives as part of the Intelligence Reform bill, but was dropped in conference. This bill is based on the House efforts, and closely tracks the previous bill.

Again, the House has acted, passing legislation last month, by an overwhelming vote of 299–128, to implement the recommendations of the 9/11 Committee. A key component is the risk-based allocation of homeland security resources.

This bill, though updated to reflect recent changes at the Department of Homeland Security, marks the continuation of a legislation effort we began last session, with the FORWARD Funding Act. That bill was unsuccessful. Hopefully, this time will be different.

In the post-Cold War world, America needs the flexibility to defend against a different type of enemy. The amorphous nature of the threat and likelihood of asymmetric attacks demands a robust approach.

But our resources are limited, and difficult choices must be made.

We will never know exactly how, when or where the next major attack may occur. But we can refine our risk-assessment capabilities, and make objective analyses and predictions. It follows that our resources should be directed based upon our best estimate of where the next strike might take place.

Two guiding principles—the ability to predict future attacks, coupled with the necessity of utilizing finite resources effectively—form the backbone of a comprehensive strategy to make our Nation more secure.

The approach is three-pronged: risks of potential terrorist attacks must be accurately assessed; the vulnerability of critical infrastructure and potential targets must be measured; and, resources should be dispersed based upon these assessments.

The Department of Homeland Security was created to accomplish these goals. Yet we find again and again that scarce resources are allocated based on factors unrelated to real security.

For example, last year California's Urban Area Security Initiative grants totaled only \$6.81 per capita. Hawaii received \$11.55 per capita, and Wyoming, \$18.06 per capita.

I recognize the environment in which we are operating, and understand this bill is not a panacea. This bill is a first step towards reducing the threat of terrorist attacks.

Congress should not act alone. The Department of Homeland Security must embrace the concept of risk-based allocation of resources. And it must act on these principles. Slow progress has been made, but the Department's intelligence analysis and vulnerability assessment capabilities must be improved.

We can do better. We must put aside pork-barrel politics and take action to protect all Americans. The security of our Nation hangs in the balance and we cannot afford to wait until it is too late.

This bill was conceived and put forth in the spirit of bipartisanship. I hope that Senators Lieberman and Collins will accept this legislation, which is a reasoned alternative to their approach and a starting point for continued discussion.

I ask my colleagues to join me in supporting this simple, straightforward approach to effectively distribute our Nation's resources and make America secure.

I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

### S. 608

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

### SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Risk-Based Homeland Security Grants Act of 2007".

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

Sec. 1. Short title; table of contents.

Sec. 2. Risk-based funding for homeland security.

Sec. 3. Essential capabilities, task forces, and standards.

Sec. 4. Effective administration of homeland security grants.

Sec. 5. Implementation and definitions.

## SEC. 2. RISK-BASED FUNDING FOR HOMELAND SECURITY.

(a) RISK-BASED FUNDING IN GENERAL.—The Homeland Security Act of 2002 (Public Law 107–296; 6 U.S.C. 361 et seq.) is amended by adding at the end the following:

## "TITLE XX—RISK-BASED FUNDING FOR HOMELAND SECURITY

### "SEC. 2001. RISK-BASED FUNDING FOR HOME-LAND SECURITY.

"(a) RISK-BASED FUNDING.—The Secretary shall ensure that homeland security grants are allocated based on an assessment of threat, vulnerability, and consequence to the maximum extent practicable.

"(b) Covered Grants.—This title applies to grants provided by the Department to States, regions, or directly eligible tribes for the primary purpose of improving the ability of first responders to prevent, prepare for, respond to, or mitigate threatened or actual terrorist attacks, especially those involving weapons of mass destruction, and grants provided by the Department for improving homeland security, including the following:

- "(1) STATE HOMELAND SECURITY GRANT PROGRAM.—The State Homeland Security Grant Program of the Department, or any successor to such grant program.
- "(2) URBAN AREA SECURITY INITIATIVE.—The Urban Area Security Initiative of the Department, or any successor to such grant program.
- "(3) LAW ENFORCEMENT TERRORISM PREVEN-TION PROGRAM.—The Law Enforcement Terrorism Prevention Program of the Department, or any successor to such grant program.
- "(4) CITIZEN CORPS PROGRAM.—The Citizen Corps Program of the Department, or any successor to such grant program.
- "(c) EXCLUDED PROGRAMS.—This title does not apply to or otherwise affect the following Federal grant programs or any grant under such a program:
- "(1) NONDEPARTMENT PROGRAMS.—Any Federal grant program that is not administered by the Department.
- "(2) FIRE GRANT PROGRAMS.—The fire grant programs authorized by sections 33 and 34 of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2229, 2229a).
- "(3) EMERGENCY MANAGEMENT PLANNING AND ASSISTANCE ACCOUNT GRANTS.—The Emergency Management Performance Grant program and the Urban Search and Rescue Grants program authorized by title VI of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5195 et seq.), the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 2000 (113 Stat. 1047 et seq.), and the Earthquake Hazards Reduction Act of 1977 (42 U.S.C. 7701 et seq.).
- "(d) EFFECT ON COVERED GRANTS.—Nothing in this Act shall be construed to require the elimination of a covered grant program.".
- (b) COVERED GRANT ELIGIBILITY AND CRITERIA.—The Homeland Security Act of 2002 (Public Law 107–296; 6 U.S.C. 361 et seq.), as amended by subsection (a), is amended by adding at the end the following:

## "SEC. 2002. COVERED GRANT ELIGIBILITY AND CRITERIA.

- "(a) GRANT ELIGIBILITY.—
- "(1) IN GENERAL.—
- "(A) GENERAL ELIGIBILITY.—Except as provided in subparagraphs (B) and (C), any State, region, or directly eligible tribe shall be eligible to apply for a covered grant.
- "(B) URBAN AREA SECURITY INITIATIVE.— Only a region shall be eligible to apply for a grant under the Urban Area Security Initiative of the Department, or any successor to such grant program.
- "(C) STATE HOMELAND SECURITY GRANT PROGRAM.—Only a State shall be eligible to apply for a grant under the State Homeland Security Grant Program of the Department, or any successor to such grant program.
- "(2) OTHER GRANT APPLICANTS.—
- "(A) IN GENERAL.—Grants provided by the Department for improving homeland security, including to seaports, airports, and other transportation facilities, shall be allocated as described in section 2001(a).
- "(B) CONSIDERATION.—Such grants shall be considered, to the extent determined appropriate by the Secretary, pursuant to the procedures and criteria established in this title, except that the eligibility requirements of paragraph (1) shall not apply.
  - "(3) CERTIFICATION OF REGIONS.—
- "(A) IN GENERAL.—The Secretary shall certify a geographic area as a region if—
- "(i) the geographic area meets the criteria under section 2007(10)(B) and (C); and
- "(ii) the Secretary determines, based on an assessment of threat, vulnerability, and consequence, that certifying the geographic area as a region under this title is in the interest of national homeland security.

- "(B) EXISTING URBAN AREA SECURITY INITIA-AREAS.—Notwithstanding TIVE subparagraphs (B) and (C) of section 2007(10), a geographic area that, on or before the date of enactment of the Risk-Based Homeland Security Grants Act of 2007, was designated as a high-threat urban area for purposes of the Urban Area Security Initiative, shall be certified by the Secretary as a region unless the Secretary determines, based on an assessment of threat, vulnerability, and consequence, that certifying the geographic area as a region is not in the interest of national homeland security.
- "(b) Grant Criteria.—In awarding covered grants, the Secretary shall assist States, local governments, and operators of airports, ports, or similar facilities in achieving, maintaining, and enhancing the essential capabilities established by the Secretary under section 2003.
  - "(c) STATE HOMELAND SECURITY PLANS.-
- "(1) SUBMISSION OF PLANS.—The Secretary shall require that any State applying to the Secretary for a covered grant shall submit to the Secretary a 3-year State homeland security plan that—
- "(A) demonstrates the extent to which the State has achieved the essential capabilities that apply to the State;
- "(B) demonstrates the needs of the State necessary to achieve, maintain, or enhance the essential capabilities that apply to the State;
- "(C) includes a prioritization of such needs based on threat, vulnerability, and consequence assessment factors applicable to the State:
  - "(D) describes how the State intends—
- "(i) to address such needs at the city, county, regional, tribal, State, and interstate level, including a precise description of any regional structure the State has established for the purpose of organizing homeland security preparedness activities funded by covered grants;
- "(ii) to use all Federal, State, and local resources available for the purpose of addressing such needs; and
- "(iii) to give particular emphasis to regional planning and cooperation, including the activities of multijurisdictional planning agencies governed by local officials, both within its jurisdictional borders and with neighboring States;
- "(E) is developed in consultation with and subject to appropriate comment by local governments within the State; and
- "(F) with respect to the emergency preparedness of first responders, addresses the unique aspects of terrorism as part of a comprehensive State emergency management plan.
- "(2) APPROVAL BY SECRETARY.—The Secretary may not award any covered grant to a State unless the Secretary has approved the applicable State homeland security plan.
- "(d) Consistency With State Plans.—The Secretary shall ensure that each covered grant is used to supplement and support, in a consistent and coordinated manner, the applicable State homeland security plan or
- "(e) APPLICATION FOR GRANT.—
- "(1) IN GENERAL.—Except as otherwise provided in this subsection, any State, region, directly eligible tribe, or operator of an airport, port, or similar facility may apply for a covered grant by submitting to the Secretary an application at such time, in such manner, and containing such information as is required under this subsection, or as the Secretary may reasonably require.
- "(2) DEADLINES FOR APPLICATIONS AND AWARDS.—All applications for covered grants shall be submitted at such time as the Secretary may reasonably require for the fiscal year for which they are submitted. The Sec-

- retary shall award covered grants pursuant to all approved applications for such fiscal year as soon as practicable, but not later than March 1 of such year.
- "(3) AVAILABILITY OF FUNDS.—All funds awarded by the Secretary under covered grants in a fiscal year shall be available for obligation through the end of the second subsequent fiscal year.
- "(4) MINIMUM CONTENTS OF APPLICATION.— The Secretary shall require that each applicant include in its application, at a minimum—
- "(A) the purpose for which the applicant seeks covered grant funds and the reasons why the applicant needs the covered grant to meet the essential capabilities for terrorism preparedness within the State, region, or directly eligible tribe or at the airport, port, or similar facility to which the application pertains;
- "(B) a description of how, by reference to the applicable State homeland security plan or plans under subsection (c), the allocation of grant funding proposed in the application, including, where applicable, the amount not passed through under section 2006(g)(1), would assist in fulfilling the essential capabilities specified in such plan or plans:
- "(C) a statement of whether a mutual aid agreement applies to the use of all or any portion of the covered grant funds:
- "(D) if the applicant is a State, a description of how the State plans to allocate the covered grant funds to regions, local governments, and Indian tribes;
  - "(E) if the applicant is a region-
- "(i) a precise geographical description of the region and a specification of all participating and nonparticipating local governments within the geographical area comprising that region;
- "(ii) a specification of what governmental entity within the region will administer the expenditure of funds under the covered grant;
- "(iii) a designation of a specific individual to serve as regional liaison; and
- "(iv) a description of how the governmental entity administering the expenditure of funds under the covered grant plans to allocate the covered grant funds to States, local governments, and Indian tribes:
- "(F) a capital budget showing how the applicant intends to allocate and expend the covered grant funds; and
- "(G) if the applicant is a directly eligible tribe, a designation of a specific individual to serve as the tribal liaison.
  - "(5) REGIONAL APPLICATIONS.—
- "(A) RELATIONSHIP TO STATE APPLICATIONS.—A regional application—
- "(i) shall be coordinated with an application submitted by the State or States of which such region is a part:
- "(ii) shall supplement and avoid duplication with such State application; and
- "(iii) shall address the unique regional aspects of such region's terrorism preparedness needs beyond those provided for in the application of such State or States.
- "(B) STATE REVIEW AND SUBMISSION.—To ensure the consistency required under subsection (d) and the coordination required under subparagraph (A) of this paragraph, an applicant that is a region shall submit its application to each State of which any part is included in the region for review and concurrence before the submission of such application to the Secretary. The regional application shall be transmitted to the Secretary through each such State within 30 days after receipt of the application by that State, unless the Governor of such a State notifies the Secretary, in writing, that such regional application is inconsistent with the State's homeland security plan and provides an explanation of the reasons therefor.

"(C) DISTRIBUTION OF REGIONAL AWARDS.—If the Secretary approves a regional application, then the Secretary shall distribute a regional award to the State or States submitting the applicable regional application under subparagraph (B), and each such State shall, not later than the end of the 45-day period beginning on the date after receiving a regional award, pass through to the region all covered grant funds or resources purchased with such funds, except those funds necessary for the State to carry out its responsibilities with respect to such regional application; Provided That, in no such case shall the State or States pass through to the region less than 80 percent of the regional award.

"(D) CERTIFICATIONS REGARDING DISTRIBUTION OF GRANT FUNDS TO REGIONS.—Any State that receives a regional award under subparagraph (C) shall certify to the Secretary, by not later than 30 days after the expiration of the period described in subparagraph (C) with respect to the grant, that the State has made available to the region the required funds and resources in accordance with subparagraph (C).

"(E) DIRECT PAYMENTS TO REGIONS.—If any State fails to pass through a regional award to a region as required by subparagraph (C) within 45 days after receiving such award and does not request or receive an extension of such period under section 2006(h)(2), the region may petition the Secretary to receive directly the portion of the regional award that is required to be passed through to such region under subparagraph (C).

''(F) REGIONAL LIAISONS.—A regional liaison designated under paragraph (4)(E)(iii) shall—

"(i) coordinate with Federal, State, local, regional, and private officials within the region concerning terrorism preparedness:

"(ii) develop a process for receiving input from Federal, State, local, regional, and private sector officials within the region to assist in the development of the regional application and to improve the region's access to covered grants; and

"(iii) administer, in consultation with State, local, regional, and private officials within the region, covered grants awarded to the region.

"(6) Tribal applications.—

"(A) SUBMISSION TO THE STATE OR STATES.— To ensure the consistency required under subsection (d), an applicant that is a directly eligible tribe shall submit its application to each State within the boundaries of which any part of such tribe is located for direct submission to the Department along with the application of such State or States.

"(B) OPPORTUNITY FOR STATE COMMENT.—
Before awarding any covered grant to a directly eligible tribe, the Secretary shall provide an opportunity to each State within the boundaries of which any part of such tribe is located to comment to the Secretary on the consistency of the tribe's application with the State's homeland security plan. Any such comments shall be submitted to the Secretary concurrently with the submission of the State and tribal applications.

"(C) FINAL AUTHORITY.—The Secretary shall have final authority to determine the consistency of any application of a directly eligible tribe with the applicable State homeland security plan or plans, and to approve any application of such tribe. The Secretary shall notify each State within the boundaries of which any part of such tribe is located of the approval of an application by such tribe.

"(D) TRIBAL LIAISON.—A tribal liaison designated under paragraph (4)(G) shall—

"(i) coordinate with Federal, State, and private sector officials to assist in the development of the application of such tribe and to improve the tribe's access to covered grants; and  $% \left( 1\right) =\left( 1\right) \left( 1\right)$ 

"(ii) administer, in consultation with State, local, regional, and private officials, covered grants awarded to such tribe.

"(E) LIMITATION ON THE NUMBER OF DIRECT GRANTS.—The Secretary may make covered grants directly to not more than 20 directly eligible tribes per fiscal year.

"(F) TRIBES NOT RECEIVING DIRECT GRANTS.—An Indian tribe that does not receive a grant directly under this section is eligible to receive funds under a covered grant from the State or States within the boundaries of which any part of such tribe is located, consistent with the homeland security plan of the State as described in subsection (c). If a State fails to comply with section 2006(g)(1), the tribe may request payment under section 2006(h)(3) in the same manner as a local government.

"'(7) EQUIPMENT STANDARDS.—If an applicant for a covered grant proposes to upgrade or purchase, with assistance provided under the grant, new equipment or systems that do not meet or exceed any applicable national voluntary consensus standards established by the Secretary under section 2005(a), the applicant shall include in the application an explanation of why such equipment or systems will serve the needs of the applicant better than equipment or systems that meet or exceed such standards.

"(f) HOMELAND SECURITY GRANTS BOARD.—
"(1) ESTABLISHMENT OF BOARD.—The Secretary shall establish a Homeland Security
Grants Board. consisting of—

"(A) the Secretary:

"(B) the Deputy Secretary of Homeland Security:

"(C) the Under Secretary for Emergency Preparedness and Response;

"(D) the Under Secretary for Border and Transportation Security;

"(E) the Under Secretary for Information Analysis and Infrastructure Protection;

"(F) the Under Secretary for Science and Technology; and

"(G) the Director of the Office of State and Local Government Coordination.

"(2) CHAIRMAN.—

"(A) IN GENERAL.—The Secretary shall be the Chairman of the Board.

"(B) EXERCISE OF AUTHORITIES BY DEPUTY SECRETARY.—The Deputy Secretary of Homeland Security may exercise the authorities of the Chairman, if the Secretary so directs.

``(3) RISK-BASED RANKING OF GRANT APPLICATIONS.—

 $\begin{tabular}{ll} ``(A) & PRIORITIZATION & OF & GRANTS.—The Board— \end{tabular}$ 

"(i) shall evaluate and annually prioritize all pending applications for covered grants based upon the degree to which they would, by achieving, maintaining, or enhancing the essential capabilities of the applicants on a nationwide basis, lessen the threat to, vulnerability of, and consequences for persons and critical infrastructure: and

"(ii) in evaluating the threat to persons and critical infrastructure for purposes of prioritizing covered grants, shall give greater weight to threats of terrorism based on their specificity and credibility, including any pattern of repetition.

"(B) MINIMUM AMOUNTS.—

"(i) IN GENERAL.—After evaluating and prioritizing grant applications under subparagraph (A), the Board shall ensure that, for each fiscal year, each State that has an approved State homeland security plan receives no less than 0.25 percent of the funds available for the State Homeland Security Grant Program, as described in section 2001(b)(1), for that fiscal year for purposes of implementing its homeland security plan in accordance with the prioritization of additional needs under subsection (c)(1)(C).

"(ii) OTHER ENTITIES.—Notwithstanding clause (i), the Board shall ensure that, for each fiscal year, American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, and the Virgin Islands each receive 0.08 percent of the funds available for the State Homeland Security Grant Program, as described in section 2001(b)(1), for that fiscal year for purposes of implementing its homeland security plan in accordance with the prioritization of additional needs under subsection (c)(1)(C).

"(4) FUNCTIONS OF UNDER SECRETARIES.— The Under Secretaries referred to in paragraph (1) shall seek to ensure that the relevant expertise and input of the staff of their directorates are available to and considered by the Board."

#### SEC. 3. ESSENTIAL CAPABILITIES, TASK FORCES, AND STANDARDS.

The Homeland Security Act of 2002 (Public Law 107-296; 6 U.S.C. 361 et seq.), as amended by section 2, is amended by adding at the end the following:

#### "SEC. 2003. ESSENTIAL CAPABILITIES FOR HOME-LAND SECURITY.

''(a) ESTABLISHMENT OF ESSENTIAL CAPABILITIES.—

"(1) IN GENERAL.—For purposes of covered grants, the Secretary shall establish clearly defined essential capabilities for State and local government preparedness for terrorism, in consultation with—

"(A) the Task Force on Essential Capabilities established under section 2004;

"(B) the Under Secretaries for Emergency Preparedness and Response, Border and Transportation Security, Information Analysis and Infrastructure Protection, and Science and Technology, and the Director of the Office of State and Local Government Coordination:

"(C) the Secretary of Health and Human Services:

"(D) other appropriate Federal agencies;

"(E) State and local first responder agencies and officials; and

"(F) consensus-based standard making organizations responsible for setting standards relevant to the first responder community.

"(2) DEADLINES.—The Secretary shall—

"(A) establish essential capabilities under paragraph (1) within 30 days after receipt of the report under section 2004(b); and

"(B) regularly update such essential capabilities as necessary, but not less than every 3 years.

"(3) Provision of Essential Capabilities.—The Secretary shall ensure that a detailed description of the essential capabilities established under paragraph (1) is provided promptly to the States and to Congress. The States shall make the essential capabilities available as necessary and appropriate to local governments and operators of airports, ports, and other similar facilities within their jurisdictions.

"(b) OBJECTIVES.—The Secretary shall ensure that essential capabilities established under subsection (a)(1) meet the following objectives:

"(1) SPECIFICITY.—The determination of essential capabilities specifically shall describe the training, planning, personnel, and equipment that different types of communities in the Nation should possess, or to which they should have access, in order to meet the Department's goals for terrorism preparedness based upon—

"(A) the most current risk assessment available by the Directorate for Information Analysis and Infrastructure Protection of the threats of terrorism against the United States:

"(B) the types of threats, vulnerabilities, geography, size, and other factors that the Secretary has determined to be applicable to each different type of community; and

- "(C) the principles of regional coordination and mutual aid among State and local governments
- "(2) FLEXIBILITY.—The establishment of essential capabilities shall be sufficiently flexible to allow State and local government officials to set priorities based on particular needs, while reaching nationally determined terrorism preparedness levels within a specified time period.
- "(3) MEASURABILITY.—The establishment of essential capabilities shall be designed to enable measurement of progress toward specific terrorism preparedness goals.
- "(4) COMPREHENSIVENESS.—The determination of essential capabilities for terrorism preparedness shall be made within the context of a comprehensive State emergency management system.
- "(c) Factors To Be Considered .-
- "(1) IN GENERAL.—In establishing essential capabilities under subsection (a)(1), the Secretary specifically shall consider the variables of threat, vulnerability, and consequences with respect to the Nation's population (including transient commuting and tourist populations) and critical infrastructure. Such consideration shall be based upon the most current risk assessment available by the Directorate for Information Analysis and Infrastructure Protection of the threats of terrorism against the United States.
- "(2) CRITICAL INFRASTRUCTURE SECTORS.— The Secretary specifically shall consider threats of terrorism against the following critical infrastructure sectors in all areas of the Nation, urban and rural:
  - "(A) Agriculture.
  - "(B) Banking and finance.
  - "(C) Chemical industries.
  - "(D) The defense industrial base.
  - "(E) Emergency services.
  - "(F) Energy.
  - "(G) Food.
  - "(H) Government.
  - "(I) Postal and shipping.
  - "(J) Public health.
- ``(K) Information and telecommunications networks.
  - "(L) Transportation.
- "(M) Water.

The order in which the critical infrastructure sectors are listed in this paragraph shall not be construed as an order of priority for consideration of the importance of such sectors

- "(3) TYPES OF THREAT.—The Secretary specifically shall consider the following types of threat to the critical infrastructure sectors described in paragraph (2), and to populations in all areas of the Nation, urban and rural:
  - "(A) Biological threats.
- "(B) Nuclear threats.
- "(C) Radiological threats.
- ``(D) Incendiary threats.
- "(E) Chemical threats.
- "(F) Explosives.
- ``(G) Suicide bombers.
- "(H) Cyber threats.
- "(I) Any other threats based on proximity to specific past acts of terrorism or the known activity of any terrorist group.

The order in which the types of threat are listed in this paragraph shall not be construed as an order of priority for consideration of the importance of such threats.

"(4) CONSIDERATION OF ADDITIONAL FAC-TORS.—In establishing essential capabilities under subsection (a)(1), the Secretary shall take into account any other specific threat to a population (including a transient commuting or tourist population) or critical infrastructure sector that the Secretary has determined to exist.

## "SEC. 2004. TASK FORCE ON ESSENTIAL CAPABILITIES.

- "(a) ESTABLISHMENT.—To assist the Secretary in establishing essential capabilities under section 2003(a)(1), the Secretary shall establish an advisory body pursuant to section 871(a) not later than 60 days after the date of the enactment of this section, which shall be known as the Task Force on Essential Capabilities.
  - "(b) Report.-
- "(1) In general.—The Task Force shall submit to the Secretary, not later than 9 months after its establishment by the Secretary under subsection (a) and every 3 years thereafter, a report on its recommendations for essential capabilities for preparedness for terrorism.
  - "(2) CONTENTS.—The report shall—
- "(A) include a priority ranking of essential capabilities in order to provide guidance to the Secretary and to Congress on determining the appropriate allocation of, and funding levels for, first responder needs:
- "(B) set forth a methodology by which any State or local government will be able to determine the extent to which it possesses or has access to the essential capabilities that States and local governments having similar risks should obtain:
- "(C) describe the availability of national voluntary consensus standards, and whether there is a need for new national voluntary consensus standards, with respect to first responder training and equipment;
- "(D) include such additional matters as the Secretary may specify in order to further the terrorism preparedness capabilities of first responders: and
- "(E) include such revisions to the contents of past reports as are necessary to take into account changes in the most current risk assessment available by the Directorate for Information Analysis and Infrastructure Protection or other relevant information as determined by the Secretary.
- "(3) Consistency with federal working group.—The Task Force shall ensure that its recommendations for essential capabilities are, to the extent feasible, consistent with any preparedness goals or recommendations of the Federal working group established under section 319F(a) of the Public Health Service Act (42 U.S.C. 247d-6(a)).
- "(4) COMPREHENSIVENESS.—The Task Force shall ensure that its recommendations regarding essential capabilities for terrorism preparedness are made within the context of a comprehensive State emergency management system.
- "(5) PRIOR MEASURES.—The Task Force shall ensure that its recommendations regarding essential capabilities for terrorism preparedness take into account any capabilities that State or local officials have determined to be essential and have undertaken since September 11, 2001, to prevent or prepare for terrorist attacks.
- "(c) Membership.—
- "(1) In general.—The Task Force shall consist of 35 members appointed by the Secretary, and shall, to the extent practicable, represent a geographic and substantive cross section of governmental and nongovernmental first responder disciplines from the State and local levels, including as appropriate—
- "(A) members selected from the emergency response field, including fire service and law enforcement, hazardous materials response, emergency medical services, and emergency management personnel (including public works personnel routinely engaged in emergency response):
- "(B) health scientists, emergency and inpatient medical providers, and public health professionals, including experts in emergency health care response to chemical, bio-

- logical, radiological, and nuclear terrorism, and experts in providing mental health care during emergency response operations;
- "(C) experts from Federal, State, and local governments, and the private sector, representing standards-setting organizations, including representation from the voluntary consensus codes and standards development community, particularly those with expertise in first responder disciplines; and
- "(D) State and local officials with expertise in terrorism preparedness, subject to the condition that if any such official is an elected official representing 1 of the 2 major political parties, an equal number of elected officials shall be selected from each such party.
- "(2) COORDINATION WITH THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.—In the selection of members of the Task Force who are health professionals, including emergency medical professionals, the Secretary shall coordinate the selection with the Secretary of Health and Human Services.
- "(3) Ex officio members.—The Secretary and the Secretary of Health and Human Services shall each designate 1 or more officers of their respective Departments to serve as ex officio members of the Task Force. One of the ex officio members from the Department of Homeland Security shall be the designated officer of the Federal Government for purposes of subsection (e) of section 10 of the Federal Advisory Committee Act (5 App. ILS C)
- "(d) APPLICABILITY OF FEDERAL ADVISORY COMMITTEE ACT.—Notwithstanding section 871(a), the Federal Advisory Committee Act (5 U.S.C. App.), including subsections (a), (b), and (d) of section 10 of such Act, and section 552b(c) of title 5, United States Code, shall apply to the Task Force.

#### "SEC. 2005. NATIONAL STANDARDS FOR FIRST RE-SPONDER EQUIPMENT AND TRAIN-ING.

- "(a) EQUIPMENT STANDARDS.—
- "(1) IN GENERAL.—The Secretary, in consultation with the Under Secretaries for Emergency Preparedness and Response and Science and Technology and the Director of the Office of State and Local Government Coordination, shall, not later than 6 months after the date of enactment of this section, support the development of, promulgate, and update as necessary national voluntary consensus standards for the performance, use, and validation of first responder equipment for purposes of section 2002(e)(7). Such standards—
- "(A) shall be, to the maximum extent practicable, consistent with any existing voluntary consensus standards;
- "(B) shall take into account, as appropriate, new types of terrorism threats that may not have been contemplated when such existing standards were developed;
- "(C) shall be focused on maximizing interoperability, interchangeability, durability, flexibility, efficiency, efficacy, portability, sustainability, and safety; and
- "(D) shall cover all appropriate uses of the equipment.
- "(2) REQUIRED CATEGORIES.—In carrying out paragraph (1), the Secretary shall specifically consider the following categories of first responder equipment:
  - "(A) Thermal imaging equipment.
- "(B) Radiation detection and analysis equipment.
- $\mbox{``(C)}$  Biological detection and analysis equipment.
- "(D) Chemical detection and analysis equipment.
- ``(E) Decontamination and sterilization equipment.
- "(F) Personal protective equipment, including garments, boots, gloves, and hoods, and other protective clothing.

- "(G) Respiratory protection equipment.
- "(H) Interoperable communications, including wireless and wireline voice, video, and data networks.
- "(I) Explosive mitigation devices and explosive detection and analysis equipment.
  - "(J) Containment vessels.
  - "(K) Contaminant-resistant vehicles.
- "(L) Such other equipment for which the Secretary determines that national voluntary consensus standards would be appropriate.
- "(b) Training Standards.—
- "(1) IN GENERAL.—The Secretary, in consultation with the Under Secretaries for Emergency Preparedness and Response and Science and Technology and the Director of the Office of State and Local Government Coordination, shall support the development of, promulgate, and regularly update as necessary national voluntary consensus standards for first responder training carried out with amounts provided under covered grant programs, that will enable State and local government first responders to achieve optimal levels of terrorism preparedness as quickly as practicable. Such standards shall give priority to providing training to—
- "(A) enable first responders to prevent, prepare for, respond to, and mitigate terrorist threats, including threats from chemical, biological, nuclear, and radiological weapons and explosive devices capable of inflicting significant human casualties; and
- "(B) familiarize first responders with the proper use of equipment, including software, developed pursuant to the standards established under subsection (a).
- "(2) REQUIRED CATEGORIES.—In carrying out paragraph (1), the Secretary specifically shall include the following categories of first responder activities:
  - "(A) Regional planning.
  - "(B) Joint exercises.
- "(C) Intelligence collection, analysis, and sharing.
- "(D) Emergency notification of affected populations.
- (E) Detection of biological, nuclear, radiological, and chemical weapons of mass destruction.
- "(F) Such other activities for which the Secretary determines that national voluntary consensus training standards would be appropriate.
- "(3) CONSISTENCY.—In carrying out this subsection, the Secretary shall ensure that such training standards are consistent with the principles of emergency preparedness for all hazards.
- "(c) CONSULTATION WITH STANDARDS ORGANIZATIONS.—In establishing national voluntary consensus standards for first responder equipment and training under this section, the Secretary shall consult with relevant public and private sector groups, including—
- "(1) the National Institute of Standards and Technology;
- "(2) the National Fire Protection Association;
- "(3) the National Association of County and City Health Officials;
- "(4) the Association of State and Territorial Health Officials;
- "(5) the American National Standards Institute:
- "(6) the National Institute of Justice;
- "(7) the Inter-Agency Board for Equipment Standardization and Interoperability;
- "(8) the National Public Health Performance Standards Program;
  "(9) the National Institute for Occupa-
- "(9) the National Institute for Occupational Safety and Health;
- "(10) ASTM International;
- "(11) the International Safety Equipment Association;

- "(12) the Emergency Management Accreditation Program;
- "(13) the National Domestic Preparedness Consortium; and
- "(14) to the extent the Secretary considers appropriate, other national voluntary consensus standards development organizations, other interested Federal, State, and local agencies, and other interested persons.
- "'(d) COORDINATION WITH SECRETARY OF HHS.—In establishing any national voluntary consensus standards under this section for first responder equipment or training that involve or relate to health professionals, including emergency medical professionals, the Secretary shall coordinate activities under this section with the Secretary of Health and Human Services."

#### SEC. 4. EFFECTIVE ADMINISTRATION OF HOME-LAND SECURITY GRANTS.

(a) USE OF GRANT FUNDS AND ACCOUNT-ABILITY.—The Homeland Security Act of 2002 (Public Law 107–296; 6 U.S.C. 361 et seq.), as amended by sections 2 and 3, is amended by adding at the end the following:

#### "SEC. 2006. USE OF FUNDS AND ACCOUNTABILITY REQUIREMENTS.

- "(a) IN GENERAL.—A covered grant may be used for—
- "(1) purchasing, upgrading, or maintaining equipment, including computer software, to enhance terrorism preparedness and response:
- "(2) exercises to strengthen terrorism preparedness and response;
- "(3) training for prevention (including detection) of, preparedness for, or response to attacks involving weapons of mass destruction, including training in the use of equipment and computer software;
- "(4) developing or updating response plans; "(5) establishing or enhancing mechanisms
- for sharing terrorism threat information; "(6) systems architecture and engineering, program planning and management, strategy formulation and strategic planning, lifecycle systems design, product and technology evaluation, and prototype development for terrorism preparedness and re-
- sponse purposes; "(7) additional personnel costs resulting from—
- "(A) elevations in the threat alert level of the Homeland Security Advisory System by the Secretary, or a similar elevation in threat alert level issued by a State, region, or local government with the approval of the Secretary:
- "(B) travel to and participation in exercises and training in the use of equipment and on prevention activities:
- "(C) the temporary replacement of personnel during any period of travel to and participation in exercises and training in the use of equipment and on prevention activities; and
- "(D) participation in information, investigative, and intelligence-sharing activities specifically related to terrorism prevention;
- "(8) the costs of equipment (including software) required to receive, transmit, handle, and store classified information;
- "(9) target hardening to reduce the vulnerability of high-value targets, as determined by the Secretary;
- "(10) protecting critical infrastructure against potential attack by the addition of barriers, fences, gates, and other such devices, except that the cost of such measures may not exceed the greater of—
- "(A) \$1,000,000 per project; or
- "(B) such greater amount as may be approved by the Secretary, which may not exceed 10 percent of the total amount of the covered grant:
- "(11) the costs of commercially available interoperable communications equipment

(which, where applicable, is based on national, voluntary consensus standards) that the Secretary, in consultation with the Chairman of the Federal Communications Commission, deems best suited to facilitate interoperability, coordination, and integration between and among emergency communications systems, and that complies with prevailing grant guidance of the Department for interoperable communications;

"(12) educational curricula development for first responders to ensure that they are prepared for terrorist attacks;

"(13) training and exercises to assist public elementary and secondary schools in developing and implementing programs to instruct students regarding age-appropriate skills to prepare for and respond to an act of terrorism:

"(14) paying of administrative expenses directly related to administration of the grant, except that such expenses may not exceed 3 percent of the amount of the grant; and

"(15) other appropriate activities as determined by the Secretary.

"(b) Prohibited Uses.—Funds provided as a covered grant may not be used—

"(1) to supplant State or local funds that have been obligated for a homeland security or other first responder-related project;

"(2) to construct buildings or other physical facilities, except for—

"(A) activities under section 611 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5196); and

"(B) upgrading facilities to protect against, test for, and treat the effects of biological agents, which shall be included in the homeland security plan approved by the Secretary under section 2002(c);

"(3) to acquire land; or

"(4) for any State or local government cost-sharing contribution.

"(c) MULTIPLE-PURPOSE FUNDS.—Nothing in this section shall be construed to preclude State and local governments from using covered grant funds in a manner that also enhances first responder preparedness for emergencies and disasters unrelated to acts of terrorism, if such use assists such governments in achieving essential capabilities for terrorism preparedness established by the Secretary under section 2003.

"(d) REIMBURSEMENT OF COSTS.—In addition to the activities described in subsection (a), a covered grant may be used to provide a reasonable stipend to paid-on-call or volunteer first responders who are not otherwise compensated for travel to or participation in training covered by this section. Any such reimbursement shall not be considered compensation for purposes of rendering such a first responder an employee under the Fair Labor Standards Act of 1938 (29 U.S.C. 201 et seq.)

seq.).

"(e) ASSISTANCE REQUIREMENT.—The Secretary may not request that equipment paid for, wholly or in part, with funds provided as a covered grant be made available for responding to emergencies in surrounding States, regions, and localities, unless the Secretary undertakes to pay the costs directly attributable to transporting and operating such equipment during such response.

"(f) FLEXIBILITY IN UNSPENT HOMELAND SE-CURITY GRANT FUNDS.—Upon request by the recipient of a covered grant, the Secretary may authorize the grantee to transfer all or part of funds provided as the covered grant from uses specified in the grant agreement to other uses authorized under this section, if the Secretary determines that such transfer is in the interests of homeland security.

"(g) STATE, REGIONAL, AND TRIBAL RESPON-SIBILITIES.—

"(1) PASS-THROUGH.—The Secretary shall require a recipient of a covered grant that is a State to obligate or otherwise make available to local governments, first responders,

and other local groups, to the extent required under the State homeland security plan or plans specified in the application for the grant, not less than 80 percent of the grant funds, resources purchased with the grant funds having a value equal to at least 80 percent of the amount of the grant, or a combination thereof, by not later than the end of the 45-day period beginning on the date the grant recipient receives the grant funds.

"(2) CERTIFICATIONS REGARDING DISTRIBU-TION OF GRANT FUNDS TO LOCAL GOVERN-MENTS.—Any State that receives a covered grant shall certify to the Secretary, by not later than 30 days after the expiration of the period described in paragraph (1) with respect to the grant, that the State has made available for expenditure by local governments, first responders, and other local groups the required amount of grant funds pursuant to paragraph (1).

"(3) QUARTERLY REPORT ON HOMELAND SECU-RITY SPENDING.—Each recipient of a covered grant shall submit a quarterly report to the Secretary not later than 30 days after the end of each fiscal quarter. Each such report shall include, for each recipient of a covered grant or a pass-through under paragraph (1)—

- "(A) the amount obligated to that recipient in that quarter:
- "(B) the amount expended by that recipient in that quarter; and
- "(C) a summary description of the items purchased by such recipient with such amount.
- "(4) ANNUAL REPORT ON HOMELAND SECURITY SPENDING.—Each recipient of a covered grant shall submit an annual report to the Secretary not later than 60 days after the end of each fiscal year. Each recipient of a covered grant that is a region shall simultaneously submit its report to each State of which any part is included in the region. Each recipient of a covered grant that is a directly eligible tribe shall simultaneously submit its report to each State within the boundaries of which any part of such tribe is located. Each report shall include the following:
- "(A) The amount, ultimate recipients, and dates of receipt of all funds received under the grant during the previous fiscal year.
- "(B) The amount and the dates of disbursements of all such funds expended in compliance with paragraph (1) or pursuant to mutual aid agreements or other sharing arrangements that apply within the State, region, or directly eligible tribe, as applicable, during the previous fiscal year.
- "(C) How the funds were utilized by each ultimate recipient or beneficiary during the preceding fiscal year.
- "(D) The extent to which essential capabilities identified in the applicable State homeland security plan or plans were achieved, maintained, or enhanced as the result of the expenditure of grant funds during the preceding fiscal year.
- "(E) The extent to which essential capabilities identified in the applicable State homeland security plan or plans remain unmet.
- "(5) INCLUSION OF RESTRICTED ANNEXES.—A recipient of a covered grant may submit to the Secretary an annex to the annual report under paragraph (4) that is subject to appropriate handling restrictions, if the recipient believes that discussion in the report of unmet needs would reveal sensitive but unclassified information.
- "(6) Provision of Reports.—The Secretary shall ensure that each annual report under paragraph (4) is provided to the Under Secretary for Emergency Preparedness and Response and the Director of the Office of State and Local Government Coordination.

- "(h) INCENTIVES TO EFFICIENT ADMINISTRATION OF HOMELAND SECURITY GRANTS.—
- "(1) PENALTIES FOR DELAY IN PASSING THROUGH LOCAL SHARE.—If a recipient of a covered grant that is a State fails to pass through to local governments, first responders, and other local groups funds or resources required by subsection (g)(1) within 45 days after receiving funds under the grant, the Secretary may—
- "(A) reduce grant payments to the grant recipient from the portion of grant funds that is not required to be passed through under subsection (g)(1);
- "(B) terminate payment of funds under the grant to the recipient, and transfer the appropriate portion of those funds directly to local first responders that were intended to receive funding under that grant; or
- "(C) impose additional restrictions or burdens on the recipient's use of funds under the grant, which may include—
- "(i) prohibiting use of such funds to pay the grant recipient's grant-related overtime or other expenses;
- "(ii) requiring the grant recipient to distribute to local government beneficiaries all or a portion of grant funds that are not required to be passed through under subsection (g)(1): or
- "(iii) for each day that the grant recipient falls to pass through funds or resources in accordance with subsection (g)(1), reducing grant payments to the grant recipient from the portion of grant funds that is not required to be passed through under subsection (g)(1), except that the total amount of such reduction may not exceed 20 percent of the total amount of the grant.
- "(2) EXTENSION OF PERIOD.—The Governor of a State may request in writing that the Secretary extend the 45-day period under section 2002(e)(5)(E) or paragraph (1) for an additional 15-day period. The Secretary may approve such a request, and may extend such period for additional 15-day periods, if the Secretary determines that the resulting delay in providing grant funding to the local government entities that will receive funding under the grant will not have a significant detrimental impact on such entities' terrorism preparedness efforts.
- "(3) Provision of non-local share to local government.—
- "(A) IN GENERAL.—The Secretary may upon request by a local government pay to the local government a portion of the amount of a covered grant awarded to a State in which the local government is located, if—
- "(i) the local government will use the amount paid to expedite planned enhancements to its terrorism preparedness as described in any applicable State homeland security plan or plans:
- "(ii) the State has failed to pass through funds or resources in accordance with subsection (g)(1); and
- "(iii) the local government complies with subparagraph (B).
- "(B) SHOWING REQUIRED.—To receive a payment under this paragraph, a local government must demonstrate that—
- "(i) it is identified explicitly as an ultimate recipient or intended beneficiary in the approved grant application;
- "(ii) it was intended by the grantee to receive a severable portion of the overall grant for a specific purpose that is identified in the grant application;
- "(iii) it petitioned the grantee for the funds or resources after expiration of the period within which the funds or resources were required to be passed through under subsection (g)(1); and
- "(iv) it did not receive the portion of the overall grant that was earmarked or designated for its use or benefit.

- "(C) EFFECT OF PAYMENT.—Payment of grant funds to a local government under this paragraph—
- "(i) shall not affect any payment to another local government under this paragraph; and
- "(ii) shall not prejudice consideration of a request for payment under this paragraph that is submitted by another local government.
- "(D) DEADLINE FOR ACTION BY SECRETARY.— The Secretary shall approve or disapprove each request for payment under this paragraph by not later than 15 days after the date the request is received by the Department.
- "(i) REPORTS TO CONGRESS.—The Secretary shall submit an annual report to Congress by December 31 of each year—
- "(1) describing in detail the amount of Federal funds provided as covered grants that were directed to each State, region, and directly eligible tribe in the preceding fiscal year;
- "(2) containing information on the use of such grant funds by grantees; and
  - "(3) describing-
- "(A) the Nation's progress in achieving, maintaining, and enhancing the essential capabilities established under section 2003(a) as a result of the expenditure of covered grant funds during the preceding fiscal year; and
- "(B) an estimate of the amount of expenditures required to attain across the United States the essential capabilities established under section 2003(a)."
- (b) Sense of Congress Regarding Interoperable Communications.—
  - (1) FINDING.—Congress finds that—
- (A) many emergency response providers (as defined under section 2 of the Homeland Security Act of 2002 (6 U.S.C. 101), as amended by this Act) working in the same jurisdiction or in different jurisdictions cannot effectively and efficiently communicate with one another: and
- (B) their inability to do so threatens the public's safety and may result in unnecessary loss of lives and property.
- (2) SENSE OF CONGRESS.—It is the sense of Congress that interoperable emergency communications systems and radios should continue to be deployed as soon as practicable for use by the emergency response provider community, and that upgraded and new digital communications systems and new digital radios should meet prevailing national voluntary consensus standards for interoperability.
- (c) Sense of Congress Regarding Citizen Corps Councils.—
- (1) FINDING.—Congress finds that Citizen Corps councils help to enhance local citizen participation in terrorism preparedness by coordinating multiple Citizen Corps programs, developing community action plans, assessing possible threats, and identifying local resources.
- (2) SENSE OF CONGRESS.—It is the sense of Congress that individual Citizen Corps councils should seek to enhance the preparedness and response capabilities of all organizations participating in the councils, including by providing funding to as many of their participating organizations as practicable to promote local terrorism preparedness programs.
- (d) REQUIRED COORDINATION.—The Secretary of Homeland Security shall ensure that there is effective and ongoing coordination of Federal efforts to prevent, prepare for, and respond to acts of terrorism and other major disasters and emergencies among the divisions of the Department of Homeland Security, including the Directorate of Emergency Preparedness and Response and the Office for State and Local Government Coordination and Preparedness.

- (e) COORDINATION OF INDUSTRY EFFORTS.— Section 102(f) of the Homeland Security Act of 2002 (6 U.S.C. 112(f)) is amended—
- (1) in paragraph (9), by striking "and" after the semicolon;
- (2) in paragraph (10), by striking the period and inserting "; and"; and
  - (3) by adding at the end the following:
- "(11) coordinating industry efforts, with respect to functions of the Department of Homeland Security, to identify private sector resources and capabilities that could be effective in supplementing Federal, State, and local government agency efforts to prevent or respond to a terrorist attack."
- (f) STUDY REGARDING NATIONWIDE EMERGENCY NOTIFICATION SYSTEM.—
- (1) STUDY.—The Secretary of Homeland Security, in consultation with the heads of other appropriate Federal agencies and representatives of providers and participants in the telecommunications industry, shall conduct a study to determine whether it is cost effective, efficient, and feasible to establish and implement an emergency telephonic alert notification system that will—
- (A) alert persons in the United States of imminent or current hazardous events caused by acts of terrorism; and
- (B) provide information to individuals regarding appropriate measures that may be undertaken to alleviate or minimize threats to their safety and welfare posed by such events.
- (2) TECHNOLOGIES TO CONSIDER.—In conducting the study under paragraph (1), the Secretary shall consider the use of the telephone, wireless communications, and other existing communications networks to provide such notification.
- (3) REPORT.—Not later than 9 months after the date of enactment of this Act, the Secretary shall submit to Congress a report regarding the conclusions of the study conducted under paragraph (1).
- (g) STUDY OF EXPANSION OF AREA OF JURIS-DICTION OF OFFICE OF NATIONAL CAPITAL RE-GION COORDINATION.—
- (1) STUDY.—The Secretary of Homeland Security, acting through the Director of the Office of National Capital Region Coordination, shall conduct a study of the feasibility and desirability of modifying the definition of "National Capital Region" applicable under section 882 of the Homeland Security Act of 2002 (6 U.S.C. 462) to expand the geographic area under the jurisdiction of the Office of National Capital Region Coordination.
- (2) FACTORS.—In conducting the study under paragraph (1), the Secretary shall analyze whether expanding the geographic area under the jurisdiction of the Office of National Region Coordination will—
- (A) promote coordination among State and local governments within the Region, including regional governing bodies, and coordination of the efforts of first responders; and
- (B) enhance the ability of such State and local governments and the Federal Government to prevent and respond to a terrorist attack within the Region.
- (3) REPORT.—Not later than 6 months after the date of the enactment of this Act, the Secretary shall submit a report to Congress on the study conducted under paragraph (1), and shall include in the report such recommendations (including recommendations for legislation to amend section 882 of the Homeland Security Act of 2002 (6 U.S.C. 462)) as the Secretary considers appropriate.
- (h) STUDY OF RISK ALLOCATION FOR PORT SECURITY GRANTS.—
- (1) STUDY.—The Secretary of Homeland Security shall conduct a study of the factors to be used for the allocation of funds based on risk for port security grants made under section 70107 of title 46, United States Code.

- (2) FACTORS.—In conducting the study, the Secretary shall analyze the volume of international trade and economic significance of each port.
- (3) REPORT.—Not later than 90 days after the enactment of the Act, the Secretary shall submit a report to Congress on the study and shall include recommendations for using such factors in allocating grant funds to ports.
- (i) STUDY OF ALLOCATION OF ASSISTANCE TO FIREFIGHTER GRANTS.—
- (1) STUDY.—The Secretary of Homeland Security shall conduct a study of the allocation of grant fund awards made under the Assistance to Firefighter Grants program and shall analyze the distribution of awards by State.
- (2) FACTORS.—In conducting the study, the Secretary shall analyze the number of awards and the per capita amount of grant funds awarded to each State and the level of unmet firefighting equipment needs in each State. The study shall also analyze whether allowing local departments to submit more than 1 annual application and expanding the list of eligible applicants for such grants to include States will enhance the ability of State and local governments to respond to fires.
- (3) REPORT.—Not later than 90 days after the date of enactment of the Act, the Secretary shall submit a report to Congress on the study and shall include recommendations for legislation amending the factors used in allocating grant funds to insure that critical firefighting needs are addressed by the program in all areas of the Nation.

## SEC. 5. IMPLEMENTATION; DEFINITIONS; TABLE OF CONTENTS.

- (a) TECHNICAL AND CONFORMING AMEND-MENT.—Section 1014 of the USA PATRIOT ACT (42 U.S.C. 3714) is amended—
  - (1) by striking subsection (c)(3);
- (2) by redesignating subsection (c) as subsection (d); and
- (3) by inserting after subsection (b) the following:
- "(c) ADMINISTRATION.—Grants under this section shall be administered in accordance with title XX of the Homeland Security Act of 2002."
- (b) Temporary Limitations on Application.—
- (1) 1-YEAR DELAY IN APPLICATION.—The following provisions of title XX of the Homeland Security Act of 2002, as added by this Act, shall not apply during the 1-year period beginning on the date of enactment of this Act—
- (A) Subsections (b), (c), and (e)(4) (A) and (B) of section 2002; and
- (B) In section 2002(f)(3)(A)(i), the phrase "by achieving, maintaining, or enhancing the essential capabilities of the applicants on a nationwide basis,".
- (2) 2-YEAR DELAY IN APPLICATION.—The following provisions of title XX of the Homeland Security Act of 2002, as added by this Act, shall not apply during the 2-year period beginning on the date of enactment of this
- (A) Subparagraphs (D) and (E) of section 2006(g)(4); and
  - (B) Section 2006(i)(3).
  - (c) Definitions.—
- (1) TITLE XX.—Title XX of the Homeland Security Act of 2002, as amended by sections 2, 3, and 4, is amended by adding at the end the following:

### SEC. 2007. DEFINITIONS.

- "In this title:
- "(1) BOARD.—The term 'Board' means the Homeland Security Grants Board established under section 2002(f).
- "(2) CONSEQUENCE.—The term 'consequence' means the assessment of the effect of a completed attack.

- "(3) COVERED GRANT.—The term 'covered grant' means any grant to which this title applies under section 2001(b).
- "(4) DIRECTLY ELIGIBLE TRIBE.—The term 'directly eligible tribe' means any Indian tribe or consortium of Indian tribes that—
- "(A) meets the criteria for inclusion in the qualified applicant pool for self-governance that are set forth in section 402(c) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 458bb(c));
- "(B) employs at least 10 full-time personnel in a law enforcement or emergency response agency with the capacity to respond to calls for law enforcement or emergency services; and
- "(C)(i) is located on, or within 5 miles of, an international border or waterway;
- "(ii) is located within 5 miles of a facility designated as high-risk critical infrastructure by the Secretary;
- "(iii) is located within or contiguous to 1 of the 50 largest metropolitan statistical areas in the United States; or
- "(iv) has more than 1,000 square miles of Indian country, as that term is defined in section 1151 of title 18. United States Code.
- "(5) ELEVATIONS IN THE THREAT ALERT LEVEL.—The term 'elevations in the threat alert level' means any designation (including those that are less than national in scope) that raises the homeland security threat level to either the highest or second-highest threat level under the Homeland Security Advisory System referred to in section 201(d)(7).
- "(6) EMERGENCY PREPAREDNESS.—The term 'emergency preparedness' shall have the same meaning that term has under section 602 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5195a).
- "(7) ESSENTIAL CAPABILITIES.—The term 'essential capabilities' means the levels, availability, and competence of emergency personnel, planning, training, and equipment across a variety of disciplines needed to effectively and efficiently prevent, prepare for, and respond to acts of terrorism consistent with established mactices
- "(8) FIRST RESPONDER.—The term 'first responder' shall have the same meaning as the term 'emergency response provider' under section 2.
- "(9) INDIAN TRIBE.—The term 'Indian tribe' means any Indian tribe, band, nation, or other organized group or community, including any Alaskan Native village or regional or village corporation as defined in or established pursuant to the Alaskan Native Claims Settlement Act (43 U.S.C. 1601 et seq.), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.
- "(10) REGION.—The term 'region' means any geographic area—
- "(A) certified by the Secretary under section 2002(a)(3);
- "(B) consisting of all or parts of 2 or more counties, municipalities, or other local governments and including a city with a core population exceeding 500,000 according to the most recent estimate available from the United States Census; and
- "(C) that, for purposes of an application for a covered grant—
- "(i) is represented by 1 or more local governments or governmental agencies within such geographic area; and
- "(ii) is established by law or by agreement of 2 or more such local governments or governmental agencies, such as through a mutual aid agreement.
- "(11) RISK-BASED FUNDING.—The term 'riskbased funding' means the allocation of funds based on an assessment of threat, vulnerability, and consequence.

"(12) TASK FORCE.—The term 'Task Force' means the Task Force on Essential Capabilities established under section 2004.

"(13) THREAT.—The term 'threat' means the assessment of the plans, intentions, and capability of an adversary to implement an identified attack scenario.

"(14) VULNERABILITY.—The term 'vulnerability' means the degree to which a facility is available or accessible to an attack, including the degree to which the facility is inherently secure or has been hardened against such an attack.".

(2) DEFINITION OF EMERGENCY RESPONSE PROVIDERS.—Paragraph (6) of section 2 of the Homeland Security Act of 2002 (6 U.S.C. 101(6)) is amended by striking "includes" and all that follows and inserting "includes Federal, State, and local governmental and nongovernmental emergency public safety, law enforcement, fire, emergency response, emergency medical (including hospital emergency facilities), and related personnel, organizations, agencies, and authorities."

(d) TABLE OF CONTENTS.—Section 1(b) of the Homeland Security Act of 2002 (6 U.S.C. 101 note) is amended in the table of contents by adding at the end the following:

## "TITLE XX—RISK-BASED FUNDING FOR HOMELAND SECURITY

"Sec. 2001. Risk-based funding for homeland security

"Sec. 2002. Covered grant eligibility and criteria

"Sec. 2003. Essential capabilities for home-

land security
"Sec. 2004. Task Force on Essential Capa-

bilities
"Sec. 2005. National standards for first responder equipment and training
"Sec. 2006. Use of funds and accountability

 $\begin{array}{c} {\rm requirements} \\ {\rm ``Sec.\ 2007.\ Definitions''.} \end{array}$ 

Mr. CORNYN. Mr. President, I rise today to join with my colleague, Sen. DIANNE FEINSTEIN of California, and several of our distinguished colleagues in introducing The Risk-Based Homeland Security Grants Act of 2007.

Senator Feinstein, myself, and other Senators have been working now for several years on changing how our homeland security dollars are distributed throughout the country. Some have been talking about the need for a risk-based allocation of assistance as long as the Department of Homeland Security has been in existence. Throughout these debates, Senator Feinstein has been a tireless advocate in this effort, and I would like to thank her for her fine leadership and collaboration in crafting this legislation.

The attacks on our country on September 11, 2001 were unprecedented in our history, and they brought with them the need for similarly unprecedented security measures. Our Nation needed to respond quickly to the devastation that day delivered to our country, so the Federal Government created a system that worked to raise overall national emergency preparedness to ensure we could better guard against another such terrorist attack.

And so, we embarked on the task of shoring up our airline, transportation, border, and port security. We worked to protect our critical infrastructure, to protect our cyber security, our agriculture and food-supply systems.

But taxpayer dollars are not limitless, and Congress must work to ensure every penny be directed where it will do the most good. It is imperative that we guard the places across our Nation where terrorists are most likely to strike, and where such strikes could do the most damage to our people, our government, and our national economy. We believe this is the most responsible way to prepare for any future attack.

We need to have a system that will protect our most vulnerable assets and populations—one that recognizes the need to protect the critical infrastructure and vital components of our national economy. I am reminded of this often when I travel around my home State of Texas. Recently, I met with officials and business leaders from Houston and Southeast Texas and discussed their homeland security needs. Their needs are enormous considering the vast amount of critical infrastructure and energy facilities in and among large population centers. The potential consequences of a terrorist attack on any of these facilities would be devastating, not only to the local communities, but to the economic engine of the whole country. Unfortunately, we got a small taste of effects of a disaster along America's energy coast during the storms of 2005—hurricanes Katrina and Rita

The legislation that Senator Feinstein and I are proposing would require that Federal Homeland Security funds be allocated to States according to a risk-based assessment. It is vital that we better allocate our limited resources to the vulnerable places in the country we most need to protect, and that that these funds are distributed in an efficient and timely manner.

Since we began this effort, I am pleased that there has been progress made. The considerations of threat, vulnerability, and consequence have been incorporated into more homeland security programs. But I'm concerned that we haven't done enough. And I'm concerned that our homeland security dollars are being treated as a pie in which all States get to claim a piece, regardless of risk.

This approach is inconsistent if we truly evaluate the 9/11 Commission recommendations. They clearly call for allocation of money based on an assessment of risks.

Our legislation provides for a distribution formula for homeland security grants based on risk, which considers three main criteria: threat, vulnerability, and consequence. It requires States to quickly pass on Federal funds to areas where they are most needed. It provides greater flexibility in using the funds, allowing a State to use them for other hazards consistent with federally established capability standards. And it allows States to retain authority to administer grant programs, but there are penalties for states that do not pass funds to local governments within 45 days, and if a State fails to pass the funds through, local governments may petition the Department of Homeland Security to receive the funds directly. It is our hope and intent that, by introducing this bill, we can positively contribute and enrich the public discourse on this critical issue, and help move the Nation toward a more rational and effective distribution of our homeland security resources.

Continuing to spread Homeland Security funds throughout the Nation—irrespective of the actual risk to particular states and communities—would be to ignore much of what we have learned as part of our effort to assess our vulnerabilities since the attacks of September 11. So I would urge that we swiftly work to pass this legislation, to better ensure the safety of our citizens.

By Mr. ROCKEFELLER (for himself and Ms. SNOWE):

S. 609. A bill to amend section 254 of the Communications Act of 1934 to provide that funds received as universal service contributions and the universal service support programs established pursuant to that section are not subject to certain provisions of title 31, United States Code, commonly known as the Antideficiency Act; to the Committee on Commerce, Science, and Transportation.

Mr. ROCKEFELLER. Mr. President, today I join with my colleagues, Senator OLYMPIA SNOWE and Vice-Chairman TED STEVENS, to re-introduce the Antideficiency Act to protect the Universal Service Program.

This is a bipartisan effort to ensure that all of the fundamental universal service program can continue to operate smoothly and effectively. Last year, this legislation garnered the support of 55 members, and I hope that it will gain additional support in the 110th Congress. It is also important to note that the House also has a similar bipartisan legislation.

For many years, I have fought hard for universal service, including the E-Rate. It is essential for all of the universal service programs to operate in a timely manner.

The Universal Service Fund is accomplishing its mission. Our country has a strong telecommunications network, and rural customers are getting service at affordable rates. Lifeline and Linkup programs help the poorest of customers keep basic telephone access which is essential in our modern world. Rural health care is helping connect our rural clinics to modern medicine and specialists.

Over the past decade, the E-Rate discounts have helped to connect our classrooms and our libraries to the Internet and modern technology. In 1996, when the Telecommunications Act passed, only 14 percent of classrooms were connected, and just 5 percent of the poorest classrooms were connected. The latest data is encouraging with 93 percent of all classrooms connected and 89 percent of the poorest classrooms connected. Since 1998. West Virginia schools and libraries have received over \$70 million in E-Rate discounts. While this is extraordinary success, the need for E-Rate discounts remains because schools and libraries

face monthly telecommunication costs and Internet access fees. Every school and library will periodically need to upgrade its internal connections.

This legislation gives the Universal Service Fund a permanent exemption from the Antideficiency Act. Over the last few years, we have done one year exemptions. It makes good sense to enact a long term solution for the Universal Service Fund.

### By Mr. ROCKEFELLER:

S. 610. A bill to clarify the effective date of the modification of treatment for retirement annuity purposes of part-time service before April 7, 1986, of certain Department of Veterans Affairs health-care professionals; to the Committee on Veterans' Affairs.

Mr. ROCKEFELLER. Mr. President, today, I am introducing a bill to change an unfair administrative decision that hurts aging, retired VA nurses. This bill is designed to correct a problem from legislation enacted in 2001, to help VA nurses' retirement. That legislation improved nurses' pensions, and Congress intended it to be retroactive. Unfortunately, administrative officials took a very narrow view of that law. Currently VA nurses, who retired between 1986 and 2002, do not get the full pension benefits as current retirees do.

In the 1980s, VA aggressively re-

In the 1980s, VA aggressively recruited nurses to fill a huge need at VA medical centers by promising full retirement for part-time work. At the time, nurses joined the VA, and they believed in the promise.

Sadly, the VA and the Office of Personnel Management (OPM) will not fulfill that promise. This legislation would explicitly require the Federal Government to honor its commitment to our retired VA nurses. Pension benefits are a vital promise. It is disturbing when we do not fulfill our obligations, and we simply must correct this error.

Nurses play a critical role in our health care system, including the VA. Recruiting and retaining nurses is important, and this pension shortfall does not help. It is time to deliver full pension benefits to the retired nurses who cared for our veterans, but sadly retired in the wrong years, between 1986 and 2002.

By Mr. LUGAR (for himself and Mr. BIDEN):

S. 613. A bill to enhance the overseas stabilization and reconstruction capabilities of the United States Government, and for other purposes; to the Committee on Foreign Relations.

Mr. LUGAR. Mr. President, this legislation authorizes the creation of a civilian readiness corps to address post-conflict situations and other emergencies overseas. The Senate already embraced the creation of such a corps when it unanimously passed S. 3322 last June. Unfortunately, that bill, introduced by Senator BIDEN and me and cosponsored by Senators HAGEL, ALEXANDER and WARNER languished in the

House of Representatives. We have hopes that the 110th Congress will now bring this idea to fruition.

In his State of the Union address last month, the President endorsed the need for such a corps:

"A second task we can take on together is to design and establish a volunteer Civilian Reserve Corps. Such a corps would function much like our military reserve. It would ease the burden on the Armed Forces by allowing us to hire civilians with critical skills to serve on missions abroad when American needs them. It would give people across America who do not wear the uniform a chance to serve in the defining struggle of our time." President Bush, January 23, 2007, State of the Union speech, Washington, DC.

The legislation I am introducing today is an updated version of S. 3322. It is the result of a conversation begun in 2003 between Members of the Senate Foreign Relations Committee and the leadership of the State Department. The concept has gone through a number of evolutions and has passed the Committee unanimously both as a freestanding bill and as part of the State Department authorization bill. I am asking the Senate to pass it now again as a free-standing bill and send it to the House with our unanimous approval.

International crises are inevitable, and in most cases, U.S. national security interests will be threatened by sustained instability. The war on terrorism necessitates that we not leave nations crumbling and ungoverned. We have already seen how terrorists can exploit nations afflicted by lawlessness and desperate circumstances. They seek out such places to establish training camps, recruit new members, and tap into a global black market in weapons.

In this international atmosphere, the United States must have the right structures, personnel, and resources in place when an emergency occurs. A delay in our response of a few weeks, or even days, can mean the difference between success and failure. Clearly we need a full range of tools to prevail. Our Committee's focus has been on boosting the civilian side of our stabilization and reconstruction capabilities, while encouraging improved mechanisms for civilian and military agencies to work together on these missions.

Those who were once unconvinced of the need for such a corps have only to look at our experience in Iraq and Afghanistan to understand its value.

This legislation continues to build on the original legislation, S. 2127, that Senators BIDEN and HAGEL and I introduced in early 2004 to encourage and support a well-organized, sufficiently resourced and strongly led civilian counterpart to the military in post-conflict zones. It is our view that the civilian side needs both operational capability and a significant surge capacity. This legislation gives statutory

status to the State Department's Office of the Coordinator of Reconstruction and Stabilization and makes the position of Coordinator subject to the advice and consent of the Senate. The legislation authorizes the establishment of a federal response capability with both active and standby components, as well as a civilian reserve that draws upon the talent and willingness to serve that resides among our people. It provides flexibility in personnel management, pay, and benefits to build the corps and create surge capacity in an emergency. Finally, it authorizes expenditures for a crisis response fund, for the civilian response corps, and for a substantial training, planning and operational capacity for the office.

The State Department has made progress through the Office of the Coordinator of Reconstruction and Stabilization that was established in July of 2004. The Office has already done a great deal of the preliminary work needed to build an effective corps. But now it is time for the Office to recruit, train, and organize the corps so that we have deployable units.

We need to have a 250-person active duty component made up of State Department and USAID employees. We need a 2,000 person standby component drawn from both State and USAID, but also from other Federal agencies that have employees who are willing to volunteer and have the necessary skill sets. And we need to begin building a civilian reserve, recruiting at least 500 highly skilled persons and eventually many more.

The 250-person active duty personnel should include people with skills that are more technical than the broader diplomatic requirements—civil engineering, police expertise, agricultural knowledge, health, education, and political organization. They should have experience in difficult situations overseas and be trained and available for rapid deployment with the military for both initial assessments and programming purposes. They would be the first civilian team on the ground in postconflict situations, probably well in advance of the establishment of an embassy.

Such a 250-person corps would be no larger than a typical army company. But it would be a force multiplier. It would be equipped with the authority and training to take broad operational responsibility for stabilization missions. Establishment of such a corps is a modest investment when seen as part of the overall national security budget. Even in peace time, we maintain active duty military forces of almost 1.4 million men and women who train and plan for the possibility of war. Given how critical post conflict situations have been to American national security in the last decade, I believe it is reasonable to have a mere 250 civilians who are training for these situations and are capable of being deployed anywhere in the world, at any time they may be needed.

Congress must now be willing to provide the funding to make this corps a reality. This legislation authorizes a \$75 million crisis response fund to be made available as a contingency for stabilization and reconstruction crises. Of this amount, the administration is authorized to spend \$25 million for the organization, training, and emergency deployment of the response corps. This legislation authorizes the crisis response fund and \$80 million for the operations of the new State Department office and the active duty component, including training, equipment, and travel.

We have a long way to go in creating the kind of robust civilian capacity that we need. Both the State Department and the Defense Department are keenly aware of the importance of this legislation. If we cannot plan better as a government, the United States may come to depend even more on our military for tasks and functions far beyond its current role. But I remain optimistic that we can build on the progress already made to create a strong and reliable civilian component that boosts our stabilization and reconstruction capabilities. Passing this legislation once again will demonstrate that there is a keen understanding in the Senate that we need to move forward. It will support executive branch actions already taken and encourage further progress. We hope that our friends in the House of Representatives, several of whom are considering introducing their own legislation, will move forward with the Senate in this endeavor. I urge adoption of this legislation.

I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

### S. 613

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.

### SECTION 1. SHORT TITLE.

This Act may be cited as the "Reconstruction and Stabilization Civilian Management Act of 2007".

## SEC. 2. FINDING; PURPOSE.

(a) FINDING.—Congress finds that the resources of the United States Armed Forces have been burdened by having to undertake stabilization and reconstruction tasks in the Balkans, Afghanistan, Iraq, and other countries of the world that could have been performed by civilians, which has resulted in lengthy deployments for Armed Forces personnel.

(b) PURPOSE.—The purpose of this Act is to provide for the continued development, as a core mission of the Department of State and the United States Agency for International Development, of an effective expert civilian response capability to carry out reconstruction and stabilization activities in a country or region that is at risk of, in, or is in transition from, conflict or civil strife.

### SEC. 3. DEFINITIONS.

In this Act:

(1) ADMINISTRATOR.—The term "Administrator" means the Administrator of the

United States Agency for International Development.

(2) APPROPRIATE CONGRESSIONAL COMMITTEES.—The term "appropriate congressional committees" means—

(A) the Committee on Foreign Relations of the Senate; and

(B) the Committee on Foreign Affairs of the House of Representatives.

(3) DEPARTMENT.—Except as otherwise provided in this Act, the term "Department" means the Department of State.

(4) EXECUTIVE AGENCY.—The term "executive agency" has the meaning given that term in section 105 of title 5, United States Code.

(5) SECRETARY.—The term "Secretary" means the Secretary of State.

#### SEC. 4. SENSE OF CONGRESS.

It is the sense of Congress that-

(1) the civilian element of United States joint civilian-military operations should be strengthened in order to enhance the execution of current and future reconstruction and stabilization activities in foreign countries or regions that are at risk of, in, or are in transition from, conflict or civil strife;

(2) the capability of civilian agencies of the United States Government to carry out reconstruction and stabilization activities in such countries or regions should also be enhanced through a new rapid response corps of civilian experts supported by the establishment of a new system of planning, organization, personnel policies, and education and training, and the provision of adequate resources:

(3) the international community, including nongovernmental organizations, and the United Nations and its specialized agencies, should be further encouraged to participate in planning and organizing reconstruction and stabilization activities in such countries or regions:

(4) the executive branch has taken a number of steps to strengthen civilian capability, including the establishment of an office headed by a Coordinator for Reconstruction and Stabilization in the Department, the Presidential designation of the Secretary as the interagency coordinator and leader of reconstruction and stabilization efforts, and Department of Defense directives to the military to support the Office of Reconstruction and Stabilization and to work closely with counterparts in the Department of State and other civilian agencies to develop and enhance personnel, training, planning, and analysis;

(5) the Secretary and the Administrator should work with the Secretary of Defense to augment existing personnel exchange programs among the Department, the United States Agency for International Development, and the Department of Defense, including the regional commands and the Joint Staff, to enhance the stabilization and reconstruction skills of military and civilian personnel and their ability to undertake joint operations: and

(6) the heads of other executive agencies should establish personnel exchange programs that are designed to enhance the stabilization and reconstruction skills of military and civilian personnel.

# SEC. 5. AUTHORITY TO PROVIDE ASSISTANCE FOR RECONSTRUCTION AND STABILIZATION CRISES.

Chapter 1 of part III of the Foreign Assistance Act of 1961 (22 U.S.C. 2351 et seq.) is amended by inserting after section 617 the following new section:

## "SEC. 618. ASSISTANCE FOR A RECONSTRUCTION AND STABILIZATION CRISIS.

"(a) Assistance.—

"(1) IN GENERAL.—If the President determines that it is important to the national

interests of the United States for United States civilian agencies or non-Federal employees to assist in stabilizing and reconstructing a country or region that is at risk of, in, or is in transition from, conflict or civil strife, the President may, in accordance with the provisions set forth in section 614(a)(3), notwithstanding any other provision of law, and on such terms and conditions as the President may determine, furnish assistance to respond to the crisis using funds referred to in paragraph (2).

"(2) FUNDS.—The funds referred to in this paragraph are funds as follows:

"(A) Funds made available under this section, including funds authorized to be appropriated by subsection (d).

"(B) Funds made available under other provisions of this Act and transferred or reprogrammed for purposes of this section.

"(b) SPECIAL AUTHORITIES.—In furtherance of a determination made under subsection (a), the President may exercise the authorities contained in sections 552(c)(2) and 610 without regard to the percentage and aggregate dollar limitations contained in such sections.

"(c) AVAILABILITY OF FUNDS FOR RESPONSE READINESS CORPS.—Of the funds made available for this section in any fiscal year, including funds authorized to be appropriated by subsection (d) and funds made available under other provisions of this Act and transferred or reprogrammed for purposes of this section, \$25,000,000 may be made available for expenses related to the development, training, and operations of the Response Readiness Corps established under section 61(c) of the State Department Basic Authorities Act of 1956

"(d) AUTHORIZATION OF APPROPRIATIONS.—

"(1) AUTHORIZATION.—There is authorized to be appropriated \$75,000,000 to provide assistance authorized in subsection (a) and, to the extent authorized in subsection (c), for the purpose described in subsection (c). Such amount is in addition to amounts otherwise made available for purposes of this section, including funds made available under other provisions of this Act and transferred or reprogrammed for purposes of this section.

"(2) REPLENISHMENT.—There is authorized to be appropriated each fiscal year such sums as may be necessary to replenish funds expended under this section.

"(3) AVAILABILITY.—Funds authorized to be appropriated under this subsection shall be available without fiscal year limitation.".

# SEC. 6. OFFICE OF THE COORDINATOR FOR RECONSTRUCTION AND STABILIZATION

Title I of the State Department Basic Authorities Act of 1956 (22 U.S.C. 2651 et seq.) is amended by adding at the end the following new section:

### "SEC. 61. RECONSTRUCTION AND STABILIZATION.

"(a) OFFICE OF THE COORDINATOR FOR RECONSTRUCTION AND STABILIZATION.—

"(1) ESTABLISHMENT.—There is established within the Department of State the Office of the Coordinator for Reconstruction and Stabilization.

"(2) COORDINATOR FOR RECONSTRUCTION AND STABILIZATION.—The head of the Office shall be the Coordinator for Reconstruction and Stabilization, who shall be appointed by the President, by and with the advice and consent of the Senate. The Coordinator shall report directly to the Secretary and shall have the rank and status of Ambassador at Large.

"(3) FUNCTIONS.—The functions of the Office of the Coordinator for Reconstruction and Stabilization include the following:

"(A) Monitoring, in coordination with relevant bureaus within the Department of State, political and economic instability

worldwide to anticipate the need for mobilizing United States and international assistance for the stabilization and reconstruction of countries or regions that are at risk of, in, or are in transition from, conflict or civil strife

- "(B) Assessing the various types of stabilization and reconstruction crises that could occur and cataloging and monitoring the non-military resources and capabilities of Executive agencies that are available to address such crises.
- "(C) Planning to address requirements, such as demobilization, policing, human rights monitoring, and public information, that commonly arise in stabilization and reconstruction crises.
- "(D) Coordinating with relevant Executive agencies (as that term is defined in section 105 of title 5, United States Code) to develop interagency contingency plans to mobilize and deploy civilian personnel to address the various types of such crises.
- "(E) Entering into appropriate arrangements with other Executive agencies to carry out activities under this section and the Reconstruction and Stabilization Civilian Management Act of 2007.
- "(F) Identifying personnel in State and local governments and in the private sector who are available to participate in the Response Readiness Corps established under subsection (c) or to otherwise participate in or contribute to stabilization and reconstruction activities.
- "(G) Taking steps to ensure that training of civilian personnel to perform such stabilization and reconstruction activities is adequate and, as appropriate, includes security training that involves exercises and simulations with the Armed Forces, including the regional commands.
- "(H) Sharing information and coordinating plans for stabilization and reconstruction activities, as appropriate, with the United Nations and its specialized agencies, the North Atlantic Treaty Organization, nongovernmental organizations, and other foreign national and international organizations.
- "(I) Coordinating plans and procedures for joint civilian-military operations with respect to stabilization and reconstruction activities.
- "(J) Maintaining the capacity to field on short notice an evaluation team to undertake on-site needs assessment.
- "(b) RESPONSE TO STABILIZATION AND RECONSTRUCTION CRISIS.—If the President makes a determination regarding a stabilization and reconstruction crisis under section 618 of the Foreign Assistance Act of 1961, the President may designate the Coordinator, or such other individual as the President may determine appropriate, as the Coordinator of the United States response. The individual so designated, or, in the event the President does not make such a designation, the Coordinator for Reconstruction and Stabilization, shall—
- "(1) assess the immediate and long-term need for resources and civilian personnel;
- "(2) identify and mobilize non-military resources to respond to the crisis; and
- "(3) coordinate the activities of the other individuals or management team, if any, designated by the President to manage the United States response.".

### SEC. 7. RESPONSE READINESS CORPS.

- (a) IN GENERAL.—Section 61 of the State Department Basic Authorities Act of 1956 (as added by section 6) is amended by adding at the end the following new subsection:
  - "(c) Response Readiness Corps.-
- "(1) IN GENERAL.—The Secretary, in consultation with the Administrator of the United States Agency for International Development and the heads of other appro-

priate departments and agencies of the United States Government, is authorized to establish and maintain a Response Readiness Corps (hereafter referred to in this subsection as the 'Corps') to provide assistance in support of stabilization and reconstruction activities in foreign countries or regions that are at risk of, in, or are in transition from, conflict or civil strife.

"(2) FEDERAL COMPONENTS.—

- "(A) ACTIVE AND STANDBY COMPONENTS.— The Corps shall have active and standby components consisting of United States Government personnel as follows:
- "(i) An active component, consisting of not more than 250 personnel who are recruited, employed, and trained in accordance with this paragraph.
- "(ii) A standby component, consisting of not more than 2000 personnel who are recruited and trained in accordance with this paragraph.
- "(B) AUTHORIZED MEMBERS OF STANDBY COMPONENT.—Personnel in the standby component of the Corps may include employees of the Department of State (including Foreign Service Nationals), employees of the United States Agency for International Development, employees of any other executive agency (as that term is defined in section 105 of title 5, United States Code), and employees of the legislative branch and judicial branch of Government.—
- "(i) who are assigned to the standby component by the Secretary following nomination for such assignment by the head of the department or agency of the United States Government concerned or by an appropriate official of the legislative or judicial branch of Government, as applicable; and

"(ii) who-

- "(I) have the training and skills necessary to contribute to stabilization and reconstruction activities; and
- "(II) have volunteered for deployment to carry out stabilization and reconstruction activities.
- "(C) RECRUITMENT AND EMPLOYMENT.—The recruitment and employment of personnel to the Corps shall be carried out by the Secretary, the Administrator of the United States Agency for International Development, and the heads of the other departments and agencies of the United States Government participating in the establishment and maintenance of the Corps.
- "(D) TRAINING.—The Secretary is authorized to train the members of the Corps under this paragraph to perform services necessary to carry out the purpose of the Corps under paragraph (1).
- "(E) COMPENSATION.—Members of the active component of the Corps under subparagraph (A)(i) shall be compensated in accordance with the appropriate salary class for the Foreign Service, as set forth in sections 402 and 403 of the Foreign Service Act of 1980 (22 U.S.C. 3962, 3963), or in accordance with the relevant authority under sections 3101 and 3392 of title 5, United States Code.

"(3) CIVILIAN RESERVE.—

- "(A) CIVILIAN RESERVE.—The Corps shall have a reserve (hereafter referred to in this subsection as the 'Civilian Reserve') of non-United States Government personnel who are trained and available as needed to perform services necessary to carry out the purpose of the Corps under paragraph (1). The Civilian Reserve shall be established by the Secretary, in consultation with the Administrator of the Unites States Agency for International Development and the heads of other appropriate departments and agencies of the United States Government.
- "(B) COMPOSITION.—Beginning not later than one year after the date of the enactment of the Reconstruction and Stabilization Civilian Management Act of 2007, the Ci-

vilian Reserve shall include at least 500 personnel, who may include retired employees of the United States Government, contractor personnel, nongovernmental organization personnel, State and local government employees, and individuals from the private sector, who—

- "(i) have the training and skills necessary to enable them to contribute to stabilization and reconstruction activities;
- "(ii) have volunteered to carry out stabilization and reconstruction activities; and
- "(iii) are available for training and deployment to carry out the purpose of the Corps under paragraph (1).
  - "(4) USE OF RESPONSE READINESS CORPS.-
- ''(A) FEDERAL ACTIVE COMPONENT.—Members of the active component of the Corps under paragraph (2)(A)(i) are authorized to be available—
- "(i) for activities in direct support of stabilization and reconstruction activities; and
- "(ii) if not engaged in activities described in clause (i), for assignment in the United States, United States diplomatic missions, and United States Agency for International Development missions.
- "(B) FEDERAL STANDBY COMPONENT AND CI-VILIAN RESERVE.—The Secretary may deploy members of the Federal standby component of the Corps under paragraph (2)(A)(ii), and members of the Civilian Reserve under paragraph (3), in support of stabilization and reconstruction activities in a foreign country or region if the President makes a determination regarding a stabilization and reconstruction crisis under section 618 of the Foreign Assistance Act of 1961."
- (b) EMPLOYMENT AUTHORITY.—The full-time personnel in the active component of the Response Readiness Corps under section 61(c)(2)(A)(i) of the State Department Basic Authorities Act of 1956 (as added by subsection (a)) are in addition to any other full-time personnel of the Department or the United States Agency for International Development authorized to be employed under any other provision of law.
- (c) REPORT.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall submit to the appropriate congressional committees a report on the status of efforts to establish the Response Readiness Corps under this section. The report should include recommendations for any legislation necessary to implement section 61(c) of the State Department Basic Authorities Act of 1956 (as so added).

## SEC. 8. STABILIZATION AND RECONSTRUCTION TRAINING AND EDUCATION.

Section 701 of the Foreign Service Act of 1980 (22 U.S.C. 4021) is amended—

- (1) by redesignating subsection (g) as subsection (h); and
- (2) by inserting after subsection (f) the following new subsection:
- "(g) STABILIZATION AND RECONSTRUCTION CURRICULUM.—
- "(1) ESTABLISHMENT AND MISSION.—The Secretary, in cooperation with the Secretary of Defense and the Secretary of the Army, is authorized to establish a stabilization and reconstruction curriculum for use in programs of the Foreign Service Institute, the National Defense University, and the United States Army War College.
- "(2) CURRICULUM CONTENT.—The curriculum should include the following:
- "(A) An overview of the global security environment, including an assessment of transnational threats and an analysis of United States policy options to address such threats.
- "(B) A review of lessons learned from previous United States and international experiences in stabilization and reconstruction activities.

- "(C) An overview of the relevant responsibilities, capabilities, and limitations of various Executive agencies (as that term is defined in section 105 of title 5, United States Code) and the interactions among them.
- "(D) A discussion of the international resources available to address stabilization and reconstruction requirements, including resources of the United Nations and its specialized agencies, nongovernmental organizations, private and voluntary organizations, and foreign governments, together with an examination of the successes and failures experienced by the United States in working with such entities.
- "(E) A study of the United States interagency system.
- "(F) Foreign language training.
- "(G) Training and simulation exercises for joint civilian-military emergency response operations"

## SEC. 9. SERVICE RELATED TO STABILIZATION AND RECONSTRUCTION.

- (a) PROMOTION PURPOSES.—Service in stabilization and reconstruction operations overseas, membership in the Response Readiness Corps under section 61(c) of the State Department Basic Authorities Act of 1956 (as added by section 7), and education and training in the stabilization and reconstruction curriculum established under section 701(g) of the Foreign Service Act of 1980 (as added by section 8) should be considered among the favorable factors for the promotion of employees of Executive agencies.
- (b) PERSONNEL TRAINING AND PROMOTION.— The Secretary and the Administrator should take steps to ensure that, not later than 3 years after the date of the enactment of this Act, at least 10 percent of the employees of the Department and the United States Agency for International Development in the United States are members of the Response Readiness Corps or are trained in the activities of, or identified for potential deployment in support of, the Response Readiness Corps. The Secretary should provide such training as needed to Ambassadors and Deputy Chiefs of Mission.
- (c) OTHER INCENTIVES AND BENEFITS.—The Secretary and the Administrator may establish and administer a system of awards and other incentives and benefits to confer appropriate recognition on and reward any individual who is assigned, detailed, or deployed to carry out stabilization or reconstruction activities in accordance with this Act.

## SEC. 10. AUTHORITIES RELATED TO PERSONNEL.

- (a) CONTRACTING AUTHORITY.—
- (1) IN GENERAL.—The Secretary, or the Administrator with the concurrence of the Secretary, may enter into contracts to procure the services of nationals of the United States (as defined in section 101(a)(22) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(22)) or aliens authorized to be employed in the United States as personal services contractors for the purpose of carrying out this Act, without regard to Civil Service or classification laws, for service in the Office of the Coordinator for Reconstruction and Stabilization or for service in foreign countries to assist in stabilizing and reconstructing a country or region that is at risk of, in, or is in transition from, conflict or civil strife.
- (2) NOT EMPLOYEES.—Individuals performing services under contracts described in paragraph (1) shall not by virtue of performing such services be considered to be employees of the United States Government for purposes of any law administered by the Office of Personnel Management (except that the Secretary or Administrator may determine the applicability to such individuals of any law administered by the Secretary or

Administrator concerning the performance of such services by such individuals).

- (b) EXPERTS AND CONSULTANTS.—The Secretary and the Administrator may, to the extent necessary to obtain services without delay, employ experts and consultants under section 3109 of title 5, United States Code, for the purpose of carrying out this Act, without requiring compliance with any otherwise applicable requirements for that employment as the Secretary or Administrator may determine, except that such employment shall be terminated after 60 days if by that time the applicable requirements are not complied with.
- (c) AUTHORITY TO ACCEPT AND ASSIGN DETAILS.—The Secretary is authorized to accept details or assignments of employees of Executive agencies, members of the uniformed services, and employees of State or local governments on a reimbursable or non-reimbursable basis for the purpose of carrying out this Act. The assignment of an employee of a State or local government under this subsection shall be consistent with subchapter VI of chapter 33 of title 5, United States Code.
  - (d) DUAL COMPENSATION WAIVER.—
- (1) ANNUITANTS UNDER CIVIL SERVICE RE-TIREMENT SYSTEM OR FEDERAL EMPLOYEES RE-TIREMENT SYSTEM.—Notwithstanding sections 8344(i) and 8468(f) of title 5, United States Code, the Secretary or the head of another executive agency, as authorized by the Secretary, may waive the application of subsections (a) through (b) of such section 8344 and subsections (a) through (e) of such section 8468 with respect to annuitants under the Civil Service Retirement System or the Federal Employees Retirement System who are assigned, detailed, or deployed to assist in stabilizing and reconstructing a country or region that is at risk of, in, or is in transition from, conflict or civil strife during the period of their reemployment.
- (2) ANNUITANTS UNDER FOREIGN SERVICE RETIREMENT AND DISABILITY SYSTEM OR FOREIGN SERVICE PENSION SYSTEM.—The Secretary may waive the application of subsections (a) through (d) of section 824 of the Foreign Service Act (22 U.S.C. 4064) for annuitants under the Foreign Service Retirement and Disability System or the Foreign Service Pension System who are reemployed on a temporary basis in order to be assigned, detailed, or deployed to assist in stabilization and reconstruction activities under this Act.
- (e) INCREASE IN PREMIUM PAY CAP.—The Secretary, or the head of another executive agency as authorized by the Secretary, may compensate an employee detailed, assigned, or deployed to assist in stabilizing and reconstructing a country or region that is at risk of, in, or is in transition from, conflict or civil strife, without regard to the limitations on premium pay set forth in section 5547 of title 5, United States Code, to the extent that the aggregate of the basic pay and premium pay of such employee for a year does not exceed the annual rate payable for level II of the Executive Schedule.
- (f) EXTENSION OF CERTAIN FOREIGN SERVICE BENEFITS.—The Secretary, or the head of another executive agency as authorized by the Secretary, may extend to any individuals assigned, detailed, or deployed to carry out stabilization and reconstruction activities in accordance with this Act, the benefits or privileges set forth in sections 412, 413, 704, and 901 of the Foreign Service Act of 1980 (22 U.S.C. 972, 22 U.S.C. 3973, 22 U.S.C. 4024, and ner that such benefits and privileges are extended to members of the Foreign Service.
- (g) COMPENSATORY TIME.—Notwithstanding any other provision of law, the Secretary may, subject to the consent of an individual who is assigned, detailed, or deployed to

- carry out stabilization and reconstruction activities in accordance with this Act, grant such individual compensatory time off for an equal amount of time spent in regularly or irregularly scheduled overtime work. Credit for compensatory time off earned shall not form the basis for any additional compensation. Any such compensatory time not used within 26 pay periods shall be forfeited.
- (h) ACCEPTANCE OF VOLUNTEER SERVICES.—
- (1) IN GENERAL.—The Secretary may accept volunteer services for the purpose of carrying out this Act without regard to section 1342 of title 31, United States Code.
- (2) Types of volunteers.—Donors of voluntary services accepted for purposes of this section may include—
  - (A) advisors:
  - (B) experts:
  - (C) consultants; and
- (D) persons performing services in any other capacity determined appropriate by the Secretary.
- (3) SUPERVISION.—The Secretary shall—
- (A) ensure that each person performing voluntary services accepted under this section is notified of the scope of the voluntary services accepted:
- (B) supervise the volunteer to the same extent as employees receiving compensation for similar services; and
- (C) ensure that the volunteer has appropriate credentials or is otherwise qualified to perform in each capacity for which the volunteer's services are accepted.
- (4) APPLICABILITY OF LAW RELATING TO FEDERAL GOVERNMENT EMPLOYEES.—A person providing volunteer services accepted under this section shall not be considered an employee of the Federal Government in the performance of those services, except for the purposes of the following provisions of law:
- (A) Chapter 81 of title 5, United States Code, relating to compensation for work-related injuries.
- (B) Chapter 11 of title 18, United States Code, relating to conflicts of interest.
- (5) APPLICABILITY OF LAW RELATING TO VOL-UNTEER LIABILITY PROTECTION.—
- (A) IN GENERAL.—A person providing volunteer services accepted under this section shall be deemed to be a volunteer of a non-profit organization or governmental entity, with respect to the accepted services, for purposes of the Volunteer Protection Act of 1997 (42 U.S.C. 14501 et seq.).
- (B) INAPPLICABILITY OF EXCEPTIONS TO VOL-UNTEER LIABILITY PROTECTION.—Section 4(d) of such Act (42 U.S.C. 14503(d)) does not apply with respect to the liability of a person with respect to services of such person that are accepted under this section.
  - (i) AUTHORITY FOR OUTSIDE ADVISORS.-
- (1) IN GENERAL.—The Secretary may establish temporary advisory commissions composed of individuals with appropriate expertise to facilitate the carrying out of this Act.
- (2) INAPPLICABILITY OF FACA.—The requirements of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the activities of a commission established under this subsection.

### SEC. 11. AUTHORIZATION OF APPROPRIATIONS.

There is authorized to be appropriated for each fiscal year, \$80,000,000 for personnel, education and training, equipment, and travel costs for purposes of carrying out this Act and the amendments made by this Act (other than the amendment made by section 5).

By Mr. LAUTENBERG (for himself, Mr. Brownback, Mr. Menendez, Mr. Reid, Mrs. Clinton, Mr. Kennedy, Mr. Dodd, Mr. Lieberman, Mr. Feingold, and Mr. Coleman):

- S. 615. A bill to provide the non-immigrant spouses and children of non-immigrant aliens who perished in the September 11, 2001, terrorist attacks an opportunity to adjust their status to that of an alien lawfully admitted for permanent residence, and for other purposes; to the Committee on the Judiciary.
- Mr. LAUTENBERG. Mr. President, I ask unanimous consent that the full text of the bill be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

#### S. 615

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.

#### SECTION 1. SHORT TITLE.

This Act may be cited as the "September 11 Family Humanitarian Relief and Patriotism Act".

# SEC. 2. ADJUSTMENT OF STATUS FOR CERTAIN NONIMMIGRANT VICTIMS OF TERRORISM.

- (a) Adjustment of Status.—
- (1) IN GENERAL.—The status of any alien described in subsection (b) shall be adjusted by the Secretary of Homeland Security to that of an alien lawfully admitted for permanent residence, if the alien—
- (A) applies for such adjustment not later than 2 years after the date on which the Secretary promulgates final regulations to implement this section; and
- (B) is otherwise admissible to the United States for permanent residence, except in determining such admissibility the grounds for inadmissibility specified in paragraphs (4), (5), (6)(A), (7)(A), and (9)(B) of section 212(a) of the Immigration and Nationality Act (8 U.S.C. 1182(a)) shall not apply.
- (2) RULES IN APPLYING CERTAIN PROVISIONS.—
- (A) IN GENERAL.—In the case of an alien described in subsection (b) who is applying for adjustment of status under this section—
- (i) the provisions of section 241(a)(5) of the Immigration and Nationality Act (8 U.S.C. 1231(a)(5)) shall not apply; and
- (ii) the Secretary of Homeland Security may grant the alien a waiver on the grounds of inadmissibility under subparagraphs (A) and (C) of section 212(a)(9) of such Act (8 U.S.C. 1182(a)(9)).
- (B) STANDARDS.—In granting waivers under subparagraph (A)(ii), the Secretary shall use standards used in granting consent under subparagraphs (A)(iii) and (C)(ii) of such section 212(a)(9).
- (3) RELATIONSHIP OF APPLICATION TO CERTAIN ORDERS.—
- (A) APPLICATION PERMITTED.—An alien present in the United States who has been ordered excluded, deported, removed, or ordered to depart voluntarily from the United States under any provision of the Immigration and Nationality Act (8 U.S.C. 1101 et seq.) may, notwithstanding such order, apply for adjustment of status under paragraph (1).
- (B) MOTION NOT REQUIRED.—An alien described in subparagraph (A) may not be required, as a condition of submitting or granting such application, to file a separate motion to reopen, reconsider, or vacate such order
- (C) EFFECT OF DECISION.—If the Secretary of Homeland Security grants a request under subparagraph (A), the Secretary shall cancel the order. If the Secretary renders a final administrative decision to deny the request, the order shall be effective and enforceable to the same extent as if the application had not been made.

- (b) ALIENS ELIGIBLE FOR ADJUSTMENT OF STATUS.—The benefits provided by subsection (a) shall apply to any alien who—
- (1) was lawfully present in the United States as a nonimmigrant alien described in section 101(a)(15) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(15)) on September 10, 2001;
- (2) was, on such date, the spouse, child, dependent son, or dependent daughter of an alien who—
- (A) was lawfully present in the United States as a nonimmigrant alien described in section 101(a)(15) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(15)) on such date; and
- (B) died as a direct result of a specified terrorist activity; and
- (3) was deemed to be a beneficiary of, and by, the September 11th Victim Compensation Fund of 2001 (49 U.S.C. 40101 note).
- (c) STAY OF REMOVAL; WORK AUTHORIZA-
- (1) IN GENERAL.—The Secretary of Homeland Security shall establish, by regulation, a process by which an alien subject to a final order of removal may seek a stay of such order based on the filing of an application under subsection (a).
- (2) DURING CERTAIN PROCEEDINGS.—Notwithstanding any provision of the Immigration and Nationality Act (8 U.S.C. 1101 etc.), the Secretary of Homeland Security shall not order any alien to be removed from the United States, if the alien is in removal proceedings under any provision of such Act and has applied for adjustment of status under subsection (a), except where the Secretary has rendered a final administrative determination to deny the application.
- (3) WORK AUTHORIZATION.—The Secretary of Homeland Security shall authorize an alien who has applied for adjustment of status under subsection (a) to engage in employment in the United States during the pendency of such application.
- (d) AVAILABILITY OF ADMINISTRATIVE REVIEW.—The Secretary of Homeland Security shall provide to applicants for adjustment of status under subsection (a) the same right to, and procedures for, administrative review as are provided to—
- (1) applicants for adjustment of status under section 245 of the Immigration and Nationality Act (8 U.S.C. 1255); or
- (2) aliens subject to removal proceedings under section 240 of such Act (8 U.S.C. 1229a).

  SEC. 3. CANCELLATION OF REMOVAL FOR CERTAIN IMMIGRANT VICTIMS OF TER-

RORISM.

- (a) IN GENERAL.—Subject to the provisions of the Immigration and Nationality Act (8 U.S.C. 1101 et seq.), other than subsections (b)(1), (d)(1), and (e) of section 240A of such Act (8 U.S.C. 1229b), the Secretary of Homeland Security shall, under such section 240A, cancel the removal of, and adjust to the status of an alien lawfully admitted for permanent residence, an alien described in subsection (b), if the alien applies for such relief.
- (b) ALIENS ELIGIBLE FOR CANCELLATION OF REMOVAL.—The benefits provided by subsection (a) shall apply to any alien who—
- (1) was, on September 10, 2001, the spouse, child, dependent son, or dependent daughter of an alien who died as a direct result of a specified terrorist activity; and
- (2) was deemed to be a beneficiary of, and by, the September 11th Victim Compensation Fund of 2001 (49 U.S.C. 40101 note).
- (c) STAY OF REMOVAL; WORK AUTHORIZATION.—
- (1) IN GENERAL.—The Secretary of Homeland Security shall provide by regulation for an alien subject to a final order of removal to seek a stay of such order based on the filing of an application under subsection (a).

- (2) WORK AUTHORIZATION.—The Secretary of Homeland Security shall authorize an alien who has applied for cancellation of removal under subsection (a) to engage in employment in the United States during the pendency of such application.
- (d) MOTIONS TO REOPEN REMOVAL PROCEEDINGS.—
- (1) IN GENERAL.—Notwithstanding any limitation imposed by law on motions to reopen removal proceedings (except limitations premised on an alien's conviction of an aggravated felony (as defined in section 101(a)(43) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(43))), any alien who has become eligible for cancellation of removal as a result of the enactment of this section may file 1 motion to reopen removal proceedings to apply for such relief.
- (2) FILING PERIOD.—The Secretary of Homeland Security shall designate a specific time period in which all such motions to reopen are required to be filed. The period shall begin not later than 60 days after the date of enactment of this Act and shall extend for a period not to exceed 240 days.

#### SEC. 4. EXCEPTIONS.

Notwithstanding any other provision of this Act, an alien may not be provided relief under this Act if the alien is—

- (1) inadmissible under paragraph (2) or (3) of section 212(a) of the Immigration and Nationality Act (8 U.S.C. 1182(a)), or deportable under paragraph (2) or (4) of section 237(a) of such Act (8 U.S.C. 1227(a)), including any individual culpable for a specified terrorist activity; or
- (2) a family member of an alien described in paragraph (1).

#### SEC. 5. EVIDENCE OF DEATH.

For purposes of this Act, the Secretary of Homeland Security shall use the standards established under section 426 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT ACT) Act of 2001 (115 Stat. 362) in determining whether death occurred as a direct result of a specified terrorist activity.

## SEC. 6. DEFINITIONS.

- (a) APPLICATION OF IMMIGRATION AND NATIONALITY ACT PROVISIONS.—Except as otherwise specifically provided in this Act, the definitions used in the Immigration and Nationality Act (8 U.S.C. 1101 et seq.), other than the definitions applicable exclusively to title III of such Act, shall apply in the administration of this Act.
- (b) SPECIFIED TERRORIST ACTIVITY.—For purposes of this Act, the term "specified terrorist activity" means any terrorist activity conducted against the Government or the people of the United States on September 11, 2001

## By Ms. COLLINS (for herself and Mr. Feingold):

- S. 616. A bill to promote health care coverage parity for individuals participating in legal recreational activities or legal transportation activities; to the Committee on Health, Education, Labor, and Pensions.
- Ms. COLLINS. Mr. President, I am pleased to join with my colleague from Wisconsin, Senator Feingold, in introducing legislation to prohibit health insurers from denying benefits to plan participants if they are injured while engaging in legal recreational activities like skiing, snowmobiling, or horseback riding.

Among the many rules that were issued at the end of the Clinton administration was one that was intended to

ensure non-discrimination in health coverage in the group market. This rule was issued jointly on January 8, 2001, by the Department of Labor, the Internal Revenue Service and the Health Care Financing Administration—now the Centers for Medicare and Medicaid Services—in accordance with the Health Insurance Portability and Accountability Act, HIPAA, of 1996.

While I was pleased that the rule prohibits health plans and issuers from denying coverage to individuals who engage in certain types of recreational activities, such as skiing, horseback riding, snowmobiling or motorcycling, I am concerned that it would allow insurers to deny health benefits for an otherwise covered injury that results from participation in these activities.

The rule states that "While a person cannot be excluded from a plan for engaging in certain recreational activities, benefits for a particular injury can, in some cases, be excluded based on the source of the injury." A plan could, for example, include a general exclusion for injuries sustained while doing a specified list of recreational activities, even though treatment for those injuries—a broken arm, for instance—would have been covered under the plan if the individual had tripped and fallen.

Because of this loophole, an individual who was injured while skiing or running could be denied health care coverage, while someone who is injured while drinking and driving a car would be protected.

This clearly is contrary to Congressional intent. One of the purposes of HIPAA was to prohibit plans and issuers from establishing eligibility rules for health coverage based on certain health-related factors, including evidence of insurability. To underscore that point, the conference report language stated that "the inclusion of evidence of insurability in the definition of health status is intended to ensure, among other things, that individuals are not excluded from health care coverage due to their participation in activities motorcycling, such as snowmobiling, all-terrain vehicle riding, horseback riding, skiing and other similar activities." The conference report also states that "this provision is meant to prohibit insurers or employers from excluding employees in a group from coverage or charging them higher premiums based on their health status and other related factors that could lead to higher health costs."

Mr. PRESIDENT, millions of Americans participate in these legal and common recreational activities which, if practiced with appropriate precautions, do not significantly increase the likelihood of serious injury. Moreover, in enacting HIPAA, Congress simply did not intend that people would be allowed to purchase health insurance only to find out, after the fact, that they have no coverage for an injury resulting from a common recreational activity. If this rule is allowed to

stand, millions of Americans will be forced to forgo recreational activities that they currently enjoy lest they have an accident and find out that they are not covered for needed care resulting from that accident.

The legislation that we are introducing today will clarify that individuals participating in activities routinely enjoyed by millions of Americans cannot be denied access to health care coverage or health benefits as a result of their activities. The bill should not be controversial. In fact, it passed the Senate by unanimous consent at the end of the 108th Congress.

I am therefore hopeful that we will be able to move quickly on this legislation this year, and I urge all of my colleagues to join us as cosponsors.

## By Mr. SMITH:

S. 617. A bill to make the National Parks and Federal Recreational Lands Pass available at a discount to certain veterans; to the Committee on Energy and Natural Resources.

Mr. SMITH. Mr. President, I rise today to introduce the Veterans Eagle Parks Pass Act. This legislation would provide admission to any Federal park that charges an admissions fee by creating a "Veterans Eagle Pass" for honorably discharged veterans. I am pleased to continue the efforts of my colleague Congressman Thomas Reynolds, who performed yeoman's work to introduce and push forward this legislation in the House of Representatives.

Currently, an annual America the Beautiful lands pass is available to anyone for eighty dollars. My legislation would allow honorably discharged veterans to buy an annual pass for only ten dollars. I feel very strongly that those who fought so hard to protect our great nation should have better and easier access to its public lands. It is only fitting to offer our veterans improved entrance to America's great public lands like Yosemite National Park in California, Fort Sumter National Monument in South Carolina, Arthur R. Marshall Loxahatchee National Wildlife Refuge in Florida, and Crater Lake National Park in my home State of Oregon.

America's terrain is diverse, from flat plains to high mountains, raging rivers to still lakes. Our country is truly bountiful. Many veterans are avid outdoorsmen and understand the value and quality of our land. In a time of such turmoil abroad, I see no more appropriate opportunity to reward our veterans for their commitment and service to our nation.

I am pleased that this legislation has received the support of the American Legion, AMVETS, and Veterans of Foreign Wars. We owe it to our veterans to provide them with this service.

By Mr. LEAHY (for himself, Mr. SPECTER, Mr. LOTT, Mr. REID, and Ms. LANDRIEU):

S. 618. A bill to further competition in the insurance industry; to the Committee on the Judiciary.

Mr. LEAHY. Mr. President, so people understand. I know the Senator from Pennsylvania has spoken briefly about this and had remarks on it printed in the RECORD.

Our Nation's competition laws are powerful tools to ensure that consumer welfare is the benchmark of fair and accountable industry practices. These competition laws are what make businesses work in America. The vast majority of the companies doing business in the United States are subject to our antitrust laws. Consumers benefit from lower prices, more choices, better services

There are only a few industries that operate outside the Federal antitrust laws. The bipartisan measure I have introduced would end the insurance industry's exemption from the requirement of those laws. I am joined in this effort, as I said before, by the ranking member of the Senate Judiciary Committee. Senator Specter has a strong record of supporting effective competition in every industry through our antitrust laws. Of course, as I have also said, I am joined by the majority leader and by Senator Lott, who is the deputy Republican leader.

Senator LOTT probably wishes he was not in this position, but he represents many of the gulf coast residents who can speak personally and painfully to the abuses that insurers can wreak on their policyholders. The insurance industry's practices affect us all. Perhaps nowhere has the industry and its practices come under as much scrutiny as along the gulf coast in the wake of hurricanes Katrina and Rita. Insurers have been too often denying claims and delaying payments to residents along the gulf coast instead of honoring their contractual commitments. The behavior of insurers in Mississippi has been so outrageous that the State's attorney general recently convened a grand jury to investigate some of the practices.

It seems to me, insurance companies are very eager to collect premiums when times are good but reluctant to compensate policyholders when tragedy strikes. Senator Lott knows all too well the difficulties his constituents have had with insurers. His State was hit hard by Hurricane Katrina. I commend the Senator from Mississippi for his tireless efforts in trying to ensure resources are in place to rebuild. I know he is joined in that effort by his colleague from Mississippi, Senator COCHRAN.

I have worked with others to support efforts to rebuild the Gulf Coast. Most recently, I was pleased to assist Senator Landrieu in her successful efforts to convince the Attorney General to dispatch additional law enforcement to the New Orleans region. People in the gulf coast are Americans. They are our fellow citizens. They have been utterly failed by a woefully unprepared Government, and they should not also be bullied and neglected by insurance companies in their time of need.

The insurance industry has operated largely beyond the reach of Federal

antitrust laws for more than six decades. Assuming there ever was a justification to exempt insurers from Federal Government oversight, I find it hard to believe there is still a reason to exempt them—not in the age of instant communication, the age of the Internet, or the ability to compare not only risks but payments. In fact, we need real oversight, which can be brought about by removing them from the antitrust exemption. We deserve confidence that the industry is not engaging in the most egregious forms of anticompetitive conduct, such as price-fixing, agreements not to pay, or market allocation.

Antitrust laws are the beacon of good competition policy. Insurers may object to being subject to the same antitrust laws as everyone else, but why shouldn't they be subject to the same laws as every other company in this country? If they are operating in an honest and appropriate and open way, they have nothing to fear.

I have more on this, but I ask unanimous consent that my full statement be placed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD as follows:

Mr. LEAHY. Mr. President, to reiterate, our Nation's competition laws are powerful tools to ensure that consumer welfare is the benchmark for fair and accountable industry practices. The vast majority of the companies doing business in the United States are subject to the strictures of the antitrust laws, and consumers benefit through lower prices, more choices, and better services. Only a few industries operate outside the federal antitrust laws, and I am pleased to introduce today a bipartisan measure that will end the insurance industry's exemption from the requirements of those laws.

I am joined in this effort by the ranking member of the Senate Judiciary Committee who has a strong record of supporting effective competition in every industry through our antitrust laws. I am joined as well by Senator REID and Senator LOTT. Senator LOTT represents many of the gulf coast residents who can speak personally, and painfully, to the abuses that insurers can wreak on their policy holders.

Insurance industry practices affect all of us. They affect each of our constituents; they affect every business in every state. But perhaps nowhere has the industry and its practices come under as much scrutiny as along the gulf coast in the wake of Hurricanes Katrina and Rita. Insurers have been too often denying claims and delaying payouts to residents along the gulf coast instead of honoring their contractual commitments to their customers, and thereby contributing to the rebuilding and rejuvenation of the area.

The behavior of insurers in Mississippi has been so outrageous that the state's attorney general recently convened a grand jury to investigate certain practices. Hundreds of policyholders had to go to court to force the insurance companies to fulfill their obligations.

It seems some insurance companies are eager to collect premiums when times are good, but reluctant to aid policyholders when tragedy strikes.

Senator LOTT knows all too well the difficulties his constituents have had with insurers. His state was hit hard by Hurricane

Katrina, and I commend him on his tireless efforts to ensure that resources are in place to rebuild. I have worked with them in other contexts to support efforts to rebuild the gulf coast. Most recently, I was honored to have assisted Senator Landrieu in her successful efforts to convince the attorney general to dispatch additional law enforcement to the New Orleans region.

Our fellow citizens on the gulf coast who have had to cope with the devastation and destruction of the 2005 hurricanes, and who were utterly failed by their woefully unprepared government, should not also be bullied or neglected by insurance companies in their time of need—insurance companies whose business is based on compensating people after a tragic loss.

Unfortunately, the insurance industry has operated largely beyond the reach of federal antitrust laws for more than six decades. If there ever was, there is no longer any justification to exempt the insurance industry from federal government oversight.

Such oversight could provide confidence that the industry is not engaging in the most egregious forms of anticompetitive conduct—price fixing, agreements not to pay, and market allocations.

The Insurance Industry Competition Act we introduce today will simply give the Department of Justice and the Federal Trade Commission the authority to apply the antitrust laws to anticompetitive behavior by insurance companies. Our antitrust laws are the beacon of good competition policy. Competition is good for consumers and good for our economy.

Insurers may object to being subject to the same antitrust laws as everyone else, but if they are operating in an honest and appropriate way, they should have nothing to fear. American consumers and American businesses rely on insurance—it is a vital part of our economy—and they have the right to be confident that the cost of their insurance, and the decisions by their insurance carriers about which claims will be paid, reflect competitive market conditions, not collusive behavior.

I thank Senator REID and Senator SPECTER for joining me in this important effort. And I thank Senator LOTT for his support, and for using the lessons of his constituents' experiences to shed light on an industry that for too long, in too many ways, has been out of the reach of federal antitrust authorities.

Mr. LEAHY. Mr. President, I see the Senator from Mississippi on the floor and the Senator from Pennsylvania. If they are seeking time, I would ask how much time they need.

Mr. LOTT. Mr. President, I wish to withhold until the Senator from Pennsylvania makes his brief remarks.

Mr. LEAHY. How much time does the Senator from Pennsylvania want? Because this is coming out of time I had set aside for something else.

Mr. SPECTER. Less than 5 minutes. Mr. LEAHY. I yield 5 minutes to the Senator from Pennsylvania.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. SPECTER. Mr. President, I thank my distinguished colleague from Vermont.

As noted earlier, legislation was introduced in the last Congress by Senator Leahy and myself and others to deal with the problem of the McCarran-Ferguson Act. We held hearings on this matter in the Judiciary Committee. On recent matters which have evolved

from Hurricane Katrina, which will be amplified by the distinguished Senator from Mississippi, Mr. LOTT, there is a more pressing need to enter into this arena.

There have been various attempts over the years to limit McCarran-Ferguson, and they have not succeeded because, as amplified in a more detailed statement which I will include for the RECORD, there were safe harbors proposed. They became very complicated. We have provided in this legislation that the Commission decide what is to be violative of the antitrust laws, a line which has been successful on the health industry.

The economy of the United States functions much better when the antitrust laws are available and enforceable. We see a great many problems at the present time with what is happening with the sports teams. The National Football League enjoys a limited antitrust exemption, and they are proposing the Sunday ticket to DIRECTV, which has a monopoly. Cable companies can't get the Sunday ticket. They now have the Thursday to Saturday ticket. It is only on the NFL channel. I had a talk with the commissioner of the NFL recently, who was living in New York City, and he couldn't get the Sunday ticket because his highrise wouldn't allow him to put a dish on top of the building.

May I note for the record the distinguished junior Senator from Montana is nodding in the affirmative. He lives in an area—now he is smiling. He lives in an area where you need a satellite, and his constituents do, and some of mine in Pennsylvania do, and in my home State of Kansas. Now baseball is coming along with extra innings and exclusive to DIRECTV.

The impact of the antitrust exemption on the insurance industry has been even more profound. But it is noted when we have the Federal Trade Commission authorized to issue guidelines in identifying joint practices where the antitrust concerns ought to be addressed, that is the way to approach it, as the Federal Trade Commission did in the health care industry.

I think this is a significant step forward, and I am glad to see that the majority leader, Senator Reid, is behind this legislation. We can pass it out of committee, we can take it up on the Senate floor, and I think we can provide better protection for the American consumers.

Mr. President, I ask unanimous consent that the full text of my statement be included in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

#### INSURANCE INDUSTRY ANTITRUST ENFORCEMENT ACT OF 2007

Mr. SPECTER. Mr. President, the Insurance Industry Antitrust Enforcement Act of 2007 would subject the insurance industry to the antitrust laws which apply to almost every other industry in America. Congress enacted the McCarran-Ferguson Act in 1945

in response to a controversial Supreme Court case in which the Court held that the business of insurance constituted interstate commerce. That ruling opened the door to federal regulation of insurance, a business that had historically been regulated and taxed by the states. McCarran-Ferguson reaffirmed the power of the states to regulate and tax insurance.

In doing so, Congress exempted the insurance industry practices from antitrust scrutiny to the extent that such practices are "regulated by state law." Since then, the courts have liberally interpreted the phrase "regulated by state law." They have held that insurance industry practices are exempt from the antitrust laws so long as regulators have been given jurisdiction over the challenged practices—regardless of whether the regulators ever exercise that jurisdiction.

Over the years, state regulators have either chosen not to regulate, or failed to regulate, practices that would have violated the antitrust laws absent McCarran-Ferguson. With McCarran-Ferguson, such practices escape both regulatory and federal antitrust oversight. The most notorious practices to come to light involved bid-rigging and customer allocation by insurance broker Marsh & McClennan and several of the nation's largest insurers. Under the scheme, Marsh steered unsuspecting clients to insurers with which it had lucrative payoff agreements. To make the scheme work, Marsh solicited fictitious bids from other complicit insurers to make the bid submitted by the selected insurer-the one that offered Marsh the highest payoff—seem competitive.

Even though the scheme eliminated competition among the insurance companies that were involved, those companies could not be prosecuted under federal antitrust law. Several states prosecuted the insurance companies under a variety of state laws, including antitrust laws, but federal prosecutors could not bring their significant resources to bear. There simply is no justification for that. Federal law enforcement should have the power to prosecute such blatant violations of the antitrust laws.

This is not the first attempt to subject the insurance industry to federal antitrust law. In the wake of numerous insolvencies, mismanagement and other misconduct by insurers in the late 1980s, legislation was introduced repealing the exemption. That legislation, introduced by Congressman Brooks, faced opposition from insurers who claimed that many industry practices engaged in jointly by insurance companies were procompetitive and necessary for smaller insurers. The legislation provided a safe harbor, specifically listing the practices of insurance companies that would be exempt from the antitrust laws. However, it proved impossible to craft a list of safe harbors for all the information that competing insurers claimed they needed to share with one another. This bill has avoided that problem.

More recently, some have argued that the answer to insurance industry ills is full federal regulation. I do not necessarily believe that stripping the states of their authority to regulate the insurance industry is the answer. This bill does not do that. It allows states to continue to regulate their insurance industries. However, the existence of state regulation is no reason to prevent federal prosecutors from going after antitrust violators. And, there is no reason to prevent federal prosecutors from going after antitrust violators just because those violators happen to work for insurance companies.

As I have said, allowing federal prosecutors to go after those who violate the antitrust laws will not prevent states from regulating the insurance industry. If a state is actively supervising practices by its insurance indus-

try that might otherwise violate the antitrust laws, this legislation would exempt that practice from the antitrust laws. Antitrust law does not generally apply where a state is actively regulating an industry. This is as it should be and the legislation I introduce today, the Insurance Industry Antitrust Act of 2007, incorporates that standard.

The Judiciary Committee held a hearing on this issue in May. During the hearing, Marc Racicot, the President of the American Insurance Association, a trade association composed of the nation's largest insurers, acknowledged that "every state provides some form of antitrust regulation of insurers." In other words, many states already enforce their state antitrust laws with respect to insurers. So, I have to ask, why have we tied the hands of federal antitrust enforcers?

The insurers will argue that repealing the antitrust exemption for insurers will create uncertainty by throwing into question the legality of every joint practice engaged in by insurers. They will argue that the legality of each joint practice will have to be litigated in court. However, this bill has been drafted to avoid such litigation. Rather than incorporating a laundry list of safe harbors, an approach that was taken in the past, the bill would allow the Federal Trade Commission to issue guidelines identifying joint practices that do not raise antitrust concerns and would therefore not face scrutiny from antitrust enforcers.

This is a job for which the Commission is well equipped. In the past, the Commission along with the Justice Department issued "Statements of Antitrust Enforcement Policy in Health Care." The Health Care Statements identified joint conduct by health care providers that did not raise antitrust concerns and therefore would likely escape scrutiny by antitrust enforcers. The Health Care Statements were designed to give health care providers certainty about the legality of their joint conduct under the antitrust laws. Similar guidelines for the insurance industry would provide insurers with certainty, but at the same time, would ensure that joint practices that are anticompetitive receive scrutiny from the antitrust enforcement agencies.

Although many insurers oppose repeal of their antitrust exemption, others support a repeal. In particular, the Antitrust Section of the American Bar Association has long supported repeal. During the Judiciary Committee's hearing, the current head of the Antitrust Section, Donald Klawiter noted the Section's nearly 20-year history of supporting repeal. Klawiter testified that "the benefits of antitrust exemptions almost never outweigh the potential harm imposed on society by the loss of competition." the same hearing, Robert Hunter, testifying on behalf of the Consumer Federation of America, concluded that "application of the antitrust laws to the insurance industry could result in double-digit savings for America's insurance consumers.

It is my hope that this legislation will bring the benefits of competition to the insurance industry and to consumers. Too many consumers are paying too much for insurance due to the collusive atmosphere that exists in the insurance industry. This has become a particular problem along the Gulf Coast, where insurers have shared hurricane loss projections, which may result in doubledigit premium increases for Gulf Coast homeowners.

I strongly urge Members who are concerned about industry exemption from the antitrust laws and collusive insurance industry practices to support this important piece of legislation.

Mr. LOTT. Mr. President, may I get some time under the agreement?

Mr. LEAHY. How much time would the distinguished Senator need?

Mr. LOTT. Probably 5 or 6 minutes. How much would you have left then? I don't want to eat up all your time.

Mr. LEAHY. Again, we are using time that I—Mr. President, I ask unanimous consent that my time be extended by 6 minutes, and that I be allowed to yield that 6 minutes to the Senator from Mississippi.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. LOTT. Mr. President, let me say at the beginning, I appreciate the courtesy of the Senator from Vermont and his comments on our effort here; also, my colleague from Pennsylvania, Senator Specter, whom I have discussed this issue with several times over the past year.

Let me begin at the beginning of this effort. I thank my colleagues for this bipartisan effort. It shows what we can do when we work together. Now, we have a long road to go, but this is being introduced as a bipartisan measure with leaders from both sides and leaders of the Judiciary Committee joining in cosponsoring this legislation.

How did I get interested in this area? Well, it is like so many things in my life that go back only until August 29, 2005, when Hurricane Katrina devastated my hometown and the area of my State that I love so much, Mississippi and the gulf coast area. I had been active in years gone by actually in the insurance area. I had done some law practice in that area. I had done some defense work. But I never had become steeped in the laws that apply to the industry because most of the time I was dealing with an automobile accident case or something of that nature.

Well, after Hurricane Katrina we learned a lot of lessons, and we found a lot of new concerns in areas where we had to take action. One of the commitments I have made to the people—and to the Senate because the Senate has been so good in helping us in our recovery effort, in changing the laws where applicable, the Stafford Act, in providing funds. But one of the commitments I made as a result of that is to make sure we take a look at what happened to us. What did we learn from Katrina? What can we do to have more laws and the right things in place after the next natural disaster—and there will be one—or any kind of catastrophic disaster? We learned that the laws were not what they should be. They needed to be changed. We have changed them some and we need to change them some more. We learned the Federal agencies weren't necessarily set up properly to do what needed to be done in the aftermath of a disaster. We had questions about homeland security and the Federal Emergency Management Administration and how the military, the Coast Guard, and everybody interplayed together. So we have been trying to make those corrections.

We need to ask ourselves: Do we need to give some additional thought to how we deal on a national level with the coverage of people or how we help them recover? Do we need a national catastrophic insurance program? I don't know that I am satisfied I know the answer yet, but I think we need to ask that question in advance.

I also found, to my absolute horror, something I should have known, which is that the insurance industry is not covered by antitrust laws. They have a waiver. I said: How could that be? I remember hearing discussion over the years about the McCarran-Ferguson Act, but I never focused on it. When I realized that ratesetting and actually policy actions by the industry were not covered by antitrust laws, I was stunned. I understand you need a lot of information to decide on rates, but that information can be used back and forth to in effect set rates as an industry without making sure that it is not done in an anticompetitive way. Do you mean that under this exemption, that companies could collude on what actions they take or, even worse, what actions they don't take, which is what we got into after Hurricane Katrina? We had companies basically saying: Oh, no, no, you are covered by Federal flood insurance. We don't have to pay under the household policies for wind damage.

So as I got into it, I found that this happened back in 1944. At that point, there was regulation of the insurance industry, but there was a case styled the United States v. South Eastern Underwriters Association which caused a change in how insurers were regulated. Then the Congress immediately acted and said: Oh, no, we are going to say that federal antitrust laws do not apply to this industry.

Soon the courts got into this issue and took a look at what happened. They looked at the record. There were no hearings in the Senate. It was passed quickly on a voice vote, and it went quickly through the House. The conference report was debated for 2 days by the Senate, and most of the debate, as I have looked at it, looks as though everybody thought this was going to be a temporary moratorium. However, that is not the way the courts have interpreted the laws.

Under the McCarran-Ferguson Act, insurers are exempt from antitrust scrutiny, so long as they are regulated by State law. Then you get into a patchwork of State laws: Do the States actively regulate them? Is there a process for antitrust activities to be considered?

Over the years, many have advocated the repeal of this antitrust exemption. The Judiciary Committee had hearings on this last summer. The American Bar Association's antitrust section noted that the organization for nearly 20 years has supported repeal of this exemption. Look, there is a unique role for States to deal with insurance questions and needs in those States, but my question beyond that is: Should the Federal Government have the right to

make sure there are not anticompetitive activities, to make sure there is no colluding? I think we need to take a serious look at that. This legislation would do that. It would take away that exemption. It would make the insurance industry subject to the same coverage of almost every other corporation in America: antitrust legislation.

I know my time has expired. I thank the Chair for his leniency. I thank Senator Leahy for doing this. I look forward to having the hearings and testifying. This is wrong, Mr. President, and the Senate in a bipartisan way should, and I believe will, correct it.

I yield the floor.

Mr. LEAHY. Mr. President, I thank my friend from Mississippi, and I am proud to be joining with him on this. He and I have discussed this several times over the past several months. I told him last fall I would join with him on such legislation, and I am proud to do so

Mr. REID. Mr. President, I want to express my support for the "Insurance Industry Competition Act of 2007," which repeals the well-known McCarran-Ferguson Act. McCarran-Ferguson gave States the authority to regulate the business of insurance and exempted insurance from the Federal antitrust laws. Unfortunately, McCarran-Ferguson came about as a result of a Senator from my State of Nevada, McCarran, and a Senator from Michigan, Ferguson. It was passed to give a few years of relief to the insurance industry. In 1944, the United States Supreme Court ruled against the industry-wide practice of cooperating to set premium prices in United States v. Southeastern Underwriters Association. Insurers argued that most companies were too small to rely solely on their own experience in setting premiums. As a result of these protests the McCarran-Ferguson Act was passed by Congress in 1945, exempting insurance-rate fixing from the Sherman Antitrust Act, and placing responsibility for industry regulation in the hands of state governments.

Now, some 60 plus years later, insurance companies are the only businesses—other than Major League Baseball—not subject to antitrust laws. Congress began investigating the effectiveness of State insurance regulation in 1958, under the oversight of Senator O'Mahoney, who had been a principal architect of the McCarran-Ferguson Act, and found State regulation lacking, incapable of dealing with interstate and international issues, and unwilling or unable to "bring the blessings of competition" to insurance ratemaking. The same thing is true today, and its time we take action to remedy this situation. The rationale for this exemption has long since passed. Insurance should be like any other business—subject to antitrust laws.

Senator LEAHY'S bill would accomplish this. "The Insurance Industry Competition Act of 2007" would repeal the exemption and simply give the De-

partment of Justice and the Federal Trade Commission the authority to apply the antitrust laws to anticompetitive behavior by insurance companies. Such oversight could ensure that the industry is not engaging in the most egregious forms of anticompetitive conduct—price fixing, agreements not to pay, and market allocations. This Act would not affect the ability of each State to regulate the business of insurance.

If insurers around the country are operating in an honest and appropriate way, they should not object to being answerable under the same Federal antitrust laws as virtually all other businesses. American consumers should be confident that the cost of their insurance reflects competitive market conditions, not collusive behavior, and they should benefit through lower prices, more choices, and better services.

Perhaps nowhere has the insurance industry and its practices come under as much scrutiny as along the Gulf Coast in the wake of Hurricanes Katrina and Rita. Just yesterday, the AP reported that "State Farm Insurance Cos. is suspending sales of any new commercial or homeowner policies in Mississippi starting Friday." I ask Unanimous Consent that a news article dated February 14, 2007, from the Associated Press be printed in the RECORD. Insurers have been too often denying claims and delaying payouts to residents of New Orleans and all along the Gulf Coast instead of honoring their contractual commitments to their customers, and thereby contributing to the rebuilding and rejuvenation of the area. We need to act now to end this practice. I thank Senators LEAHY, SPECTER, and LOTT for their work on this important legislation.

There being no objection, the article was ordered to be printed in the RECORD, as follows:

STATE FARM: NO NEW POLICIES IN MISS.
(By Michael Kunzelman)

State Farm Insurance Cos. is suspending sales of any new commercial or homeowner policies in Mississippi starting Friday, citing in part a wave of litigation it has faced after Hurricane Katrina, a company official said Wednesday.

Mike Fernandez, vice president of public affairs for State Farm, said Mississippi's "current legal and political environment is simply untenable. We're just not in a position to accept any additional risk in this homeowners' market."

Fernandez said the action was not a direct response to any specific development in the litigation. That litigation has included a recent federal jury's \$2.5 million punitive damage award to a policyholder who sued State Farm for refusing to cover the 2005 hurricane's storm surge damage.

State Farm, the largest homeowners insurer in Mississippi with more than 30 percent of the market, agreed to settle hundreds of lawsuits by policyholders and reopen and pay thousands of other disputed claims. The landmark deal is potentially worth hundreds of millions of dollars for Mississippi homeowners devastated by Katrina.

By Mr. FEINGOLD (for himself and Ms. MIKULSKI):

S. 620. A bill to establish a demonstration project to train unemployed workers for employment as health care professionals, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

Mr. FEINGOLD. Mr. President, today I am introducing the third in a series of bills intended to support American companies and American workers. Earlier this week, I introduced a resolution which would set some minimum standards for future trade agreements into which our country enters, and legislation which would strengthen the Buy American Act. Today I am introducing legislation that would help workers who have lost their manufacturing or service sector jobs to be retrained for jobs in high-demand health care fields. I am pleased that my colleague. Senator Mikulski, is cosponsoring this important legislation and I look forward to working with her to advance it during the 110th Congress.

According to statistics from the Department of Labor, Wisconsin has lost over 90.000 manufacturing jobs between January 2000 and November 2006. Nationally, the country has lost around 3 million manufacturing jobs since January 2001, yet the administration has continued to support policies that lead to the outsourcing of American jobs. I continue to be deeply troubled by the Bush Administration's contention that the outsourcing of American service sector and other jobs is good for the economy. I am concerned about the message that this policy sends to Wisconsinites and all Americans who are currently employed in these sectors.

There is something of a silver lining to the looming cloud of manufacturing and other jobs loss: the country's workforce development system.

In spite of stretched resources and long waiting lists for services, our workforce development boards are making a tremendous effort to retrain laid-off workers and other job seekers for new jobs. And this effort is clearly evident in Wisconsin, where my State's workforce development boards—despite shoestring budgets—are leading the way in finding innovative solutions to retraining workers for new careers.

I strongly support the work of these agencies, and have urged the Administration and Senate appropriators to provide adequate funding for the job training programs authorized by the Workforce Investment Act. I look forward to the reauthorization of the Workforce Investment Act this year and I will continue to work to ensure that the workforce development boards in my state and across our country receive the resources that they need to help job seekers get the training they need to be successful.

I am committed to finding resources to retrain those who have been laid off from the manufacturing and service sectors and who wish to find new jobs in high-demand fields such as health care.

As most of my colleagues know all too well, we are facing a significant

shortage of health care workers. Congress has made some progress in addressing the nursing shortage, but we need to expand our efforts. Shortages of health professionals pose a real threat to the health of our communities by impacting access to timely, high-quality health care. Studies have shown that shortages of nurses in our hospitals and health facilities increase medical errors, which directly affects patient health.

As our population ages, and the babyboomers need more health care, our need for all types of health professionals is only going to increase. This is particularly true for the field of long-term care. According to the Bureau of Labor Statistics, we are going to need an additional 1.4 million nursing aides, home health aides, and other health professionals in long-term care before the year 2014. In total, there will be almost 1.7 million job openings in health care support occupations through 2012.

As our demand for health care workers grows, so does the number of jobs available within this sector. According to the Wisconsin Department of Workforce Development, the surging job growth in health care will translate into a real need for workers, and real opportunity. In Wisconsin alone, there will be an additional 61,910 health care positions by 2014. This represents a 27 percent increase in jobs in health care by 2014.

Workforce development agencies in my home State of Wisconsin are already working to support displaced workers in their communities by training them for health care jobs, since there is a real need for workers in these fields. These agencies are helping communities get and maintain access to high-quality health care by ensuring that there are enough health care workers to care for their communities.

As the executive director of one of the workforce development boards in my State put it, "[t]here are simply not many good quality jobs to replace manufacturing jobs lost to rural communities. The medical professions, by offering a 'living wage' and good benefits, provide an excellent alternative to manufacturing for sustaining a higher, family-oriented standard of living."

I believe we should support our communities in these efforts by providing them with the resources they need to establish, sustain, or expand these important programs. For that reason, today I am introducing the Community-Based Health Care Retraining Act. This bill would amend the Workforce Investment Act to authorize a demonstration project to provide grants to community-based coalitions, led by local workforce development boards, to create programs to retrain unemployed workers who wish to obtain new jobs in the health care professions. My bill would authorize a total of \$25 million for grants between \$100,000 and \$500,000, and, in the interest of fiscal responsibility, my legislation is fully offset.

This bill will help provide communities with the resources they need to run retraining programs for the health professions. The funds could be used for a variety of purposes, from increasing the capacity of our schools and training facilities, to providing financial and social support for workers who are in retraining programs. This bill allows for flexibility in the use of grant funds because I believe that communities know best about the resources they need to run an efficient program.

This bill represents a nexus in my efforts to support workers whose jobs have been shipped overseas and to ensure that all Americans have access to the high-quality health care that they deserve. By providing targeted assistance to train laid-off workers who wish to obtain new jobs in the health care sector, we can both help unemployed Americans and improve the availability and quality of health care that is available in our communities.

I am pleased that this bill is supported by a variety of organizations that are committed to providing highquality job training and health care services, including: the Wisconsin Association of Job Training Executives, the Wisconsin Hospital Association, Madison Area Technical College, the Northwest Wisconsin Concentrated Employment Program, the Workforce Development Board of South Central Wisconsin, the Bay Area Workforce Development Board, the Healthcare Workforce Network, the Southwest Workforce Development Wisconsin Board, Sauk County Development Corporation, the American Osteopathic Society, Umos, the Fox Valley Workforce Development Board, and the West Central Wisconsin Workforce Development Board.

In order to ensure that our workers are able to compete in the new economy, we must ensure that they have the tools they need to be trained or retrained for high-demand jobs such as those in the health care field. My bill is a small step toward providing the resources necessary to achieve this goal. I will continue to work to strengthen the American manufacturing sector and to support those workers who have been displaced due to bad trade agreements and other policies that have led to the loss of American jobs.

I ask unanimous consent that the text of this bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

### S 620

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.

## SECTION 1. SHORT TITLE.

This Act may be cited as the "Community-Based Health Care Retraining Act"

#### SEC. 2. HEALTH PROFESSIONS TRAINING DEM-ONSTRATION PROJECT.

Section 171 of the Workforce Investment Act of 1998 (29 U.S.C. 2916) is amended by adding at the end the following:

"(e) Health Professions Training Demonstration Project.—

- "(1) Definitions.—In this subsection:
- "(A) COVERED COMMUNITY.—The term 'covered community' means a community or region that—
- "(i) has experienced a significant percentage decline in positions in the manufacturing or service sectors; and
- "(ii) is determined by the Secretary of Health and Human Services (in consultation with the medical community) to be an area with a shortage of health care professionals described in clause (i) or (ii) of subparagraph (C).
- "(B) COVERED WORKER.—The term 'covered worker' means an individual who—
- "(i)(I) has been terminated or laid off, or who has received a notice of termination or layoff, from employment in a manufacturing or service sector:
- "(II)(aa) is eligible for or has exhausted entitlement to unemployment compensation; or
- "(bb) has been employed for a duration sufficient to demonstrate, to the appropriate entity at a one-stop center referred to in section 134(c), attachment to the workforce, but is not eligible for unemployment compensation due to insufficient earnings or having performed services for an employer that were not covered under a State unemployment compensation law; and
- "(III) is unlikely to return to a previous industry or occupation; or
- "(ii)(I) has been terminated or laid off, or has received a notice of termination or layoff, from employment in a manufacturing or service sector as a result of any permanent closure of, or any substantial layoff at, a plant, facility, or enterprise; or
- $\lq\lq$ (II) is employed in a manufacturing or service sector at a facility at which the employer has made a general announcement that such facility will close within 180 days.
- "(C) HEALTH CARE PROFESSIONAL.—The term 'health care professional'—
- "(i) means an individual who is involved with—
- "(I) the delivery of health care services, or related services, pertaining to—
- "(aa) the identification, evaluation, and prevention of diseases, disorders, or injuries; or
- "(bb) home-based or community-based long-term care:
- "(II) the delivery of dietary and nutrition services; or
- "(III) rehabilitation and health systems management; and
- "(ii) with respect to a covered community to be served through a grant made under paragraph (3), includes individuals in health care professions and jobs for which there is a shortage in the community, as determined by the Secretary of Health and Human Services (in consultation with the medical community), giving consideration to the amount of training time required to retrain the covered workers for the health care professions and jobs
- "(D) TRIBAL COLLEGE OR UNIVERSITY.—The term 'tribal college or university' means—
- "(i) a tribally controlled college or university, as defined in section 2 of the Tribally Controlled College or University Assistance Act of 1978 (25 U.S.C. 1801);
- "(ii) Diné College, authorized in the Navajo Community College Act (25 U.S.C. 640a et
- "(iii) any of the 1994 Institutions, as defined in section 532 of the Equity in Educational Land-Grant Status Act of 1994 (7 U.S.C. 301 note).
- "(2) ESTABLISHMENT OF PROJECT.—In accordance with subsection (b), the Secretary shall establish and carry out a health professions training demonstration project.
- "(3) GRANTS.—In carrying out the project, the Secretary, after consultation with the

- Secretary of Health and Human Services, shall make grants to eligible entities to enable the entities to carry out programs in covered communities to train covered workers for employment as health care professionals. The Secretary shall make each grant in an amount of not less than \$100,000 and not more than \$500,000.
- "(4) ELIGIBLE ENTITIES.—Notwithstanding subsection (b)(2)(B), to be eligible to receive a grant under this subsection to carry out a program in a covered community, an entity shall be a partnership that is—
- "(A) under the direction of a local workforce investment board established under section 117 that is serving the covered community; and
- "(B) composed of members serving the covered community, such as—
- $\lq\lq$ (i) an institution of higher education that provides a 4-year program of instruction;
- "(ii) an accredited community college;
  "(iii) an accredited vocational or technical
- "(iii) an accredited vocational or technica school;
  - "(iv) a tribal college or university;
- "(v) a health clinic or hospital;
- "(vi) a home-based or community-based long-term care facility or program; or
- "(vii) a health care facility administered by the Secretary of Veterans Affairs.
- "(5) APPLICATIONS.—To be eligible to receive a grant under this subsection, an entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including, at a minimum—
- "(A) a proposal to use the grant funds to establish or expand a training program in order to train covered workers for employment as health care professionals (including paraprofessionals):
- "(B) information demonstrating the need for the training and support services to be provided through the program;
- "(C) information describing the manner in which the entity will expend the grant funds, and the activities to be carried out with the funds:
- "(D) information demonstrating that the entity meets the requirements of paragraph (4); and
- "(E) with respect to training programs carried out by the applicant, information—
- "(i) on the graduation rates of the programs involved;
- "(ii) on the retention measures carried out by the applicant;
- "(iii) on the length of time necessary to complete the training programs of the applicant; and
- "(iv) on the number of qualified covered workers that are refused admittance into the training programs because of lack of capacity.
- "(6) SELECTION.—In making grants under paragraph (3), the Secretary, after consultation with the Secretary of Health and Human Services, shall—
- ''(A) consider the information submitted by the eligible entities under paragraph (5)(E); and
  - "(B) select-
- "(i) eligible entities submitting applications that meet such criteria as the Secretary of Labor determines to be appropriate; and
- "(ii) among such entities, the eligible entities serving the covered communities with the greatest need for the grants and the greatest potential to benefit from the grants.
- "(7) USE OF FUNDS.-
- "(A) In general.—An entity that receives a grant under this subsection shall use the funds made available through the grant for training and support services that meet the needs described in the application submitted under paragraph (5), which may include—

- "(i) increasing capacity, subject to subparagraph (B), at an educational institution or training center to train individuals for employment as health professionals, such as by—
- "(I) expanding a facility, subject to subparagraph (B);
  - "(II) expanding course offerings;
  - "(III) hiring faculty;
- "(IV) providing a student loan repayment program for the faculty;
- "(V) establishing or expanding clinical education opportunities;
- "(VI) purchasing equipment, such as computers, books, clinical supplies, or a patient simulator; or
  - "(VII) conducting recruitment; or
- "(ii) providing support services for covered workers participating in the training, such as—
  - "(I) providing tuition assistance;
- "(II) establishing or expanding distance education programs;
- "(III) providing transportation assistance; or
- "(IV) providing child care.
- "(B) LIMITATION.—To be eligible to use the funds to expand a facility, the eligible entity shall demonstrate to the Secretary in an application submitted under paragraph (5) that the entity can increase the capacity described in subparagraph (A)(i) of such facility only by expanding the facility.
- "(8) FUNDING.—Of the amounts appropriated to, and available at the discretion of, the Secretary or the Secretary of Health and Human Services for programmatic and administrative expenditures, a total of \$25,000,000 shall be used to establish and carry out the demonstration project described in paragraph (2) in accordance with this subsection."
  - By Mr. FEINGOLD (for himself, Mr. Grassley, Mr. Kennedy, Mr. Lieberman, and Mr. Inouye):
- S. 621. A bill to establish commissions to review the facts and circumstances surrounding injustices suffered by European Americans, European Latin Americans, and Jewish refugees during World War II; to the Committee on the Judiciary.
- Mr. FEINGOLD. Mr. President, today I introduce the Wartime Treatment Study Act. This bill would create two fact-finding commissions: one commission to review the U.S. government's treatment of German Americans, Italian Americans, and European Latin Americans during World War II, and another commission to review the U.S. government's treatment of Jewish refugees fleeing Nazi persecution during World War II. This bill is long overdue.
- I am very pleased that my colleagues Senators Grassley, Kennedy, Lieberman and Inouye have joined me as cosponsors of this important bill. I thank them for their support. And I thank Congressman Wexler, who has been the unflagging champion of this legislation in the House of Representatives.

The victory of America and its allies in the Second World War was a triumph for freedom, justice, and human rights. The courage displayed by so many Americans, of all ethnic origins, should be a source of great pride for all Americans

But, at the same time that so many brave Americans fought for freedom in Europe and the Pacific, the U.S. government was curtailing the freedom of people here at home. While, it is, of course, the right of every nation to protect itself during wartime, the U.S. Government must respect the basic freedoms for which so many Americans have given their lives to defend. War tests our principles and our values. And as our Nation's recent experience has shown, it is during times of war and conflict, when our fears are high and our principles are tested most, that we must be even more vigilant to guard against violations of the basic freedoms guaranteed by the Constitu-

Many Americans are aware that during World War II, under the authority of Executive Order 9066, our government forced more than 100,000 ethnic Japanese from their homes and ultimately into internment camps. Japanese Americans were forced to leave their homes, their livelihoods, and their communities and were held behind barbed wire and military guard by their own government. Through the work of the Commission on Wartime Relocation and Internment of Civilians, created by Congress in 1980, this shameful event finally received the official acknowledgement and condemnation it deserved. Under the Civil Liberties Act of 1988, people of Japanese ancestry who were subjected to relocation or internment later received an apology and reparations on behalf of the people of the United States.

February 19, 2007, is the "Day of Remembrance," the 65th anniversary of the signing of Executive Order 9066. On this day, we should remember the freedoms all of these individuals were forced to give up, and resolve never to make these mistakes again.

While I commend our government for finally recognizing and apologizing for the mistreatment of Japanese Americans during World War II, I believe that it is time that the government also acknowledge the mistreatment experienced by many German Americans, Italian Americans, and European Latin Americans, as well as Jewish refugees.

The Wartime Treatment Study Act would create two independent, fact-finding commissions to review this unfortunate history, so that Americans can understand why it happened and work to ensure that it never happens again. One commission will review the treatment by the U.S. government of German Americans, Italian Americans, and other European Americans, as well as European Latin Americans, during World War II.

I believe that most Americans are unaware that, as was the case with Japanese Americans, approximately 11,000 ethnic Germans, 3,200 ethnic Italians, and scores of Bulgarians, Hungarians, Romanians or other European Americans living in America were taken from their homes and placed in internment camps during World War II. We must learn from this history and explore why we turned on our fellow

Americans and failed to protect their basic freedoms.

A second commission created by this bill will review the treatment by the U.S. government of Jewish refugees who were fleeing Nazi persecution and genocide. We must review the facts here as well and determine how restrictive immigration policies failed to provide adequate safe harbor to Jewish refugees fleeing the persecution of Nazi Germany. It is a horrible truth that the United States turned away thousands of refugees, delivering many refugees to their deaths at the hands of the Nazi regime.

As I mentioned earlier, there has been a measure of justice for Japanese Americans who were denied their liberty and property. It is now time for the U.S. government to complete the accounting of this period in our nation's history. It is time to create independent, fact-finding commissions to conduct a full and through review of the treatment of all European Americans, European Latin Americans, and Jewish refugees during World War II.

Up to this point, there has been no justice for the thousands of German Americans, Italian Americans, and other European Americans who were branded "enemy aliens" and then taken from their homes, subjected to curfews, limited in their travel, deprived of their personal property, and, in the worst cases, placed in internment camps.

There has been no justice for Latin Americans of European descent who were shipped to the United States and sometimes repatriated or deported to hostile, war-torn European Axis powers, often in exchange for Americans being held in those countries.

Finally, there has been no justice for the thousands of Jews, like those aboard the German vessel the *St. Louis*, who sought refuge from hostile Nazi treatment but were callously turned away at America's shores.

The injustices to European Americans, European Latin Americans, and Jewish refugees occurred more than fifty years ago. Americans can learn from these tragedies now, while the people who survived these injustices are still with us, and are still here to teach us. We cannot put this off any longer. If we wait, the people who were affected will no longer be here to know that Congress has at last recognized their sacrifice and resolved to learn from the mistakes of the past.

We should never allow this part of our Nation's history to repeat itself. And, while we should be proud of our Nation's triumph in World War II, we should not let that justifiable pride blind us to the treatment of some Americans by their own government.

As the Day of Remembrance approaches, I urge my colleagues to join me in supporting the Wartime Treatment Study Act, and to allow this bill to become law as soon as possible. I have been seeking to enact this legislation for six years. It is time for a full

accounting of this tragic chapter in our Nation's history.

I ask unanimous consent that the text of the Wartime Treatment Study Act be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

S. 621

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

#### SECTION 1. SHORT TITLE.

This Act may be cited as the "Wartime Treatment Study Act".

#### SEC. 2. FINDINGS.

Congress makes the following findings:

(1) During World War II, the United States Government deemed as "enemy aliens" more than 600,000 Italian-born and 300,000 Germanborn United States resident aliens and their families and required them to carry Certificates of Identification and limited their travel and personal property rights. At that time, these groups were the 2 largest foreignborn groups in the United States.

(2) During World War II, the United States Government arrested, interned, or otherwise detained thousands of European Americans, some remaining in custody for years after cessation of World War II hostilities, and repatriated, exchanged, or deported European Americans, including American-born children, to European Axis nations, many to be exchanged for Americans held in those nations.

(3) Pursuant to a policy coordinated by the United States with Latin American nations, many European Latin Americans, including German and Austrian Jews, were arrested, brought to the United States, and interned. Many were later expatriated, repatriated, or deported to European Axis nations during World War II, many to be exchanged for Americans and Latin Americans held in those nations.

(4) Millions of European Americans served in the armed forces and thousands sacrificed their lives in defense of the United States.

(5) The wartime policies of the United States Government were devastating to the Italian American and German American communities, individuals, and their families. The detrimental effects are still being experienced.

(6) Prior to and during World War II, the United States restricted the entry of Jewish refugees who were fleeing persecution or genocide and sought safety in the United States. During the 1930's and 1940's, the quota system, immigration regulations, visa requirements, and the time required to process visa applications affected the number of Jewish refugees, particularly those from Germany and Austria, who could gain admittance to the United States.

(7) The United States Government should conduct an independent review to fully assess and acknowledge these actions. Congress has previously reviewed the United States Government's wartime treatment of Japanese Americans through the Commission on Wartime Relocation and Internment of Civilians. An independent review of the treatment of German Americans and Italian Americans and of Jewish refugees fleeing persecution and genocide has not yet been undertaken.

(8) Time is of the essence for the establishment of commissions, because of the increasing danger of destruction and loss of relevant documents, the advanced age of potential witnesses and, most importantly, the advanced age of those affected by the United States Government's policies. Many who suffered have already passed away and will never know of this effort.

#### SEC. 3. DEFINITIONS.

In this Act:

- (1) DURING WORLD WAR II.—The term "during World War II" refers to the period between September 1, 1939, through December 31, 1948.
  - (2) European americans.—
- (A) IN GENERAL.—The term "European Americans" refers to United States citizens and resident aliens of European ancestry, including Italian Americans, German Ameri-Hungarian Americans, Romanian Americans, and Bulgarian Americans
- (B) ITALIAN AMERICANS.—The term "Italian Americans" refers to United States citizens and resident aliens of Italian ancestry.
- (C) GERMAN AMERICANS.—The term "German Americans" refers to United States citizens and resident aliens of German ancestry.
- (3) EUROPEAN LATIN AMERICANS —The term "European Latin Americans" refers to persons of European ancestry, including Italian or German ancestry, residing in a Latin American nation during World War II.
- (4) LATIN AMERICAN NATION.—The term "Latin American nation" refers to any nation in Central America, South America, or the Carribean.

#### TITLE I—COMMISSION ON WARTIME TREATMENT OF EUROPEAN AMERICANS SEC. 101. ESTABLISHMENT OF COMMISSION ON WARTIME TREATMENT OF EURO-PEAN AMERICANS.

- (a) IN GENERAL.—There is established the Commission on Wartime Treatment of European Americans (referred to in this title as the "European American Commission")
- (b) MEMBERSHIP.—The European American Commission shall be composed of 7 members. who shall be appointed not later than 90 days after the date of enactment of this Act as follows:
- (1) Three members shall be appointed by the President.
- (2) Two members shall be appointed by the Speaker of the House of Representatives, in consultation with the minority leader.
- (3) Two members shall be appointed by the majority leader of the Senate, in consulta-
- tion with the minority leader.
  (c) TERMS.—The term of office for members shall be for the life of the European American Commission. A vacancy in the European American Commission shall not affect its powers, and shall be filled in the same manner in which the original appointment was made.
- (d) REPRESENTATION.—The European American Commission shall include 2 members representing the interests of Italian Americans and 2 members representing the interests of German Americans.
- (e) MEETINGS.—The President shall call the first meeting of the European American Commission not later than 120 days after the date of enactment of this Act.
- (f) QUORUM.—Four members of the European American Commission shall constitute a quorum, but a lesser number may hold
- (g) CHAIRMAN.—The European American Commission shall elect a Chairman and Vice Chairman from among its members. The term of office of each shall be for the life of the European American Commission.
  - (h) COMPENSATION.
- (1) IN GENERAL.—Members of the European American Commission shall serve without pav.
- REIMBURSEMENT OF EXPENSES.—All members of the European American Commission shall be reimbursed for reasonable travel and subsistence, and other reasonable and necessary expenses incurred by them in the performance of their duties.

#### SEC. 102. DUTIES OF THE EUROPEAN AMERICAN COMMISSION.

(a) IN GENERAL.—It shall be the duty of the European American Commission to review

- the United States Government's wartime treatment of European Americans and European Latin Americans as provided in subsection (b).
- OF REVIEW.—The European (b) Scope American Commission's review shall include the following:
- (1) A comprehensive review of the facts and circumstances surrounding United States Government actions during World War II with respect to European Americans and European Latin Americans pursuant to the Alien Enemies Acts (50 U.S.C. 21 et seq.), Presidential Proclamations 2526, 2527, 2655, 2662, and 2685, Executive Orders 9066 and 9095, and any directive of the United States Government pursuant to such law, proclamations, or executive orders respecting the registration, arrest, exclusion, internment, exchange, or deportation of European Americans and European Latin Americans. This review shall include an assessment of the underlying rationale of the United States Government's decision to develop related programs and policies, the information the United States Government received or acquired suggesting the related programs and policies were necessary, the perceived benefit of enacting such programs and policies, and the immediate and long-term impact of such programs and policies on European Americans and European Latin Americans and their communities.
- (2) A comprehensive review of United States Government action during World War II with respect to European Americans and European Latin Americans pursuant to the Alien Enemies Acts (50 U.S.C. 21 et seq.), Presidential Proclamations 2526, 2527, 2655, 2662, and 2685, Executive Orders 9066 and 9095, and any directive of the United States Government pursuant to such law, proclamations, or executive orders, including registration requirements, travel and property restrictions, establishment of restricted areas, raids, arrests, internment, exclusion, policies relating to the families and property that excludees and internees were forced to abandon, internee employment by American companies (including a list of such companies and the terms and type of employment), exchange, repatriation, and deportation, and the immediate and long-term effect of such actions, particularly internment, on the lives of those affected. This review shall include a list of-
- (A) all temporary detention and long-term internment facilities in the United States and Latin American nations that were used to detain or intern European Americans and European Latin Americans during World War II (in this paragraph referred to as "World War II detention facilities":):
- (B) the names of European Americans and European Latin Americans who died while in World War II detention facilities and where they were buried:
- (C) the names of children of European Americans and European Latin Americans who were born in World War II detention facilities and where they were born; and
- (D) the nations from which European Latin Americans were brought to the United States, the ships that transported them to the United States and their departure and disembarkation ports, the locations where European Americans and European Latin Americans were exchanged for persons held in European Axis nations, and the ships that transported them to Europe and their departure and disembarkation ports.
- (3) A brief review of the participation by European Americans in the United States Armed Forces including the participation of European Americans whose families were excluded, interned, repatriated, or exchanged.
- (4) A recommendation of appropriate remedies, including how civil liberties can be

protected during war, or an actual, attempted, or threatened invasion or incursion, an assessment of the continued viability of the Alien Enemies Acts (50 U.S.C. 21 et seq.), and public education programs related to the United States Government's wartime treatment of European Americans and European Latin Americans during World War II.

(c) FIELD HEARINGS.—The European American Commission shall hold public hearings in such cities of the United States as it

deems appropriate.

(d) REPORT.—The European American Commission shall submit a written report of its findings and recommendations to Congress not later than 18 months after the date of the first meeting called pursuant to section 101(e)

#### SEC. 103. POWERS OF THE EUROPEAN AMERICAN COMMISSION.

- (a) IN GENERAL.—The European American Commission or, on the authorization of the Commission, any subcommittee or member thereof, may, for the purpose of carrying out the provisions of this title, hold such hearings and sit and act at such times and places, and request the attendance and testimony of such witnesses and the production of such books, records, correspondence, memorandum, papers, and documents as the Commission or such subcommittee or member may deem advisable. The European American Commission may request the Attorney General to invoke the aid of an appropriate United States district court to require, by subpoena or otherwise, such attendance, testimony, or production.
- GOVERNMENT INFORMATION AND CO-OPERATION.—The European American Commission may acquire directly from the head of any department, agency, independent instrumentality, or other authority of the executive branch of the Government, available information that the European American Commission considers useful in the discharge of its duties. All departments, agencies, and independent instrumentalities, or other authorities of the executive branch of the Government shall cooperate with the European American Commission and furnish all information requested by the European American Commission to the extent permitted by law, including information collected under the Commission on Wartime and Internment of Civilians Act (Public Law 96-317; 50 U.S.C. App. 1981 note) and the Wartime Violation of Italian Americans Civil Liberties Act (Public Law 106-451; 50 U.S.C. App. 1981 note). For purposes of section 552a(b)(9) of title 5, United States Code (commonly known as the "Privacy Act of 1974"), the European American Commission shall be deemed to be a committee of jurisdiction.

## SEC. 104. ADMINISTRATIVE PROVISIONS.

The European American Commission is authorized to-

- (1) appoint and fix the compensation of such personnel as may be necessary, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, except that the compensation of any employee of the Commission may not exceed a rate equivalent to the rate payable under GS-15 of the General Schedule under section 5332 of such title;
- (2) obtain the services of experts and consultants in accordance with the provisions of section 3109 of such title;
- (3) obtain the detail of any Federal Government employee, and such detail shall be without reimbursement or interruption or loss of civil service status or privilege;
- (4) enter into agreements with the Administrator of General Services for procurement

of necessary financial and administrative services, for which payment shall be made by reimbursement from funds of the Commission in such amounts as may be agreed upon by the Chairman of the Commission and the Administrator:

(5) procure supplies, services, and property by contract in accordance with applicable laws and regulations and to the extent or in such amounts as are provided in appropriation Acts; and

(6) enter into contracts with Federal or State agencies, private firms, institutions, and agencies for the conduct of research or surveys, the preparation of reports, and other activities necessary to the discharge of the duties of the Commission, to the extent or in such amounts as are provided in appropriation Acts.

#### SEC. 105. FUNDING.

Of the amounts authorized to be appropriated to the Department of Justice, \$600,000 shall be available to carry out this title

#### SEC. 106. SUNSET.

The European American Commission shall terminate 60 days after it submits its report to Congress.

## TITLE II—COMMISSION ON WARTIME TREATMENT OF JEWISH REFUGEES

# SEC. 201. ESTABLISHMENT OF COMMISSION ON WARTIME TREATMENT OF JEWISH REFUGEES.

- (a) IN GENERAL.—There is established the Commission on Wartime Treatment of Jewish Refugees (referred to in this title as the "Jewish Refugee Commission").
- (b) MEMBERSHIP.—The Jewish Refugee Commission shall be composed of 7 members, who shall be appointed not later than 90 days after the date of enactment of this Act as follows:
- (1) Three members shall be appointed by the President.
- (2) Two members shall be appointed by the Speaker of the House of Representatives, in consultation with the minority leader.
- (3) Two members shall be appointed by the majority leader of the Senate, in consultation with the minority leader.
- (c) TERMS.—The term of office for members shall be for the life of the Jewish Refugee Commission. A vacancy in the Jewish Refugee Commission shall not affect its powers, and shall be filled in the same manner in which the original appointment was made.
- (d) REPRESENTATION.—The Jewish Refugee Commission shall include 2 members representing the interests of Jewish refugees.
- (e) MEETINGS.—The President shall call the first meeting of the Jewish Refugee Commission not later than 120 days after the date of enactment of this Act.
- (f) QUORUM.—Four members of the Jewish Refugee Commission shall constitute a quorum, but a lesser number may hold hearings.
- (g) CHAIRMAN.—The Jewish Refugee Commission shall elect a Chairman and Vice Chairman from among its members. The term of office of each shall be for the life of the Jewish Refugee Commission.
  - (h) COMPENSATION.—
- (1) IN GENERAL.—Members of the Jewish Refugee Commission shall serve without pay.
- (2) REIMBURSEMENT OF EXPENSES.—All members of the Jewish Refugee Commission shall be reimbursed for reasonable travel and subsistence, and other reasonable and necessary expenses incurred by them in the performance of their duties.

## SEC. 202. DUTIES OF THE JEWISH REFUGEE COMMISSION.

(a) IN GENERAL.—It shall be the duty of the Jewish Refugee Commission to review the United States Government's refusal to allow Jewish and other refugees fleeing persecution or genocide in Europe entry to the United States as provided in subsection (b).

- (b) Scope of Review.—The Jewish Refugee Commission's review shall cover the period between January 1, 1933, through December 31, 1945, and shall include, to the greatest extent practicable, the following:
- (1) A review of the United States Government's decision to deny Jewish and other refugees fleeing persecution or genocide entry to the United States, including a review of the underlying rationale of the United States Government's decision to refuse the Jewish and other refugees entry, the information the United States Government received or acquired suggesting such refusal was necessary, the perceived benefit of such refusal, and the impact of such refusal on the refugees.
- (2) A review of Federal refugee law and policy relating to those fleeing persecution or genocide, including recommendations for making it easier in the future for victims of persecution or genocide to obtain refuge in the United States.
- (c) FIELD HEARINGS.—The Jewish Refugee Commission shall hold public hearings in such cities of the United States as it deems appropriate.
- (d) REPORT.—The Jewish Refugee Commission shall submit a written report of its findings and recommendations to Congress not later than 18 months after the date of the first meeting called pursuant to section 201(e).

## SEC. 203. POWERS OF THE JEWISH REFUGEE COMMISSION.

- (a) IN GENERAL.—The Jewish Refugee Commission or, on the authorization of the Commission, any subcommittee or member thereof, may, for the purpose of carrying out the provisions of this title, hold such hearings and sit and act at such times and places, and request the attendance and testimony of such witnesses and the production of such memobooks, records, correspondence, randum, papers, and documents as the Commission or such subcommittee or member may deem advisable. The Jewish Refugee Commission may request the Attorney General to invoke the aid of an appropriate United States district court to require by subpoena or otherwise, such attendance, testimony, or production.
- (b) GOVERNMENT INFORMATION AND CO-OPERATION.—The Jewish Refugee Commission may acquire directly from the head of any department, agency, independent instrumentality, or other authority of the executive branch of the Government, available information that the Jewish Refugee Commission considers useful in the discharge of its duties. All departments, agencies, and independent instrumentalities, or other authorities of the executive branch of the Government shall cooperate with the Jewish Refugee Commission and furnish all information requested by the Jewish Refugee Commission to the extent permitted by law, including information collected as a result of the Commission on Wartime and Internment of Civilians Act (Public Law 96-317; 50 U.S.C. App. 1981 note) and the Wartime Violation of Italian Americans Civil Liberties Act (Public Law 106-451; 50 U.S.C. App. 1981 note). For purposes of section 552a(b)(9) of title 5, United States Code (commonly known as the "Privacy Act of 1974"), the Jewish Refugee Commission shall be deemed to be a committee of jurisdiction.

### SEC. 204. ADMINISTRATIVE PROVISIONS.

The Jewish Refugee Commission is authorized to—

(1) appoint and fix the compensation of such personnel as may be necessary, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, except that the compensation of any employee of the Commission may not exceed a rate equivalent to the rate payable under GS-15 of the General Schedule under section 5332 of such title:

- (2) obtain the services of experts and consultants in accordance with the provisions of section 3109 of such title;
- (3) obtain the detail of any Federal Government employee, and such detail shall be without reimbursement or interruption or loss of civil service status or privilege;
- (4) enter into agreements with the Administrator of General Services for procurement of necessary financial and administrative services, for which payment shall be made by reimbursement from funds of the Commission in such amounts as may be agreed upon by the Chairman of the Commission and the Administrator:
- (5) procure supplies, services, and property by contract in accordance with applicable laws and regulations and to the extent or in such amounts as are provided in appropriation Acts; and
- (6) enter into contracts with Federal or State agencies, private firms, institutions, and agencies for the conduct of research or surveys, the preparation of reports, and other activities necessary to the discharge of the duties of the Commission, to the extent or in such amounts as are provided in appropriation Acts.

#### SEC. 205. FUNDING.

Of the amounts authorized to be appropriated to the Department of Justice, \$600,000 shall be available to carry out this title.

#### SEC. 206. SUNSET.

The Jewish Refugee Commission shall terminate 60 days after it submits its report to Congress.

By Mr. HARKIN (for himself, Mr. Enzi, Mr. Feingold, Mr. Thomas, Mr. Dorgan, Mr. Baucus, and Mrs. McCaskill):

S. 622. A bill to enhance fair and open competition in the production and sale of agricultural commodities; to the Committee on Agriculture, Nutrition, and Forestry.

Mr. HARKIN. Mr. President, today I am introducing the "Competitive and Fair Agricultural Markets Act of 2007." Cosponsors joining me in introducing this legislation are: Senators ENZI, FEINGOLD, THOMAS, DORGAN, BAUCUS and McCaskill. This legislation seeks to level the playing field for agricultural producers by strengthening and clarifying the Packers and Stockvards Act of 1921 and the Agricultural Fair Practices Act of 1967 and strengthening enforcement of both laws by USDA. I intend to use this legislation as the basis for developing a proposed competition title in the new farm bill this year.

Consolidation is happening in all sectors of agriculture and having a negative effect on producers and consumers across the Nation. Consolidation in itself is not a violation of the Packers and Stockyards Act, but when some entities become larger and more powerful that makes enforcement of the Packers and Stockyards Act absolutely critical for independent livestock and poultry

producers. The statistics speak for themselves. For example, today, only four firms control 84 percent of the procurement of cattle and 64 percent of the procurement of hogs. Economists have stated that when four firms control over 40 percent of the industry, marketplace competitiveness begins to decline. Taken together with fewer buyers of livestock, highly integrated firms can exert tremendous power over the industry.

The Grain Inspection, Packers and Stockyards Administration, GIPSA, at USDA has the responsibility to enforce the Packers and Stockyards Act. This Act is critical, and protects livestock producers from unfair, unjustly discriminatory and anti-competitive practices in the marketplace. For years I have had my doubts about whether USDA was serious about enforcing the Packers and Stockvards Act. In 2005. I requested an audit by USDA's Inspector General to investigate USDA's oversight, and enforcement of the law. Last year, the Inspector General confirmed the concerns I had and uncovered even more systemic problems. The report described widespread inaction, management of the agency actively blocking employees from conducting investigations into anti-competitive behavior and a scheme to cover up the lack of enforcement by inflating the reported number of investigations conducted.

That is why today, the legislation I introduce will reorganize the structure in how USDA enforces the Packers and Stockyards Act and create an office of special counsel on competition matters. The special counsel would be appointed by the President with advice and consent from the U.S. Senate. Some would argue that Senate advice and consent is not needed. However, for over five years, GIPSA failed to move competition investigations forward and no one above the level of deputy administrator at GIPSA seemed to have any idea that any problems were going on, despite the fact I was sending letters to the Secretary of Agriculture pointing out that USDA was failing to enforce the law.

In the past year, GIPSA has worked in good faith to improve its enforcement activities. However, GIPSA only investigates potential violations of the law, they do not litigate and followthrough with the investigation to the end. Litigating cases is reserved only for USDA's Office of General Counsel, OGC, unless they refer it to the Department of Justice.

USDA's Office of General Counsel has not been active on cases involving anticompetitive practices in recent years since GIPSA was not referring cases to them. To be sure, only two cases involving anti-competitive practices were referred to OGC in 5 years. But there are concerns that OGC is not as committed to enforcing competition investigations as they should be. This lack of commitment was clearly evident last year in testimony provided by

OGC Assistant General Counsel in the Trade Practices Division at a hearing by the Senate Committee on Agriculture, Nutrition, and Forestry.

Concerns about OGC's attitude toward enforcing the Packers and Stockyards Act are not new. USDA's Inspector General stated in its 1997 audit that Packers and Stockyards program officials were concerned that OGC did not want to litigate competition cases "because they are complicated and time consuming" and OGC had "limited expertise" with them. In 2000, the Government Accountability Office found "disagreements" between OGC and GIPSA regarding the interpretation of the Act's competition provisions. By combining investigation and prosecution activities into the proposed special counsel office, designated to handle competition issues, it reduces the ability for investigations to be batted back and forth within USDA.

This legislation also makes many important clarifications to the Packers and Stockyards Act. The Packers and Stockvards Act prohibits unfair, unjustly discriminatory and anti-competitive practices, but some courts have ruled that producers need to prove an impact on competition in the market in order to prevail in such cases involving unfair or deceptive practices. For example, the United States Eleventh Circuit Court of Appeals ruled that a poultry grower operation failed to prove how its case involving an unfair termination of its contract adversely affected competition. The court indicated that the grower had to prove that their unfair treatment affected competition in the relevant market. That is very difficult to prove and was never the intent of the Packers and Stockyards Act.

This legislation also modifies the Packers and Stockyards Act so that poultry growers have the same enforcement protections by USDA as livestock. Currently, it is unlawful for a livestock packer or live poultry dealer to engage in any unfair, unjustly discriminatory or deceptive practice, but USDA does not have the authority to enforce violations because the enforcement section of the law is absent of any reference to poultry. This important statutory change is long overdue. In addition, to better reflect the integrated nature of the poultry industry, this legislation also ensures that protections under the law extend to all poultry growers, such as breeder hen and pullet operations, not just those who raise broilers.

The Agricultural Fair Practices Act of 1967 was passed by Congress to ensure that producers are allowed to join together as an association to strengthen their position in the marketplace without being discriminated against by handlers. Unfortunately, this act was passed with a clause that essentially abolishes the actual intent of the law. The act states that "nothing in this Act shall prevent handlers and producers from selecting their customers"

and it also states that it does not "require a handler to deal with an association of producers." This clause in effect allows handlers to think of any reason possible to not do business with certain producers, as long as the stated reason is not because they belong to an association.

I propose to expand the Agricultural Fair Practices Act to provide new needed protections for agricultural contracts. As I have mentioned earlier, consolidation in all sectors of agriculture is reducing the number of buyers of commodities and for the very few who are left, many require contracts to conduct business. With so few buyers, it increases the chances that some firms will force unfair contracts upon producers. As a result, some producers have little or no choice but to contract with a firm with questionable practices or face leaving the industry they have known for their whole lives.

This amendment to the Agricultural Fair Practices Act requires that the contract spell out in clear language what is required by the producer. This legislation prohibits confidentiality clauses, ensuring producers the ability to share the contract with family members or a lawyer to help them make an informed decision on whether or not to sign it. This legislation also prevents companies from prematurely terminating contracts without notice when producers have made large capital investments as a condition of signing the contract. And it only allows mandatory arbitration after a dispute arises and both parties agree to it in writing. Producers should not be forced to sign contracts with arbitration clauses thereby preventing them from seeking legal remedy in the courts.

Mr. President, producers deserve to have a fair and evenhanded market in which to conduct business. This legislation won't be able to turn back the clock, but it will strengthen laws and enforcement of them so that markets operate more fairly.

By Mr. SCHUMER (for himself, Mrs. CLINTON, Mr. VITTER, Ms. COLLINS, Mr. LEAHY, and Ms. STABENOW):

S. 623. A bill to amend the Public Health Service Act to provide for the licensing of comparable and interchangeable biological products, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

Mr. SCHUMER. Mr. President, I rise today to introduce the Access to Life-Saving Medicine Act with my colleague, Senator CLINTON. Recognizing the promise of generic drugs as safe and effective treatments at greatly reduced prices, I have worked for years with my colleagues in the House and the Senate to increase generic drug availability and accessibility, most notably with Senator McCAIN on a 2003 law. This legislation represents the next step in the availability of generic drugs for American consumers by creating a statutory pathway for generic

versions of biotech drugs to enter the market.

While generic drugs save American consumers an estimated eight to ten billion dollars each year, American consumers have not yet reaped the full potential savings from the generic drug market. Under current law, there is no generic approval process at the Food and Drug Administration, FDA, for an entire category of drugs, even once the patents have expired. These biologic drugs, which are an expensive and growing sector of the pharmaceutical market, will obtain monopoly pricing on the market indefinitely without the possibility of generic competitors.

Drug companies that invest in the research and development of life-saving drugs, whether biological or chemical in nature, deserve to be rewarded for their work. At the same time, patients need the ability to access affordable drugs. We have created a statutory framework for chemical drugs that balances incentives for continued innovations with access to affordable drugs for patients. But, this framework has not yet expanded to biotech drugs, which are on the cutting edge of science but for which the laws are hopelessly out of date.

Now is the time to ensure that American consumers have the same access to life-saving biotech drugs that consumers have to well-known, widely used chemical drugs. Patients need to be able to afford and access their medications, and they don't care what kind of drug they have. Patients rely on biotech drugs to treat a wide array of diseases, ranging from diabetes to cancer to AIDS, but with no generic versions of biotech drugs available, these drugs can cost tens of thousands of dollars a year-too expensive for many patients to afford. Introducing fair competition for biotech drugs is essential to make life-saving biotech treatments affordable.

The Access to Life-Saving Medicine Act will allow the FDA to approve generic versions of biologic drugs that have been determined to be both safe and effective. The FDA is not required to approve any generic biologics, but if the data is there, they will now have the ability to do so.

A report released earlier this year by Pharmaceutical Care Management Association estimated that the introduction of generic biotech drugs into the market could save Medicare Part B \$14 billion over the next ten years. We need to embrace those potential savings and provide American consumers access to affordable biotech drugs.

Moving this legislation forward and creating a statutory pathway for generic versions of biotech drugs to enter the market is one of my highest priorities in the 110th Congress. I look forward to working with my colleagues, especially Senator CLINTON, to accomplish this goal.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

Ms. CLINTON. Mr. President, I am pleased today to join with Senator SCHUMER to introduce the Access of Life-Saving Medicine Act. This legislation will have a dramatic impact on the rising costs of prescription drugs, which puts the squeeze on employers trying to provide health coverage for employees while turning a profit, on families struggling to make ends meet, and on our economy. We spend 16 percent of our national income on health care and prescription drugs and that number is on the climb.

In 2005, the cost of biologics grew 17.5 percent compared to the cost of traditional drugs, which increased 10 percent. According to CMS, the top 2 anemia drugs—both biologics—accounted for 17 percent of all Medicare Part B carrier drug spending, while two other biologics for rheumatoid arthritis and cancer accounted for an additional 13 percent. In 2006, the Medicare Part B program spent more than \$5 billion on biologic drugs.

More than \$10 billion worth of biopharmaceuticals will come off patent in the next 5 years but will continue to cost on-patent prices unless we act. Our legislation creates a pipeline for approval of safe, cost effective generic versions of these biologic drugs. Without action, the manufacturers of these biotech drugs can continue to charge monopoly prices indefinitely.

This is a perfect example of skyrocketing costs in health care—and a perfect opportunity to put the brakes on this overspending, which is bad for patients, businesses, and our country.

According to a report released in January by Engel & Novitt to the Pharmaceutical Care Management Association, passage of this bill could save, by conservative estimates, \$14 billion over the next 10 years in Medicare Part B alone.

Scientific advances over the past 20 years have made the biotechnology industry an integral part of the pharmaceutical industry, but our health care system has not kept pace. Our laws need to be updated to reflect the critical role biologics now play in treatment.

The Access to Life-Saving Medicine Act amends the Public Health Service Act to authorize the FDA to approve abbreviated applications for biological products that are "comparable" to and "interchangeable" with previously approved biological products. And because biological products are very diverse, the Secretary has discretion on a case-by-case basis to determine what studies are necessary to establish comparability and interchangeability, and may require a clinical study or studies if necessary.

To encourage the development of substitutable products, the legislation gives the first applicant to obtain approval of an interchangeable product a period of exclusive marketing during which no other interchangeable version of the product may be approved. In order to facilitate timely access to

these products, an approval may, however, be granted for a comparable version of the brand name product if it is not interchangeable.

Finally, to encourage early resolution of patent disputes which might otherwise delay competition, a patent holder must disclose relevant patents in response to a request and bring a patent infringement suit within 45 days of notice of a challenge or lose the right to certain remedies in court.

Biotech drugs hold great promise, but we break that promise when costs push treatment out of reach for American families and employers. We should bring safe, effective and affordable generic versions of these medicines to patients through passage of the Access to Life-Saving Medicine Act, saving money and lives.

This issue is part of a larger challenge. It is time to develop a health care system that reflects and responds to how people are living today, that addresses the critical problems in cost, quality, and coverage.

We can use what is right in health care—incredible ingenuity, leaders at the forefront of medical research, advances in technology, the best medical professionals in the world—to fix what is wrong.

Smart solutions to the vexing problems plaguing our health care system will require evidence-based—not ideologically-based—decision making.

My wonderful predecessor, Senator Moynihan, memorably said, "Everyone is entitled to his own opinion, but no one is entitled to his own facts." Well, right now, we see a lot of people who have their own facts that are not based on the evidence.

The fact is, building a pipeline for generic biologics is long overdue. Achieving this goal is a top priority for me in the HELP Committee when we consider FDA-related legislation this spring and I look forward to working with Senator SCHUMER and my other colleagues to get it done.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

S. 623

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled

### SECTION 1. SHORT TITLE.

This Act may be cited as the "Access to Life-Saving Medicine Act".

### SEC. 2. DEFINITIONS.

- (a) AMENDMENTS.—Section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)) is amended—
- (1) by striking "In this section, the term biological product" means" and inserting the following: "In this section:
- ``(1) The term 'biological product' means''; and
- (2) by adding at the end the following:
- "(2) The term 'abbreviated biological product application' means an abbreviated application for a license of a biological product containing the same, or similar, active ingredient as a reference product.
- "(3) The term 'reference product' means the single licensed biological product, approved under subsection (a) or subsection

(k), against which a biological product is evaluated for demonstration of safety, potency, or purity.

"(4) The term 'comparable' or 'comparability' in reference to a biological product means the absence of clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product based upon—

"(A) data derived from chemical, physical, and biological assays, and other non-clinical laboratory studies; and

"(B) data from any necessary clinical study or studies sufficient to confirm safety, purity, and potency in one or more appropriate conditions of use for which the reference product is licensed and intended to be used.

Any studies under subparagraph (B) shall be designed to avoid duplicative and unethical clinical testing.

"(5) The terms 'interchangeable' and 'interchangeability' mean, with respect to the condition of use involved, that the biological product—

"(A) is comparable to the reference product; and

"(B) can be expected to produce the same clinical result as the reference product in any given patient.

any given patient.

"(6) The term 'thorough characterization' means an analysis of structural features based upon appropriate analytical and functional testing sufficient to identify differences between a biological product and reference product relevant to safety, purity or potency.

"(7) The term 'final action' means, with respect to an abbreviated biological product application, the Secretary's issuance of a final action letter to the sponsor of an abbreviated biological product application which—

"(A) approves the application; or

"(B) disapproves the application and sets forth in detail an enumeration of the specific deficiencies in the particular application and of the specific, enumerated actions the sponsor would be required to take in order for the sponsor to receive a final action letter that approves such application.

"(8) The term 'final action date' means, with respect to an abbreviated biological product application, the date by which the Secretary must take a final action on the application pursuant to subsection (k)(11).

"(9) The term 'reviewing division' means the division responsible for the review of an application for approval of a biological product (including all scientific and medical matters, chemistry, manufacturing, and controls)."

(b) RULE OF CONSTRUCTION.—Nothing in this Act or the amendments made by this Act shall be construed to exclude an application for licensure of a biological product under section 351(k) from the definition of a human drug application in section 735(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)(C)).

# SEC. 3. REGULATION OF COMPARABLE AND INTERCHANGEABLE BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amend-

(1) in subsection (a)(1)(A), by inserting "under this subsection or subsection (k)" after "biologics license"; and

(2) by adding at the end the following subsection:

''(k) REGULATION OF COMPARABLE AND INTERCHANGEABLE BIOLOGICAL PRODUCTS.—

"(1) SUBMISSION OF AN ABBREVIATED BIO-LOGICAL PRODUCT APPLICATION.—Any person may file with the Secretary an abbreviated biological product application. Any such application shall include the following:

"(A) Data demonstrating that the biological product is comparable to or interchangeable with the reference product.

"(B) Data demonstrating that the biological product and reference product contain highly similar principal molecular structural features, notwithstanding minor differences in heterogeneity profile, impurities, or degradation patterns. The Secretary shall find the following types of products to contain highly similar principal molecular structural features:

"(i) Two protein biological products with differences in structure between them solely due to post-translational events, infidelity of translation or transcription, or minor differences in amino acid sequence.

"(ii) Two polysaccharide biological products with similar saccharide repeating units, even if the number of units differ and even if there are differences in post-polymerization modifications.

"(iii) Two glycosylated protein products with differences in structure between them solely due to post-translational events, infidelity of translation or transcription, or minor differences in amino acid sequence, and if they had similar saccharide repeating units, even if the number of units differ and even if there were differences in post-polymerization modifications.

"(iv) Two polynucleotide biological products with identical sequence of purine and pyrimidine bases (or their derivatives) bound to an identical sugar backbone (ribose, deoxyribose, or modifications of these sugars).

"(v) Closely related, complex partly definable biological products with similar therapeutic intent, such as two live viral products for the same indication.

Two biological products not enumerated in the foregoing clauses may be demonstrated to contain highly similar principal molecular structural features based upon such data and other information characterizing the two products as the Secretary determines to be necessary.

"(C) Data demonstrating that the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product.

"(D) Information to show that the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product.

"(E) Information to show that the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product.

"(F) Data demonstrating that the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

"(G) At the applicant's option, publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent.

"(H) Any additional data and information in support of the application, including publicly-available information with respect to the reference product or another biological product.

"(2) OTHER APPLICATIONS.—Any person, including a person who has not conducted and does not have a right of reference to the studies in the application for a reference product, may submit an application under

this paragraph for a biological product that differs from, or incorporates a change to, the reference product with respect to one or more characteristics described in subparagraphs (A) through (E) of paragraph (1), including a difference in safety, purity, or potency, so long as the application contains sufficient information to establish the safety, purity, and potency of the biological product relative to the reference product for its proposed condition or conditions of use.

"(3) FDA REVIEW OF ABBREVIATED BIOLOGICAL PRODUCT APPLICATIONS.—

"(A) GUIDANCE REGARDING REVIEW OF APPLICATIONS.—The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or (2), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

"(B) MEETINGS WITH SPONSORS AND APPLICANTS.—The Secretary shall meet with a sponsor of an investigation or an applicant for approval of a comparable or interchangeable biological product under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of studies needed for approval of the application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

"(C) AGREEMENTS.—Any agreement regarding the parameters of design and size of the studies of a biological product under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

"(i) with the written agreement of the sponsor or applicant; or

"(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety, purity, and potency of the biological product has been identified after the testing has begun.

"(D) PROCEDURE REGARDING CERTAIN DECISIONS.—A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

"(E) EFFECT OF DECISIONS.—The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

"(F) DELAYS BY REVIEWING DIVISIONS.—No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe, pure, and potent biological product.

"(4) APPROVAL OF COMPARABLE OR INTER-CHANGEABLE BIOLOGICAL PRODUCTS.—

"(A) DETERMINATION OF COMPARABILITY.— Upon review of an application submitted under paragraph (1) or (2) for a biological product, the Secretary shall issue a comparable biological product license for all conditions of use of the reference product sharing the same mechanism or mechanisms of action for which the applicant has demonstrated comparability for a single condition of use, or, if the mechanism or mechanisms of action are unknown, for the condition or conditions of use for which the data submitted establishes comparability, unless the Secretary finds and informs the applicant that—

"(i) information submitted in the application or any other information available to the Secretary is insufficient to show that the biological product is comparable to the reference product for the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed in the application;

"(ii) information submitted in the application or any other information available to the Secretary is insufficient to show that the biological product and the reference product contain highly similar principal molecular structural features, notwithstanding minor differences in heterogeneity profile, impurities, or degradation patterns;

"(iii) information submitted in the application or any other information available to the Secretary is insufficient to show that the biological product and reference product utilize the same mechanism or mechanisms of action for the conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product, unless the mechanism or mechanisms of action are not known for the reference product for such condition or conditions:

"(iv) information submitted in the application or any other information available to the Secretary is insufficient to show that the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference prod-

"(v) information submitted in the application or any other information available to the Secretary is insufficient to show that the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product are limited to one or more of the same use or uses as have been previously approved for the reference product;

"(vi) information submitted in the application or any other information available to the Secretary shows (I) the inactive ingredients of the biological product are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the biological product, or (II) the composition of the biological product is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included:

"(vii) information submitted in the application or any other information available to the Secretary fails to demonstrate that the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent;

"(viii) the Secretary has withdrawn or suspended the license of the reference product, for safety or effectiveness reasons, or has published a notice of opportunity for hearing to withdraw such license for safety or effectiveness reasons, or the Secretary has determined that the reference product has been withdrawn from sale for safety or effectiveness reasons; or

"(ix) the application contains an untrue statement of material fact; and provides the applicant with a detailed explanation for the decision.

"(B) DETERMINATIONS ON INTERCHANGE-ABILITY.—Subject to subparagraph (C) and paragraph (10), upon issuing a product license for a biological product under subparagraph (A), the Secretary shall make and publish one of the following determinations:

"(i) Such product is interchangeable with the reference product for one or more specified conditions of use prescribed, recommended, or suggested in the labeling of the biological product.

"(ii) Interchangeability has not been established

"'(C) DETERMINATION OF INTERCHANGE-ABILITY OF SUBSEQUENT BIOLOGICAL PRODUCT.—If the Secretary determines that an application meets the approval requirements of subparagraph (A), and, prior to the issuance of a product license, the Secretary has made a determination of interchangeability of another biological product and the reference product for which the exclusivity period under paragraph (10) has not expired, the Secretary shall—

"(i) issue the product license for the subsequent biological product; and

"(ii) defer issuing any determination of interchangeability as to the subsequent biological product and the reference product until the exclusivity period under paragraph (10) has expired.

(5) POSTMARKETING STUDIES FOR APPLICA-TIONS SUBMITTED UNDER PARAGRAPH (1).—If the Secretary has agreed with the sponsor of the reference product, at the time of approval or any time thereafter, that the sponsor shall conduct one or more postmarketing safety studies, a person submitting an application for a biological product under paragraph (1) may agree with the Secretary to conduct a similar postmarketing safety study or studies upon a reasonable showing that such study or studies would provide relevant information not available from the studies on the reference product. The Secretary shall not, as a condition of approval. propose any additional postmarketing studies for such biological product.

"(6) DESIGNATION OF OFFICIAL NAME.—If, pursuant to section 508 of the Federal Food, Drug, and Cosmetic Act, the Secretary determines that designation of an official name for a comparable biological product is necessary or desirable in the interests of usefulness or simplicity, the Secretary shall designate the same official name for the comparable biological product as the Secretary designated for the reference product. This paragraph shall not apply to products approved under paragraph (7).

"(7) OTHER APPROVAL PROVISIONS.—The Secretary shall approve, under the provisions of paragraph (4)(A), an application for a license submitted under paragraph (2), except that the Secretary shall approve such an application that would otherwise be disapproved by reason of one or more of subparagraphs (A) through (E) of paragraph (4)(A), if the application and any other information available to the Secretary are sufficient to establish the safety, purity, and potency of the comparable biological product relative to the reference product for the proposed condition or conditions of use for such product.

"(8) ESTABLISHING INTERCHANGEABILITY FOR COMPARABLE BIOLOGICAL PRODUCTS.—

"(A) IN GENERAL.—In an original application or a supplement to an application under this subsection, an applicant may submit information to the Secretary to demonstrate the interchangeability of a comparable biological product and the reference product. An applicant may withdraw an interchangeability submission at any time. A request for an interchangeability determination submitted after the filing of an application shall be considered a major amendment to the ap-

plication. Nothing in this subsection shall be construed to prohibit the Secretary from making a determination of interchangeability at any time after approval.

"(B) GUIDANCE.—Within one year after enactment of the Access to Life-Saving Medicine Act, the Secretary shall issue guidance regarding standards and requirements for interchangeability. The Secretary may make determinations of interchangeability under paragraph (4)(B) prior to issuing guidance under this subparagraph.

"(9) INTERCHANGEABILITY LABELING FOR COMPARABLE BIOLOGICAL PRODUCTS.—Upon a determination of interchangeability, the Secretary, if requested by the applicant, shall provide for the label of the comparable biological product to include a statement that the biological product is interchangeable with the reference product for the conditions of use prescribed, recommended, or suggested in the labeling for which interchangeability has been established.

"(10) EXCLUSIVITY.—

"(A) IN GENERAL.—Upon review of an abbreviated biological product application relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4)(B) that the second or subsequent biological product is interchangeable for any condition of use, and no holder of a biological product license approved under subsection (a) shall manufacture, market, sell, or distribute a rebranded interchangeable biological product, directly or indirectly, or authorize any other person to manufacture, market, sell, or distribute a rebranded interchangeable biological product, for any condition of use, until the earlier of-

"(i) 180 days after the first commercial marketing of the first interchangeable comparable biological product to be approved as interchangeable for that reference product;

"(ii) one year after—

"(I) a final court decision on all patents in suit in an action instituted under paragraph (17)(C) against the applicant that submitted the application for the first approved interchangeable comparable biological product;

"(II) the dismissal with or without prejudice of an action instituted under paragraph (17)(C) against the applicant that submitted the application for the first approved interchangeable comparable biological product;

"(iii)(I) 36 months after approval of the first interchangeable comparable biological product if the applicant has been sued under paragraph (17)(C) and such litigation is still ongoing within such 36-month period; or

"(II) one year after approval in the event that the first approved interchangeable comparable applicant has not been sued under paragraph (17)(C).

For purposes of this subparagraph, the term 'final court decision' means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

"(B) REBRANDED INTERCHANGEABLE BIOLOGI-CAL PRODUCT.—For purposes of this subsection, the term 'rebranded interchangeable biological product'—

"(i) means any rebranded interchangeable version of the reference product involved that the holder of the biological product license approved under subsection (a) for that reference product seeks to commence marketing, selling, or distributing, directly or indirectly; and

"(ii) does not include any product to be marketed, sold, or distributed—

"(I) by an entity eligible for exclusivity with respect to such product under this paragraph; or

"(II) after expiration of any exclusivity with respect to such product under this paragraph.

'(11) HEARING.—If the Secretary decides to disapprove an abbreviated biological product application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis, and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

"(12) FINAL ACTION DATE.—

"(A) IN GENERAL.—The Secretary shall take a final action on an abbreviated biological product application by the date that is 8 calendar months following the sponsor's submission of such application, or 180 days following the Secretary's notification to the applicant that its application has been accepted for filling, whichever is earlier.

"(B) EXTENSION.—The final action date provided by subparagraph (A) with respect to an application may be extended for such period of time as is agreed to by the Secretary and the applicant in a jointly executed written agreement that is counter-signed by the Secretary and the applicant no later than 30 days prior to such date.

"(13) REQUEST FOR DELAY OF FINAL AC-TION.—Notwithstanding paragraph (18) or any other provision of law, the Secretary shall not fail or refuse to take a final action on an abbreviated biological product application by the final action date on the basis that a person, other than the comparable biological product applicant, has requested (in a petition or otherwise) that the Secretary refuse to take or otherwise defer such final action, and no court shall enjoin the Secretary from taking final action or stay the effect of final action previously taken by the Secretary, except by issuance of a permanent injunction based upon an express finding of clear and convincing evidence that the person seeking to have the Secretary refuse to take or otherwise to defer final action by the final action date-

"(A) has prevailed on the merits of the person's complaint against the Secretary:

"(B) will suffer imminent and actual irreparable injury, constituting more than irrecoverable economic loss, and that also will threaten imminent destruction of such person's business; and

"(C) has an interest that outweighs the overwhelming interest that the public has in obtaining prompt access to a comparable biological product.

"(14) REPORT ON EXTENSIONS OF FINAL ACTION DATE.—The Secretary shall prepare and submit to the President, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate a report regarding any jointly executed written agreement to extend the final action date under this Act within 15 calendar days after the joint execution of any such written agreement.

"(15) REPORT ON FAILURE TO TAKE FINAL AC-TION.—The Secretary shall prepare and submit annually to the President, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate a report detailing the specific and particularized reasons enumerated by the reviewing division for each instance of the Secretary's failure to take final action by the final action date in the previous year.

"(16) REGULATIONS.—The Secretary shall establish, by regulation within 2 years after the date of the enactment of this subsection, requirements for the efficient review, approval, suspension, and revocation of abbreviated biological product applications under this subsection.

"(17) PATENTS.-

"(A) REQUEST FOR PATENT INFORMATION.—

"(i) IN GENERAL.—At any time, including at the initial stages of development, an applicant or a prospective applicant under this subsection may send a written request for patent information to the holder of the approved application for the reference product. The holder of the approved application for the reference product shall, not later than 60 days after the date on which the holder receives the request, provide to the applicant or prospective applicant a list of all those patents owned by, or licensed to, the holder of the approved application that the holder believes in good faith relate to the reference product, including patents that claim the approved biological product, any method of using such product, any component of such product, or any method or process of manufacturing such product or component.

"(ii) Costs of complying with request.— The application holder may demand payment of not more than \$1,000 to offset the cost of responding to the request for information.

"(iii) UPDATES.—For a period of two years beginning on the date on which the holder of the approved application for the reference product receives the request for information, the holder shall send to the applicant or prospective applicant updates of its response to the request for information by identifying all relevant patents issued or licensed to the holder after the initial response under clause (i). Any such update must be provided, in the case of a new patent, not later than 30 days after the date on which the patent is issued and, in the case of a license, not later than 30 days after the date on which the holder obtains the license.

"(iv) Additional requests.—The applicant may submit additional requests for patent information, subject to the requirements of this paragraph, at any time.

"(B) PATENT NOTIFICATIONS.—At any time after submitting an application under this subsection, the applicant may provide a notice of the application with respect to any one or more patents identified by the holder of the reference product pursuant to subparagraph (A). An applicant may submit additional notices at any time, and each notice shall be subject to the provisions of this subparagraph. Each notice shall—

"(i) be sent to the holder of the approved application for the reference product and to the owner of any patent identified by the holder pursuant to subparagraph (A);

"(ii) include a detailed statement of the factual and legal bases for the applicant's belief that the patents included in the notice are invalid, are unenforceable, or will not be infringed by the commercial sale of the product for which approval is being sought under this subsection; and

"(iii) identify 1 or more judicial districts in which the applicant consents to such suit being brought.

"(C) ACTION FOR INFRINGEMENT.—Within 45 days after the date on which the holder of the approved application for the reference product, or the owner of a patent, receives a notice under subparagraph (B), the holder or patent owner may bring an action for infringement only with respect to the patent

or patents included in the notice, and only in a judicial district identified pursuant to subparagraph (B)(iii).

"(D) LIMITATION ON DECLARATORY JUDG-MENT ACTIONS.—With respect to any patent relating to a product that is the subject of an application under this subsection, the recipient of a notice under subparagraph (B) with respect to that application may not, prior to the commercial marketing of the product, bring any action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any such patent that was not identified in the notice. With respect to any such patent identified in the notice, any such action may, notwithstanding chapter 87 of title 28, United States Code, be brought only in a judicial district identified in the notice.

"(E) DISCRETION OF APPLICANTS.—An applicant or prospective applicant for a comparable biological product under this subsection may not be compelled, by court order or otherwise, to initiate the procedures set forth in this paragraph. Nothing in this paragraph requires an applicant or a prospective applicant to invoke the procedures set forth in this paragraph.

"(18) PETITIONS AND CIVIL ACTIONS REGARD-ING APPROVAL OF CERTAIN APPLICATIONS.—

"(A) IN GENERAL.—With respect to a pending application submitted under paragraph (1) or (2), if a petition is submitted to the Secretary that seeks to have the Secretary take, or refrain from taking, any form of action relating to the approval of the application, including a delay in the effective date of the application, the following applies, subject to subparagraph (E):

"(i)(I) The Secretary may not, on the basis of the petition, delay approval of the application unless the Secretary determines, within 30 days after receiving the petition, that a delay is necessary to protect the public health. Consideration of a petition shall be separate and apart from the review and approval of the application.

"(II) With respect to a determination by the Secretary under subclause (I) that a delay is necessary to protect the public health:

"(aa) The Secretary shall publish on the Internet site of the Food and Drug Administration a statement providing the reasons underlying the determination.

"(bb) Not later than 10 days after making the determination, the Secretary shall provide notice to the sponsor of the application and an opportunity for a meeting with the Commissioner to discuss the determination.

"(ii) The Secretary shall take final agency action on the petition not later than 180 days after the date on which the petition is submitted. The Secretary shall not extend such period, even with the consent of the petitioner, for any reason, including based upon the submission of comments relating to the petition or supplemental information supplied by the petitioner.

"(iii) The Secretary may not consider the petition for review unless it is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date:

\_\_\_\_\_\_. I received or expect to receive payments, including cash and other forms of

- consideration, from the following persons or organizations to file this petition:
  \_\_\_\_\_\_\_. I verify under penalty of perjury that the foregoing is true and correct.'.
- jury that the foregoing is true and correct...

  "(B) EXHAUSTION OF ADMINISTRATIVE REMEDIES.—
- "(i) FINAL AGENCY ACTION WITHIN 180 DAYS.— The Secretary shall be considered to have taken final agency action on a petition referred to in subparagraph (A) if—
- "(I) during the 180-day period referred to in clause (ii) of such subparagraph, the Secretary makes a final decision within the meaning of section 10.45(d) of title 21, Code of Federal Regulations (or any successor regulations); or
- "(II) such period expires without the Secretary having made such a final decision.
- "(ii) DISMISSAL OF CERTAIN CIVIL ACTIONS.—
  If a civil action is filed with respect to a petition referred to in subparagraph (A) before final agency action within the meaning of clause (i) has occurred, the court shall dismiss the action for failure to exhaust administrative remedies.
- "(C) APPLICABILITY OF CERTAIN REGULATIONS.—The provisions of this section are in addition to the requirements for the submission of a petition to the Secretary that apply under section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations).
- "(D) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITIONS.—The Secretary shall annually submit to the Congress a report that specifies—
- "(i) the number of applications under this subsection that were approved during the preceding 12-month period;
- "(ii) the number of such applications whose effective dates were delayed by petitions referred to in subparagraph (A) during such period; and
- "(iii) the number of days by which the applications were so delayed.
- "(E) EXCEPTION.—This paragraph does not apply to a petition that is made by the sponsor of an application under this subsection and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.
- "(F) DEFINITION.—For purposes of this paragraph, the term 'petition' includes any request to the Secretary, without regard to whether the request is characterized as a petition"
  - (b) Additional Amendments.—
- (1) PATENTS.—Section 271(e) of title 35, United States Code, is amended—
- (A) in paragraph (2)—
- (i) by striking "or" at the end of subparagraph (A);
- (ii) by adding "or" at the end of subparagraph (B);
- (iii) by inserting after subparagraph (B) the following:
- "(C) a notice described in section 351(k)(17)(B) of the Public Health Service Act, but only with respect to a patent identified in such notice,"; and
- (iv) in the matter following subparagraph (C) (as inserted by clause (iii) of this subparagraph), by inserting before the period the following: ", or if the notice described in subparagraph (C) is provided in connection with an application to obtain a license to engage in the commercial manufacture, use, or sale of a biological product claimed in a patent or the use of which is claimed in a patent or the expiration of such patent": and
- (B) by adding at the end the following paragraph:
- "(6)(A) This paragraph applies, in lieu of paragraph (4), in the case of a patent—
- "(i) which is disclosed in a response to a request for patent information pursuant to subparagraph (A) of section 351(k)(17) of the Public Health Service Act;

- "(ii) with respect to which a notice was provided pursuant to subparagraph (B) of such section; and
- "(iii) for which an action for infringement of the patent—
- "(I) was brought after the expiration of the 45-day period described in subparagraph (C) of such section; or
- "(II) was brought before the expiration of the 45-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.
- "(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the person who submitted the notice described in subparagraph (A)(ii) infringed the patent, or that any person induced or contributed to infringement of the patent, shall be a reasonable royalty.
- "(C) The owner of a patent that should have been disclosed in response to a request for patent information made by an applicant pursuant to subparagraph (A)(i) of section 351(k)(17) of the Public Health Service Act, but that was not timely disclosed under that subparagraph, may not bring an action under this section for infringement of that patent."
- (2) Conforming amendments.—
- (A) TITLE 28.—Section 2201(b) of title 28, United States Code, is amended by inserting before the period the following: ", or section 351 of the Public Health Service Act".
- (B) PUBLIC HEALTH SERVICE ACT.—Subjection (j) of section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by inserting "or subsection (k)" after "subsection (a)".
  - By Mr. KENNEDY (for himself, Mr. CORNYN, Mr. HARKIN, Mr. McCain, Mr. Durbin, Mr. Lugar, Mr. Dodd, Mr. Smith, Mr. Reed, Ms. Snowe, Mr. Lautenberg, Ms. Murkowski, Mr. Bingaman, Ms. Collins, Ms. Mirkulski, Mr. Stevens, Mrs. Murray, Mr. Domenici, Mrs. Clinton, Mr. Cochran, Mrs. Feinstein, Mr. Leahy, Mr. Obama, Mr. Sanders, Mr. Brown, Mr. Schumer, Mr. Akaka, Mr. Kohl, Ms. Cantwell, Mr. Carper, and Mr. Nelson of Florida):
- S. 625. A bill to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products; to the Committee on Health, Education, Labor, and Pensions.

Mr. KENNEDY. Mr. President, today, we are introducing legislation to give the Food and Drug Administration broad authority to regulate tobacco products. Congress cannot in good conscience allow the Federal agency most responsible for protecting the public health to remain powerless to deal with the enormous risks of tobacco, the most deadly of all consumer products. Health experts believe this legislation is the most important action Congress could take to protect children from this deadly addiction.

This is a bipartisan, bicameral initiative. The bill that Senator CORNYN and I are introducing already has over 25 cosponsors. Congressman WAXMAN and DAVIS will introduce identical legislation in the House. Our bill has the sup-

port of a broad coalition of public health organizations led by the Campaign for Tobacco-Free Kids, the American Cancer Society, the American Heart Association and the American Lung Association. They all recognize the importance of enacting this bill this year.

The legislation we are introducing today is well known. It is the same bill that passed the Senate in 2004, and that we introduced in the last Congress. However, in this new Congress, the likelihood of passage is greatly enhanced. Last November's election swept away many of the barriers to passage from prior years. We believe 2007 is the year that legislation empowering the FDA to regulate tobacco products will finally become law.

We intend to move forward on the legislation quickly. I have already scheduled a hearing in the HELP Committee for February 27, and a markup is planned soon thereafter.

The stakes are vast. Four thousand children have their first cigarette every day, and one thousand become daily smokers. More than one-third of them will die prematurely from to-bacco-induced diseases. Cigarettes kill well over 400,000 Americans each year. That is more lives lost than from automobile accidents, alcohol abuse, illegal drugs, AIDS, murder, and suicide combined. Congress's response to a public health problem of this magnitude is long overdue.

Regulating the conduct of tobacco companies is as necessary today as it has been in years past. The facts presented in the Federal Government's landmark lawsuit against the tobacco industry demonstrate that the misconduct is substantial and ongoing. The decision of the court states: "The evidence in this case clearly establishes that Defendants have not ceased engaging in unlawful activity . . . Defendants continue to engage in conduct that is materially indistinguishable from their previous actions, activity that continues to this day."

We must deal firmly with tobacco company marketing practices that target children and mislead the public. The Food and Drug Administration needs broad authority to regulate the sale, distribution, and advertising of cigarettes and smokeless tobacco.

The tobacco industry currently spends over \$15 billion a year to promote its products. Much of that money is spent in ways designed to tempt children to start smoking, before they are mature enough to appreciate the enormity of the health risk. The industry knows that nearly 90 percent of smokers begin as children and are addicted by the time they reach adulthood.

Documents obtained from tobacco companies prove, in the companies' own words, the magnitude of the industry's efforts to trap children into dependency on their deadly product. Studies by the Institute of Medicine and the Centers for Disease Control show the substantial role of industry

advertising in decisions by young people to use tobacco products.

If we are serious about reducing youth smoking, FDA must have the power to prevent industry advertising designed to appeal to children wherever it will be seen by children. This legislation will give FDA the authority to stop tobacco advertising that glamorizes smoking to kids. It grants FDA full authority to regulate tobacco advertising "consistent with and to the full extent permitted by the First Amendment."

FDA authority must also extend to the sale of tobacco products. Nearly every State makes it illegal to sell cigarettes to children under 18, but surveys show that those laws are rarely enforced and frequently violated. FDA must have the power to limit the sale of cigarettes to face-to-face transactions in which the age of the purchaser can be verified by identification. This means an end to self-service displays and vending machine sales. There must also be serious enforcement efforts with real penalties for those caught selling tobacco products to children. This is the only way to ensure that children under 18 are not able to buy cigarettes.

The FDA conducted the longest rulemaking proceeding in its history, studying which regulations would most effectively reduce the number of children who smoke. Seven hundred thousand public comments were received in the course of that rulemaking. At the conclusion of its proceeding, the agency promulgated rules on the manner in which cigarettes are advertised and sold. Due to litigation, most of those regulations were never implemented. If we are serious about curbing youth smoking as much as possible, as soon as possible; it makes no sense to require FDA to reinvent the wheel by conducting a new multi-year rulemaking process on the same issues. This legislation will give the youth access and advertising restrictions already developed by FDA the immediate force of law, as if they had been issued under the new statute.

The legislation also provides for stronger warnings on all cigarette and smokeless tobacco packages, and in all print advertisements. These warnings will be more explicit in their description of the medical problems which can result from tobacco use. The FDA is given the authority to change the text of these warning labels periodically, to keep their impact strong.

The nicotine in cigarettes is highly addictive. Medical experts say that it is as addictive as heroin or cocaine. Yet for decades, tobacco companies vehemently denied the addictiveness of their products. No one can forget the parade of tobacco executives who testified under oath before Congress that smoking cigarettes is not addictive. Overwhelming evidence in industry documents obtained through the discovery process proves that the companies not only knew of

addictiveness for decades, but actually relied on it as the basis for their marketing strategy. As we now know, cigarette manufacturers chemically manipulated the nicotine in their products to make it even more addictive.

A newly released analysis by the Harvard School of Public Health demonstrates that cigarette manufacturers are still manipulating nicotine levels. Between 1998 and 2005, they significantly increased the nicotine yield from major brand name cigarettes. The average increase in nicotine yield over the period was 11 percent.

The tobacco industry has a long, dishonorable history of providing misleading information about the health consequences of smoking. These companies have repeatedly sought to characterize their products as far less hazardous than they are. They made minor innovations in product design seem far more significant for the health of the user than they actually were. It is essential that FDA have clear and unambiguous authority to prevent such misrepresentations in the future. The largest disinformation campaign in the history of the corporate world must end.

Given the addictiveness of tobacco products, it is essential that the FDA regulate them for the protection of the public. Over 40 million Americans are currently addicted to cigarettes. No responsible public health official believes that cigarettes should be banned. A ban would leave 40 million people without a way to satisfy their drug dependency. FDA should be able to take the necessary steps to help addicted smokers overcome their addiction, and to make the product less toxic for smokers who are unable or unwilling to stop. To do so, FDA must have the authority to reduce or remove hazardous ingredients from cigarettes, to the extent that it becomes scientifically feasible. The inherent risk in smoking should not be unnecessarily com-

Recent statements by several tobacco companies make clear that they plan to develop what they characterize as "reduced risk" cigarettes. Some are already on the market making unsubstantiated claims. This legislation will require manufacturers to submit such "reduced risk" products to the FDA for analysis before they can be marketed. No health-related claims will be permitted until they have been verified to the FDA's satisfaction. These safeguards are essential to prevent deceptive industry marketing campaigns, which could lull the public into a false sense of health safety.

Smoking is the number one preventable cause of death in America. Congress must vest FDA not only with the responsibility for regulating tobacco products, but with full authority to do the job effectively.

This legislation will give the FDA the legal authority it needs to reduce youth smoking by preventing tobacco advertising which targets children, to prevent the sale of tobacco products to minors, to help smokers overcome their addiction, to make tobacco products less toxic for those who continue to use them, and to prevent the tobacco industry from misleading the public about the dangers of smoking.

Enacting this bill this year is the right thing to do for America's children. They are depending on us. By passing this legislation, we can help them live longer, healthier lives.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

#### S. 625

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

## SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

- (a) SHORT TITLE.—This Act may be cited as the "Family Smoking Prevention and Tobacco Control Act".
- (b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:
- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.
- Sec. 3. Purpose.
- Sec. 4. Scope and effect.
- Sec. 5. Severability.

## TITLE I—AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION

- Sec. 101. Amendment of Federal food, drug, and Cosmetic Act.
- Sec. 102. Final rule.
- Sec. 103. Conforming and other amendments to general provisions.

# TITLE II—TOBACCO PRODUCT WARNINGS; CONSTITUENT AND SMOKE CONSTITUENT DISCLOSURE

- Sec. 201. Cigarette label and advertising warnings.
- Sec. 202. Authority to revise cigarette warning label statements.
- Sec. 203. State regulation of cigarette advertising and promotion.
- Sec. 204. Smokeless Tobacco labels and advertising warnings.
- Sec. 205. Authority to revise Smokeless Tobacco product warning label statements.
- Sec. 206. Tar, Nicotine, and other smoke constituent disclosure to the public.

## TITLE III—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

Sec. 301. Labeling, recordkeeping, records inspection.

Sec. 302. Study and report.

## SEC. 2. FINDINGS.

The Congress finds the following:

- (1) The use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults.
- (2) A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects.
  - (3) Nicotine is an addictive drug.
- (4) Virtually all new users of tobacco products are under the minimum legal age to purchase such products.
- (5) Tobacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents.
- (6) Because past efforts to restrict advertising and marketing of tobacco products

have failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed.

- (7) Federal and State governments have lacked the legal and regulatory authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products
- (8) Federal and State public health officials, the public health community, and the public at large recognize that the tobacco industry should be subject to ongoing oversight.
- (9) Under article I, section 8 of the Constitution, the Congress is vested with the responsibility for regulating interstate commerce and commerce with Indian tribes.
- (10) The sale, distribution, marketing, advertising, and use of tobacco products are activities in and substantially affecting interstate commerce because they are sold, marketed, advertised, and distributed in interstate commerce on a nationwide basis, and have a substantial effect on the Nation's economy.
- (11) The sale, distribution, marketing, advertising, and use of such products substantially affect interstate commerce through the health care and other costs attributable to the use of tobacco products.
- (12) It is in the public interest for Congress to enact legislation that provides the Food and Drug Administration with the authority to regulate tobacco products and the advertising and promotion of such products. The benefits to the American people from enacting such legislation would be significant in human and economic terms.
- (13) Tobacco use is the foremost preventable cause of premature death in America. It causes over 400,000 deaths in the United States each year and approximately 8,600,000 Americans have chronic illnesses related to smoking.
- (14) Reducing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco induced disease. Such a reduction in youth smoking would also result in approximately \$75,000,000,000 in savings attributable to reduced health care costs.
- (15) Advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products and these efforts have resulted in increased use of such products by youth. Past efforts to oversee these activities have not been successful in adequately preventing such increased use.
- (16) In 2003, the cigarette manufacturers spent more than \$15,000,000,000 to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use.
- (17) Tobacco product advertising often misleadingly portrays the use of tobacco as socially acceptable and healthful to minors.
- (18) Tobacco product advertising is regularly seen by persons under the age of 18, and persons under the age of 18 are regularly exposed to tobacco product promotional efforts.
- (19) Through advertisements during and sponsorship of sporting events, tobacco has become strongly associated with sports and has become portrayed as an integral part of sports and the healthy lifestyle associated with rigorous sporting activity.
- (20) Children are exposed to substantial and unavoidable tobacco advertising that leads to favorable beliefs about tobacco use, plays a role in leading young people to overestimate the prevalence of tobacco use, and

increases the number of young people who begin to use tobacco.

- (21) The use of tobacco products in motion pictures and other mass media glamorizes its use for young people and encourages them to use tobacco products.
- (22) Tobacco advertising expands the size of the tobacco market by increasing consumption of tobacco products including tobacco use by young people.
- (23) Children are more influenced by tobacco marketing than adults: more than 80 percent of youth smoke three heavily marketed brands, while only 54 percent of adults, 26 and older, smoke these same brands.
- (24) Tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market. Children, who tend to be more price-sensitive than adults, are influenced by advertising and promotion practices that result in drastically reduced eigarette prices.
- (25) Comprehensive advertising restrictions will have a positive effect on the smoking rates of young people.
- (26) Restrictions on advertising are necessary to prevent unrestricted tobacco advertising from undermining legislation prohibiting access to young people and providing for education about tobacco use.
- (27) International experience shows that advertising regulations that are stringent and comprehensive have a greater impact on overall tobacco use and young people's use than weaker or less comprehensive ones.
- (28) Text only requirements, although not as stringent as a ban, will help reduce underage use of tobacco products while preserving the informational function of advertising
- (29) It is in the public interest for Congress to adopt legislation to address the public health crisis created by actions of the tobacco industry.
- (30) The final regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register (61 Fed. Reg. 44615-44618) for inclusion as part 897 of title 21. Code of Federal Regulations, are consistent with the First Amendment to the United States Constitution and with the standards set forth in the amendments made by this subtitle for the regulation of tobacco products by the Food and Drug Administration and the restriction on the sale and distribution, including access to and the advertising and promotion of, tobacco products contained in such regulations are substantially related to accomplishing the public health goals of this Act.
- (31) The regulations described in paragraph (30) will directly and materially advance the Federal Government's substantial interest in reducing the number of children and adolescents who use cigarettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use. An overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18. Tobacco advertising and promotion plays a crucial role in the decision of these minors to begin using tobacco products. Less restrictive and less comprehensive approaches have not and will not be effective in reducing the problems addressed by such regulations. The reasonable restrictions on the advertising and promotion of tobacco products contained in such regulations will lead to a significant decrease in the number of minors using and becoming addicted to those products.
- (32) The regulations described in paragraph (30) impose no more extensive restrictions on communication by tobacco manufacturers and sellers than are necessary to reduce the number of children and adolescents who use cigarettes and smokeless tobacco and to pre-

- vent the life-threatening health consequences associated with tobacco use. Such regulations are narrowly tailored to restrict those advertising and promotional practices which are most likely to be seen or heard by youth and most likely to entice them into tobacco use, while affording tobacco manufacturers and sellers ample opportunity to convey information about their products to adult consumers.
- (33) Tobacco dependence is a chronic disease, one that typically requires repeated interventions to achieve long-term or permanent abstinence.
- (34) Because the only known safe alternative to smoking is cessation, interventions should target all smokers to help them quit completely.
- (35) Tobacco products have been used to facilitate and finance criminal activities both domestically and internationally. Illicit trade of tobacco products has been linked to organized crime and terrorist groups.
- (36) It is essential that the Food and Drug Administration review products sold or distributed for use to reduce risks or exposures associated with tobacco products and that it be empowered to review any advertising and labeling for such products. It is also essential that manufacturers, prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria, and will benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products.
- (37) Unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health to the extent that the individuals, who would otherwise not consume tobacco products or would consume such products less, use tobacco products purporting to reduce risk. Those who use products sold or distributed as modified risk products that do not in fact reduce risk, rather than quitting or reducing their use of tobacco products. have a substantially increased likelihood of suffering disability and premature death. The costs to society of the widespread use of products sold or distributed as modified risk products that do not in fact reduce risk or that increase risk include thousands of unnecessary deaths and injuries and huge costs to our health care system.
- (38) As the National Cancer Institute has found, many smokers mistakenly believe that "low tar" and "light" cigarettes cause fewer health problems than other cigarettes. As the National Cancer Institute has also found, mistaken beliefs about the health consequences of smoking "low tar" and "light" cigarettes can reduce the motivation to quit smoking entirely and thereby lead to disease and death.
- (39) Recent studies have demonstrated that there has been no reduction in risk on a population-wide basis from "low tar" and "light" cigarettes and such products may actually increase the risk of tobacco use.
- (40) The dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in insuring that statements about modified risk tobacco products are complete, accurate, and relate to the overall disease risk of the product.
- (41) As the Federal Trade Commission has found, consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification.

(42) Permitting manufacturers to make unsubstantiated statements concerning modified risk tobacco products, whether express or implied, even if accompanied by disclaimers would be detrimental to the public health

(43) The only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products is to empower the Food and Drug Administration to require that products that tobacco manufacturers sold or distributed for risk reduction be approved in advance of marketing, and to require that the evidence relied on to support approval of these products is rigorous.

#### SEC. 3. PURPOSE.

The purposes of this Act are-

(1) to provide authority to the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products:

(2) to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;

(3) to authorize the Food and Drug Administration to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products;

(4) to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products;

(5) to vest the Food and Drug Administration with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products:

(6) in order to ensure that consumers are better informed, to require tobacco product manufacturers to disclose research which has not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products;

(7) to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers;

(8) to impose appropriate regulatory controls on the tobacco industry;

(9) to promote cessation to reduce disease risk and the social costs associated with to-bacco related diseases; and

(10) to strengthen legislation against illicit trade in tobacco products.

#### SEC. 4. SCOPE AND EFFECT.

(a) Intended Effect.—Nothing in this Act (or an amendment made by this Act) shall be construed to—

(1) establish a precedent with regard to any other industry, situation, circumstance, or legal action; or

(2) affect any action pending in Federal, State, or Tribal court, or any agreement, consent decree, or contract of any kind.

(b) AGRICULTURAL ACTIVITIES.—The provisions of this Act (or an amendment made by this Act) which authorize the Secretary to take certain actions with regard to tobacco and tobacco products shall not be construed to affect any authority of the Secretary of Agriculture under existing law regarding the growing, cultivation, or curing of raw tobacco.

#### SEC. 5. SEVERABILITY.

If any provision of this Act, the amendments made by this Act, or the application of any provision of this Act to any person or circumstance is held to be invalid, the re-

mainder of this Act, the amendments made by this Act, and the application of the provisions of this Act to any other person or circumstance shall not be affected and shall continue to be enforced to the fullest extent possible.

# TITLE I—AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION

#### SEC. 101. AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) DEFINITION OF TOBACCO PRODUCTS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

"(rr)(1) The term 'tobacco product' means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

"(2) The term 'tobacco product' does not mean—

"(A) a product in the form of conventional food (including water and chewing gum), a product represented for use as or for use in a conventional food, or a product that is intended for ingestion in capsule, tablet, softgel, or liquid form; or

"(B) an article that is approved or is regulated as a drug by the Food and Drug Administration.

"(3) The products described in paragraph (2)(A) shall be subject to chapter IV or chapter V of this Act and the articles described in paragraph (2)(B) shall be subject to chapter V of this Act.

"(4) A tobacco product may not be marketed in combination with any other article or product regulated under this Act (including a drug, biologic, food, cosmetics, medical device, or a dietary supplement)."

(b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) by redesignating chapter IX as chapter X.

(2) by redesignating sections 901 through 909 as sections 1001 through 1009;

(3) in section 1009 (as so redesignated), by striking "section 908" and inserting "section 1008" and

(4) by inserting after chapter VIII the following:

# "CHAPTER IX—TOBACCO PRODUCTS "SEC. 900. DEFINITIONS.

"In this chapter:

"(1) ADDITIVE.—The term 'additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring, coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical.

"(2) BRAND.—The term 'brand' means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, or packaging, logo, registered trademark or brand name, identifiable pattern of colors, or any combination of such attributes.

"(3) CIGARETTE.—The term 'cigarette' has the meaning given that term by section 3(1) of the Federal Cigarette Labeling and Advertising Act, but also includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

"(4) CIGARETTE TOBACCO.—The term 'cigarette tobacco' means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements for cigarettes shall also apply to cigarette tobacco.

"(5) COMMERCE.—The term 'commerce' has the meaning given that term by section 3(2) of the Federal Cigarette Labeling and Advertising Act.

"(6) COUNTERFEIT TOBACCO PRODUCT.—The term 'counterfeit tobacco product' means a tobacco product (or the container or labeling of such a product) that, without authorization, bears the trademark, trade name, or other identifying mark, imprint or device, or any likeness thereof, of a tobacco product listed in a registration under section 905(i)(1).

"(7) DISTRIBUTOR.—The term 'distributor' as regards a tobacco product means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for purposes of this chapter.

"(8) ILLICIT TRADE.—The term 'illicit trade' means any practice or conduct prohibited by law which relates to production, shipment, receipt, possession, distribution, sale, or purchase of tobacco products including any practice or conduct intended to facilitate such activity.

"(9) INDIAN TRIBE.—The term 'Indian tribe' has the meaning given such term in section 4(e) of the Indian Self Determination and Education Assistance Act.

"(10) LITTLE CIGAR.—The term 'little cigar' has the meaning given that term by section 3(7) of the Federal Cigarette Labeling and Advertising Act.

"(11) NICOTINE.—The term 'nicotine' means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.

"(12) PACKAGE.—The term 'package' means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

"(13) RETAILER.—The term 'retailer' means any person who sells tobacco products to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted.

"(14) ROLL-YOUR-OWN TOBACCO.—The term 'roll-your-own tobacco' means any tobacco which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

"(15) SMOKE CONSTITUENT.—The term 'smoke constituent' means any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the cigarette to the smoke or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product.

"(16) SMOKELESS TOBACCO.—The term 'smokeless tobacco' means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

"(17) STATE.—The term 'State' means any State of the United States and, for purposes of this chapter, includes the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

- "(18) TOBACCO PRODUCT MANUFACTURER. The term 'tobacco product manufacturer' means any person, including any repacker or relabeler, who-
- "(A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or
- "(B) imports a finished cigarette or smokeless tobacco product for sale or distribution in the United States.
- "(19) United states.—The term 'United States' means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico. Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef. Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

#### "SEC. 901. FDA AUTHORITY OVER TOBACCO PRODUCTS.

- "(a) IN GENERAL.—Tobacco products shall be regulated by the Secretary under this chapter and shall not be subject to the provisions of chapter V. unless-
- '(1) such products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease (within the meaning of section 201(g)(1)(B) or section 201(h)(2); or
- "(2) a claim is made for such products under section 201(g)(1)(C) or 201(h)(3);
- other than modified risk tobacco products approved in accordance with section 911.
- (b) APPLICABILITY.—This chapter shall apply to all tobacco products subject to the regulations referred to in section 102 of the Family Smoking Prevention and Tobacco Control Act, and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter.
  - '(c) Scope.
- "(1) IN GENERAL.—Nothing in this chapter, or any policy issued or regulation promulgated thereunder, or in sections 101(a), 102, or 103 of title I, title II, or title III of the Family Smoking Prevention and Tobacco Control Act, shall be construed to affect, expand, or limit the Secretary's authority over (including the authority to determine whether products may be regulated), or the regulation of, products under this Act that are not tobacco products under chapter V or any other chapter.
  - "(2) LIMITATION OF AUTHORITY.-
- "(A) IN GENERAL.—The provisions of this chapter shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.
- EXCEPTION.—Notwithstanding paragraph (A), if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer. the producer shall be subject to this chapter in the producer's capacity as a manufacturer.
- "(C) RULE OF CONSTRUCTION.—Nothing in this chapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer affecting production.

#### "SEC. 902. ADULTERATED TOBACCO PRODUCTS.

- "A tobacco product shall be deemed to be adulterated if-
- "(1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health;
- '(2) it has been prepared, packed, or held under insanitary conditions whereby it may

- have been contaminated with filth, or whereby it may have been rendered injurious to health;
- "(3) its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;
- "(4) it is, or purports to be or is represented as, a tobacco product which is subject to a tobacco product standard established under section 907 unless such tobacco product is in all respects in conformity with such standard:
- "(5)(A) it is required by section 910(a) to have premarket approval and does not have an approved application in effect; or
- "(B) it is in violation of the order approving such an application;
- "(6) the methods used in, or the facilities or controls used for, its manufacture, packing, or storage are not in conformity with under applicable requirements section 906(e)(1) or an applicable condition prescribed by an order under section 906(e)(2); or "(7) it is in violation of section 911.

#### "SEC. 903. MISBRANDED TOBACCO PRODUCTS.

- "(a) IN GENERAL.—A tobacco product shall be deemed to be misbranded-"(1) if its labeling is false or misleading in
- any particular; "(2) if in package form unless it bears a
- label containing-
- "(A) the name and place of business of the tobacco product manufacturer, packer, or distributor;
- "(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count:
- "(C) an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco; and
- "(D) the statement required under section 921(a),
- except that under subparagraph (B) reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary:
- "(3) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use:
- (4) if it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name prominently printed in type as required by the Secretary by regulation;
- (5) if the Secretary has issued regulations requiring that its labeling bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protection of users unless its labeling conforms in all respects to such regulations:
- '(6) if it was manufactured, prepared, propagated, compounded, or processed in any State in an establishment not duly registered under section 905(b), 905(c), 905(d), or 905(h), if it was not included in a list required by section 905(i), if a notice or other information respecting it was not provided as required by such section or section 905(j), or if it does not bear such symbols from the uniform system for identification of tobacco products prescribed under section 905(e) as the Secretary by regulation requires;
- "(7) if, in the case of any tobacco product distributed or offered for sale in any State-"(A) its advertising is false or misleading
- in any particular; or
- "(B) it is sold or distributed in violation of regulations prescribed under section 906(d);

- "(8) unless, in the case of any tobacco product distributed or offered for sale in any State, the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that tobacco product-
- "(A) a true statement of the tobacco product's established name as described in paragraph (4), printed prominently; and
  - (B) a brief statement of-
- "(i) the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications; and
- "(ii) in the case of specific tobacco products made subject to a finding by the Secretary after notice and opportunity for comment that such action is appropriate to protect the public health, a full description of the components of such tobacco product or the formula showing quantitatively each ingredient of such tobacco product to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing;
- "(9) if it is a tobacco product subject to a tobacco product standard established under section 907, unless it bears such labeling as may be prescribed in such tobacco product standard; or
  - "(10) if there was a failure or refusal—
- "(A) to comply with any requirement prescribed under section 904 or 908; or
- "(B) to furnish any material or information required under section 909.
- "(b) PRIOR APPROVAL OF LABEL STATE-MENTS.—The Secretary may, by regulation, require prior approval of statements made on the label of a tobacco product. No regulation issued under this subsection may require prior approval by the Secretary of the content of any advertisement, except for modified risk tobacco products as provided in section 911. No advertisement of a tobacco product published after the date of enactment of the Family Smoking Prevention and Tobacco Control Act shall, with respect to the language of label statements as prescribed under section 4 of the Cigarette Labeling and Advertising Act and section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 or the regulations issued under such sections, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act.

#### "SEC. 904. SUBMISSION OF HEALTH INFORMA-TION TO THE SECRETARY.

- REQUIREMENT.—Not later than "(a) months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, each tobacco product manufacturer or importer, or agents thereof, shall submit to the Secretary the following information:
- "(1) A listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand.
- "(2) A description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams of nicotine in accordance with regulations promulgated by the Secretary in accordance with section 4(a)(5) of the Federal Cigarette Labeling and Advertising Act.
- "(3) A listing of all constituents, including smoke constituents as applicable, identified by the Secretary as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and subbrand. Effective beginning 2 years after the date of enactment of this chapter, the manufacturer, importer, or

agent shall comply with regulations promulgated under section 916 in reporting information under this paragraph, where applicable.

"(4) All documents developed after the date of enactment of the Family Smoking Prevention and Tobacco Control Act that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.

"(b) DATA SUBMISSION.—At the request of the Secretary, each tobacco product manufacturer or importer of tobacco products, or agents thereof, shall submit the following:

"(1) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on the health, toxicological, behavioral, or physiologic effects of tobacco products and their constituents (including smoke constituents), ingredients, components, and additives.

"(2) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) that relate to the issue of whether a reduction in risk to health from tobacco products can occur upon the employment of technology available or known to the manufacturer.

"(3) Any or all documents (including underlying scientific or financial information) relating to marketing research involving the use of tobacco products or marketing practices and the effectiveness of such practices used by tobacco manufacturers and distributors

An importer of a tobacco product not manufactured in the United States shall supply the information required of a tobacco product manufacturer under this subsection.

"(c) TIME FOR SUBMISSION.-

"(1) IN GENERAL.—At least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the manufacturer of such product shall provide the information required under subsection (a).

"(2) DISCLOSURE OF ADDITIVE.—If at any time a tobacco product manufacturer adds to its tobacco products a new tobacco additive or increases the quantity of an existing tobacco additive, the manufacturer shall, except as provided in paragraph (3), at least 90 days prior to such action so advise the Secretary in writing.

"(3) DISCLOSURE OF OTHER ACTIONS.—If at any time a tobacco product manufacturer eliminates or decreases an existing additive, or adds or increases an additive that has by regulation been designated by the Secretary as an additive that is not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use, the manufacturer shall within 60 days of such action so advise the Secretary in writing.

"(d) DATA LIST.—

"(1) IN GENERAL.—Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Secretary) the list established under subsection (e).

"(2) CONSUMER RESEARCH.—The Secretary shall conduct periodic consumer research to ensure that the list published under paragraph (1) is not misleading to lay persons. Not later than 5 years after the date of enactment of the Family Smoking Prevention

and Tobacco Control Act, the Secretary shall submit to the appropriate committees of Congress a report on the results of such research, together with recommendations on whether such publication should be continued or modified.

"(e) DATA COLLECTION.—Not later than 12 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand. The Secretary shall publish a public notice requesting the submission by interested persons of scientific and other information concerning the harmful and potentially harmful constituents in tobacco products and tobacco smoke.

#### "SEC. 905. ANNUAL REGISTRATION.

``(a) DEFINITIONS.—In this section:

"(1) Manufacture, Preparation, compounding, or Processing.—The term 'manufacture, preparation, compounding, or processing' shall include repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.

"(2) NAME.—The term 'name' shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

"(b) REGISTRATION BY OWNERS AND OPERATORS.—On or before December 31 of each year every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person.

"(c) REGISTRATION OF NEW OWNERS AND OPERATORS.—Every person upon first engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products in any establishment owned or operated in any State by that person shall immediately register with the Secretary that person's name, place of business, and such establishment.

"(d) REGISTRATION OF ADDED ESTABLISH-MENTS.—Every person required to register under subsection (b) or (c) shall immediately register with the Secretary any additional establishment which that person owns or operates in any State and in which that person begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products.

"(e) Uniform Product Identification Sys-TEM.—The Secretary may by regulation prescribe a uniform system for the identification of tobacco products and may require that persons who are required to list such tobacco products under subsection (i) shall list such tobacco products in accordance with such system.

"(f) PUBLIC ACCESS TO REGISTRATION INFOR-MATION.—The Secretary shall make available for inspection, to any person so requesting, any registration filed under this section.

"(g) BIENNIAL INSPECTION OF REGISTERED ESTABLISHMENTS.—Every establishment in any State registered with the Secretary under this section shall be subject to inspection under section 704, and every such establishment engaged in the manufacture, compounding, or processing of a tobacco product or tobacco products shall be so inspected by 1 or more officers or employees duly designated by the Secretary at least

once in the 2-year period beginning with the date of registration of such establishment under this section and at least once in every successive 2-year period thereafter.

(h) Foreign Establishments Shall Reg-ISTER.—Any establishment within any foreign country engaged in the manufacture. preparation, compounding, or processing of a tobacco product or tobacco products, shall register under this section under regulations promulgated by the Secretary. Such regulations shall require such establishment to provide the information required by subsection (i) of this section and shall include provisions for registration of any such establishment upon condition that adequate and effective means are available, by arrangement with the government of such foreign country or otherwise, to enable the Secretary to determine from time to time whether tobacco products manufactured, prepared, compounded, or processed in such establishment, if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).

"(i) REGISTRATION INFORMATION.—

"(1) PRODUCT LIST.—Every person who registers with the Secretary under subsection (b), (c), (d), or (h) shall, at the time of registration under any such subsection, file with the Secretary a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution and which has not been included in any list of tobacco products filed by that person with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by—

"(A) in the case of a tobacco product contained in the applicable list with respect to which a tobacco product standard has been established under section 907 or which is subject to section 910, a reference to the authority for the marketing of such tobacco product and a copy of all labeling for such tobacco product;

"(B) in the case of any other tobacco product contained in an applicable list, a copy of all consumer information and other labeling for such tobacco product, a representative sampling of advertisements for such tobacco product, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and

"(C) if the registrant filing a list has determined that a tobacco product contained in such list is not subject to a tobacco product standard established under section 907, a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular tobacco product.

"(2) BIANNUAL REPORT OF ANY CHANGE IN PRODUCT LIST.—Each person who registers with the Secretary under this section shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following:

"(A) A list of each tobacco product introduced by the registrant for commercial distribution which has not been included in any list previously filed by that person with the Secretary under this subparagraph or paragraph (1). A list under this subparagraph shall list a tobacco product by its established name and shall be accompanied by the other information required by paragraph (1).

"(B) If since the date the registrant last made a report under this paragraph that person has discontinued the manufacture, preparation, compounding, or processing for commercial distribution of a tobacco product included in a list filed under subparagraph (A) or paragraph (1), notice of such discontinuance, the date of such discontinuance, and the identity of its established name.

"(C) If since the date the registrant reported under subparagraph (B) a notice of discontinuance that person has resumed the manufacture, preparation, compounding, or processing for commercial distribution of the tobacco product with respect to which such notice of discontinuance was reported, notice of such resumption, the date of such resumption, the identity of such tobacco product by established name, and other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary under this subparagraph.

"(D) Any material change in any information previously submitted under this paragraph or paragraph (1).

"(j) REPORT PRECEDING INTRODUCTION OF CERTAIN SUBSTANTIALLY-EQUIVALENT PROD-UCTS INTO INTERSTATE COMMERCE.—

"(1) IN GENERAL.—Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the United States as of June 1, 2003, shall, at least 90 days prior to making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall prescribe)—

"(A) the basis for such person's determination that the tobacco product is substantially equivalent, within the meaning of section 910, to a tobacco product commercially marketed (other than for test marketing) in the United States as of June 1, 2003, that is in compliance with the requirements of this Act: and

"(B) action taken by such person to comply with the requirements under section 907 that are applicable to the tobacco product.

"(2) APPLICATION TO CERTAIN POST JUNE 1, 2003 PRODUCTS.—A report under this subsection for a tobacco product that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after June 1, 2003, and prior to the date that is 15 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act shall be submitted to the Secretary not later than 15 months after such date of enactment.

"(3) Exemptions.—

"(A) IN GENERAL.—The Secretary may by regulation, exempt from the requirements of this subsection tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if the Secretary determines that—

"(i) such modification would be a minor modification of a tobacco product authorized for sale under this Act;

"(ii) a report under this subsection is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; and

 $\lq\lq(iii)$  an exemption is otherwise appropriate.

"(B) REGULATIONS.—Not later than 9 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue regulations to implement this paragraph.

#### "SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS.

"(a) IN GENERAL.—Any requirement established by or under section 902, 903, 905, or 909 applicable to a tobacco product shall apply to such tobacco product until the applicability of the requirement to the tobacco product has been changed by action taken under section 907, section 910, section 911, or subsection (d) of this section, and any requirement established by or under section 902, 903, 905, or 909 which is inconsistent with a requirement imposed on such tobacco product under section 907, section 910, section 911, or subsection (d) of this section shall not apply to such tobacco product.

"(b) INFORMATION ON PUBLIC ACCESS AND COMMENT.—Each notice of proposed rule-making or other notification under section 907, 908, 909, 910, or 911 or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

"(1) the manner in which interested persons may examine data and other information on which the notice or findings is based; and

"(2) the period within which interested persons may present their comments on the notice or findings (including the need therefore) orally or in writing, which period shall be at least 60 days but may not exceed 90 days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefore.

"(c) LIMITED CONFIDENTIALITY OF INFORMATION.—Any information reported to or otherwise obtained by the Secretary or the Secretary's representative under section 903, 904, 907, 908, 909, 910, 911, or 704, or under subsection (e) or (f) of this section, which is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of that section shall be considered confidential and shall not be disclosed, except that the information may be disclosed to other officers or employees concerned with carrying out this chapter, or when relevant in any proceeding under this chapter.

"(d) Restrictions.—

"(1) IN GENERAL.—The Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health. The Secretary may by regulation impose restrictions on the advertising and promotion of a tobacco product consistent with and to full extent permitted by the first amendment to the Constitution. The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account

"(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

"(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

No such regulation may require that the sale or distribution of a tobacco product be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products.

"(2) LABEL STATEMENTS.—The label of a tobacco product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Secretary may in such regulation prescribe.

"(3) LIMITATIONS.—

"(A) IN GENERAL.—No restrictions under paragraph (1) may—

"(i) prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets; or

"(ii) establish a minimum age of sale of tobacco products to any person older than 18 years of age.

"(B) MATCHBOOKS.—For purposes of any regulations issued by the Secretary, matchbooks of conventional size containing not more than 20 paper matches, and which are customarily given away for free with the purchase of tobacco products shall be considered as adult written publications which shall be permitted to contain advertising. Notwithstanding the preceding sentence, if the Secretary finds that such treatment of matchbooks is not appropriate for the protection of the public health, the Secretary may determine by regulation that matchbooks shall not be considered adult written publications.

"(e) GOOD MANUFACTURING PRACTICE RE-QUIREMENTS.—

"(1) METHODS, FACILITIES, AND CONTROLS TO CONFORM.—

'(A) IN GENERAL.—The Secretary may, in accordance with subparagraph (B), prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing and storage of a tobacco product, conform to current good manufacturing practice, as prescribed in such regulations, to assure that the public health is protected and that the tobacco product is in compliance with this chapter. Good manufacturing practices may include the testing of raw tobacco for pesticide chemical residues regardless of whether a tolerance for such chemical residues has been established.

"(B) REQUIREMENTS.—The Secretary shall—

"(i) before promulgating any regulation under subparagraph (A), afford the Tobacco Products Scientific Advisory Committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated;

"(ii) before promulgating any regulation under subparagraph (A), afford opportunity for an oral hearing;

"(iii) provide the Tobacco Products Scientific Advisory Committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A): and

"(iv) in establishing the effective date of a regulation promulgated under this subsection, take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities, and shall provide for a reasonable period of time for such manufacturers to conform to good manufacturing practices.

"(2) EXEMPTIONS; VARIANCES.—

"(A) PETITION.—Any person subject to any requirement prescribed under paragraph (1) may petition the Secretary for a permanent or temporary exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as the Secretary shall prescribe and shall—

"(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the tobacco product will be in compliance with this chapter;

"(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement; and

"(iii) contain such other information as the Secretary shall prescribe.

"(B) REFERRAL TO THE TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—The Secretary may refer to the Tobacco Products Scientific Advisory Committee any petition submitted under subparagraph (A). The Tobacco Products Scientific Advisory Committee shall report its recommendations to the Secretary with respect to a petition referred to it within 60 days after the date of the petition's referral. Within 60 days after—

"(i) the date the petition was submitted to the Secretary under subparagraph (A); or

"(ii) the day after the petition was referred to the Tobacco Products Scientific Advisory Committee

whichever occurs later, the Secretary shall by order either deny the petition or approve it.

- "(C) APPROVAL.—The Secretary may approve—
- "(i) a petition for an exemption for a tobacco product from a requirement if the Secretary determines that compliance with such requirement is not required to assure that the tobacco product will be in compliance with this chapter; and
- "(ii) a petition for a variance for a tobacco product from a requirement if the Secretary determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, controls, and facilities prescribed by the requirement are sufficient to assure that the tobacco product will be in compliance with this chapter.
- "(D) CONDITIONS.—An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product to be granted the variance under the petition as may be necessary to assure that the tobacco product will be in compliance with this chapter.
- "(E) HEARING.—After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.
- "(3) COMPLIANCE.—Compliance with requirements under this subsection shall not be required before the period ending 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act.
- "(f) RESEARCH AND DEVELOPMENT.—The Secretary may enter into contracts for research, testing, and demonstrations respecting tobacco products and may obtain tobacco products for research, testing, and demonstration purposes without regard to section 3324(a) and (b) of title 31, United States Code, and section 5 of title 41, United States Code.

#### "SEC. 907. TOBACCO PRODUCT STANDARDS.

"(a) IN GENERAL.—

"(1) SPECIAL RULE FOR CIGARETTES.—A cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sec-

tions of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this paragraph.

"(2) REVISION OF TOBACCO PRODUCT STANDARDS.—The Secretary may revise the tobacco product standards in paragraph (1) in accordance with subsection (b).

"(3) TOBACCO PRODUCT STANDARDS.—The Secretary may adopt tobacco product standards in addition to those in paragraph (1) if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health. This finding shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account—

"(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

"(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

"(4) CONTENT OF TOBACCO PRODUCT STANDARDS.—A tobacco product standard established under this section for a tobacco product.—

"(A) shall include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—

"(i) for the reduction of nicotine yields of the product;

"(ii) for the reduction or elimination of other constituents, including smoke constituents, or harmful components of the product; or

"(iii) relating to any other requirement under subparagraph (B):

"(B) shall, where appropriate for the protection of the public health, include—

"(i) provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product:

"(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product:

"(iii) provisions for the measurement of the tobacco product characteristics of the tobacco product;

"(iv) provisions requiring that the results of each or of certain of the tests of the to-bacco product required to be made under clause (ii) show that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and

"(v) a provision requiring that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d); and

"(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper use of the tobacco product."

"(5) PERIODIC RE-EVALUATION OF TOBACCO PRODUCT STANDARDS.—The Secretary shall provide for periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data. The Secretary may provide for testing under paragraph (4)(B) by any person.

"(6) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—In carrying out duties under this section, the Secretary shall endeavor to—

"(A) use personnel, facilities, and other technical support available in other Federal agencies:

"(B) consult with other Federal agencies concerned with standard-setting and other nationally or internationally recognized standard-setting entities; and "(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, agricultural, or consumer organizations who in the Secretary's judgment can make a significant contribution.

"(b) ESTABLISHMENT OF STANDARDS.—

"(1) NOTICE.—

"(A) IN GENERAL.—The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any tobacco product standard.

"(B) REQUIREMENTS OF NOTICE.—A notice of proposed rulemaking for the establishment or amendment of a tobacco product standard for a tobacco product shall—

"(i) set forth a finding with supporting justification that the tobacco product standard is appropriate for the protection of the public health;

"(ii) set forth proposed findings with respect to the risk of illness or injury that the tobacco product standard is intended to reduce or eliminate; and

"(iii) invite interested persons to submit an existing tobacco product standard for the tobacco product, including a draft or proposed tobacco product standard, for consideration by the Secretary.

"(C) STANDARD.—Upon a determination by the Secretary that an additive, constituent (including smoke constituent), or other component of the product that is the subject of the proposed tobacco product standard is harmful, it shall be the burden of any party challenging the proposed standard to prove that the proposed standard will not reduce or eliminate the risk of illness or injury.

"(D) FINDING.—A notice of proposed rulemaking for the revocation of a tobacco product standard shall set forth a finding with supporting justification that the tobacco product standard is no longer appropriate for the protection of the public health.

"(E) Consideration by secretary.—The Secretary shall consider all information submitted in connection with a proposed standard, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or non-tobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand, and shall issue the standard if the Secretary determines that the standard would be appropriate for the protection of the public health.

"(F) COMMENT.—The Secretary shall provide for a comment period of not less than 60 days.

"(2) PROMULGATION.—

"(A) In general.—After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a tobacco product standard and after consideration of such comments and any report from the Tobacco Products Scientific Advisory Committee, the Secretary shall—

"(i) promulgate a regulation establishing a tobacco product standard and publish in the Federal Register findings on the matters referred to in paragraph (1); or

"(ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

"(B) EFFECTIVE DATE.—A regulation establishing a tobacco product standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade.

"(3) POWER RESERVED TO CONGRESS.—Because of the importance of a decision of the Secretary to issue a regulation establishing a tobacco product standard—

"(A) banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll your own tobacco products; or

"(B) requiring the reduction of nicotine yields of a tobacco product to zero,

Congress expressly reserves to itself such power.

"(4) AMENDMENT: REVOCATION.—

"(A) AUTHORITY.—The Secretary, upon the Secretary's own initiative or upon petition of an interested person may by a regulation, promulgated in accordance with the requirements of paragraphs (1) and (2)(B), amend or revoke a tobacco product standard.

"(B) EFFECTIVE DATE.—The Secretary may declare a proposed amendment of a tobacco product standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if the Secretary determines that making it so effective is in the public interest.

"(5) Reference to advisory committee.—

"(A) IN GENERAL.—The Secretary may refer a proposed regulation for the establishment, amendment, or revocation of a tobacco product standard to the Tobacco Products Scientific Advisory Committee for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment.

"(B) INITIATION OF REFERRAL.—The Secretary may make a referral under this paragraph—

"(i) on the Secretary's own initiative; or

"(ii) upon the request of an interested person that—

``(I) demonstrates good cause for the referral; and

"(II) is made before the expiration of the period for submission of comments on the proposed regulation.

"(C) PROVISION OF DATA.—If a proposed regulation is referred under this paragraph to the Tobacco Products Scientific Advisory Committee, the Secretary shall provide the Advisory Committee with the data and information on which such proposed regulation is based.

"(D) REPORT AND RECOMMENDATION.—The Tobacco Products Scientific Advisory Committee shall, within 60 days after the referral of a proposed regulation under this paragraph and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation.

"(E) PUBLIC AVAILABILITY.—The Secretary shall make a copy of each report and recommendation under subparagraph (D) publicly available.

#### "SEC. 908. NOTIFICATION AND OTHER REMEDIES.

``(a) NOTIFICATION.—If the Secretary determines that—

"(1) a tobacco product which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health; and

"(2) notification under this subsection is necessary to eliminate the unreasonable risk

of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all persons who should properly receive such notification in order to eliminate such risk. The Secretary may order notification by any appropriate means, including public service announcements. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

"(b) No Exemption From Other Liability.—Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided under such order shall be taken into account.

"(c) RECALL AUTHORITY.-

"(1) IN GENERAL.—If the Secretary finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

"(2) AMENDMENT OF ORDER TO REQUIRE RECALL.—

"(A) IN GENERAL.—If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the tobacco product with respect to which the order was issued, the Secretary shall, except as provided in subparagraph (B), amend the order to require a recall. The Secretary shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

"(B) NOTICE.—An amended order under subparagraph (A)—

"(i) shall not include recall of a tobacco product from individuals; and

"(ii) shall provide for notice to persons subject to the risks associated with the use of such tobacco product.

In providing the notice required by clause (ii), the Secretary may use the assistance of retailers and other persons who distributed such tobacco product. If a significant number of such persons cannot be identified, the Secretary shall notify such persons under section 705(b).

"(3) REMEDY NOT EXCLUSIVE.—The remedy provided by this subsection shall be in addition to remedies provided by subsection (a) of this section.

#### "SEC. 909. RECORDS AND REPORTS ON TOBACCO PRODUCTS.

"(a) IN GENERAL.—Every person who is a tobacco product manufacturer or importer of a tobacco product shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such tobacco product is not adulterated or misbranded and to otherwise protect public health. Regulations prescribed under the preceding sentence—

"(1) may require a tobacco product manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed tobacco products may have caused or contributed to a serious unexpected adverse experience associated with the use of the product or any significant increase in the frequency of a serious, expected adverse product experience;

"(2) shall require reporting of other significant adverse tobacco product experiences as determined by the Secretary to be necessary to be reported:

"(3) shall not impose requirements unduly burdensome to a tobacco product manufacturer or importer, taking into account the cost of complying with such requirements and the need for the protection of the public health and the implementation of this chapter:

"(4) when prescribing the procedure for making requests for reports or information, shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information:

"(5) when requiring submission of a report or information to the Secretary, shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information; and

"(6) may not require that the identity of any patient or user be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine risks to public health of a tobacco product, or to verify a record, report, or information submitted under this chapter.

In prescribing regulations under this subsection, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (6) continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

"(b) REPORTS OF REMOVALS AND CORRECTIONS.—

"(1) IN GENERAL.—Except as provided in paragraph (2), the Secretary shall by regulation require a tobacco product manufacturer or importer of a tobacco product to report promptly to the Secretary any corrective action taken or removal from the market of a tobacco product undertaken by such manufacturer or importer if the removal or correction was undertaken—

"(A) to reduce a risk to health posed by the tobacco product; or

"(B) to remedy a violation of this chapter caused by the tobacco product which may present a risk to health.

A tobacco product manufacturer or importer of a tobacco product who undertakes a corrective action or removal from the market of a tobacco product which is not required to be reported under this subsection shall keep a record of such correction or removal.

"(2) EXCEPTION.—No report of the corrective action or removal of a tobacco product may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a).

### "SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TOBACCO PRODUCTS.

"(a) IN GENERAL.—

"(1) NEW TOBACCO PRODUCT DEFINED.—For purposes of this section the term 'new tobacco product' means—

"(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of June 1, 2003; or

"(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after June 1, 2003.

"(2) PREMARKET APPROVAL REQUIRED.—

"(A) NEW PRODUCTS.—Approval under this section of an application for premarket approval for any new tobacco product is required unless—

"(i) the manufacturer has submitted a report under section 905(j); and

"(ii) the Secretary has issued an order that the tobacco product—

"(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of June 1, 2003; and

 $``(\Pi)(aa)$  is in compliance with the requirements of this Act; or

"(bb) is exempt from the requirements of section 905(j) pursuant to a regulation issued under section 905(j)(3).

"(B) APPLICATION TO CERTAIN POST JUNE 1, 2003 PRODUCTS.—Subparagraph (A) shall not apply to a tobacco product—

"(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after June 1, 2003, and prior to the date that is 15 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act; and

"(ii) for which a report was submitted under section 905(j) within such 15-month period

except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

"(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

"(A) IN GENERAL.—In this section and section 905(j), the terms 'substantially equivalent' or 'substantial equivalence' mean, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product—

``(i) has the same characteristics as the predicate tobacco product; or

"(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

"(B) CHARACTERISTICS.—In subparagraph (A), the term 'characteristics' means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

"(C) LIMITATION.—A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

"(4) HEALTH INFORMATION.—

"(A) SUMMARY.—As part of a submission under section 905(j) respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health

information related to the tobacco product or state that such information will be made available upon request by any person.

"(B) REQUIRED INFORMATION.—Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

"(b) APPLICATION.-

"(1) CONTENTS.—An application for premarket approval shall contain—

"(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product presents less risk than other tobacco products:

"(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of

such tobacco product;

"(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such to-bacco product;

"(D) an identifying reference to any tobacco product standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

"(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

"(F) specimens of the labeling proposed to be used for such tobacco product; and

"(G) such other information relevant to the subject matter of the application as the Secretary may require.

"(2) REFERENCE TO TOBACCO PRODUCTS SCI-ENTIFIC ADVISORY COMMITTEE.—Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

"(A) may, on the Secretary's own initiative; or

"(B) may, upon the request of an applicant, refer such application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Secretary may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation.

"(c) ACTION ON APPLICATION.—

"(1) DEADLINE.—

"(A) IN GENERAL.—As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall—

"(i) issue an order approving the application if the Secretary finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or

"(ii) deny approval of the application if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

"(B) RESTRICTIONS ON SALE AND DISTRIBUTION.—An order approving an application for a tobacco product may require as a condition to such approval that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d).

"(2) DENIAL OF APPROVAL.—The Secretary shall deny approval of an application for a tobacco product if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

"(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

"(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 906(e):

"(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

"(D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 907, compliance with which is a condition to approval of the application, and there is a lack of adequate information to justify the deviation from such standard.

"(3) DENIAL INFORMATION.—Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

"(4) Basis for finding as to whether approval of a tobacco product is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

"(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

"(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

"(5) Basis for action.-

"(A) INVESTIGATIONS.—For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

"(B) OTHER EVIDENCE.—If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

"(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

"(1) IN GENERAL.—The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee, and after due notice and opportunity for informal hearing to the holder of an approved application for a tobacco product, issue an order withdrawing approval of the application if the Secretary finds—

"(A) that the continued marketing of such tobacco product no longer is appropriate for the protection of the public health;

"(B) that the application contained or was accompanied by an untrue statement of a material fact;

"(C) that the applicant—

- "(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 909;
- "(ii) has refused to permit access to, or copying or verification of, such records as required by section 704; or
- "(iii) has not complied with the requirements of section 905;
- "(D) on the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 906(e) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity:
- "(E) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was approved, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or
- "(F) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was approved, that such tobacco product is not shown to conform in all respects to a tobacco product standard which is in effect under section 907, compliance with which was a condition to approval of the application, and that there is a lack of adequate information to justify the deviation from such standard.
- "(2) APPEAL.—The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with section 912.
- "(3) TEMPORARY SUSPENSION.—If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco product under an approved application would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market, the Secretary shall by order temporarily suspend the approval of the application approved under this section. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.
- "(e) SERVICE OF ORDER.—An order issued by the Secretary under this section shall be served—
- "(1) in person by any officer or employee of the department designated by the Secretary;
- "(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Secretary.
  - "(f) Records.-
- "(1) ADDITIONAL INFORMATION.—In the case of any tobacco product for which an approval of an application filed under subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, as the Secretary may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination of,

- whether there is or may be grounds for withdrawing or temporarily suspending such approval.
- "(2) ACCESS TO RECORDS.—Each person required under this section to maintain records, and each person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.
- "(g) INVESTIGATIONAL TOBACCO PRODUCT EXEMPTION FOR INVESTIGATIONAL USE.—The Secretary may exempt tobacco products intended for investigational use from the provisions of this chapter under such conditions as the Secretary may by regulation prescribe.

#### "SEC. 911. MODIFIED RISK TOBACCO PRODUCTS.

- "(a) IN GENERAL.—No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless approval of an application filed pursuant to subsection (d) is effective with respect to such product.
  - "(b) Definitions.—In this section:
- "(1) MODIFIED RISK TOBACCO PRODUCT.—The term 'modified risk tobacco product' means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.
- "(2) SOLD OR DISTRIBUTED.—
- "(A) IN GENERAL.—With respect to a tobacco product, the term 'sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products' means a tobacco product—
- "(i) the label, labeling, or advertising of which represents explicitly or implicitly that—
- "(I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;
- "(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or
- "(III) the tobacco product or its smoke does not contain or is free of a substance;
- "(ii) the label, labeling, or advertising of which uses the descriptors 'light', 'mild', or 'low' or similar descriptors; or
- "(iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.
- "(B) LIMITATION.—No tobacco product shall be considered to be 'sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products', except as described in subparagraph (A).
- "(c) TOBACCO DEPENDENCE PRODUCTS.—A product that is intended to be used for the treatment of tobacco dependence, including smoking cessation, is not a modified risk tobacco product under this section and is subject to the requirements of chapter V.
- "(d) FILING.—Any person may file with the Secretary an application for a modified risk tobacco product. Such application shall include—
- "(1) a description of the proposed product and any proposed advertising and labeling;

- "(2) the conditions for using the product;
- "(3) the formulation of the product;
- "(4) sample product labels and labeling;
- "(5) all documents (including underlying scientific information) relating to research findings conducted, supported, or possessed by the tobacco product manufacturer relating to the effect of the product on tobaccorelated diseases and health-related conditions, including information both favorable and unfavorable to the ability of the product to reduce risk or exposure and relating to human health;
- "(6) data and information on how consumers actually use the tobacco product; and "(7) such other information as the Secretary may require.
- "(e) PUBLIC AVAILABILITY.—The Secretary shall make the application described in subsection (d) publicly available (except matters in the application which are trade secrets or otherwise confidential, commercial information) and shall request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying such application
  - "(f) ADVISORY COMMITTEE.-
- "(1) IN GENERAL.—The Secretary shall refer to the Tobacco Products Scientific Advisory Committee any application submitted under this subsection.
- "(2) RECOMMENDATIONS.—Not later than 60 days after the date an application is referred to the Tobacco Products Scientific Advisory Committee under paragraph (1), the Advisory Committee shall report its recommendations on the application to the Secretary.
  - "(g) APPROVAL.—
- "(1) Modified Risk products.—Except as provided in paragraph (2), the Secretary shall approve an application for a modified risk tobacco product filed under this section only if the Secretary determines that the applicant has demonstrated that such product, as it is actually used by consumers, will—
- "(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and
- "(B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.
  - "(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—
- "(A) IN GENERAL.—The Secretary may approve an application for a tobacco product that has not been approved as a modified risk tobacco product pursuant to paragraph (1) if the Secretary makes the findings required under this paragraph and determines that the applicant has demonstrated that—
- "(i) the approval of the application would be appropriate to promote the public health;
- "(ii) any aspect of the label, labeling, and advertising for such product that would cause the tobacco product to be a modified risk tobacco product under subsection (b)(2) is limited to an explicit or implicit representation that such tobacco product or its smoke contains or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;
- "(iii) scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards set forth in paragraph (1); and
- "(iv) the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is anticipated in subsequent studies.

- "(B) ADDITIONAL FINDINGS REQUIRED.—In order to approve an application under subparagraph (A) the Secretary must also find that the applicant has demonstrated that—
- "(i) the magnitude of the overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;
- "(ii) the product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the anticipated overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;
- "(iii) testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product—
- "(I) is or has been demonstrated to be less harmful: or
- "(II) presents or has been demonstrated to present less of a risk of disease than 1 or more other commercially marketed tobacco products; and
- "(iv) approval of the application is expected to benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.
  - "(C) CONDITIONS OF APPROVAL.—
- "(i) IN GENERAL.—Applications approved under this paragraph shall be limited to a term of not more than 5 years, but may be renewed upon a finding by the Secretary that the requirements of this paragraph continue to be satisfied based on the filing of a new application.
- "(ii) AGREEMENTS BY APPLICANT.—Applications approved under this paragraph shall be conditioned on the applicant's agreement to conduct post-market surveillance and studies and to submit to the Secretary the results of such surveillance and studies to determine the impact of the application approval on consumer perception, behavior, and health and to enable the Secretary to review the accuracy of the determinations upon which the approval was based in accordance with a protocol approved by the Secretary.
- "(iii) Annual submission.—The results of such post-market surveillance and studies described in clause (ii) shall be submitted annually.
- "(3) BASIS.—The determinations under paragraphs (1) and (2) shall be based on—
- "(A) the scientific evidence submitted by the applicant; and
- "(B) scientific evidence and other information that is available to the Secretary.
- "(4) BENEFIT TO HEALTH OF INDIVIDUALS AND OF POPULATION AS A WHOLE.—In making the determinations under paragraphs (1) and (2), the Secretary shall take into account—
- "(A) the relative health risks to individuals of the tobacco product that is the subject of the application;
- "(B) the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application;
- "(C) the increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application;
- "(D) the risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the

- use of products for smoking cessation approved under chapter V to treat nicotine dependence; and
- "(E) comments, data, and information submitted by interested persons.
- "(h) Additional Conditions for Approval.—
- "(1) Modified risk products.—The Secretary shall require for the approval of an application under this section that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products.
  - "(2) Comparative claims.—
- "(A) IN GENERAL.—The Secretary may require for the approval of an application under this subsection that a claim comparing a tobacco product to 1 or more other commercially marketed tobacco products shall compare the tobacco product to a commercially marketed tobacco product that is representative of that type of tobacco product on the market (for example the average value of the top 3 brands of an established regular tobacco product).
- "(B) QUANTITATIVE COMPARISONS.—The Secretary may also require, for purposes of subparagraph (A), that the percent (or fraction) of change and identity of the reference tobacco product and a quantitative comparison of the amount of the substance claimed to be reduced shall be stated in immediate proximity to the most prominent claim.
  - "(3) Label disclosure.—
- "(A) IN GENERAL.—The Secretary may require the disclosure on the label of other substances in the tobacco product, or substances that may be produced by the consumption of that tobacco product, that may affect a disease or health-related condition or may increase the risk of other diseases or health-related conditions associated with the use of tobacco products.
- "(B) CONDITIONS OF USE.—If the conditions of use of the tobacco product may affect the risk of the product to human health, the Secretary may require the labeling of conditions of use.
- ''(4) Time.—The Secretary shall limit an approval under subsection (g)(1) for a specified period of time.
- "(5) ADVERTISING.—The Secretary may require that an applicant, whose application has been approved under this subsection, comply with requirements relating to advertising and promotion of the tobacco product.
- "(i) POSTMARKET SURVEILLANCE AND STUDIES —
- "(1) IN GENERAL.—The Secretary shall require that an applicant under subsection (g)(1) conduct post market surveillance and studies for a tobacco product for which an application has been approved to determine the impact of the application approval on consumer perception, behavior, and health, to enable the Secretary to review the accuracy of the determinations upon which the approval was based, and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product. The results of post-market surveillance and studies shall be submitted to the Secretary on an annual basis.
- "(2) SURVEILLANCE PROTOCOL.—Each applicant required to conduct a surveillance of a tobacco product under paragraph (1) shall, within 30 days after receiving notice that the applicant is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the receipt of such protocol, shall determine if

- the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection of the data or other information designated by the Secretary as necessary to protect the public health.
- "(j) WITHDRAWAL OF APPROVAL.—The Secretary, after an opportunity for an informal hearing, shall withdraw the approval of an application under this section if the Secretary determines that—
- "(1) the applicant, based on new information, can no longer make the demonstrations required under subsection (g), or the Secretary can no longer make the determinations required under subsection (g):
- "(2) the application failed to include material information or included any untrue statement of material fact;
- "(3) any explicit or implicit representation that the product reduces risk or exposure is no longer valid, including if—
- "(A) a tobacco product standard is established pursuant to section 907;
- "(B) an action is taken that affects the risks presented by other commercially marketed tobacco products that were compared to the product that is the subject of the application; or
- "(C) any postmarket surveillance or studies reveal that the approval of the application is no longer consistent with the protection of the public health;
- "(4) the applicant failed to conduct or submit the postmarket surveillance and studies required under subsection (g)(2)(C)(ii) or (i); or
- "(5) the applicant failed to meet a condition imposed under subsection (h).
- "(k) CHAPTER IV OR V.—A product approved in accordance with this section shall not be subject to chapter IV or V.
- "(1) IMPLEMENTING REGULATIONS OR GUIDANCE.—
- "(1) SCIENTIFIC EVIDENCE.—Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue regulations or guidance (or any combination thereof) on the scientific evidence required for assessment and ongoing review of modified risk tobacco products. Such regulations or guidance shall—
- "(A) establish minimum standards for scientific studies needed prior to approval to show that a substantial reduction in morbidity or mortality among individual tobacco users is likely;
- "(B) include validated biomarkers, intermediate clinical endpoints, and other feasible outcome measures, as appropriate:
- "(C) establish minimum standards for post market studies, that shall include regular and long-term assessments of health outcomes and mortality, intermediate clinical endpoints, consumer perception of harm reduction, and the impact on quitting behavior and new use of tobacco products, as appropriate;
- "(D) establish minimum standards for required postmarket surveillance, including ongoing assessments of consumer perception; and
- "(E) require that data from the required studies and surveillance be made available to the Secretary prior to the decision on renewal of a modified risk tobacco product.
- "(2) Consultation.—The regulations or guidance issued under paragraph (1) shall be developed in consultation with the Institute of Medicine, and with the input of other appropriate scientific and medical experts, on the design and conduct of such studies and surveillance.
- "(3) REVISION.—The regulations or guidance under paragraph (1) shall be revised on

a regular basis as new scientific information becomes available.

"(4) NEW TOBACCO PRODUCTS.—Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue a regulation or guidance that permits the filing of a single application for any tobacco product that is a new tobacco product under section 910 and for which the applicant seeks approval as a modified risk tobacco product under this section.

"(m) DISTRIBUTORS.—No distributor may take any action, after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, with respect to a tobacco product that would reasonably be expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

#### "SEC. 912. JUDICIAL REVIEW.

- "(a) RIGHT TO REVIEW.—
- ''(1) IN GENERAL.—Not later than 30 days after—
- "(A) the promulgation of a regulation under section 907 establishing, amending, or revoking a tobacco product standard; or
- "(B) a denial of an application for approval under section 910(c),

any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business.

"(2) REQUIREMENTS.—

"(A) COPY OF PETITION.—A copy of the petition filed under paragraph (1) shall be transmitted by the clerk of the court involved to the Secretary.

"(B) RECORD OF PROCEEDINGS.—On receipt of a petition under subparagraph (A), the Secretary shall file in the court in which such petition was filed—

"(i) the record of the proceedings on which the regulation or order was based; and

"(ii) a statement of the reasons for the issuance of such a regulation or order.

"(C) DEFINITION OF RECORD.—In this section, the term 'record' means—

"(i) all notices and other matter published in the Federal Register with respect to the regulation or order reviewed:

"(ii) all information submitted to the Secretary with respect to such regulation or order;

"(iii) proceedings of any panel or advisory committee with respect to such regulation or order;

"(iv) any hearing held with respect to such regulation or order; and

"(v) any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order

"(b) STANDARD OF REVIEW.—Upon the filing of the petition under subsection (a) for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5, United States Code, and to grant appropriate relief, including interim relief, as provided for in such chapter. A regulation or denial described in subsection (a) shall be reviewed in accordance with section 706(2)(A) of title 5, United States Code.

"(c) Finality of Judgment.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon cer-

tiorari or certification, as provided in section 1254 of title 28, United States Code.

"(d) OTHER REMEDIES.—The remedies provided for in this section shall be in addition to, and not in lieu of, any other remedies provided by law.

"(e) REGULATIONS AND ORDERS MUST RECITE BASIS IN RECORD.—To facilitate judicial review, a regulation or order issued under section 906, 907, 908, 909, 910, or 916 shall contain a statement of the reasons for the result of the proceedings held in connection with its issuance.

### "SEC. 913. EQUAL TREATMENT OF RETAIL OUT-

"The Secretary shall issue regulations to require that retail establishments for which the predominant business is the sale of to-bacco products comply with any advertising restrictions applicable to retail establishments accessible to individuals under the age of 18.

# "SEC. 914. JURISDICTION OF AND COORDINATION WITH THE FEDERAL TRADE COMMISSION.

"(a) JURISDICTION.—

"(1) IN GENERAL.—Except where expressly provided in this chapter, nothing in this chapter shall be construed as limiting or diminishing the authority of the Federal Trade Commission to enforce the laws under its jurisdiction with respect to the advertising, sale, or distribution of tobacco products.

"(2) ENFORCEMENT.—Any advertising that violates this chapter or a provision of the regulations referred to in section 102 of the Family Smoking Prevention and Tobacco Control Act, is an unfair or deceptive act or practice under section 5(a) of the Federal Trade Commission Act and shall be considered a violation of a rule promulgated under section 18 of that Act.

"(b) COORDINATION.—With respect to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act and section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986—

"(1) the Chairman of the Federal Trade Commission shall coordinate with the Secretary concerning the enforcement of such Act as such enforcement relates to unfair or deceptive acts or practices in the advertising of cigarettes or smokeless tobacco; and

"(2) the Secretary shall consult with the Chairman of such Commission in revising the label statements and requirements under such sections.

#### "SEC. 915. CONGRESSIONAL REVIEW PROVISIONS.

"In accordance with section 801 of title 5, United States Code, Congress shall review, and may disapprove, any rule under this chapter that is subject to section 801. This section and section 801 do not apply to the final rule referred to in paragraphs (1) and (2) of section 102(a) of the Family Smoking Prevention and Tobacco Control Act.

#### "SEC. 916. REGULATION REQUIREMENT.

"(a) TESTING, REPORTING, AND DISCLO-SURE.—Not later than 24 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary, acting through the Commissioner of Food and Drugs, shall promulgate regulations under this Act that meet the requirements of subsection (b).

"(b) CONTENTS OF RULES.—The regulations promulgated under subsection (a) shall require testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents, by brand and sub-brand that the Secretary determines should be tested to protect the public health. The regulations may require that tobacco product manufacturers, packagers, or importers make disclosures relating to the results of the testing of tar and nicotine

through labels or advertising or other appropriate means, and make disclosures regarding the results of the testing of other constituents, including smoke constituents, ingredients, or additives, that the Secretary determines should be disclosed to the public to protect the public health and will not mislead consumers about the risk of tobacco related disease.

"(c) AUTHORITY.—The Food and Drug Administration shall have the authority under this chapter to conduct or to require the testing, reporting, or disclosure of tobacco product constituents, including smoke constituents.

### "SEC. 917. PRESERVATION OF STATE AND LOCAL AUTHORITY.

"(a) IN GENERAL.—

"(1) Preservation.—Except as provided in paragraph (2)(A), nothing in this chapter, or rules promulgated under this chapter, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this chapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products. No provision of this chapter shall limit or otherwise affect any State, Tribal. or local taxation of tobacco products.

"(2) PREEMPTION OF CERTAIN STATE AND LOCAL REQUIREMENTS.—

"(A) IN GENERAL.—No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to tobacco product standards, premarket approval, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

"(B) EXCEPTION.—Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products. Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 552(b)(4) of title 5, United States Code, shall be treated as a trade secret and confidential information by the State.

"(b) RULE OF CONSTRUCTION REGARDING PRODUCT LIABILITY.—No provision of this chapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

#### "SEC. 918. TOBACCO PRODUCTS SCIENTIFIC AD-VISORY COMMITTEE.

"(a) ESTABLISHMENT.—Not later than 1 year after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish an 11-member advisory committee, to be known as the 'Tobacco Products Scientific Advisory Committee' (in this section referred to as the 'Advisory Committee').

"(b) Membership.—

"(1) IN GENERAL.-

"(A) MEMBERS.—The Secretary shall appoint as members of the Tobacco Products Scientific Advisory Committee individuals who are technically qualified by training and

experience in the medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products, who are of appropriately diversified professional backgrounds. The committee shall be composed of—

"(i) 7 individuals who are physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty;

"(ii) 1 individual who is an officer or employee of a State or local government or of the Federal Government;

"(iii) 1 individual as a representative of the general public:

"(iv) I individual as a representative of the interests in the tobacco manufacturing industry; and

"(v) I individual as a representative of the interests of the tobacco growers.

"(B) NONVOTING MEMBERS.—The members of the committee appointed under clauses (iv) and (v) of subparagraph (A) shall serve as consultants to those described in clauses (i) through (iii) of subparagraph (A) and shall be nonvoting representatives.

"(2) LIMITATION.—The Secretary may not appoint to the Advisory Committee any individual who is in the regular full-time employ of the Food and Drug Administration or any agency responsible for the enforcement of this Act. The Secretary may appoint Federal officials as ex officio members.

"(3) CHAIRPERSON.—The Secretary shall designate 1 of the members of the Advisory Committee to serve as chairperson.

"(c) DUTIES.—The Tobacco Products Scientific Advisory Committee shall provide advice, information, and recommendations to the Secretary—

"(1) as provided in this chapter;

"(2) on the effects of the alteration of the nicotine yields from tobacco products;

"(3) on whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and

"(4) on its review of other safety, dependence, or health issues relating to tobacco products as requested by the Secretary.

"(d) COMPENSATION; SUPPORT; FACA.—

"(1) COMPENSATION AND TRAVEL.—Members of the Advisory Committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which may not exceed the daily equivalent of the rate in effect under the Senior Executive Schedule under section 5382 of title 5, United States Code, for each day (including travel time) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5. United States Code, for persons in the Government service employed intermittently.

"(2) ADMINISTRATIVE SUPPORT.—The Secretary shall furnish the Advisory Committee clerical and other assistance.

"(3) NONAPPLICATION OF FACA.—Section 14 of the Federal Advisory Committee Act does not apply to the Advisory Committee.

"(e) PROCEEDINGS OF ADVISORY PANELS AND COMMITTEES.—The Advisory Committee shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made under this subsection information which is exempt from disclosure under section 552(b) of title 5, United States Code.

#### "SEC. 919. DRUG PRODUCTS USED TO TREAT TO-BACCO DEPENDENCE.

"The Secretary shall-

"(1) at the request of the applicant, consider designating nicotine replacement products as fast track research and approval products within the meaning of section 506;

"(2) consider approving the extended use of nicotine replacement products (such as nicotine patches, nicotine gum, and nicotine lozenges) for the treatment of tobacco dependence; and

"(3) review and consider the evidence for additional indications for nicotine replacement products, such as for craving relief or relapse prevention.

#### "SEC. 920. USER FEE.

"(a) ESTABLISHMENT OF QUARTERLY USER FEE.—The Secretary shall assess a quarterly user fee with respect to every quarter of each fiscal year commencing fiscal year 2008, calculated in accordance with this section, upon each manufacturer and importer of tobacco products subject to this chapter.

"(b) FUNDING OF FDA REGULATION OF TO-BACCO PRODUCTS.—The Secretary shall make user fees collected pursuant to this section available to pay, in each fiscal year, for the costs of the activities of the Food and Drug Administration related to the regulation of tobacco products under this chapter.

"(c) Assessment of User Fee.-

"(1) AMOUNT OF ASSESSMENT.—Except as provided in paragraph (4), the total user fees assessed each year pursuant to this section shall be sufficient, and shall not exceed what is necessary, to pay for the costs of the activities described in subsection (b) for each fiscal year.

 $\lq\lq(2)$  Allocation of assessment by class of tobacco products.—

"(A) IN GENERAL.—Subject to paragraph (3), the total user fees assessed each fiscal year with respect to each class of importers and manufacturers shall be equal to an amount that is the applicable percentage of the total costs of activities of the Food and Drug Administration described in subsection (b)

"(B) APPLICABLE PERCENTAGE.—For purposes of subparagraph (A), the applicable percentage for a fiscal year shall be the following:

"(i) 92.07 percent shall be assessed on manufacturers and importers of cigarettes;

"(ii) 0.05 percent shall be assessed on manufacturers and importers of little cigars;

"(iii) 7.15 percent shall be assessed on manufacturers and importers of cigars other than little cigars:

 $\lq\lq$ (iv) 0.43 percent shall be assessed on manufacturers and importers of snuff;

"(v) 0.10 percent shall be assessed on manufacturers and importers of chewing tobacco;

"(vi) 0.06 percent shall be assessed on manufacturers and importers of pipe tobacco; and

"(vii) 0.14 percent shall be assessed on manufacturers and importers of roll-your-own tobacco.

"(3) DISTRIBUTION OF FEE SHARES OF MANUFACTURERS AND IMPORTERS EXEMPT FROM USER FEE.—Where a class of tobacco products is not subject to a user fee under this section, the portion of the user fee assigned to such class under paragraph (2) shall be allocated by the Secretary on a pro rata basis among the classes of tobacco products that are subject to a user fee under this section. Such pro rata allocation for each class of tobacco products that is subject to a user fee under this section shall be the quotient of—

"(A) the percentage assigned to such class under paragraph (2); divided by

"(B) the sum of the percentages assigned to all classes of tobacco products subject to this section.

"(4) ANNUAL LIMIT ON ASSESSMENT.—The total assessment under this section—

"(A) for fiscal year 2008 shall be \$85,000,000;

"(B) for fiscal year 2009 shall be \$175,000,000; "(C) for fiscal year 2010 shall be \$300,000,000;

"(C) for fiscal year 2010 shall be \$300,000,000 and
"(D) for each subsequent fiscal year shall

"(D) for each subsequent fiscal year, shall not exceed the limit on the assessment imposed during the previous fiscal year, as adjusted by the Secretary (after notice, published in the Federal Register) to reflect the greater of—

"(i) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average) for the 12-month period ending on June 30 preceding the fiscal year for which fees are being established; or

"(ii) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

"(5) TIMING OF USER FEE ASSESSMENT.—The Secretary shall notify each manufacturer and importer of tobacco products subject to this section of the amount of the quarterly assessment imposed on such manufacturer or importer under subsection (f) during each quarter of each fiscal year. Such notifications shall occur not earlier than 3 months prior to the end of the quarter for which such assessment is made, and payments of all assessments shall be made not later than 60 days after each such notification.

"(d) DETERMINATION OF USER FEE BY COM-PANY MARKET SHARE.—

"(1) IN GENERAL.—The user fee to be paid by each manufacturer or importer of a given class of tobacco products shall be determined in each quarter by multiplying—

"(A) such manufacturer's or importer's market share of such class of tobacco products: by

"(B) the portion of the user fee amount for the current quarter to be assessed on manufacturers and importers of such class of tobacco products as determined under subsection (e).

"(2) NO FEE IN EXCESS OF MARKET SHARE.— No manufacturer or importer of tobacco products shall be required to pay a user fee in excess of the market share of such manufacturer or importer.

"(e) Determination of Volume of Domestic Sales.—

"(1) IN GENERAL.—The calculation of gross domestic volume of a class of tobacco product by a manufacturer or importer, and by all manufacturers and importers as a group, shall be made by the Secretary using information provided by manufacturers and importers pursuant to subsection (f), as well as any other relevant information provided to or obtained by the Secretary.

"(2) MEASUREMENT.—For purposes of the calculations under this subsection and the information provided under subsection (f) by the Secretary, gross domestic volume shall be measured by—

"(A) in the case of cigarettes, the number of cigarettes sold;

"(B) in the case of little cigars, the number of little cigars sold;

"(C) in the case of large cigars, the number of cigars weighing more than 3 pounds per thousand sold; and

"(D) in the case of other classes of tobacco products, in terms of number of pounds, or fraction thereof, of these products sold.

"(f) Measurement of Gross Domestic Volume.—

"(1) IN GENERAL.—Each tobacco product manufacturer and importer shall submit to the Secretary a certified copy of each of the returns or forms described by this paragraph that are required to be filed with a Government agency on the same date that those returns or forms are required to be filed with such agency. The returns and forms described by this paragraph are those returns and forms related to the removal, as defined by section 5702(j) of the Internal Revenue Code of 1986, of tobacco products into domestic commerce or the payment of the taxes imposed under chapter 52 of such Code.

- "(2) PENALTIES.—Any person that knowingly fails to provide information required under this subsection or that provides false information under this subsection shall be subject to the penalties described in section 1001 of title 18, United States Code. In addition, such person may be subject to a civil penalty in an amount not to exceed 2 percent of the value of the kind of tobacco products manufactured or imported by such person during the applicable quarter, as determined by the Secretary.
- "(h) EFFECTIVE DATE.—The user fees prescribed by this section shall be assessed in fiscal year 2008, based on domestic sales of tobacco products during fiscal year 2007 and shall be assessed in each fiscal year thereafter."

#### SEC. 102. FINAL RULE.

- (a) CIGARETTES AND SMOKELESS TOBACCO.—
- (1) IN GENERAL.—Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register a final rule regarding cigarettes and smokeless tobacco, which is hereby deemed to be in compliance with the Administrative Procedures Act and other applicable law.
- (2) CONTENTS OF RULE.—Except as provided in this subsection, the final rule published under paragraph (1), shall be identical in its provisions to part 897 of the regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register (61 Fed. Reg., 44615–44618). Such rule shall—
- (A) provide for the designation of jurisdictional authority that is in accordance with this subsection:
- (B) strike Subpart C—Labels and section 897.32(c); and
- (C) become effective not later than 1 year after the date of enactment of this Act.
- (3) AMENDMENTS TO RULE.—Prior to making amendments to the rule published under paragraph (1), the Secretary shall promulgate a proposed rule in accordance with the Administrative Procedures Act.
- (4) RULE OF CONSTRUCTION.—Except as provided in paragraph (3), nothing in this section shall be construed to limit the authority of the Secretary to amend, in accordance with the Administrative Procedures Act, the regulation promulgated pursuant to this section.
- (b) LIMITATION ON ADVISORY OPINIONS.—As of the date of enactment of this Act, the following documents issued by the Food and Drug Administration shall not constitute advisory opinions under section 10.85(d)(1) of title 21, Code of Federal Regulations, except as they apply to tobacco products, and shall not be cited by the Secretary of Health and Human Services or the Food and Drug Administration as binding precedent:
- (1) The preamble to the proposed rule in the document entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents" (60 Fed. Reg. 41314–41372 (August 11, 1995)).
- (2) The document entitled "Nicotine in Cigarettes and Smokeless Tobacco Products is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act" (60 Fed. Reg. 41453–41787 (August 11, 1995)).

- (3) The preamble to the final rule in the document entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" (61 Fed. Reg. 44396–44615 (August 28, 1996)).
- (4) The document entitled "Nicotine in Cigarettes and Smokeless Tobacco is a Drug and These Products are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act; Jurisdictional Determination" (61 Fed. Reg. 44619–45318 (August 28, 1996)).

#### SEC. 103. CONFORMING AND OTHER AMEND-MENTS TO GENERAL PROVISIONS.

- (a) AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Except as otherwise expressly provided, whenever in this section an amendment is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference is to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).
- (b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended—
- (1) in subsection (a), by inserting "tobacco product," after "device,";
- (2) in subsection (b), by inserting "tobacco product," after "device,";
- (3) in subsection (c), by inserting "tobacco product," after "device,";
- (4) in subsection (e) (as amended by sections 2(c) and 3(b) of the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109-462; 120 Stat. 3472)), by inserting ", or 909" before "or the refusal to permit access to":
- (5) in subsection (g), by inserting "tobacco product," after "device,";
- (6) in subsection (h), by inserting "tobacco product," after "device,";
- (7) in subsection (j), by striking "708, or 721" and inserting "708, 721, 904, 905, 906, 907, 908, 909, or section 921(b)";
- (8) in subsection (k), by inserting "tobacco product," after "device,";
- (9) by striking subsection (p) and inserting the following:
- "(p) The failure to register in accordance with section 510 or 905, the failure to provide any information required by section 510(j), 510(k), 905(i), or 905(j), or the failure to provide a notice required by section 510(j)(2) or 905(i)(2).":
- (10) by striking subsection (q)(1) and inserting the following:
- "(q)(1) The failure or refusal—
- "(A) to comply with any requirement prescribed under section 518, 520(g), 903(b), or 908:
- "(B) to furnish any notification or other material or information required by or under section 519, 520(g), 904, 909, or section 921; or
- "(C) to comply with a requirement under section 522 or 913.";
- (11) in subsection (q)(2), by striking "device," and inserting "device or tobacco product.":
- (12) in subsection (r), by inserting "or tobacco product" after the term "device" each time that such term appears; and
- (13) by adding at the end (as amended by section 4(a) of the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109–462; 120 Stat. 3475)) the following:
- "(jj) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 303(f).
- "(kk) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 911.
- "(ll)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to

- render such tobacco product a counterfeit tobacco product.
- "(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.
- "(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.
- "(mm) The charitable distribution of tobacco products.
- "(nn) The failure of a manufacturer or distributor to notify the Attorney General of their knowledge of tobacco products used in illicit trade.".
- (c) Section 303.—Section 303 (21 U.S.C. 333(f)) is amended by redesignating the subsection that follows subsection (e) as subsection (f) and in subsection (f) (as so redesignated)—
- (1) in paragraph (1)(A), by inserting "or to-bacco products" after "devices";
- (2) in paragraph (2)(C), by striking "paragraph (3)(A)" and inserting "paragraph (4)(A)";
- (3) by redesignating paragraphs (3), (4), and (5) as paragraphs (4), (5), and (6), and inserting after paragraph (2) the following:
- "(3) If the Secretary finds that a person has committed repeated violations of restrictions promulgated under section 906(d) at a particular retail outlet then the Secretary may impose a no-tobacco-sale order on that person prohibiting the sale of tobacco products in that outlet. A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1).";
  - (4) in paragraph (4) as so redesignated—
  - (A) in subparagraph (A)-
- (i) by striking "assessed" the first time it appears and inserting "assessed, or a no-to-bacco-sale order may be imposed,"; and
- (ii) by striking "penalty" and inserting "penalty, or upon whom a no-tobacco-order is to be imposed,":
  - $(B) \ in \ subparagraph \ (B) \!\!\!\!-\!\!\!\!\!-$
- (i) by inserting after "penalty," the following: "or the period to be covered by a notobacco-sale order,"; and
- (ii) by adding at the end the following: "A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order."; and
  - (C) by adding at the end the following:
- "(D) The Secretary may compromise, modify, or terminate, with or without conditions, any no-tobacco-sale order.";
  - (5) in paragraph (5) as so redesignated—
- (A) by striking "(3)(A)" as redesignated, and inserting "(4)(A)";
- (B) by inserting "or the imposition of a notobacco-sale order" after the term "penalty" the first 2 places such term appears; and
- (C) by striking "issued." and inserting "issued, or on which the no-tobacco-sale order was imposed, as the case may be."; and
- (6) in paragraph (6), as so redesignated, by striking the term "paragraph (4)" each place such term appears and inserting "paragraph (5)".
- (d) SECTION 304.—Section 304 (21 U.S.C. 334) is amended—
- (1) in subsection (a)(2)—
- (A) by striking "and" before "(D)"; and

- (B) by striking "device." and inserting the following: "device, and (E) Any adulterated or misbranded tobacco product.";
- (2) in subsection (d)(1), by inserting "to-bacco product," after "device,";
- (3) in subsection (g)(1), by inserting "or tobacco product" after the term "device" each place such term appears; and
- (4) in subsection (g)(2)(A), by inserting "or tobacco product" after the term "device" each place such term appears.
- (e) SECTION 702.—Section 702(a) (21 U.S.C. 372(a)) is amended by adding at the end of paragraph (1) the following: "For a tobacco product, to the extent feasible, the Secretary shall contract with the States in accordance with this paragraph to carry out inspections of retailers within that State in connection with the enforcement of this Act.".
- (f) Section 703.—Section 703 (21 U.S.C. 373) is amended—
- (1) by inserting "tobacco product," after the term "device," each place such term appears; and
- (2) by inserting "tobacco products," after the term "devices," each place such term appears.
- (g) Section 704.—Section 704 (21 U.S.C. 374) is amended—
- (1) in subsection (a)(1)(A), by inserting "to-bacco products," after the term "devices," each place such term appears;
- (2) in subsection (a)(1)(B), by inserting "or tobacco product" after the term "restricted devices" each place such term appears; and
- (3) in subsection (b), by inserting "tobacco product," after "device,".
- (h) SECTION 705.—Section 705(b) (21 U.S.C. 375(b)) is amended by inserting "tobacco products," after "devices,".
- (i) SECTION 709.—Section 709 (21 U.S.C. 379) is amended by inserting "tobacco product," after "device,".
- (j) Section 801.—Section 801 (21 U.S.C. 381) is amended—
- (1) in subsection (a)—
- (A) by inserting "tobacco products," after the term "devices," the first time such term appears:
- (B) by inserting "or section 905(j)" after "section 510"; and
- (C) by striking the term "drugs or devices" each time such term appears and inserting "drugs, devices, or tobacco products";
- (2) in subsection (e)(1), by inserting "to-bacco product," after "device,"; and
  - (3) by adding at the end the following:
- "(p)(1) Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report regarding—
- "(A) the nature, extent, and destination of United States tobacco product exports that do not conform to tobacco product standards established pursuant to this Act;
- "(B) the public health implications of such exports, including any evidence of a negative public health impact; and
- "(C) recommendations or assessments of policy alternatives available to Congress and the Executive Branch to reduce any negative public health impact caused by such exports.
- "(2) The Secretary is authorized to establish appropriate information disclosure requirements to carry out this subsection." (k) SECTION 1003.—Section 1003(d)(2)(C) (as
- (k) Section 1003.—Section 1003(d)(2)(C) (as redesignated by section 101(b)) is amended—
  (1) by striking "and" after "cosmetics,";
- and
  (2) inserting ", and tobacco products" after
  "devices".
- (1) GUIDANCE AND EFFECTIVE DATES.—
- (1) IN GENERAL.—The Secretary of Health and Human Services shall issue guidance—

- (A) defining the term "repeated violation", as used in section 303(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)) as amended by subsection (c), by identifying the number of violations of particular requirements over a specified period of time at a particular retail outlet that constitute a repeated violation;
- (B) providing for timely and effective notice to the retailer of each alleged violation at a particular retail outlet;
- (C) providing for an expedited procedure for the administrative appeal of an alleged violation;
- (D) providing that a person may not be charged with a violation at a particular retail outlet unless the Secretary has provided notice to the retailer of all previous violations at that outlet:
- (E) establishing a period of time during which, if there are no violations by a particular retail outlet, that outlet will not be considered to have been the site of repeated violations when the next violation occurs; and
- (F) providing that good faith reliance on the presentation of a false government issued photographic identification that contains a date of birth does not constitute a violation of any minimum age requirement for the sale of tobacco products if the retailer has taken effective steps to prevent such violations, including—
- (i) adopting and enforcing a written policy against sales to minors;
- (ii) informing its employees of all applicable laws:
- (iii) establishing disciplinary sanctions for employee noncompliance; and
- (iv) requiring its employees to verify age by way of photographic identification or electronic scanning device.
- (2) GENERAL EFFECTIVE DATE.—The amendments made by subsection (c), other than the amendment made by paragraph (2) of such subsection, shall take effect upon the issuance of guidance described in paragraph
- (3) SPECIAL EFFECTIVE DATE.—The amendments made by paragraph (2) of subsection (c) shall take effect on the date of enactment of this Act.

#### TITLE II—TOBACCO PRODUCT WARNINGS; CONSTITUENT AND SMOKE CON-STITUENT DISCLOSURE

# SEC. 201. CIGARETTE LABEL AND ADVERTISING WARNINGS.

Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) is amended to read as follows:

#### "SEC. 4. LABELING.

- "(a) Label Requirements.—
- "(1) IN GENERAL.—It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:
- "WARNING: Cigarettes are addictive"
- "WARNING: Tobacco smoke can harm your children'.
- "WARNING: Cigarettes cause fatal lung disease".
- "WARNING: Cigarettes cause cancer".
- "WARNING: Cigarettes cause strokes and heart disease".
- "WARNING: Smoking during pregnancy can harm your baby'.
  - "WARNING: Smoking can kill you"
- "WARNING: Tobacco smoke causes fatal lung disease in non-smokers'.
- "WARNING: Quitting smoking now greatly reduces serious risks to your health".
  - "(2) PLACEMENT; TYPOGRAPHY; ETC.-
- "(A) IN GENERAL.—Each label statement required by paragraph (1) shall be located in

the upper portion of the front and rear panels of the package, directly on the package underneath the cellophane or other clear wrapping. Except as provided in subparagraph (B), each label statement shall comprise at least the top 30 percent of the front and rear panels of the package. The word 'WARNING' shall appear in capital letters and all text shall be in conspicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in which case the text may be in a smaller conspicuous and legible type size, provided that at least 60 percent of such area is occupied by required text. The text shall be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (b)(4).

"(B) HINGED LID BOXES.—For any cigarette brand package manufactured or distributed before January 1, 2000, which employs a hinged lid style (if such packaging was used for that brand in commerce prior to June 21, 1997), the label statement required by paragraph (1) shall be located on the hinged lid area of the package, even if such area is less than 25 percent of the area of the front panel. Except as provided in this paragraph, the provisions of this subsection shall apply to such packages.

"(3) DOES NOT APPLY TO FOREIGN DISTRIBU-TION.—The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture, package, or import cigarettes for sale or distribution within the United States.

"(4) APPLICABILITY TO RETAILERS.—A retailer of cigarettes shall not be in violation of this subsection for packaging that is supplied to the retailer by a tobacco product manufacturer, importer, or distributor and is not altered by the retailer in a way that is material to the requirements of this subsection except that this paragraph shall not relieve a retailer of liability if the retailer sells or distributes tobacco products that are not labeled in accordance with this subsection.

"(b) ADVERTISING REQUIREMENTS.—

- "(1) IN GENERAL.—It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a) of this section.
- "(2) TYPOGRAPHY, ETC.—Each label statement required by subsection (a) of this section in cigarette advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent (including a smoke constituent) yield shall comprise at least 20 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and location at the top of each advertisement within the trim area. The Secretary may revise the required type sizes in such area in such manner as the Secretary determines appropriate. The word 'WARN-ING' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black if the background is white and white if the background is black, under the plan submitted under paragraph (4) of this subsection. The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital 'W' of the word

'WARNING' in the label statements. The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement. The label statements shall be in English, except that in the case

"(A) an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

"(B) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

"(3) MATCHBOOKS.—Notwithstanding paragraph (2), for matchbooks (defined as containing not more than 20 matches) customarily given away with the purchase of tobacco products, each label statement required by subsection (a) may be printed on the inside cover of the matchbook.

(4) Adjustment by secretary.—The Secretary may, through a rulemaking under section 553 of title 5, United States Code, adjust the format and type sizes for the label statements required by this section or the text, format, and type sizes of any required tar, nicotine yield, or other constituent (including smoke constituent) disclosures, or to establish the text, format, and type sizes for any other disclosures required under the Federal Food, Drug, and Cosmetic Act. The text of any such label statements or disclosures shall be required to appear only within the 20 percent area of cigarette advertisements provided by paragraph (2) of this subsection. The Secretary shall promulgate regulations which provide for adjustments in the format and type sizes of any text required to appear in such area to ensure that the total text required to appear by law will fit within such area.

"(c) Marketing Requirements.—

"(1) RANDOM DISPLAY.—The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

"(2) ROTATION.—The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

"(3) REVIEW.—The Secretary shall review each plan submitted under paragraph (2) and approve it if the plan—

"(A) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

"(B) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

"(4) APPLICABILITY TO RETAILERS.—This subsection and subsection (b) apply to a retailer only if that retailer is responsible for

or directs the label statements required under this section except that this paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that is not labeled in accordance with the requirements of this subsection and subsection (b).".

# SEC. 202. AUTHORITY TO REVISE CIGARETTE WARNING LABEL STATEMENTS.

Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by section 201, is further amended by adding at the end the following:

"(d) CHANGE IN REQUIRED STATEMENTS.— The Secretary may, by a rulemaking conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the label requirements, require color graphics to accompany the text, increase the required label area from 30 percent up to 50 percent of the front and rear panels of the package, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act, if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products."

#### SEC. 203. STATE REGULATION OF CIGARETTE AD-VERTISING AND PROMOTION.

Section 5 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1334) is amended by adding at the end the following:

"(c) EXCEPTION.—Notwithstanding subsection (b), a State or locality may enact statutes and promulgate regulations, based on smoking and health, that take effect after the effective date of the Family Smoking Prevention and Tobacco Control Act, imposing specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes."

# SEC. 204. SMOKELESS TOBACCO LABELS AND ADVERTISING WARNINGS.

Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402) is amended to read as follows:

#### "SEC. 3. SMOKELESS TOBACCO WARNING.

"(a) GENERAL RULE.-

"(1) It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this Act, one of the following labels:

"WARNING: This product can cause mouth cancer'.

"WARNING: This product can cause gum disease and tooth loss'.

"WARNING: This product is not a safe alternative to cigarettes'.

"WARNING: Smokeless tobacco is addictive'.

"(2) Each label statement required by paragraph (1) shall be—

"(A) located on the 2 principal display panels of the package, and each label statement shall comprise at least 30 percent of each such display panel; and

"(B) in 17-point conspicuous and legible type and in black text on a white background, or white text on a black background, in a manner that contrasts by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (b)(3), except that if the text of a label statement would occupy more than 70 percent of the area specified by subparagraph (A), such text may appear in a smaller type size, so long as at least 60 percent of such warning area is occupied by the label statement.

"(3) The label statements required by paragraph (1) shall be introduced by each tobacco product manufacturer, packager, importer,

distributor, or retailer of smokeless tobacco products concurrently into the distribution chain of such products.

"(4) The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of any smokeless tobacco product that does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

"(5) A retailer of smokeless tobacco products shall not be in violation of this subsection for packaging that is supplied to the retailer by a tobacco products manufacturer, importer, or distributor and that is not altered by the retailer unless the retailer offers for sale, sells, or distributes a smokeless tobacco product that is not labeled in accordance with this subsection.

"(b) Required Labels.—

"(1) It shall be unlawful for any tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products to advertise or cause to be advertised within the United States any smokeless tobacco product unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

"(2) Each label statement required by subsection (a) in smokeless tobacco advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent yield shall—

"(A) comprise at least 20 percent of the area of the advertisement, and the warning area shall be delineated by a dividing line of contrasting color from the advertisement; and

"(B) the word 'WARNING' shall appear in capital letters and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black on a white background, or white on a black background, in an alternating fashion under the plan submitted under paragraph

"(3)(A) The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

"(B) The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

"(C) The Secretary shall review each plan submitted under subparagraph (B) and approve it if the plan—

"(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection: and

"(ii) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

"(D) This paragraph applies to a retailer only if that retailer is responsible for or directs the label statements under this section, unless the retailer displays in a location open to the public, an advertisement that is not labeled in accordance with the requirements of this subsection.

"(c) Television and Radio Advertising.— It is unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.".

#### SEC. 205. AUTHORITY TO REVISE SMOKELESS TO-BACCO PRODUCT WARNING LABEL STATEMENTS.

Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402), as amended by section 204, is further amended by adding at the end the following:

'(d) AUTHORITY TO REVISE WARNING LABEL STATEMENTS.—The Secretary may, by a rulemaking conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the label requirements, require color graphics to accompany the text, increase the required label area from 30 percent up to 50 percent of the front and rear panels of the package, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act, if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products."

# SEC. 206. TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT DISCLOSURE TO THE PUBLIC.

Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by sections 201 and 202, is further amended by adding at the end the following: "(e) TAR, NICOTINE, AND OTHER SMOKE CONSTITUTION DISCLOSURE—

"(1) IN GENERAL.—The Secretary shall, by a rulemaking conducted under section 553 of title 5. United States Code, determine (in the Secretary's sole discretion) whether cigarette and other tobacco product manufacturers shall be required to include in the area of each cigarette advertisement specified by subsection (b) of this section, or on the package label, or both, the tar and nicotine yields of the advertised or packaged brand. Any such disclosure shall be in accordance with the methodology established under such regulations, shall conform to the type size requirements of subsection (b) of this section, and shall appear within the area specified in subsection (b) of this section.

"(2) RESOLUTION OF DIFFERENCES.—Any differences between the requirements established by the Secretary under paragraph (1) and tar and nicotine yield reporting requirements established by the Federal Trade Commission shall be resolved by a memorandum of understanding between the Secretary and the Federal Trade Commission.

"(3) Cigarette and other tobacco prod-UCT CONSTITUENTS.—In addition to the disclosures required by paragraph (1), the Secretary may, under a rulemaking conducted under section 553 of title 5, United States Code, prescribe disclosure requirements regarding the level of any cigarette or other tobacco product constituent including any smoke constituent. Any such disclosure may be required if the Secretary determines that disclosure would be of benefit to the public health, or otherwise would increase consumer awareness of the health consequences of the use of tobacco products, except that no such prescribed disclosure shall be required on the face of any cigarette package or advertisement. Nothing in this section shall prohibit the Secretary from requiring such prescribed disclosure through a cigarette or other tobacco product package or advertisement insert, or by any other means under the Federal Food, Drug, and Cosmetic

"(4) RETAILERS.—This subsection applies to a retailer only if that retailer is responsible for or directs the label statements required under this section, except that this subsection shall not relieve a retailer of liability if the retailer sells or distributes tobacco products that are not labeled in accordance with the requirements of subsection (a).".

# TITLE III—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

### SEC. 301. LABELING, RECORDKEEPING, RECORDS INSPECTION.

Chapter IX of the Federal Food, Drug, and Cosmetic Act, as added by section 101, is further amended by adding at the end the following:

# "SEC. 921. LABELING, RECORDKEEPING, RECORDS INSPECTION.

- "(a) ORIGIN LABELING.—The label, packaging, and shipping containers of tobacco products for introduction or delivery for introduction into interstate commerce in the United States shall bear the statement 'sale only allowed in the United States.'
- "(b) REGULATIONS CONCERNING RECORD-KEEPING FOR TRACKING AND TRACING.—
- "(1) IN GENERAL.—Not later than 9 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall promulgate regulations regarding the establishment and maintenance of records by any person who manufactures, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products.
- "(2) INSPECTION.—In promulgating the regulations described in paragraph (1), the Secretary shall consider which records are needed for inspection to monitor the movement of tobacco products from the point of manufacture through distribution to retail outlets to assist in investigating potential illicit trade, smuggling or counterfeiting of tobacco products.
- "(3) CODES.—The Secretary may require codes on the labels of tobacco products or other designs or devices for the purpose of tracking or tracing the tobacco product through the distribution system.
- "(4) SIZE OF BUSINESS.—The Secretary shall take into account the size of a business in promulgating regulations under this section.
- "(5) RECORDKEEPING BY RETAILERS.—The Secretary shall not require any retailer to maintain records relating to individual purchasers of tobacco products for personal consumption.
- "(c) RECORDS INSPECTION.—If the Secretary has a reasonable belief that a tobacco product is part of an illicit trade or smuggling or is a counterfeit product, each person who manufactures, processes, transports, distributes, receives, holds, packages, exports, or imports tobacco products shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times and within reasonable limits and in a reasonable manner, upon the presentation of appropriate credentials and a written notice to such person, to have access to and copy all records (including financial records) relating to such article that are needed to assist the Secretary in investigating potential illicit trade, smuggling or counterfeiting of tobacco products.
- "(d) KNOWLEDGE OF ILLEGAL TRANS-
- "(1) NOTIFICATION.—If the manufacturer or distributor of a tobacco product has knowledge which reasonably supports the conclusion that a tobacco product manufactured or distributed by such manufacturer or distributor that has left the control of such person may be or has been—
- "(A) imported, exported, distributed or offered for sale in interstate commerce by a person without paying duties or taxes required by law; or
- "(B) imported, exported, distributed or diverted for possible illicit marketing,

the manufacturer or distributor shall promptly notify the Attorney General of such knowledge.

- "(2) KNOWLEDGE DEFINED.—For purposes of this subsection, the term 'knowledge' as applied to a manufacturer or distributor means—
- "(A) the actual knowledge that the manufacturer or distributor had; or
- "(B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care."

#### SEC. 302. STUDY AND REPORT.

- (a) STUDY.—The Comptroller General of the United States shall conduct a study of cross-border trade in tobacco products to—
- (1) collect data on cross-border trade in tobacco products, including illicit trade and trade of counterfeit tobacco products and make recommendations on the monitoring of such trade;
- (2) collect data on cross-border advertising (any advertising intended to be broadcast, transmitted, or distributed from the United States to another country) of tobacco products and make recommendations on how to prevent or eliminate, and what technologies could help facilitate the elimination of, cross-border advertising
- cross-border advertising.

  (b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the study described in subsection (a).
  - By Mr. KENNEDY (for himself, Mr. Bond, Mr. akaka, Mr. Leahy, Mr. Menendez, Mr. Craig, and Mr. Shelby):
- S. 626 A bill to amend the Public Health Service Act to provide for arthritis research and public health, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

Mr. KENNEDY. Mr. President, it is a privilege to join Senator BOND in introducing "The Arthritis Prevention, Control and Cure Act."

Our goal in this important initiative is to provide a strong federal response to arthritis. Early diagnosis, treatment, and appropriate management of arthritis can control its symptoms, improve the quality of life of patients, and Federal action will improve the lives of the family members and caregivers of those affected by the disease.

Arthritis exits in more than a hundred different forms. It's one of the most devastating diseases impairing the health of the American people. It's second only to heart disease as a cause of work disability. It undermines everyday activities such as walking, dressing and bathing for more than seven million Americans.

One out of very five adults in the United States suffers from some form of arthritis. The number of patients in the U.S. with arthritis will keep growing as the number of older Americans continues to increase dramatically in the next few decades. Today, 8.7 million adults, ages 18 through 44, have arthritis and millions of others are at risk of developing the disease.

In fact, arthritis is one of the most prevalent chronic illnesses and the leading cause of disability among Americans over age 15. More than 40 percent of adults with arthritis are limited in their activities because of their arthritis. By 2030, nearly 25 percent of the projected United States adult population will have arthritis and these numbers don't account for the current trends in obesity, which may contribute to future cases of the disease.

It is an illness that affects all types of people in the U.S., not just older Americans. Arthritis knows no boundaries. Men, women and children are all afflicted with the disease. According to the Arthritis Foundation, 24 million women and 17 million men have been diagnosed with arthritis by their doctors. Women are still disproportionately affected by the disease.

Nearly 3 out of every 1,000 American children are affected by arthritis. The devastating effects of pediatric arthritis justifies greater investment by the federal government in research and to identify more effective treatments.

Special concerns are raised by juvenile arthritis because of its impact on family relationships, school life, dating, sports and other aspects active, growing youths. Teens and young adults entering the workforce face even greater challenges.

Arthritis an other rheumatic diseases cost our economy \$128 billion annually, according to the Centers for Disease Control and Prevention. In 2003, the cost was equivalent to 1.2 percent of the nation's gross domestic product. \$80 million of that amount were direct costs for medical care and \$47 million were indirect costs for lost earnings. National medical costs attributed to arthritis grew by 24 percent between 1997 and 2003, with an increase attributed to the growing number of people affected with the disease.

In 1975, Congress enacted the National Arthritis Act to encourage basic and clinical research, establish Multipurpose Arthritis Centers and expand clinical knowledge of the illness. The act was successful in implementing and continued funding of research and has led to important advances in the control, treatment and prevention of the illness.

Early diagnosis, treatment and management can control symptoms and improve the quality of life. Weight control and exercise can help lower risks. Patient education, training and selfmanagement also contribute to greater control of these diseases. Innovative and increasingly effective drug therapies, joint replacements, and other therapeutic alternatives are being developed.

Despite much research identifying effective interventions, many of them are not being used well enough and the inevitable result is unnecessary loss of life, poorer health and poorer quality of life.

Our legislation will expand the effort to find new ways to prevent, treat and care for patients with arthritis and related rheumatic diseases. It will enhance the National Arthritis Action Plan by providing additional support to federal, state and private efforts to prevent and manage arthritis. It will establish a National Arthritis Education and Outreach Campaign to inform the health care profession and the public about the most successful self-management strategies for controlling the illness.

With greater coordination and intensification of federal research, this bill will organize a National Arthritis and Rheumatic Diseases Summit to look at the challenges and opportunities related to these efforts.

In addition, the bill will provide greater attention to juvenile arthritis research by offering planning grants for research specific to juveniles and by prioritizing the activities that create better understanding of the incidence and outcomes associated with juvenile arthritis.

Finally the bill contains incentives to encourage health professionals to enter the field of pediatric rheumatology by education loan repayment and career development awards.

I urge my colleagues to support this public health initiative to reduce the pain and disability of arthritis. Early diagnosis, effective treatment and greater investment in research and prevention can help us wage a stronger battle against one of the most widespread and devastating conditions affecting our Nation.

By Mr. HARKIN (for himself, Mr. SMITH, Mr. SPECTER, and Mr. MARTINEZ):

S. 627. A bill to amend the Juvenile Justice and Delinquency Prevention Act of 1974 to improve the health and well-being of maltreated infants and toddlers through the creation of a National Court Teams Resource Center, to assist local Court Teams, and for other purposes; to the Committee on the Judiciary.

Mr. HARKIN. Mr. President, I am honored to join with the distinguished senior Senator from Oregon, Senator SMITH, to introduce the Safe Babies Act of 2007.

It is a tragic fact that America's child welfare system is failing our most vulnerable. From birth to age five, children develop their social, emotional, cognitive and moral capacities more rapidly than at any other time in life. Early experiences and relationships are absolutely critical to future development; they set the stage for how well individuals learn, think, control their emotions, and relate to others.

This critical period is a time of tremendous promise, but also a time of great vulnerability. Unfortunately, infants and toddlers are disproportionately affected by child abuse and neglect. Children between birth and age three are twice as likely as older children to become victims of maltreatment, and are three times more likely to be placed in foster care. Abuse and

neglect during this significant period can lead to perilous developmental outcomes, including school failure, delinquency and crime, substance abuse, and mental health problems.

Yet the current child welfare system does a particularly poor job of serving infants and toddlers. Once in foster care, infants and toddlers are more likely to be abused. And they stay in foster care longer than older children. More than 40 percent of infants and toddlers involved in a maltreatment investigation are developmentally delayed, yet only 10 percent of these young people currently receive treatment for developmental problems.

A Federal review of 19 States' per-

A Federal review of 19 States' performance on child welfare outcomes found that all of the States received failing grades on outcomes related to providing adequate physical and mental health services.

Without intervention, we put our future generation at risk and perpetuate the cycle of maltreatment. But we can alter these developmental outcomes by ensuring that children are in safe, permanent homes and have access to necessary mental and physical health care. The Safe Babies Act authorizes funding for juvenile courts to create Court Teams for the integrated handling of infant and toddler abuse and neglect cases. By bringing together the legal, child welfare, and children's services communities, we can promote the health and well-being of our babies and toddlers.

First, this bill establishes a National Court Teams Resource Center. This Resource Center would provide grants and technical assistance to juvenile courts for the creation of local Court Teams to better handle infant and toddler abuse and neglect cases. Few judges have all the necessary knowledge about early childhood development and they frequently lack resources in the community for services necessary for young children. They are often frustrated by the piecemeal provision of services and the overburdened child welfare system. To adequately serve children, they need the expertise of child welfare workers, Guardians Ad Litem, Court Appointed Special Advocates, substance abuse treatment providers and mental health care providers. Court Teams bring together this expertise. Through monthly case reviews, judges can coordinate efforts by all members of the team to ensure efficient and effective provision of services. The goal of these courts is to prevent multiple placements for infants and toddlers in foster care, secure needed services, and find a permanent home for these children as quickly as possible.

Court Teams work with families in an effort to reunite children with their parents. By bringing together multiple service providers, they can facilitate opportunities for parents to learn to create a safe and nurturing home environment. Court Teams ensure support for future reunification only when the parent is ready and able to step up to provide an appropriate and safe environment. We know from research that each visit between a child and birth parent triples the likelihood of achieving permanence. Through the Court Teams, judges are able to coordinate education and supervision so parents can visit their children and continue to nurture a loving bond.

Although reunification with parents is the ultimate goal, when that is not possible, Court Teams are also focusing on Plan B. By conducting concurrent planning, Court Teams are more likely to find an appropriate placement that will lead to permanency and minimize disruptions. By supporting training for foster parents and newly reunified biological parents, we can prevent children from being bounced around in the foster care system.

Court Teams are also able to coordinate services for children. Judges and child welfare services are able to collaborate to include necessary medical and developmental interventions. By improving access to mental health and substance abuse treatment for parents and children, Court Teams make sure children are able to access needed services and increase the chances of successful, healthy development.

Finally, Court Teams provide services and supports for families to preserve and stabilize homes for children. Judges are able to use court oversight to ensure compliance, facilitate visits with caregivers to promote positive attachments, and make sure that children are in safe environments after placement.

The Safe Babies Act will make an important impact in the way we treat infants and toddlers in the court system. By facilitating involvement from all parties, Court Teams are better equipped to ensure that young children have the community support and services they need. Early evaluation research in the Miami/Dade County court project finds a high rate of permanency for children in the court and increased quality of parent-child interaction. By finding permanent homes, children were able to escape the limbo of the foster care system. More importantly, the court was successful in preventing any future recurrence of abuse or neglect.

Together we can work to protect the safety and well-being of our infants and toddlers. With this legislation, we have the opportunity to ensure that children are placed quickly in safe and loving homes. I look forward to working with my colleagues to ensure that this legislation is passed and signed into law.

Mr. SMITH. Mr. President, I rise today with my colleague from Iowa, Senator Harkin, to introduce the Safe Babies Act of 2007. The safety and wellbeing of our nation's children, including its most vulnerable infants and toddlers, is very important and I am confident that this bill will take an important step forward in protecting them.

Mr. President, in our Nation millions of children are reported abused or neglected each year. Of these, more than 900,000 are confirmed maltreated by child protective service organizations and our court systems. Abuse and neglect of children causes about 1,500 deaths each year. Children who are under the age of four are at the greatest risk for injury or death—making up nearly 80 percent of child maltreatment fatalities. We also know that shaken-baby syndrome, SBS, is a form of abuse that affects more than 1,200 babies each year.

Studies also tell us that younger children who are abused or neglected are vulnerable to long-term challenges associated with their maltreatment. Their long-term outcomes show much higher rates for social, emotional and cognitive impairment. They also are more likely to adopt high risk behaviors and develop substance abuse and mental health problems than their peers who have not been abused.

These numbers tell us very loudly that there is a problem in America. Our most vulnerable and innocent are being abused and need our help.

Children who come through our Nation's court systems need more support. While the hardworking judges, attorneys, child welfare workers and volunteers do so much to help stop the child abuse and neglect they see every day, they too often see families returning to the courts generation after generation. They see their workloads expand. They see too many families in strife.

The Safe Babies Act will help these most vulnerable children. This bill puts into motion a proven model for helping infants and toddlers to recover from their abuse, and for families to stop the cycle of abuse and reunite. This model is made up of a judicial and mental health partnership, or "court team," that provides the needed abuse and neglect prevention and early intervention services to children and their families. It is based on a model developed by the Honorable Cindy Lederman of the Miami-Dade Juvenile Court in Miami. Seeing the success she has had with this model. It has been replicated in courts across the nation.

In my home State of Oregon, our Salem courts have developed the "Foster Attachment" program based on Judge Lederman's model. This program brings together the courts, local treatment providers, and child welfare agencies to provide substance abuse treatment and mental health treatment, as well as parenting intervention to help parents who have had their children removed due to methamphetamine use.

I look forward to the passage of this important legislation and to working with my colleague Senator Harkin to ensure its passage. There is no issue of greater importance than the safety and welfare of our next generation. I urge my colleagues on both sides of the aisle to support this important bill.

By Mr. COLEMAN (for himself and Mr. BAYH):

S. 628: A bill to provide grants for rural health information technology development activities; to the Committee on Health, Education, Labor, and Pensions.

Mr. COLEMAN. Mr. President, I ask unanimous consent that the text of the bill I introduced today, the Critical Access to Health Information Technology Act of 2007, be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

#### S. 628

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

#### SECTION 1. SHORT TITLE.

This Act may be cited as the "Critical Access to Health Information Technology Act of 2007".

## SEC. 2. HEALTH INFORMATION TECHNOLOGY GRANT PROGRAM.

- (a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall establish and implement a program to award grants to increase access to health care in rural areas by improving health information technology, including the reporting, monitoring, and evaluation required under this section.
- (b) STATE GRANTS.—The Secretary shall award grants to States to be used to carry out the State plan under subsection (e) through the awarding of subgrants to local entities within the State. Amounts awarded under such a grant may only be used in the fiscal year in which the grant is awarded or in the immediately subsequent fiscal year.
- (c) AMOUNT OF GRANT.—From amounts appropriated under subsection (k) for each fiscal year, the Secretary shall award a grant to each State that complies with subsection (e) in an amount that is based on the total number of critical access hospitals in the State (as certified by the Secretary under section 1817(e) of the Social Security Act) bears to the total number of critical access hospitals in all States that comply with subsection (e).
- (d) LEAD AGENCY.—A State that receives a grant under this section shall designate a lead agency to—
- (1) administer, directly or through other governmental or nongovernmental agencies, the financial assistance received under the grant:
- (2) develop, in consultation with appropriate representatives of units of general purpose local government and the hospital association of the State, the State plan; and
- (3) coordinate the expenditure of funds and provision of services under the grant with other Federal and State health care programs.
- (e) STATE PLAN.—To be eligible for a grant under this section, a State shall establish a State plan that shall—
  - (1) identify the State's lead agency;
- (2) provide that the State shall use the amounts provided to the State under the grant program to address health information technology improvements and to pay administrative costs incurred in connection with providing the assistance to local grant recipients:
- (3) provide that benefits shall be available throughout the entire State; and
- (4) require that the lead agency consult with the hospital association of such State and rural hospitals located in such State on the most appropriate ways to use the funds received under the grant.

- (f) AWARDING OF LOCAL GRANTS.-
- (1) IN GENERAL.—The lead agency of a State shall use amounts received under a grant under subsection (a) to award local grants on a competitive basis. In determining whether a local entity is eligible to receive a grant under this subsection, the lead agency shall utilize the following selection criteria:
- (A) The extent to which the entity demonstrates a need to improve its health information reporting and health information technology.
- (B) The extent to which the entity will serve a community with a significant low-income or other medically underserved population.
- (2) APPLICATION AND APPROVAL.—To be eligible to receive a local grant under this subsection, an entity shall be a governmentowned or private nonprofit hospital (including a non-Federal short-term general acute care facility that is a critical access hospital located outside a Metropolitan Statistical Area, in a rural census tract of a Metropolitan Statistical Area as determined under the most recent version of the Goldsmith Modification or the Rural-Urban Commuting Area codes, as determined by the Office of Rural Health Policy of the Health Resources and Services Administration, or is located in an area designated by any law or regulation of the State in which the hospital is located as a rural area (or is designated by such State as a rural hospital or organization)) that submits an application to the lead agency of the State that-
- (A) includes a description of how the hospital intends to use the funds provided under the grant;
- (B) includes such information as the State lead agency may require to apply the selection criteria described in paragraph (1);
- (C) includes measurable objectives for the use of the funds provided under the grant;
- (D) includes a description of the manner in which the applicant will evaluate the effectiveness of the activities carried out under the grant:
- (E) contains an agreement to maintain such records, make such reports, and cooperate with such reviews or audits as the lead agency and the Secretary may find necessary for purposes of oversight of program activities and expenditures:
- (F) contains a plan for sustaining the activities after Federal support for the activities has ended; and
- (G) contains such other information and assurances as the Secretary may require.
  - (3) USE OF AMOUNTS.—
- (A) IN GENERAL.—An entity shall use amounts received under a local grant under this section to—
- (i) offset the costs incurred by the entity after December 31, 2007, that are related to clinical health care information systems and health information technology designed to improve quality of health care and patient safety; and
- (ii) offset costs incurred by the entity after December 31, 2007, that are related to enabling health information technology to be used for the collection and use of clinically specific data, promoting the interoperability of health care information across health care settings, including reporting to Federal and State agencies, and facilitating clinic decision support through the use of health information technology.
- (B) ELIGIBLE COSTS.—Costs that are eligible to be offset under subparagraph (A) shall include the cost of—
- (i) purchasing, leasing, and installing computer software and hardware, including handheld computer technologies, and related services:
- (ii) making improvements to existing computer software and hardware;

- (iii) purchasing or leasing communications capabilities necessary for clinical data access, storage, and exchange;
- (iv) services associated with acquiring, implementing, operating, or optimizing the use of new or existing computer software and hardware and clinical health care information systems;
- (v) providing education and training to staff on information systems and technology designed to improve patient safety and quality of care; and
- (vi) purchasing, leasing, subscribing, integrating, or servicing clinical decision support tools that integrate patient-specific clinic data with well-established national treatment guidelines, and provide ongoing continuous quality improvement functions that allow providers to assess improvement rates over time and against averages for similar providers.
- (4) Grant limit.—The amount of a local grant under this subsection shall not exceed \$250,000
- (g) REPORTING, MONITORING, AND EVALUATION.—The lead agency of a State that receives a grant under this section shall annually report to the Secretary—
  - (1) the amounts received under the grant;
- (2) the amounts allocated to State grant recipients under the grant;
- (3) the breakdown of types of expenditures made by the local grant recipients with such funds; and
- (4) such other information required by the Secretary to assist the Secretary in monitoring the effectiveness of activities carried out under this grant.
- (h) REVIEW OF COMPLIANCE WITH STATE PLAN.—The Secretary shall review and monitor State compliance with the requirements of this section and the State plan submitted under subsection (e). If the Secretary, after reasonable notice to a State and opportunity for a hearing, finds that there has been a failure by the State to comply substantially with any provision or requirement set forth in the State plan or the requirements of this section, the Secretary shall notify the lead agency involved of such finding and that no further payments to the State will be made with respect to the grant until the Secretary is satisfied that the State is in compliance or that the noncompliance will be promptly corrected
- (i) PREEMPTION OF CERTAIN LAWS.—The provisions of this section shall preempt applicable Federal and State procurement laws with respect to health information technology purchased under this section.
- nology purchased under this section.

  (j) RELATION TO OTHER PROGRAMS.—
  Amounts appropriated under this section shall be in addition to appropriations for Federal programs for Rural Hospital FLEX grants, Rural Health Outreach grants, and Small Rural Hospital Improvement Program grants.
- (k) AUTHORIZATION OF APPROPRIATIONS.— There is authorized to be appropriated to carry out this section, \$10,000,000 for each of fiscal years 2008 through 2010.

# SEC. 3. REPLACEMENT OF THE INTERNATIONAL STATISTICAL CLASSIFICATION OF DISEASES.

- (a) IN GENERAL.—Not later than October 1, 2008, the Secretary of Health and Human Services shall promulgate a final rule concerning the replacement of the International Statistical Classification of Diseases, 9th revision, Clinical Modification (referred to in this section as the "ICD-9-CM"), under the regulation promulgated under section 1173(c) of the Social Security Act (42 U.S.C. 1320d-2(c)), including for purposes of part A of title XVIII, or part B where appropriate, of such Act, with the use of each of the following:
- (1) The International Statistical Classification of Diseases and Related Health Prob-

- lems, 10th revision, Clinical Modification (referred to in this section as "ICD-10-CM".
- (2) The International Statistical Classification of Diseases and Related Health Problems, 10th revision, Clinical Modification Coding System (referred to in this section as "ICD-10-PCS").
  - (b) IMPLEMENTATION.—
- (1) IN GENERAL.—The Secretary of Health and Human Services shall ensure that the rule promulgated under subsection (a) is implemented by not later than October 1, 2011. In carrying out the preceding sentence, the Secretary shall ensure that such rule ensure that Accredited Standards Committee X12 HIPAA transactions version (v) 4010 is upgraded to a newer version 5010, and that the National Council for Prescription Drug Programs Telecommunications Standards version 51 is updated to a newer version (to be released by the named by the National Council for Prescription Drug Programs Telecommunications Standards) that supersedes, in part, existing legislation and regulations under the Health Insurance Portability and Accountability Act of 1996.
- (2) AUTHORITY.—The Secretary of Health and Human Services shall have the authority to adopt, without notice and comment rule-making, standards for electronic health care transactions under section 1173 of the Social Security Act (42 U.S.C. 1320d-2) that are recommended to the Secretary by the Accredited Standards Committee X12 of the American National Standards Institute in relation to the replacement of ICD-9-CM with ICD-10-CM and ICD-10-PCS. Such modifications shall be published in the Federal Register.
- (c) NOTICE OF INTENT.—Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall issue and publish in the Federal Register a Notice of Intent that—
- (1) adoption of Accredited Standards Committee X12 HIPAA transactions version (v) 5010 shall occur not later than April 1, 2009, and compliance with such rule shall apply to transactions occurring on or after April 1, 2011:
- (2) adoption of the National Council for Prescription Drug Programs Telecommunications Standards version 5.1 with a new version will occur not later than April 1, 2009, and compliance with such rule shall apply to transactions occurring on or after April 1, 2011;
- (3) adoption of ICD-10-CM and ICD-10-PCS will occur not later than October 1, 2008, and compliance with such rules shall apply to transactions occurring on or after October 1, 2011; and
- (4) covered entities and health technology vendors under the Health Insurance Potability and Accountability Act of 1996 shall begin the process of planning for and implementing the updating of the new versions and editions referred to in this subsection.

  (d) ASSURANCES OF CODE AVAILABILITY.—
- (d) ASSURANCES OF CODE AVAILABILITY.—
  The Secretary of Health and Human Services shall take such action as may be necessary to ensure that procedure codes are promptly available for assignment and use under ICD–9-CM until such time as ICD–9-CM is replaced as a code set standard under section 1173(c) of the Social Security Act with ICD–10-PCS.
- (e) DEADLINE.—Notwithstanding section 1172(f) of the Social Security Act (42 U.S.C. 1320d-1(f)), the Secretary of Health and Human Services shall adopt the modifications provided for in this section without a recommendation of the National Committee on Vital and Health Statistics unless such recommendation is made to the Secretary on or before a date specified by the Secretary as consistent with the implementation of the replacement of ICD-9-CM with ICD-10-CM and ICD-10-PCS for transactions occurring on or after October 1, 2011.

- (f) LIMITATION ON JUDICIAL REVIEW.—The rule promulgated under subsection (a) shall not be subject to judicial review.
- (g) APPLICATION.—The rule promulgated under subsection (a) shall apply to transactions occurring on or after October 1, 2011.
- (h) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as effecting the application of classification methodologies or codes, such as the Current Procedural Terminology (CPT) as maintained and distributed by the American Medical Association and the Healthcare Common Procedure Coding System (HCPCS) as maintained and distributed by the Department of Health and Human Services, other than under the International Statistical Classification of Disease and Related Health Problems.

#### By Mr. COLEMAN:

S. 629. A bill to amend the Consolidated Farm and Rural Development Act to provide direct and guaranteed loans, loan guarantees, and grants to complete the construction and rehabilitation of rural critical access hospitals; to the Committee on Agriculture, Nutrition, and Forestry.

Mr. COLEMAN. Mr. President, I ask unanimous consent that the text of the bill I introduce today, to amend the Consolidated Farm and Rural Development Act to provide direct and guaranteed loans, loan guarantees, and grants to complete the construction and rehabilitation of critical access hospitals, be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

#### S. 629

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.

# SECTION 1. LOANS, LOAN GUARANTEES, AND GRANTS FOR RURAL CRITICAL ACCESS HOSPITAL RECONSTRUCTION AND REHABILITATION.

- (a) IN GENERAL.—Section 306(a) of the Consolidated Farm and Rural Development Act (7 U.S.C. 1926(a)) is amended—
- (1) in paragraph (1)—
- (A) by designating the first through fifth sentences as subparagraphs (A) through (E), respectively; and
  - (B) by adding at the end the following:
- "(F) LOANS AND LOAN GUARANTEES FOR RURAL CRITICAL ACCESS HOSPITAL RECONSTRUCTION AND REHABILITATION.—Notwithstanding any other provision of law, the Secretary shall use such sums as are necessary of the funds of the Commodity Credit Corporation for the cost of making community facility direct and guaranteed loans under this paragraph, in a total amount of not to exceed an additional \$1,600,000,000 for the period of fiscal years 2008 through 2012, to complete the construction and rehabilitation of critical access hospitals (as defined in section 1861(mm) of the Social Security Act (42 U.S.C. 1395x(mm)))."; and
- (2) in paragraph (19), by adding at the end the following:
- "(D) GRANTS FOR RURAL CRITICAL ACCESS HOSPITAL RECONSTRUCTION AND REHABILITATION.—Notwithstanding any other provision of law, of the funds of the Commodity Credit Corporation, the Secretary shall make available an additional \$5,000,000 for the period of fiscal years 2008 through 2012 to make essential community facility grants under this paragraph to complete the construction and rehabilitation of critical access hospitals (as defined in section 1861(mm) of the Social Security Act (42 U.S.C. 1395x(mm)))."

- (b) CONFORMING AMENDMENTS.—Section 306 of the Consolidated Farm and Rural Development Act (7 U.S.C. 1926) (as amended by subsection (a)(1)) is amended—
- (1) by striking "Sec. 306. (a)(1)(A) The Secretary is also authorized to" and inserting the following:

#### "SEC. 306. WATER, WASTE DISPOSAL, AND COM-MUNITY FACILITY LOANS, LOAN GUARANTEES, AND GRANTS.

- "(a) AUTHORITY.—
- "(1) WATER, WASTE DISPOSAL, AND COMMUNITY FACILITIES.—
  - "(A) IN GENERAL.—The Secretary may";
- (2) by striking "(B) The Secretary may also" and inserting the following:
- "(B) RURAL EMPOWERMENT ZONES AND RURAL ENTERPRISE COMMUNITIES.—The Secretary may";
- (3) by striking "(C) The Secretary may also" and inserting the following:
- "(C) ELECTRIC BORROWERS.—The Secretary may":
- (4) by striking "(D) When any" and inserting the following:
- "(D) Gross income.—If any"; and
- (5) by striking "(E) With respect" and inserting the following:
  - "(E) BOND COUNSEL.—With respect".

# By Mr. COLEMAN (for himself, Mr. DURBIN, and Mr. HARKIN):

S. 630. A bill to amend part C of title XVIII of the Social Security Act to provide for a minimum payment rate by Medicare Advantage organizations for services furnished by a critical access hospital and a rural health clinic under the Medicare program; to the Committee on Finance.

Mr. COLEMAN. Mr. President, I ask unanimous consent that the text of the bill I introduce today, the Rural Health Services Preservation Act of 2007, be printed in the RECORD.

There being no objection, the bill the of the was ordered to be printed in the RECORD, as follows:

#### S. 630

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

#### SECTION 1. SHORT TITLE.

This Act may be cited as the "Rural Health Services Preservation Act of 2007".

# SEC. 2. MINIMUM PAYMENT RATE BY MEDICARE ADVANTAGE ORGANIZATIONS FOR SERVICES FURNISHED BY A CRITICAL ACCESS HOSPITAL AND A RURAL HEALTH CLINIC.

(a) IN GENERAL.—Section 1857(e) of the Social Security Act (42 U.S.C. 1395w-27(e)) is amended by adding at the end the following:

"(4) Minimum payment rate for services FURNISHED BY A CRITICAL ACCESS HOSPITAL AND A RURAL HEALTH CLINIC.—A contract under this section between an MA organization and the Secretary for the offering of an MA plan shall require the organization to provide for a payment rate under the plan for inpatient and outpatient critical access hospital services and rural health clinic services furnished to enrollees of the plan and for extended care services furnished by a critical access hospital under an agreement entered into under section 1883 to such enrollees (whether or not the services are furnished pursuant to an agreement between such organization and a critical access hospital or a rural health clinic) that is not less

"(A) the applicable payment rate established under part A or part B (which includes the payment of an interim rate and a subsequent cost reconciliation) with respect to

the critical access hospital for such inpatient, outpatient, and extended care services or the rural health clinic for such rural health clinic services; or

- "(B) if the critical access hospital or the rural health clinic determines appropriate, 103 percent of the applicable interim payment rate established under part A or part B with respect to the critical access hospital for such inpatient, outpatient, and extended care services or the rural health clinic for such rural health clinic services."
- (b) EFFECTIVE DATE.—The amendments made by this section shall apply to Medicare Advantage contract years beginning on or after January 1, 2008.

#### By Mr. COLEMAN

S. 631. A bill to amend title XVIII of the Social Security Act to provide for coverage of remote patient management services for chronic health care conditions under the Medicare Program; to the Committee on Finance.

Mr. COLEMAN. Mr. President, I ask unanimous consent that the text of the bill I introduce today, the Remote Monitoring Access Act of 2007, be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

#### S 631

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

#### SECTION 1. SHORT TITLE.

This Act may be cited as the "Remote Monitoring Access Act of 2007".

#### SEC. 2. FINDINGS.

Congress finds the following:

- (1) Remote patient monitoring can make chronic disease management more effective and efficient for patients and the health care system.
- (2) By collecting, analyzing, and transmitting clinical health information to a health care practitioner, remote monitoring technologies allow patients and physicians to manage the patient's condition in a consistent and real-time fashion.
- (3) Utilization of these technologies not only improves the quality of care given to patients, it also reduces the need for frequent physician office appointments, costly emergency room visits, and unnecessary hospitalizations.
- (4) Monitoring a patient's disease from the home reduces the need for face-to-face physician interactions, thereby minimizing unnecessary travel and missed work and providing particular value to individuals residing in rural or underserved communities who would otherwise face potentially significant access barriers to receiving needed care.
- (5) Four major areas in which remote management technologies are emerging in health care are the treatment of congestive heart failure, diabetes, cardiac arrhythmia, and sleep apnea (sleep disordered breathing). Prompt transmission of clinical data on each of these conditions, to the physician or the patient as appropriate, are essential to providing timely and appropriate therapeutic interventions which can then reduce expensive hospitalizations.
- (6) Despite these innovations, remote management technologies have failed to diffuse rapidly. A significant barrier to wider adoption is the relative lack of payment mechanisms in fee-for-service Medicare to reimburse for remote, non-face-to-face management.
- (7) This Act will eliminate this barrier to new technologies by requiring Medicare to

reimburse doctors for time spent analyzing data transmitted to them by remote patient management technologies.

- (8) This Act also promotes high quality care by requiring the Secretary of Health and Human Services to consult with physician groups to create a standard of care and a quality standard for remote patient management services for the covered chronic conditions.
- (9) This Act provides physicians with a financial incentive to meet or exceed the standard of care and quality standards.

# SEC. 3. COVERAGE OF REMOTE PATIENT MANAGEMENT SERVICES FOR CHRONIC HEALTH CARE CONDITIONS.

- (a) IN GENERAL.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) is amended.—
- (1) in subparagraph (Z), by striking "and" at the end;
- (2) in subparagraph (AA), by inserting "and" at the end; and
- (3) by inserting after subparagraph (AA) the following new subparagraph:
- "(BB) remote patient management services (as defined in subsection (ccc));".
- (b) SERVICES DESCRIBED.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:
  - "Remote Patient Management Services
- "(ccc)(1) The term 'remote patient management services' means the remote monitoring and management of an individual with a covered chronic health condition (as defined in paragraph (2)) through the utilization of a system of technology that allows a remote interface to collect and transmit clinical data between the individual and the responsible physician or supplier for the purposes of clinical review or response by the physician or supplier.
- "(2) For purposes of paragraph (1), the term 'covered chronic health condition' includes—
  - "(A) heart failure;
- "(B) diabetes;
- "(C) cardiac arrhythmia;
- "(D) sleep apnea; and
- "(E) any other chronic condition determined by the Secretary to be appropriate for treatment through remote patient management services.
- "(3)(A) The Secretary, in consultation with appropriate physician groups, shall develop guidelines on the frequency of billing for remote patient management services. Such guidelines shall be determined based on medical necessity and shall be sufficient to ensure appropriate and timely monitoring of individuals being furnished such services.
- "(B) The Secretary, acting through the Agency for Health Care Research and Quality, shall do the following:
- "(i) Not later than 1 year after the date of enactment of the Remote Monitoring Access Act of 2007, develop, in consultation with appropriate physician groups, a standard of care and quality standards for remote patient management services for the covered chronic health conditions specified in subparagraphs (A), (B), (C), and (D) of paragraph (2).
- "(ii) If the Secretary makes a determination under paragraph (2)(E) with respect to a chronic condition, develop, in consultation with appropriate physician groups, a standard of care and quality standards for remote patient management services for such condition within 1 year of such determination.
- "(iii) Periodically review and update such standards of care and quality standards under this subparagraph as necessary.".
- (c) Payment Under the Physician Fee Schedule.—Section 1848 of the Social Security Act (42 U.S.C. 1395w-4) is amended—

- (1) in subsection (c)—
- (A) in paragraph (2)(B)—
- (i) in clause (ii)(II), by striking "and (v)" and inserting ", (v), and (vi)"; and
- (ii) by adding at the end the following new clause:
- "(vi) BUDGETARY TREATMENT OF CERTAIN SERVICES.—The additional expenditures attributable to services described in section 1861(s)(2)(BB) shall not be taken into account in applying clause (ii)(II) for 2008."; and
- (B) by adding at the end the following new paragraph:
- "(7) TREATMENT OF REMOTE PATIENT MANAGEMENT SERVICES.—In determining relative value units for remote patient management services (as defined in section 1861(ccc)), the Secretary, in consultation with appropriate physician groups, shall take into consideration—
- "(A) costs associated with such services, including physician time involved, installation and information transmittal costs, costs of remote patient management technology (including devices and software), and resource costs necessary for patient monitoring and follow-up (but not including costs of any related item or non-physician service otherwise reimbursed under this title); and
- "(B) the level of intensity of services provided, based on—
- "(i) the frequency of evaluation necessary to manage the individual being furnished the services:
- "(ii) the amount of time necessary for, and the complexity of the evaluation, including the information that must be obtained, reviewed, and analyzed; and
- "(iii) the number of possible diagnoses and the number of management options that must be considered."; and
- (2) in subsection (j)(3), by inserting "(2)(BB)," after "(2)(AA),".
- (d) INCENTIVE PAYMENTS.—Section 1833 of the Social Security Act (42 U.S.C. 13951) is amended by adding at the end the following new subsection:
- "(v) INCENTIVE FOR MEETING CERTAIN STANDARDS OF CARE AND QUALITY STANDARDS IN THE FURNISHING OF REMOTE PATIENT MAN-AGEMENT SERVICES.—In the case of remote patient management services (as defined in section 1861(ccc)) that are furnished by a physician who the Secretary determines meets or exceeds the standards of care and quality standards developed by the Secretary under paragraph (3)(B) of such section for such services, in addition to the amount of payment that would otherwise be made for such services under this part, there shall also be paid to the physician (or to an employer or facility in cases described in subclause (A) of section 1842(b)(6)) (on a monthly or quarterly basis) from the Federal Supplementary Medical Insurance Trust Fund an amount equal to 10 percent of the payment amount for the service under this part.
- (e) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2008.

# By Mr. COLEMAN (for himself and Ms. KLOBUCHAR):

S. 632. A bill to provide for a hospital in Cass County, Minnesota; to the Committee on Finance.

Mr. COLEMAN. Mr. President, I ask unanimous consent that the text of the bill I introduce today, to provide for a hospital in Cass County, Minnesota, be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows: S. 632

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.

#### SECTION 1. MEDICARE CRITICAL ACCESS HOS-PITAL DESIGNATION.

Section 405(h) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173; 117 Stat. 2269) is amended by adding at the end the following new paragraph:

- "(3) EXCEPTION.—
- "(A) IN GENERAL.—The amendment made by paragraph (1) shall not apply to the certification by the State of Minnesota on or after January 1, 2006, under section 1820(c)(2)(B)(i)(II) of the Social Security Act (42 U.S.C. 1395i-4(c)(2)(B)(i)(II)) of one hospital that meets the criteria described in subparagraph (B) and is located in Cass County, Minnesota, as a necessary provider of health care services to residents in the area of the hospital.
- "(B) CRITERIA DESCRIBED.—A hospital meets the criteria described in this subparagraph if the hospital—
- "(i) has been granted an exception by the State to an otherwise applicable statutory restriction on hospital construction or licensing prior to the date of enactment of this subparagraph; and
- "(ii) is located on property which the State has approved for conveyance to a county within the State prior to such date of enactment."

#### By Mr. COLEMAN:

S. 633. A bill to provide assistance to rural schools, hospitals, and communities for the conduct of collaborative efforts to secure a progressive and innovative system to improve access to mental health care for youth, seniors and families; to the Committee on Health, Education, Labor, and Pensions.

Mr. COLEMAN. Mr. President, I ask unanimous consent that the text of the bill I introduce today, the Working Together for Rural Access to Mental Health and Wellness for Children and Seniors Act, be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

#### S. 633

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

#### SECTION 1. SHORT TITLE.

This Act may be cited as the "Working Together for Rural Access to Mental Health and Wellness for Children and Seniors Act". SEC. 2. FINDINGS AND PURPOSE.

- (a) FINDINGS.—Congress makes the following findings:
- (1) Providing adequate mental health care in rural communities is a national problem. Mental health is an integral part of a person's general health and well-being. In rural areas, where specialized mental health services are scarce, accessing mental health professional services is difficult. Primary care is often the only system for delivering mental health services.
- (2) Rural primary care providers are seeing an increase in mental health issues in their clinics
- (3) The need is overwhelming with the Surgeon General estimating 21 percent of children experience the signs or symptoms of a mental disorder. Left untreated, these problems lead to rampant school failure, drug abuse, and often incarceration.

- (4) The Department of Health and Human Services indicates that 1 in 5 children and adolescents may have a diagnosable disorder, yet 70 percent to 80 percent receive little or no help.
- (5) Few schools have the resources to implement a full range of school mental health interventions. Identifying sustainable and flexible funding sources for these programs is extremely important.
- (6) Health, and especially mental health, is a fundamental cornerstone for ensuring that all youth have an equal opportunity to succeed at school.
- (7) Promoting and expanding telemental health collaborations to strengthen delivery of mental health services in remote and underserved areas is needed.
- (8) Telemental health is an effective tool for diagnosing and treating some mental health conditions. For rural and remote areas, telemental health offers patients access and care.
- (b) PURPOSE.—It is the purpose of this Act to—
- (1) provide assistance to rural schools, hospitals, and communities for the conduct of collaborative efforts to secure a progressive and innovative system to improve access to mental health care for youth, seniors and families:
- (2) increase access of elementary and secondary school students to mental health services in rural areas by operating a mobile health services van program in such areas; or
- (3) increase access of individuals of all ages to mental health services in rural areas by providing telemental health services in such areas.

# SEC. 3. RURAL ACCESS TO MENTAL HEALTH SERVICES GRANT PROGRAM.

- (a) STATE GRANTS.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall award grants to States to enable such States to award subgrants to carry out the purposes of this Act.
  - (b) ELIGIBILITY AND AMOUNT.—
- (1) ELIGIBILITY.—To be eligible for a grant under subsection (a), a State shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including an assurance that the State will designate a lead agency in accordance with subsection (c) and submit a State plan in accordance with subsection (d).
- (2) AMOUNT.—The Secretary shall award a grant to a State under this section in an amount that is based on the respective number of critical access hospitals (as defined in section 1861 (mm)(1) of the Social Security Act (42 U.S.C. 1395x(mm)(1)) in the State as such compares to the total number of critical access hospitals in all States that are awarded grants under this section.
  - (c) STATE LEAD AGENCY.-
- (1) IN GENERAL.—To be eligible to receive a grant under this section, the governor of a State shall select a lead agency within the State to administer the State programs under the grant. If the governor of the State selects a lead agency other than the State Office of Rural Health, the governor shall ensure the involvement of the State Office of Rural Health in the development and administration of the State program under this section.
- (2) DUTIES.—The lead agency of a State shall—
- (A) administer, directly or through other governmental or nongovernmental agencies, amounts received under a grant under subsection (a): and
- (B) develop the State plan under subsection (d) and coordinate the expenditure of funds in consultation with appropriate representatives of the State and local edu-

- cational agencies and the rural mental health providers and State hospital associations
- (d) STATE PLAN.—To be eligible to receive a grant under subsection (a), a State shall submit to the Secretary a State plan that shall—
- (1) identify the lead agency of the State:
- (2) contain assurances that the State shall use the amounts provided to the State under the grant to address—
- (A) in the case of mobile van services, the mental health needs of elementary school and secondary school students; or
- (B) in the case of telemental health services, the mental health needs of individuals of all ages through telemental health services, and to pay administrative costs incurred in connection with providing the assistance to grant recipients;
- (3) contain assurances that benefits and services under the grant shall be available throughout the entire State; and
- (4) contain assurances that the lead agency shall consult with rural mental health providers and hospital associations that represent such providers in such State on the most appropriate ways to use the funds received under the grant.
  - (e) AWARDING OF SUBGRANTS.—
- (1) IN GENERAL.—The lead agency of the State shall use amounts received under a grant under subsection (a) to award subgrants to eligible entities on a competitive basis.
- (2) ELIGIBILITY.—To be eligible to receive a subgrant under paragraph (1), a grant applicant shall be located in or serving a rural area and be a government-owned or private nonprofit hospital (or, in the case of a mobile van services program, a governmental, tribal, or private nonprofit school district or educational institution which provides elementary education or secondary education (kindergarten through grade 12) and that collaborates with such a hospital), a community mental health center, a primary care clinic, or other nonprofit agency providing mental health services.
- (3) SELECTION CRITERIA.—In establishing procedures for the awarding of subgrants under paragraph (1), the lead agency of the State shall provide for the use of the following selection criteria:
- (A) The extent to which a grant applicant demonstrates a need to improve the access of mental health services within the community served by such applicant.
- (B) The extent to which a grant applicant will serve a rural community with a significant low-income or other population that is underserved with respect to the provision of mental health services.
- (4) APPLICATION AND APPROVAL.—To be eligible to receive a subgrant under paragraph (1), an entity shall submit an application to the lead agency of the State that includes—
- (A) a description of the manner in which the entity intends to use amounts provided under the subgrant:
- (B) such information as the lead agency may require to apply the selection criteria under paragraph (3);
- (C) measurable objectives for the use of funds provided under the subgrant;
- (D) a description of the manner in which the applicant will evaluate the effectiveness of the program carried out under the
- (E) an agreement to maintain such records, make such reports, and cooperate with such reviews or audits as the lead agency and the Secretary may find necessary for purposes of oversight of program activities and expenditures:
- (F) a plan for sustaining activities and services funded under the subgrant after

- Federal support for such activities and services has ended; and
- (G) such other information and assurances as the Secretary may require.
- (5) USE OF FUNDS.—A recipient of a subgrant under paragraph (1) shall use amounts awarded under the grant to—
- (A) in the case of mobile van health services, offset costs incurred after December 31, 2007, that are related to operating a mobile van outreach program under which a hospital and one or more elementary or secondary schools provide mental health care services to students of such schools in the rural area, which may include the costs of—
- (i) purchasing or leasing a mobile van in which mental health services are provided to elementary school or secondary school students;
- (ii) repairs and maintenance for such a mobile van;
- (iii) purchasing or leasing communications capabilities reasonable and necessary to operate the mobile van;
- (iv) providing education and training to staff on operating the mobile van program; and
- (v) providing for additional mental health services professional staff that are employed to provide mental health services as part of the mobile van program; and
- (B) in the case of telemental health services, offset costs incurred after December 31, 2007, that are related to providing telemental health services to persons of all ages in the rural area, which may include the cost of—
- (i) purchasing, leasing, repairing, maintaining, or upgrading telemental health services equipment;
- (ii) operating telemental health services equipment, including telecommunications, utilities, and software costs;
- (iii) providing education and training to staff concerning the provision of telemental health services; and
- (iv) employing additional mental health services professional staff to provide telemental health services.
- (6) LIMITS.—The amount awarded to an entity as a subgrant under paragraph (1) for any fiscal year shall not exceed \$300,000
- (f) REPORTING, MONITORING, AND EVALUATION.—The lead agency of each State that receives a grant under subsection (a) shall submit a report to the Secretary that contains—
  - (1) the amounts received under the grant;
- (2) the amounts allocated as subgrants under subsection (e);
- (3) the types of expenditures made by subgrant recipients with such funds; and
- (4) such other information as may be required by the Secretary to assist the Secretary in monitoring the effectiveness of this section.
- (g) REVIEW OF COMPLIANCE WITH STATE PLAN.—
- (1) IN GENERAL.—The Secretary shall review and monitor State compliance with the requirements of this section and the State plan submitted under subsection (d).
- (2) FAILURE TO COMPLY.—If the Secretary, after reasonable notice to a State and opportunity for a hearing, determines that there has been a failure by the State to comply substantially with any provision or requirement set forth in the State plan or a requirement of this section, the Secretary shall notify the lead agency of the State of such determination and that no further payments to the State will be made with respect to the State grant until the Secretary is satisfied that there is no longer any failure to comply or that the noncompliance will be promptly corrected.
- (h) INTERACTION OF FEDERAL AND STATE LAW.—Federal and State procurement laws shall be preempted to the extent necessary to carry out this section.

- (i) Definitions.—In this section:
- (1) HOSPITAL.—The term "hospital" means a non-Federal short-term general acute care facility located in or serving a rural area.
- (2) MOBILE VAN.—The term "mobile van" means a mobile wellness center the purpose of which is to improve access to, and focuses on, early intervention of mental health, and that provides consultation, education, comprehensive interdisciplinary education, and collaborative treatment planning services.
- (3) RURAL AREA.—The term "rural area", with respect to the location of an eligible applicant, or with respect to the location of mental health services, means that the entity or services—
- (A) is located in a rural census tract of a metropolitan statistical area, as determined under the most recent version of the Goldsmith Modification, the Rural-Urban Commuting Area codes, as determined by the Office of Rural Health Policy of the Health Resources and Services Administration; or
- (B) is located in an area designated by any law or regulation of such State as a rural area (or, in the case of a hospital, is designated by such State as a rural hospital).
- (4) TELEMENTAL HEALTH SERVICES.—The term "telemental health services" means mental health services that are provided through the use of videoconferencing or similar means of electronic communications and information technology.
- (5) TELEMENTAL HEALTH SERVICES EQUIPMENT.—The term "telemental health services equipment" includes telecommunications and peripheral equipment used to provide patient evaluations, case management, medication management, crisis response, pre-admission and pre-discharge planning, treatment planning, individual and group therapy, family therapy, mental status evaluations, case conferences, family visits, staff training, and administrative activities relating to the mental health services.
- (j) AUTHORIZATION OF APPROPRIATIONS.— There are authorized to be appropriated to carry out this section, \$10,000,000 for each of fiscal years 2008 through 2010.

# By Mr. DODD (for himself and Mr. HATCH):

S. 634. A bill to amend the Public Health Service Act to establish grant programs to provide for education and outreach on newborn screening and coordinated followup care once newborn screening has been conducted, to reauthorize programs under part A of title XI of such Act, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

Mr. DODD. Mr. President, I am pleased today to join with my colleague Senator HATCH to introduce legislation to protect the most vulnerable members of our society: newborn infants. Many people know the joy of parenthood. These parents know the sense of worry about whether their kids are doing well, are feeling well, and are safe. Nothing is of greater importance than the health and wellbeing of our children.

Thanks to incredible advances in medical technology, it is now possible to test newborns for more than 50 genetic and metabolic disorders. Many of these disorders, if undetected, would lead to severe disability or death. However, babies that are properly diagnosed and treated can, in many cases, go on to live healthy lives. So newborn screening can literally save lives.

Frighteningly, the disorders that newborn screening tests for can come without warning. For most of these disorders, there is no medical history of the condition in the family and no way to predict the health of a baby based on the health of the parents. Although the disorders that are tested for are quite rare, there is a chance that any one newborn will be affected. In that sense, this is an issue that has a direct impact on the lives of all families.

Fortunately, some screening has become common practice in every state. Each year, over four million infants have blood taken from their heel after birth to detect these disorders that could threaten their life and long-term health. As a result, about one in 4,000 babies is diagnosed with one of these disorders. That means that newborn screening could protect the health or save the life of approximately 1,000 newborns each year. That is 1,000 tragedies that can be averted families that can know the joy of a new infant rather than absolute heartbreak.

In 2004, the American College of Medical Genetics (ACMG) completed a report commissioned by the U.S. Department of Health and Human Services which recommended that every baby born in the U.S. be screened for twenty-nine disorders, including certain metabolic conditions and hearing deficiency. Unfortunately, as of February 2007, only 11 States and the District of Columbia require infants to be screened for all twenty-nine of these recommended disorders. If diagnosed early, all of these conditions can be successfully managed or treated to prevent or mitigate severe and often lifelong health problems.

For every baby saved, another two are estimated to be born with potentially detectable disorders that go undetected because they are not screened. These infants and their families face the prospect of disability or death from a preventable disorder. The survival of a newborn may very well come down to the state in which it is born, because not all states test for every detectable disorder.

The Government Accountability Office, GAO, released a report in 2003 highlighting the need for this legislation. According to the report, most states do not educate parents and health care providers about the availability of tests beyond what is mandated by a State. States also reported that they do not have the resources to purchase the technology and train the staff needed to expand newborn screening programs. Finally, even when States do detect an abnormal screening result, the majority do not inform parents directly

The legislation that we are introducing today will give states an additional helping hand toward meeting the advisory's committee's recommendation by providing \$25 million for states to expand and improve their newborn screening programs. In order

to access these resources, states will be required to commit to screening for all 29 disorders.

Our legislation will also authorize \$15 million for two types of grants. The first seeks to address the lack of information available to health care professionals and parents about newborn screening. Every parent should have the knowledge necessary to protect their child. The tragedy of a newborn's death is only compounded by the frustration of learning that the death was preventable. This bill authorizes grants to provide education and training to health care professionals, state laboratory personnel, families and consumer advocates.

The second type of grant will support States in providing follow-up care for those children diagnosed by a disorder detected through newborn screening. While these families are the fortunate ones, in many cases they are still faced with the prospect of extended and complex treatment and major lifestyle changes. We need to remember that care does not stop at diagnosis.

To ensure the quality of laboratories involved in newborn screening, so that tests are as accurate as possible and infants receive appropriate care, the legislation authorizes \$5 million for the Centers for Disease Control and Prevention, CDC, to carry out a number of functions such as quality assurance for newborn screening tests, performance evaluation services, and technical assistance and technology transfer to newborn screening labs.

In the event of a public health emergency, such as Hurricane Katrina, newborn screening may seem like a low priority. However, if babies aren't tested and, when necessary, treated within the first few days of life, they may suffer irreparable harm or even death. In the wake of a public health crisis, contingency planning for newborn screening is essential. Our legislation requires the CDC, in consultation with the Health Resources and Services Administration, HRSA, to develop a national contingency plan for newborn screening in the event of a public health emergency within 180 days of enactment of the bill.

Finally, the bill directs the CDC, in consultation with HRSA, to establish a national surveillance program for newborn screening, and authorizes \$15 million for that purpose. Such a program will help us conduct research to better understand these rare disorders, and will hopefully lead us toward more effective treatments and cures.

I urge my colleagues to support this important legislation so that every newborn child will have the best possible opportunity that America can offer to live a long, healthy and happy life. I look forward to working with the Chairman of the Health, Education, Labor and Pensions (HELP) Committee, Senator Kennedy, and Ranking Member Enzi to advance this legislation as early as possible.

I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

#### S. 634

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.

#### SECTION 1. SHORT TITLE.

This Act may be cited as the "Newborn Screening Saves Lives Act of 2007".

#### SEC. 2. FINDINGS.

Congress finds the following:

- (1) Each year more than 4,000,000 babies born in the United States are screened by State and private laboratories to detect some conditions that may threaten their long-term health.
- (2) However, there is a lack of uniformity in the number of conditions for which newborns are screened throughout the United States. While a newborn may be screened and treated for a debilitating condition in one State, in another State, the condition may go undetected and result in permanent disability or even death.
- (3) Approximately 4,000 infants born each year are diagnosed with these detectable and treatable disorders. If diagnosed early, these conditions can be successfully managed or treated to prevent severe and often lifelong health consequences.
- (4) In 2004, the American College of Medical Genetics (ACMG) completed a report commissioned by the Department of Health and Human Services which recommended that every baby born in the United States be screened for 29 specific disorders, including certain metabolic conditions and hearing deficiencies.
- (5) Currently only 11 States and the District of Columbia require infants to be screened for all 29 of these recommended disorders.
- (6) Continuity, especially during a public health emergency, plays a critical role in the screening, diagnosis, referral, and treatment of these disorders. Currently there is no national contingency plan for maintaining continuity of newborn screening systems following a public health emergency.

# SEC. 3. AMENDMENT TO TITLE III OF THE PUBLIC HEALTH SERVICE ACT.

Part Q of title III of the Public Health Service Act (42 U.S.C. 280h et seq.) is amended by adding at the end the following:

#### "SEC. 399AA. NEWBORN SCREENING.

- (a) Authorization of Grant Programs.— "(1) GRANTS TO ASSIST HEALTH CARE PRO-FESSIONALS.—From funds appropriated under subsection (h), the Secretary, acting through the Associate Administrator of the Maternal and Child Health Bureau of the Health Resources and Services Administration (referred to in this section as the 'Associate Administrator') and in consultation with the Advisory Committee on Heritable Disorders in Newborns and Children (referred to in this section as the 'Advisory Committee'), shall award grants to eligible entities to enable such entities to assist in providing health care professionals and newborn screening laboratory personnel with-
  - $\mbox{``(A)}$  education in newborn screening; and
  - "(B) training in-
- "(i) relevant and new technologies in newborn screening; and
- "(ii) congenital, genetic, and metabolic disorders.
- "(2) GRANTS TO ASSIST FAMILIES.—
- "(A) IN GENERAL.—From funds appropriated under subsection (h), the Secretary, acting through the Associate Administrator and in consultation with the Advisory Com-

- mittee, shall award grants to eligible entities to enable such entities to develop and deliver educational programs about newborn screening to parents, families, and patient advocacy and support groups. The educational materials accompanying such educational programs shall be provided at appropriate literacy levels.
- "(B) AWARENESS OF THE AVAILABILITY OF PROGRAMS.—To the extent practicable, the Secretary shall make relevant health care providers aware of the availability of the educational programs supported pursuant to subparagraph (A).
- "(3) Grants for quality newborn screen-Ing followup.—From funds appropriated under subsection (h), the Secretary, acting through the Associate Administrator and in consultation with the Advisory Committee, shall award grants to eligible entities to enable such entities to establish, maintain, and operate a system to assess and coordinate treatment relating to congenital, genetic, and metabolic disorders.
- "(b) APPLICATION.—An eligible entity that desires to receive a grant under this section shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require.
  - "(c) SELECTION OF GRANT RECIPIENTS.—
- "(1) IN GENERAL.—Not later than 120 days after receiving an application under subsection (b), the Secretary, after considering the approval factors under paragraph (2), shall determine whether to award the eligible entity a grant under this section.
  - "(2) APPROVAL FACTORS.—
- "(A) REQUIREMENTS FOR APPROVAL.—An application submitted under subsection (b) may not be approved by the Secretary unless the application contains assurances that the eligible entity—
- "(i) will use grant funds only for the purposes specified in the approved application and in accordance with the requirements of this section; and
- "(ii) will establish such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement and accounting of Federal funds paid to the eligible entity under the grant.
- "(B) EXISTING PROGRAMS.—Prior to awarding a grant under this section, the Secretary shall—
- "(i) conduct an assessment of existing educational resources and training programs and coordinated systems of followup care with respect to newborn screening; and
- "(ii) take all necessary steps to minimize the duplication of the resources and programs described in clause (i).
- "(d) COORDINATION.—The Secretary shall take all necessary steps to coordinate programs funded with grants received under this section.
- "(e) USE OF GRANT FUNDS.—
- "(1) Grants to assist health care professionals.—An eligible entity that receives a grant under subsection (a)(1) may use the grant funds to work with appropriate medical schools, nursing schools, schools of public health, schools of genetic counseling, internal education programs in State agencies, nongovernmental organizations, and professional organizations and societies to develop and deliver education and training programs that include—
- "(A) continuing medical education programs for health care professionals and newborn screening laboratory personnel in newborn screening;
- "(B) education, technical assistance, and training on new discoveries in newborn screening and the use of any related technology;
- "(C) models to evaluate the prevalence of, and assess and communicate the risks of,

- congenital conditions, including the prevalence and risk of some of these conditions based on family history;
- "(D) models to communicate effectively with parents and families about—
- "(i) the process and benefits of newborn screening;
- "(ii) how to use information gathered from newborn screening;
- "(iii) the meaning of screening results, including the possibility of false positive findings:
- "(iv) the right of refusal of newborn screening, if applicable; and
- "(v) the potential need for followup care after newborns are screened;
- "(E) information and resources on coordinated systems of followup care after newborns are screened;
- "(F) information on the disorders for which States require and offer newborn screening and options for newborn screening relating to conditions in addition to such disorders;
- "(G) information on additional newborn screening that may not be required by the State, but that may be available from other sources: and
- "(H) other items to carry out the purpose described in subsection (a)(1) as determined appropriate by the Secretary.
- "(2) Grants to assist families.—An eligible entity that receives a grant under subsection (a)(2) may use the grant funds to develop and deliver to parents, families, and patient advocacy and support groups, educational programs about newborn screening that include information on—
  - "(A) what newborn screening is;
  - "(B) how newborn screening is performed;
  - "(C) who performs newborn screening;
- ``(D) where newborn screening is performed;
- "(E) the disorders for which the State requires newborns to be screened;
- "(F) different options for newborn screening for disorders other than those included by the State in the mandated newborn screening program:
- "(G) the meaning of various screening results, including the possibility of false positive and false negative findings;
- "(H) the prevalence and risk of newborn disorders, including the increased risk of disorders that may stem from family history;
- "(I) coordinated systems of followup care after newborns are screened; and
- "(J) other items to carry out the purpose described in subsection (a)(2) as determined appropriate by the Secretary.
- "(3) GRANTS FOR QUALITY NEWBORN SCREEN-ING FOLLOWUP.—An eligible entity that receives a grant under subsection (a)(3) shall use the grant funds to—
- "(A) expand on existing procedures and systems, where appropriate and available, for the timely reporting of newborn screening results to individuals, families, primary care physicians, and subspecialists in congenital, genetic, and metabolic disorders;
- "(B) coordinate ongoing followup treatment with individuals, families, primary care physicians, and subspecialists in congenital, genetic, and metabolic disorders after a newborn receives an indication of the presence or increased risk of a disorder on a screening test:
- "(C) ensure the seamless integration of confirmatory testing, tertiary care medical services, comprehensive genetic services including genetic counseling, and information about access to developing therapies by participation in approved clinical trials involving the primary health care of the infant;
- "(D) analyze data, if appropriate and available, collected from newborn screenings to identify populations at risk for disorders affecting newborns, examine and respond to

health concerns, recognize and address relevant environmental, behavioral, socioeconomic, demographic, and other relevant risk factors; and

- "(E) carry out such other activities as the Secretary may determine necessary.
  - "(f) Reports to Congress.—
- "(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall submit to the appropriate committees of Congress reports—
- "(A) evaluating the effectiveness and the impact of the grants awarded under this section—
  - "(i) in promoting newborn screening—
- "(I) education and resources for families; and
- "(II) education, resources, and training for health care professionals:
- "(ii) on the successful diagnosis and treatment of congenital, genetic, and metabolic disorders; and
- "(iii) on the continued development of coordinated systems of followup care after newborns are screened;
- "(B) describing and evaluating the effectiveness of the activities carried out with grant funds received under this section; and
- "(C) that include recommendations for Federal actions to support—
- "(i) education and training in newborn screening; and
- ``(ii) followup care after newborns are screened.
- "(2) TIMING OF REPORTS.—The Secretary shall submit—
- "(A) an interim report that includes the information described in paragraph (1), not later than 30 months after the date on which the first grant funds are awarded under this section; and
- "(B) a subsequent report that includes the information described in paragraph (1), not later than 60 months after the date on which the first grant funds are awarded under this section.
- "(g) DEFINITION OF ELIGIBLE ENTITY.—In this section, the term 'eligible entity' means—
- (1) a State or a political subdivision of a State:
- "(2) a consortium of 2 or more States or political subdivisions of States:
  - "(3) a territory;
- "(4) an Indian tribe or a hospital or outpatient health care facility of the Indian Health Service: or
- "(5) a nongovernmental organization with appropriate expertise in newborn screening, as determined by the Secretary.
- "(h) NATIONAL CONTINGENCY PLAN FOR NEWBORN SCREENING.—
- "(1) IN GENERAL.—Not later than 180 days after the date of enactment of this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Associate Administrator, shall develop a national contingency plan for newborn screening for use in the event of a public health emergency
- "(2) REQUIREMENTS.—The contingency plan developed under paragraph (1) shall include a plan for—
- "(A) the collection and transport of specimens:
- "(B) the shipment of specimens to State newborn screening laboratories;
  - "(C) the processing of specimens;
- "(D) the reporting of screening results to physicians and families;
- "(E) the diagnostic confirmation of positive screening results;
- "(F) ensuring the availability of treatment and management resources;
- "(G) educating families about newborn screening; and
- "(H) carrying out other activities determined appropriate by the Secretary.

- "(i) AUTHORIZATION OF APPROPRIATIONS.— There are authorized to be appropriated to carry out this section—
- "(1) \$15,000,000 for fiscal year 2008; and
- "(2) such sums as may be necessary for each of fiscal years 2009 through 2012.".

#### SEC. 4. IMPROVED NEWBORN AND CHILD SCREENING FOR HERITABLE DIS-ORDERS.

Section 1109 of the Public Health Service Act (42 U.S.C. 300b-8) is amended—

- (1) in subsection (c)(2)-
- (A) in subparagraph (E), by striking "and" after the semicolon.
- (B) by redesignating subparagraph (F) as subparagraph (G); and
- (C) by inserting after subparagraph (E) the following:
- "(F) an assurance that the entity has adopted and implemented, is in the process of adopting and implementing, or will use grant amounts received under this section to adopt and implement the guidelines and recommendations of the Advisory Committee on Heritable Disorders in Newborns and Children established under section 1111 (referred to in this section as the 'Advisory Committee') that are adopted by the Secretary and in effect at the time the grant is awarded or renewed under this section, which shall include the screening of each newborn for the heritable disorders recommended by the Advisory Committee and adopted by the Secretary and the reporting of results; and"; and
- (2) in subsection (i), by striking "such sums" and all that follows through the period at the end and inserting "\$25,000,000 for fiscal year 2008 and such sums as may be necessary for each of the fiscal years 2009 through 2012.".

# SEC. 5. EVALUATING THE EFFECTIVENESS OF NEWBORN- AND CHILD-SCREENING PROGRAMS.

Section 1110 of the Public Health Service Act (42 U.S.C. 300b-9) is amended by adding at the end the following:

"(d) AUTHORIZATION OF APPROPRIATIONS.— There are authorized to be appropriated to carry out this section \$5,000,000 for fiscal year 2008 and such sums as may be necessary for each of the fiscal years 2009 through 2012"

# SEC. 6. ADVISORY COMMITTEE ON HERITABLE DISORDERS IN NEWBORNS AND CHILDREN.

Section 1111 of the Public Health Service Act (42 U.S.C. 300b–10) is amended—

- (1) in subsection (b)-
- (A) by redesignating paragraph (3) as paragraph (5);
- (B) in paragraph (2), by striking "and" after the semicolon:
- (C) by inserting after paragraph (2) the following:
- "(3) recommend a uniform screening panel for newborn screening programs that includes the heritable disorders for which all newborns should be screened, including secondary conditions that may be identified as a result of the laboratory methods used for screening;
- "(4) develop a model decision-matrix for newborn screening program expansion, and periodically update the recommended uniform screening panel described in paragraph (3) based on such decision-matrix; and"; and
- (D) in paragraph (5) (as redesignated by subparagraph (A)), by striking the period at the end and inserting ", including recommendations, advice, or information dealing with—
- "(A) followup activities, including those necessary to achieve rapid diagnosis in the short term, and those that ascertain long-term case management outcomes and appropriate access to related services;
- "(B) diagnostic and other technology used in screening:

- "(C) the availability and reporting of testing for conditions for which there is no existing treatment;
- "(D) minimum standards and related policies and procedures for State newborn screening programs;
- "(E) quality assurance, oversight, and evaluation of State newborn screening programs;
- "(F) data collection for assessment of newborn screening programs;
- $\mbox{``(G)}$  public and provider awareness and education;
- "(H) language and terminology used by State newborn screening programs;
- "(I) confirmatory testing and verification of positive results; and
- "(J) harmonization of laboratory definitions for results that are within the expected range and results that are outside of the expected range."; and
  - (2) by adding at the end the following:
  - "(d) Decision on Recommendations.
- "(1) IN GENERAL.—Not later than 180 days after the Advisory Committee issues a recommendation pursuant to this section, the Secretary shall adopt or reject such recommendation.
- "(2) PENDING RECOMMENDATIONS.—The Secretary shall adopt or reject any recommendation issued by the Advisory Committee that is pending on the date of enactment of the Newborn Screening Saves Lives Act of 2007 by not later than 180 days after the date of enactment of such Act.
- "(3) DETERMINATIONS TO BE MADE PUBLIC.— The Secretary shall publicize any determination on adopting or rejecting a recommendation of the Advisory Committee pursuant to this subsection, including the justification for the determination.
- "(e) CONTINUATION OF OPERATION OF COM-MITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act (5 U.S.C. App.), the Advisory Committee shall continue to operate during the 5-year period beginning on the date of enactment of the Newborn Screening Saves Lives Act of 2007."

#### SEC. 7. LABORATORY QUALITY AND SURVEIL-LANCE.

Part A of title XI of the Public Health Service Act (42 U.S.C. 300b-1 et seq.) is amended by adding at the end the following: "SEC. 1112. LABORATORY QUALITY.

- "(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Advisory Committee on Heritable Disorders in Newborns and Children established under section 1111, shall provide for—
- "(1) quality assurance for laboratories involved in screening newborns and children for heritable disorders, including quality assurance for newborn-screening tests, performance evaluation services, and technical assistance and technology transfer to newborn screening laboratories to ensure analytic validity and utility of screening tests; and
- $\lq\lq(2)$  population-based pilot testing for new screening tools for evaluating use on a mass scale.
- "(b) AUTHORIZATION OF APPROPRIATIONS.— For the purpose of carrying out this section, there are authorized to be appropriated \$5,000,000 for fiscal year 2008 and such sums as may be necessary for each of the fiscal years 2009 through 2012.

# "SEC. 1113. SURVEILLANCE PROGRAMS FOR HERITABLE DISORDERS SCREENING.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, in consultation with the Associate Administrator of the Maternal and Child Health Bureau of the Health Resources and Services Administration, shall carry out programs—

- "(1) to collect, analyze, and make available data on the heritable disorders recommended by the Advisory Committee on Heritable Disorders in Newborns and Children established under section 1111, including data on the causes of such disorders and on the incidence and prevalence of such disorders;
- "(2) to operate regional centers for the conduct of applied epidemiological research on the prevention of such disorders;
- "(3) to provide information and education to the public on the prevention of such disorders; and
- "(4) to conduct research on and to promote the prevention of such disorders, and secondary health conditions among individuals with such disorders.
  - "(b) Grants and Contracts.—
- "(1) IN GENERAL.—In carrying out subsection (a), the Secretary may make grants to and enter into contracts with public and nonprofit private entities.
- "(2) SUPPLIES AND SERVICES IN LIEU OF AWARD FUNDS.—
- "(A) IN GENERAL.—Upon the request of a recipient of an award of a grant or contract under paragraph (1), the Secretary may, subject to subparagraph (B), provide supplies, equipment, and services for the purpose of aiding the recipient in carrying out the purposes for which the award is made and, for such purposes, may detail to the recipient any officer or employee of the Department of Health and Human Services.
- "(B) REDUCTION.—With respect to a request described in subparagraph (A), the Secretary shall reduce the amount of payments under the award involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.
- "(3) APPLICATION FOR AWARD.—The Secretary may make an award of a grant or contract under paragraph (1) only if an application for the award is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out the purposes for which the award is to be made.
- "(c) BIENNIAL REPORT.—Not later than February 1 of fiscal year 2008 and of every second such year thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report that, with respect to the preceding 2 fiscal years—
- "(1) contains information regarding the incidence and prevalence of heritable disorders and the health status of individuals with such disorders and the extent to which such disorders have contributed to the incidence and prevalence of infant mortality and affected quality of life;
- "(2) contains information under paragraph (1) that is specific to various racial and ethnic groups (including Hispanics, non-Hispanic whites, Blacks, Native Americans, and Asian Americans);
- "(3) contains an assessment of the extent to which various approaches of preventing heritable disorders and secondary health conditions among individuals with such disorders have been effective;
- "(4) describes the activities carried out under this section;
- "(5) contains information on the incidence and prevalence of individuals living with heritable disorders, information on the health status of individuals with such disorders, information on any health disparities experienced by such individuals, and rec-

- ommendations for improving the health and wellness and quality of life of such individuals:
- "(6) contains a summary of recommendations from all heritable disorders research conferences sponsored by the Centers for Disease Control and Prevention; and
- "(7) contains any recommendations of the Secretary regarding this section.
- "(d) APPLICABILITY OF PRIVACY LAWS.—The provisions of this section shall be subject to the requirements of section 552a of title 5, United States Code. All Federal laws relating to the privacy of information shall apply to the data and information that is collected under this section.
  - "(e) COORDINATION.
- "(1) IN GENERAL.—In carrying out this section, the Secretary shall coordinate, to the extent practicable, programs under this section with programs on birth defects and developmental disabilities authorized under section 317C.
- "(2) PRIORITY IN GRANTS AND CONTRACTS.— In making grants and contracts under this section, the Secretary shall give priority to entities that demonstrate the ability to coordinate activities under a grant or contract made under this section with existing birth defects surveillance activities.
- "(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated \$15,000,000 for fiscal year 2008 and such sums as may be necessary for each of the fiscal years 2009 through 2012.".

Mr. HATCH. I am pleased to introduce today, along with my colleague Senator Christopher Dodd, the Newborn Screening Saves Lives Act of 2007.

Every State and U.S. territory routinely screens newborns for certain genetic, metabolic, hormonal and functional disorders. Most of these birth defects have no immediate visible effects on a baby but, unless detected and treated early, can cause physical problems, mental retardation and, in some cases, death

Babies who have these diseases and babies who do not have these diseases look the same at birth. Fortunately, most babies are given a clean bill of health when tested. In cases where babies are found to have metabolic disorders or hearing impairment, early diagnosis and proper treatment can make the difference between healthy development and lifelong impairment.

Except for hearing screening, all newborn screening tests are done using a few drops of blood from the newborn's heel. Newborn screening checks for diseases that can cause problems with the way the body gets energy, how the body makes hormones, or how the body makes blood cells.

Currently each state or region operates by law its own newborn screening program. Individual programs vary widely in the number and types of conditions for which they test. According to the National Newborn Screening and Genetics Resources Center, some States test for as few as four disorders, while others test for 30 or more.

Disparities among States in screening tests given at birth result in too many babies with serious birth defects not being diagnosed and treated in time to avoid death or long term disability. Many States offer only limited

educational materials for parents and health care providers about the availability of newborn screening tests; therefore parents are often unaware of the importance of testing and may learn too late that their newborn has an abnormal metabolic condition which could have been treated.

In 2004, the American College of Medical Genetics completed a report commissioned by the Department of Health and Human Services which recommended that every baby born in the United States be screened for 29 disorders, including certain metabolic conditions and hearing deficiency. Currently, only 11 States and the District of Columbia require the recommended screening for all 29 disorders.

Last year there was much success in improving newborn screening in my home State of Utah, which increased testing from 4 to 36 disorders. The expansion of newborn screening is a major advancement for children's healthcare in Utah, as the screening should identify an additional 15 to 20 than infants every year in time to help them get the treatment they need to live a fuller and healthier life.

Enactment of the Newborn Screening Saves Lives Act would provide necessary resource materials to educate parents and health providers about newborn screening and help states expand and improve their newborn screening programs. Other important provisions of this legislation help ensure the quality of laboratories involved in newborn screening and call for establishing a system for collecting and analyzing data from newborn screening programs.

The bill will establish grant programs to provide for education and outreach on newborn screening and coordinated follow-up care once newborn screening has been conducted. It will help States expand and improve their newborn screening programs, educate parents and providers and improve follow-up care for infants. The bill also contains provisions for a contingency plan for newborn screening in the case of a national public health emergency, such as that which was witnessed in the wake of Hurricanes Katrina and Rita.

The Newborn Screening Saves Lives Act of 2007 is endorsed by the March of Dimes, the American Academy of Pediatrics, Easter Seals, and the American Public Health Labs. These groups recognize that expanded newborn screening will help pediatricians and other healthcare providers identify rare disorders than can be easily confused with common pediatric problems. Diagnosing and treating these conditions will help prevent irreversible brain damage, permanent disabilities, and possibly death. I urge my colleagues to take a stand for newborn health and support this bill.

#### By Mr. SCHUMER:

S. 636. A bill to amend the Internal Revenue Code of 1986 to extend the reporting period for certain statements sent to taxpayers; to the Committee on Finance.

Mr. SCHUMER. Mr. President, I rise today to introduce the "Reduce Wasteful Tax Forms Act of 2007." This bill extends the deadline from January 31 to February 15 for certain types of 1099 forms to be sent to taxpayers. 1099 forms are used to report non-wage income, such as income from dividends and capital gains. These forms are distributed by brokerage firms and financial institutions to their investors, who must report the information on their income tax returns.

Due to recent changes in tax laws that govern income from interest and dividends, there has been a significant increase in the number of inaccurate forms sent out by firms in order to meet the January 31 deadline. The problem is that much of the tax data for certain types of investment income cannot be calculated until after the first of the year, resulting in a compressed window for calculating data in compliance with the new laws and mailing the forms. Once accurate data becomes available, financial institutions must send taxpavers an amended form with the correct information.

These amended forms create confusion for taxpavers, and in some cases. those who receive an amended 1099 may have to re-file their taxes. If taxpayers underpaid in their initial return, they could face interest charges and penalties if they do not file again before the April 15 deadline. The January 31 deadline results in tons of wasted paper, confusion for taxpayers, and wasted expenses incurred in sending the amended forms.

This problem affects an increasing number of taxpayers. According to recent press reports in the Wall Street Journal and USA Today, prior to 2003, an average of 5 to 8 percent of 1099 forms required correcting. That number has since jumped to an average of 13 percent, translating into millions of amended 1099s being sent to taxpayers each year.

My legislation would extend the deadline for sending 1099 forms to taxpayers to February 15, by which time the vast majority of required data will be available to ensure the accuracy of the forms. The bill extends the deadline only for certain types of 1099 forms used to report investment income; it would not extend the deadline for 1099 forms sent to independent contractors or for statements that only report interest earned on bank deposits. Accordingly, this extension will not delay filing for the vast majority of taxpayers.

This year, the IRS granted several brokerage firms an extension to the January 31 deadline. However, this bill would provide a permanent extension for all firms and financial institutions to remove the uncertainty for taxpayers that arises due to this unnecessarily early deadline. My bill will help taxpayers by reducing confusion, the financial industry by cutting costs and waste, and the environment by eliminating millions of unnecessary mailings.

I hope that my colleagues will join me in supporting this legislation, and I look forward to working with other Finance Committee members to have it considered during the 110th Congress. Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

#### S. 636

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.

#### SECTION 1. SHORT TITLE.

This Act may be cited as the "Reduce Wasteful Tax Forms Act of 2007"

#### SEC. 2. EXTENSION OF REPORTING PERIOD FOR CERTAIN STATEMENTS SENT TO TAXPAYERS.

- (a) IN GENERAL.—The following provisions of the Internal Revenue Code of 1986 are each amended by striking "January 31" and inserting "February 15". serting "February 15"
- (1) Subsection (c) of section 6042 (returns regarding payments of dividends and corporate earnings and profits).
- (2) Subsection (d) of section 6043A (returns relating to taxable mergers and acquisitions).
- (3) Subsection (e) of section 6044 (returns regarding payments of patronage dividends). (4) Subsection (b) of section 6045 (returns of
- brokers).
- (5) Subsection (b) of section 6050N (returns regarding payments of royalties).
- (b) STATEMENTS REGARDING CERTAIN RE-TURNS RELATING TO SECURITIES.—Section 6041(d) of the Internal Revenue Code of 1986 is amended by striking "January 31" and inserting "January 31 (February 15, in the case of statements regarding returns relating to payments made by financial institutions to customers in connection with securities (including securities lending))".
- (c) STATEMENTS RELATING TO CERTAIN SUB-STITUTE PAYMENTS.—Section 6045(d) of the Internal Revenue Code of 1986 is amended—
- (1) by striking "at such time and", and (2) by inserting after "other item." the following new sentence: "The written statement required under the preceding sentence shall be furnished on or before February 15 of the year following the calendar year during which such payment was made."
- (d) STATEMENTS REGARDING CERTAIN RE-PORTS BY EMPLOYERS AND PLAN ADMINISTRA-TORS.—Section 6047(d)(2) of the Internal Revenue Code of 1986 is amended by inserting ". except that any report to any person other than the Secretary shall be furnished on or before February 15 of the year following the calendar year for which the report under paragraph (1) was required to be made" after 'regulations''.
- (e) CERTAIN STATEMENTS RELATING TO IN-TEREST PAYMENTS.—Section 6049(c)(2)(A) of the Internal Revenue Code of 1986 is amended by striking "January 31" and inserting "February 15 (January 31, in the case of any statement regarding a return relating to payments of interest made by any obligor described in subparagraph (B) or (C) of subsection (b)(1), unless such statement is combined in a statement the due date for which is February 15)".
- (f) EFFECTIVE DATE.—The amendments made by this section shall apply to returns, reports, and other statements the due date for which (determined without regard to extensions) is after December 31, 2007.

By Mr. DURBIN (for himself, Mr. KERRY, and Mr. MENENDEZ):

S. 642. A bill to codify Executive Order 12898, relating to environmental justice, to require the Administrator of the Environmental Protection Agency to fully implement the recommendations of the Inspector General of the Agency and the Comptroller General of the United States, and for other purposes: to the Committee on Environment and Public Works.

Mr. DURBIN. Mr. President, today I introduce, with Senators Kerry and MENENDEZ, an environmental justice bill that will help protect the wellbeing of minority and low-income communities throughout the United States.

In 1994, President Clinton issued an Executive Order instructing Government agencies to develop strategies to identify and address environmental inequities that might be created through agency programs. The Executive Order recognized that low-income and minority communities often end up with more than their fair share of pollution, associated health risks and environmental degradation.

More advantaged communities—with strong advocates, more resources, and better access to information—are less likely to have landfills, petrochemical plants, or waste incinerators built in their neighborhoods.

Unfortunately, the U.S. Environmental Protection Agency has not honored the 1994 Executive Order and the goal of environmental justice has not been met. In a March 2004 report, the EPA Inspector General concluded that the agency "has not fully implemented Executive Order 12898 nor consistently integrated environmental justice into its day-to-day operations. EPA has not identified minority and low-income [populations] . . . and has neither defined nor developed criteria for determining [who is] disproportionately impacted. Moreover, in 2001, the Agency restated its commitment to environmental justice in a manner that does not emphasize minority and low-income populations, the intent of the Executive Order."

Today, with the introduction of the Environmental Justice Act of 2007, we ask Congress to codify the Executive Order. The legislation also directs the EPA to implement recommendations in this area from both the EPA Inspector General and the Government Accountability Office. The recommendations include creating offices to review programs and policies for environmental justice implications, training staff to address environmental justice concerns in the rule making process and specifically assessing the impacts of future regulation and enforcement on the communities most at risk to human and environmental health problems. Finally, the bill establishes reporting requirements for the implementation of the recommendations.

I am pleased that our legislation currently has the support of 18 organizations, including: Earthjustice; Lawyers' Committee for Civil Rights Under Law; Center for Health, Environment and Justice; Natural Resources Defense Council; Advocates for Environmental Human Rights and Labor Council for Latin American Advancement.

The bill we are introducing today is an important step toward shifting the balance of environmental hazards, so the burden is not shouldered unfairly by low-income and minority communities.

I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

#### S. 642

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

#### SECTION 1. SHORT TITLE.

This Act may be cited as the "Environmental Justice Act of 2007".

### SEC. 2. CODIFICATION OF EXECUTIVE ORDER 12898.

- (a) IN GENERAL.—The President of the United States is authorized and directed to execute, administer and enforce as a matter of Federal law the provisions of Executive Order 12898, dated February 11, 1994, ("Federal Actions To Address Environmental Justice In Minority Populations and Low-Income Populations") with such modifications as are provided in this section.
- (b) DEFINITION OF ENVIRONMENTAL JUSTICE.—For purposes of carrying out the provisions of Executive Order 12898, the following definitions shall apply:
- (1) The term "environmental justice" means the fair treatment and meaningful involvement of all people regardless of race, color, national origin, educational level, or income with respect to the development, implementation, and enforcement of environmental laws and regulations in order to ensure that—
- (A) minority and low-income communities have access to public information relating to human health and environmental planning, regulations and enforcement; and
- (B) no minority or low-income population is forced to shoulder a disproportionate burden of the negative human health and environmental impacts of pollution or other environmental hazard.
- (2) The term "fair treatment" means policies and practices that ensure that no group of people, including racial, ethnic, or socioeconomic groups bear disproportionately high and adverse human health or environmental effects resulting from Federal agency programs, policies, and activities.
- (c) JUDICIAL REVIEW AND RIGHTS OF ACTION.—The provisions of section 6-609 of Executive Order 12898 shall not apply for purposes of this Act.

# SEC. 3. IMPLEMENTATION OF RECOMMENDATIONS BY ENVIRONMENTAL PROTECTION AGENCY.

- (a) INSPECTOR GENERAL RECOMMENDATIONS.—The Administrator of the Environmental Protection Agency shall, as promptly as practicable, carry out each of the following recommendations of the Inspector General of the agency as set forth in report # 2006-P-00034 entitled "EPA needs to conduct environmental justice reviews of its programs, policies and activities":
- (1) The recommendation that the agency's program and regional offices identify which programs, policies, and activities need environmental justice reviews and require these offices to establish a plan to complete the necessary reviews.

- (2) The recommendation that the Administrator of the agency ensure that these reviews determine whether the programs, policies, and activities may have a disproportionately high and adverse health or environmental impact on minority and low-income populations.
- (3) The recommendation that each program and regional office develop specific environmental justice review guidance for conducting environmental justice reviews.
- (4) The recommendation that the Administrator designate a responsible office to compile results of environmental justice reviews and recommend appropriate actions.
- (b) GAO RECOMMENDATIONS.—In developing rules under laws administered by the Environmental Protection Agency, the Administrator of the Agency shall, as promptly as practicable, carry out each of the following recommendations of the Comptroller General of the United States as set forth in GAO Report numbered GAO-05-289 entitled "EPA Should Devote More Attention to Environmental Justice when Developing Clean Air Rules":
- (1) The recommendation that the Administrator ensure that workgroups involved in developing a rule devote attention to environmental justice while drafting and finalizing the rule.
- (2) The recommendation that the Administrator enhance the ability of such workgroups to identify potential environmental justice issues through such steps as providing workgroup members with guidance and training to helping them identify potential environmental justice problems and involving environmental justice coordinators in the workgroups when appropriate.
- (3) The recommendation that the Administrator improve assessments of potential environmental justice impacts in economic reviews by identifying the data and developing the modeling techniques needed to assess such impacts.
- (4) The recommendation that the Administrator direct appropriate agency officers and employees to respond fully when feasible to public comments on environmental justice, including improving the agency's explanation of the basis for its conclusions, together with supporting data.
- (c) 2004 INSPECTOR GENERAL REPORT.—The Administrator of the Environmental Protection Agency shall, as promptly as practicable, carry out each of the following recommendations of the Inspector General of the agency as set forth in the report entitled "EPA Needs to Consistently Implement the Intent of the Executive Order on Environmental Justice" (Report No. 2004-P-00007):
- (1) The recommendation that the agency clearly define the mission of the Office of Environmental Justice (OEJ) and provide agency staff with an understanding of the roles and responsibilities of the office.
- (2) The recommendation that the agency establish (through issuing guidance or a policy statement from the Administrator) specific time frames for the development of definitions, goals, and measurements regarding environmental justice and provide the regions and program offices a standard and consistent definition for a minority and low-income community, with instructions on how the agency will implement and operationalize environmental justice into the agency's daily activities.
- (3) The recommendation that the agency ensure the comprehensive training program currently under development includes standard and consistent definitions of the key environmental justice concepts (such as "low-income", "minority", and "disproportionately impacted") and instructions for implementation of those concepts.

(d) Report.—The Administrator shall submit an initial report to Congress within 6 months after the enactment of this Act regarding the Administrator's strategy for implementing the recommendations referred to in subsections (a), (b), and (c). Thereafter, the Administrator shall provide semi-annual reports to Congress regarding his progress in implementing such recommendations as well as his progress on modifying the Administrator's emergency management procedures to incorporate environmental justice in the agency's Incident Command Structure (in accordance with the December 18, 2006, letter from the Deputy Administrator to the Acting Inspector General of the agency).

#### By Mr. AKAKA:

S. 643. A bill to amend section 1922A of title 38, United States Code, to increase the amount of supplemental insurance available for totally disabled veterans; to the Committee on Veterans' Affairs.

Mr. AKAKA. Mr. President, today I introduce the Disabled Veterans Insurance Improvement Act of 2007. The legislation would increase the amount of supplemental life insurance available to totally disabled veterans from \$20,000 to \$40,000. Many totally disabled veterans find it difficult to obtain commercial life insurance. These are the veterans we are trying to help with this legislation by providing them with a reasonable amount of life insurance coverage.

VA's Service-Disabled Veterans' Insurance, commonly known as S-DVI, was established during the Korean War to provide life insurance for veterans with service-connected disabilities. This \$10,000 benefit has never been increased.

In comparison, the Servicemembers' Group Life Insurance and Veterans' Group Life Insurance benefits, which were \$10,000 and \$20,000 respectively at their inception, have been increased over time to \$400,000. The most recent increases to these programs have been in response to public sentiment and the determination by Congress that the amount provided to the beneficiaries of servicemembers who die while fighting in Operations Enduring Freedom and Iraqi Freedom is insufficient.

Congress increased In 1992. amount of life insurance available to S-DVI policyholders by offering \$20,000 worth of supplemental coverage to those who are considered totally disabled. Forty percent of the veterans enrolled in the S-DVI program are considered totally disabled and are eligible for a premium waiver for their basic coverage. In fiscal year 2006, thirty-two percent of veterans granted new policy waivers also opted to pay for this supplemental coverage. Even with \$30,000 in coverage, the amount of life insurance available to disabled veterans falls well short of the death benefits available to servicemembers and veterans enrolled in the Servicemembers' Group Life Insurance and Veterans' Group Life Insurance programs.

The 2001 Congressionally mandated study entitled Program Evaluation of Benefits for Survivors of Veterans with Service-Connected Disabilities found the lowest area of veteran satisfaction to be the maximum amount of coverage that veterans were authorized to purchase. My bill would allow totally disabled veterans to purchase an additional \$20.000 in insurance coverage.

I ask my colleagues to support the Disabled Veterans Insurance Improvement Act of 2007. This is a modest and affordable way of increasing the life insurance coverage for those veterans with the greatest need. I realize that there are paygo implications associated with this legislation and I am actively looking for ways to pay for this bill.

I request unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

#### S 643

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.

#### SECTION 1. SHORT TITLE.

This Act may be cited as the "Disabled Veterans Insurance Act of 2007".

# SEC. 2. SUPPLEMENTAL INSURANCE FOR TOTALLY DISABLED VETERANS.

Section 1922A(a) of title 38, United States Code, is amended by striking "\$20,000" and inserting "\$40,000".

#### By Mr. COLEMAN:

S. 646: A bill to increase the nursing workforce; to the Committee on the Judiciary.

Mr. COLEMAN. Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

#### S. 646

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled

#### SECTION 1. SHORT TITLE.

This Act may be cited as the "Rural Nursing Promotion Act".

## SEC. 2. ESTABLISHMENT OF A NURSE DISTANCE EDUCATION PILOT PROGRAM.

- (a) IN GENERAL.—The Secretary of Health and Human Services, in conjunction with the Secretary of Education, shall establish a Nurse Distance Education Pilot Program through which grants may be awarded for the conduct of activities to increase accessibility to nursing education.
- (b) PURPOSE.—The purpose of the Nurse Distance Education Pilot Program established under subsection (a) shall be to increase accessibility to nursing education to—
- (1) provide assistance to individuals in rural areas who want to study nursing to enable such individuals to receive appropriate nursing education;
- (2) promote the study of nursing at all educational levels;
- (3) establish additional slots for nursing students at existing nursing education programs; and
- (4) establish new nursing education programs at institutions of higher education.
- (c) APPLICATION.—To be eligible to receive a grant under the Pilot Program under subsection (a), an entity shall submit to the Secretary of Health and Human Services an

application at such time, in such manner, and containing such information as the Secretary may require.

(d) AUTHORIZATION OF APPROPRIATIONS.— There is authorized to be appropriated, such sums as may be necessary to carry out this section.

#### SEC. 3. INCREASING THE DOMESTIC SUPPLY OF NURSES AND PHYSICAL THERA-PISTS

- (a) Not later than January 1, 2008, the Secretary of Health and Human Services, in conjunction with the Secretary of Education, shall—
- (1) submit to Congress a report concerning the source of newly licensed nurses and physical therapists in each State, that shall include—
- (A) for the most recent 3-year period for which data is available—
- (i) separate data relating to teachers at institutions of higher education for each related occupation who have been teaching for not more than 5 years; and
- (ii) separate data relating to all teachers at institutions of higher education for each related occupation regardless of length of service;
- (B) for the most recent 3-year period for which data is available, separate data for each related occupation and for each State:
- (C) a description of the barriers to increasing the supply of nursing faculty, domestically trained nurses, and domestically trained physical therapists;
- (D) separately identify those individuals receiving their initial nursing license and those individuals licensed by endorsement from another State;
- (E) with respect to those individuals receiving their initial nursing license in each year, a description of the number of individuals who received their professional education in the United States and the number of individuals who received such education outside the United States;
- (F) to the extent practicable, a description, by State of residence and country of education, of the number of nurses and physical therapists who were educated in any of the 5 countries (other than the United States) from which the most nurses and physical therapists arrived;
- (G) recommendations of strategies to be utilized by Federal and State governments that would be effective in removing the barriers described in subparagraph (C), including strategies that address barriers to advancement to become registered nurses for other health care workers, such as home health aides and nurses assistants:
- (H) recommendations for amendments to Federal laws that would increase the supply of nursing faculty, domestically trained nurses, and domestically trained physical therapists:
- (I) recommendations for Federal grants, loans, and other incentives that would provide increases in nurse educators and nurse training facilities, and other measures to increase the domestic education of new nurses and physical therapists;
- (J) identify the effects of nurse emigration on the health care systems in their countries of origin; and
- (K) recommendation for amendments to Federal law that would minimize the effects of health care shortages in the countries of origin from which immigrant nurses arrived;
- (2) enter into a contract with the Institute of Medicine of the National Academy of Sciences for the conduct of a study, and submission of a report, to determine the level of Federal investment under titles VII and VIII of the Public Health Service Act (42 U.S.C. 292 and 296 et seq.) that is necessary to eliminate the domestic nursing and physical therapist shortage by the date that is not later

than 7 years after the date on which the report is submitted; and

- (3) collaborate with the heads of other Federal agencies, as appropriate, in working with ministers of health or other appropriate officials of the 5 countries from which the most nurses and physical therapists arrived into the United States, to—
- (A) address health worker shortages caused by emigration; and
- (B) ensure that there is sufficient human resource planning or other technical assistance needed to reduce further health worker shortages in such countries.

#### SEC. 4. SHORTAGE OCCUPATIONS.

- (a) EXCEPTION TO DIRECT NUMERICAL LIMITATIONS.—Section 201(b)(1) of the Immigration and Nationality Act (8 U.S.C. 1151(b)(1)) is amended by adding at the end the following new subparagraph:
- "(F)(i) During the period beginning on the date of the enactment of the Rural Nursing Promotion Act and ending on September 30, 2017, an alien—
- "(I) who is described in section 203(b); and "(II) who is seeking admission to the United States to perform labor in shortage occupations designated by the Secretary of Labor for certification under section 212(a)(5)(A) due to the lack of sufficient United States workers able, willing, qualified, and available for such occupations and for which the employment of aliens will not adversely affect the terms and conditions of similarly employed United States workers.
- "(ii) During the period described in clause (i), the spouse or dependent of an alien described in clause (i), if accompanying or following to join such alien.".
- (b) EXCEPTION TO NONDISCRIMINATION REQUIREMENTS.—Section 202(a)(1)(A) of the Immigration and Nationality Act (8 U.S.C. 1152(a)(1)(A)) is amended by striking "201(b)(2)(A)(i)" and inserting "201(b)".
- (c) EXCEPTION TO PER COUNTRY LEVELS FOR FAMILY-SPONSORED AND EMPLOYMENT-BASED IMMIGRANTS.—Section 202(a)(2) of the Immigration and Nationality Act (8 U.S.C. 1152(a)(2)), is amended by inserting ", except for aliens described in section 201(b)," after "any fiscal year".
- (d) PROCEDURE FOR GRANTING IMMIGRANT STATUS.—Section 204 of the Immigration and Nationality Act (8 U.S.C. 1154) is amended by adding at the end the following new subsection:
- "(1) The Secretary of Homeland Security shall provide a process for reviewing and making a determination upon a petition filed with respect to an alien described in section 201(b)(1)(F) not later than 30 days after the date a completed petition has been filed for such alien."

# By Mr. WYDEN (for himself and Mr. SMITH):

S. 647. A bill to designate certain land in the State of Oregon as wilderness, and for other purposes; to the Committee on Energy and Natural Resources.

Mr. WYDEN. Mr. President, it has been more than 200 years since Lewis and Clark first laid eyes on Mount Hood. Today, I propose, with Senator SMITH, that the spectacular mountain, seen first by our pioneers, should be preserved for all time.

The Lewis and Clark Mount Hood Wilderness Act of 2007, which we introduce today, is similar to the bill Senator SMITH and I introduced in the last Congress. It does include several improvements that came about from comments and constructive suggestions

from a variety of groups at home in Oregon.

The legislation also includes input from the Energy and Natural Resources Committee. We appreciate their input and believe their views can help speed the bill's passage.

In tribute to the great river-dependent journey of Lewis and Clark, our legislation adds nine free-flowing stretches of rivers to the National Wild and Scenic River System. This reflects the views of Oregonians, but, frankly, I hear it from folks in the Midwest, where the Presiding Officer lives, and from people from every nook and cranny in this country who have all come to treasure our spectacular mountain.

This legislation contains a number of provisions of the original Mount Hood legislation I introduced in 2004. The bill protects the lower elevation forests surrounding Mount Hood and the Columbia River Gorge as Lewis and Clark saw them. These forests embody the natural beauty of our home State. They provide the clean water necessary the survival of threatened steelhead, Coho, and Chinook salmon. They provide critical habitat and diverse ecosystems for elk, deer, lynx, and the majestic bald eagle. These are the forests that provide unparalleled recreational opportunities for Oregonians and the scores and scores of visitors we get from Minnesota and every other part of the country as well.

But the legislation I offer today with Senator SMITH differs from the bill I introduced several years ago because it responds to the many comments we have heard. We have received thousands of comments on our proposed legislation. Some comments came as a result of the general public meetings I held at home in Oregon. Many of the meetings lasted over 3 hours. Everybody who wanted to speak was given the opportunity to do so. Other comments came from the second Mount Hood summit that was held at Timberline Lodge, hosted by Congressmen WALDEN and BLUMENAUER. My staff and I met with over 100 community groups and local governments, the members of the Oregon congressional delegation, the Governor, and the Bush administration. More comments came from calls and letters from Oregonians who are saying that now, now, now is the time to preserve Mount Hood.

Overwhelmingly, these comments have urged that we build on Oregon's wilderness system. This goal is as important today as it was in 1804, when Lewis and Clark first viewed Mount Hood; in 1964, when the Wilderness Act was passed; or in 1984, when wilderness protections were last designated on Mount Hood. It is time to plan now to protect this treasure for future generations

The Mount Hood National Forest is the seventh most visited national forest in our country. In the 22 years that have elapsed since any new wilderness has been designated on Mount Hood, the population in the local counties has increased significantly—25 percent in Multnomah County, 24 percent in Hood River County, and 28 percent in Clackamas County.

The predominant public use of this urban forest is nonmechanized activities such as hiking, camping, and fishing. With increasing emphasis on wild scenery, unspoiled wildlife habitats, free-flowing rivers, wilderness, and the need for opportunities for diverse outdoor recreation, sometimes it seems we are in jeopardy of loving our wild places to death. We all see Americans coming together to make sure the most special places are protected for future generations.

A few years ago, the Forest Service made a proposal to limit the number of people who could hike on the south side of Mount Hood. Suffice it to say, the public outcry in opposition was enormous. It seems to me, rather than tell people they are going to be restricted from using our public lands, part of the solution for Mount Hood lies in providing more opportunities for them to enjoy the mountain's great places. We ought to ensure that the Mount Hood National Forest can meet the increased demand for outdoor experiences, and the legislation I offer today with Senator SMITH provides these opportunities. Hundreds of people spoke at the public meetings I held throughout the State. I have received 2,500 written comments urging additional wilderness on Mount Hood. There are a few key areas the citizens continually come back and refer to:

First, by astonishing numbers, they want to see additional wilderness on Mount Hood. A large number of Oregonians didn't think enough wilderness had been included, for example, in the legislation that was considered by the other body.

A second area is mountain biking. Some mountain bikers expressed concern that their recreation opportunities not be unfairly curtailed. Senator SMITH and I had many discussions with them to ensure that would not be the case.

Third, fire protection and forest health was something referred to by many Oregonians. Citizens were concerned about the health of the forest. Those living in towns on the mountain and the gorge were concerned about fire protection in their communities, and we sought to address those issues as well.

An additional concern was developed recreation, with some citizens worried about maintaining a role for developed recreation, such as skiing, on Mount Hood.

In each of these areas, Senator SMITH and I tried to follow up and be responsive to what citizens at home were saying.

With respect to additional wilderness, there are currently 189,200 acres of designated wilderness in the Mount Hood National Forest. This bill increases wilderness on Mount Hood by designating approximately 128,000 acres of new wilderness.

The bill adds the areas surrounding the oldest Mount Hood wilderness—the mountain itself—which was designated in the original Wilderness Act of 1964. These additions include cathedral old growth forests, special trails, lava beds that were created during the Mount Hood eruptions, and much of the legendary route that Oregon's pioneers used when they came to our great State.

To the north and west of the mountain, we add the viewshed of the Columbia Gorge to the current Mark O. Hatfield Wilderness. These areas encompass the spectacular ridges that frame the gorge that we marvel at from I-84 and include perhaps the greatest concentration of waterfalls in all of North America.

To the southwest of the mountain, we add lands to the current Salmon Huckleberry Wilderness to conserve their diverse wildlife and protect unique recreational areas such as those around the extremely popular Mirror Lake. These lands include Alder Creek, the source of drinking water for the city of Sandy, and that city unanimously endorsed the draft proposal.

Over to the east are proposed additions to the Badger Creek Wilderness area. These areas provide a critical link between westside forests and eastside ecosystems. This area is known for its spectacular colors in the fall and the best deer and elk hunting in our entire Mount Hood National Forest.

Among the areas we are protecting is the newly designated Richard L. Kohnstamm Memorial area. It is dedicated in honor of Mr. Kohnstamm who restored the historic Timberline Lodge built originally by the Works Progress Administration in 1937. Our new 2007 bill adds 2,730 acres of Marion County lands in the Bull of the Woods Wilderness Additions, while removing lands where users identified potential conflicts.

Second, in the area of wild and scenic rivers, we protect over 79 miles of wild and scenic rivers on nine free-flowing rivers. This protects some of the most pristine rivers in our State. Among those proposed rivers are the picturesque waterfalls and glacial outwash of the East Fork of the Hood River, and the ancestral hunting and fishing grounds of Fish Creek. Over 17 miles of extraordinary salmon and steelhead habitat on the Collowash River have also been added for protection under our legislation.

Mountain biking is an area where there has been a lot of debate. We believed the local riders raised valid concerns, and we took two steps. First, we proposed the Mount Hood National Recreation Area. This area was so popular in our last bill that Senator SMITH and I decided to greatly expand it to include 34,640 acres, an increase of over 16,000 additional acres. It is going to offer permanent environmental protection to those beautiful areas, while

providing mountain bikers, recreational users, and others an opportunity to enjoy recreation on the mountain.

Additionally, I made boundary adjustments to ensure that all open mountain biking trails were not included in this proposed legislation.

With respect to fire protection and forest health, we tried to make clear that where there are healthy, older trees, they should not be harvested on Mount Hood or in the gorge. Older healthy stands are most resistant to fire and disease. However, there is an enormous backlog of overcrowded plantation, second growth that really ought to be thinned. The legislation includes provisions that would give the Forest Service a mandate to prepare an assessment for promoting forests resilient to fire, insects, and disease. This also includes provisions to study and encourage the development of biomass in conjunction with forest health work.

We happen to think that biomass is one of the most exciting new fields for Oregonians to get into. The opportunity to generate clean energy, help small rural communities, create family wage jobs, is something that we should not miss out on. This legislation tries to tap the potential for progress in the biomass field as well.

Finally, we add fire-safe community zones so that the Secretary of Agriculture will construct a system of fire-safe buffer zones around the communities of Cascade Locks and Government Camp.

With respect to developed recreation, we wanted to facilitate recreational opportunities in this area and thus adopted a provision that came from the other body known as "fee retention" that would establish a special account for the Mount Hood National Forest.

In addition, in order to help address growth while ensuring access to recreational opportunities, we have adopted provisions originally coming, again, from language from the other body directing the Secretary of Agriculture and the State of Oregon to develop an integrated transportation plan for the Mount Hood region.

I commend particularly my colleague in the other body, Congressman BLU-MENAUER, one of the real pioneers in thinking about transportation.

Finally, with respect to key relationships with our tribes and our local governmental bodies, we have incorporated provisions on local and tribal relationships, emphasizing the rich history of the Mount Hood area and affirming the rights of Native peoples to access the mountains as they have for generations.

The protections of these important Oregon places is going to depend on the hard work and dedication of all Oregonians. I am very pleased—I am summing up, and the Senate has been patient in giving me this extra time—to say that this has been a bipartisan effort by the Oregon congressional delegation. Senator SMITH joins me in in-

troducing this legislation. We believe this brings together our county commissioners, entrepreneurs, environmentalists, Chamber of Commerce, State-elected officials, the Governor. All of those who feel so strongly about protecting Mount Hood rolled up their sleeves, went to work, and joined myself and Senator SMITH to try to find common ground to make sure that Mount Hood would be protected for all time

We are looking forward to perfecting the legislation together in the coming weeks and looking forward to seeing a swift adoption by Congress.

The grandeur of Mount Hood and our special treasures is pretty much in the chromosomes of Oregonians. Protecting our treasures is something about which we feel so strongly. Today is a special day for us because, once again, the citizens of our State have come together and have worked with myself and Senator SMITH to take action to protect our treasures.

Mr. President, Oregon's Mount Hood is a cherished State treasure. This wild place is often photographed, visited and enjoyed by scores of Oregonians and non-Oregonians. Today, I am introducing, along with my colleague Senator SMITH, a bi-partisan Oregon Wilderness bill: the "Lewis and Clark Mount Hood Wilderness Act of 2007." This bill is similar to the one Senator SMITH and I introduced in the last Congress, but it includes several improvements that resulted from comments received from stakeholders. The bill also includes input from the Energy and Natural Resources Committee, which we hope will help speed the bill's passage. In tribute to the great riverdependent journey of Lewis and Clark, our legislation adds nine free-flowing stretches of rivers to the National Wild and Scenic River System. This reflects the Oregonian wish to protect but also actively experience our State's treasures

This bill contains many elements of the Mount Hood bill I introduced in 2004, while also incorporating many new provisions to protect and improve the Mount Hood region. This bill protects the lower elevation forests surrounding Mount Hood and the Columbia River Gorge as Lewis and Clark saw them. These forests embody the natural beauty of Oregon. They provide the clean water necessary for the survival of threatened steelhead, Coho and Chinook salmon. These forests provide critical habitat and diverse ecosystems for elk, deer, lynx and the majestic bald eagle. And these are the forests that provide unparalleled recreational opportunities for Oregonians and our visitors.

But the bill I introduce today differs from the bill I introduced 2 years ago because it responds to the many comments I heard in the ensuing years. I received thousands of comments on proposed Mount Hood legislation. Some comments came as a result of the general public meetings I held in Oregon.

Many of the meetings lasted over 3 hours, and everyone who wanted to speak was given an opportunity to do so. Other comments came from the second Mount Hood Summit held at Timberline Lodge hosted by Representatives WALDEN and BLUMENAUER. I and my staff met with over 100 community groups and local governments, the members of the Oregon congressional delegation, the Governor, and the Bush administration. And still more comments came from letters and phone calls from Oregonians.

Overwhelmingly, these comments urged me to protect and build on Oregon's Wilderness system. This goal is as important today as it was in 1804, when Lewis and Clark first viewed Mount Hood, 1964, when the Wilderness Act was passed, or 1984, when wilderness protections were last designated on Mount Hood—if not more so. To succeed, we must provide the tools that help us create a planned future on Mount Hood. This bill does both.

The Mount Hood National Forest is the seventh most visited National Forest in the United States. In the 22 years that have elapsed since any new wilderness has been designated in the Mount Hood area, the population in local counties has increased significantly—25 percent in Multnomah County, 24 percent in Hood River County, and 28 percent in Clackamas County.

The predominant public use of this urban forest is non-mechanized activity like hiking, camping, and fishing. With increasing emphasis on wild scenery, unspoiled wildlife habitats, free flowing rivers, wilderness and the need for opportunities for diverse outdoor recreation, sometimes it seems we are in jeopardy of "loving our wild places to death."

A few years ago, the Forest Service made a proposal to limit the number of people that could hike the south side of Mount Hood and the public outcry was enormous. Seems to me, rather than tell people that they are going to be restricted from using our public lands, part of the solution for the future of the Mountain lies in providing more opportunities for them to enjoy the Mountain's great places. We should ensure the Mount Hood National Forest can meet the increased use and demand for outdoor experiences—my bill will provide those opportunities.

Of the hundreds of people who attended the meetings I held throughout the State of Oregon, the vast majority spoke in favor of more wilderness. Additionally, I have received more than 2,500 written comments supporting additional wilderness for Mount Hood.

This is what I have heard: First and foremost, I heard that Oregonians in astonishing numbers support protecting Mount Hood and the Columbia River Gorge with additional wilderness. A large number of Oregonians didn't think that enough wilderness areas had been included in the House proposal.

Some mountain bikers expressed concerns that their recreation opportunities not be unfairly curtailed.

Some people were worried about forest health, and those living in towns on the mountain and in the gorge were concerned about fire protection for their communities.

Some people were worried about maintaining a role for developed recreation, like skiing, on Mt. Hood.

This is what my bill does to address those concerns: There are currently 189,200 acres of designated wilderness in the Mount Hood National Forest. This bill increases wilderness on Mount Hood by designating approximately 128,600 new acres of wilderness.

This bill adds the areas surrounding the oldest Mt. Hood Wilderness-the mountain itself—which was designated in the original Wilderness Act of 1964. These additions include cathedral old growth forests, the historic Tilly Jane trail, lava beds that were created during the Mt. Hood eruptions, and much of the legendary route that Oregon's pioneers used when they were settling our great State. To the north and west of the mountain, I would add the viewshed of the Columbia Gorge to the current Mark O. Hatfield wilderness. These areas encompass the spectacular ridges framing the Gorge that we all marvel at from 1-84 and include perhaps the greatest concentration of waterfalls in North America. To the southwest of the mountain I add lands to the current Salmon Huckleberry Wilderness to conserve their diverse wildlife and protect unique recreational areas like those around popular Mirror Lake. These lands include Alder Creek, the source of drinking water for the City of Sandy, which unanimously endorsed the draft proposal. Over to the east are proposed additions to the Badger Creek Wilderness. These areas provide a critical link between Westside forests and Eastside ecosystems. This area is known for beautiful fall color and the best deer and elk hunting in the entire Mount Hood National Forest. Among the areas we are protecting is the newly designated Richard L. Kohnstamm Memorial Area. It is dedicated in honor of Mr. Kohnstamm who restored the historic Timberline Lodge-built originally by the Works Progress Administration in 1937—to its former grandeur. Our new 2007 bill adds 2730 acres of Marion County lands in the Bull of the Woods Wilderness Additions, while removing lands where users identified potential conflicts.

My proposal seeks to protect over 79.6 miles of wild and scenic rivers on nine free flowing rivers. This includes some of the most pristine and beautiful rivers in Oregon. Among those proposed rivers are the picturesque waterfalls and glacial outwash of the East Fork of the Hood River, and the ancestral hunting and fishing grounds of Fish Creek. Over 17 miles of superb salmon and steelhead habitat on the Collowash River have also been proposed for protection.

I believe that local riders raised some valid concerns, so I did two things. I have proposed Mount Hood National Recreation Area. This area was so popular in our last bill that Senator SMITH and I decided to greatly expand it to include 34,640 acres—an increase of over 16,700 acres. It will offer greater. permanent environmental protections to those beautiful areas, while providing mountain bikers and other recreational users an opportunity to continue to recreate in these areas. Additionally, I made boundary adjustments to ensure all open mountain biking trails were not included in my proposed wilderness.

I protect wilderness, where there are healthy, older trees that should never be harvested on Mount Hood or in the Gorge. Older, healthy stands are the most resistant to fire and disease. However, there is an enormous backlog of plantation. over-crowded. secondgrowth that should be thinned. My bill includes provisions that would give the Forest Service a mandate to prepare an assessment for promoting forests resilient to fire, insects and disease. This also includes provisions to study and encourage the development of biomass in conjunction with forest health work. In addition, I added fire safe community zones so that the Secretary will construct a system of fire safe buffer zones around the communities of Cascade Locks and Government Camp.

In order to facilitate developed recreation opportunities, I have adopted the House provisions establishing a "feeretention" provision that will establish an account for the Mount Hood National Forest. In addition, in order to help address growth while ensuring access to recreational opportunities, I have adopted provisions, originally coming from the language passed in the House last Congress, directing the Secretary and the State of Oregon to develop an integrated transportation plan for the Mount Hood region.

I have also incorporated provisions on local and tribal relationships emphasizing the rich history of the Mount Hood region and affirming the rights of Native peoples to access the mountain's resources, as they have for generations.

The protection of these important Oregon places will depend on the hard work and dedication of all Oregonians and particularly that of my Oregon colleagues here in the Congress. I am especially pleased that Senator SMITH has joined me in developing this bipartisan legislation and putting forth our proposal for wilderness. I am hopeful everyone will pull together: county Commissioners, environmentalists, entrepreneurs, chambers of commerce, State elected officials, the Governor, and the Oregon delegation here in the Capitol. I look forward to perfecting legislation together in the coming weeks, and seeing its swift adoption by Congress thereafter. Then the grandeur of Mount Hood and other Oregon treasures can be assured for future generaI ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the material was ordered to be printed in the Record, as follows:

#### S. 647

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

#### SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Lewis and Clark Mount Hood Wilderness Act of 2007".

(b) Table of Contents.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Definitions.

TITLE I—DESIGNATION OF WILDERNESS AREAS

Sec. 101. Designation of Lewis and Clark Mount Hood wilderness areas.

Sec. 102. Richard L. Kohnstamm Memorial Area.

Sec. 103. Map and legal descriptions.

Sec. 104. Administration.

Sec. 105. Buffer zones.

Sec. 106. Fire safe community zones. Sec. 107. Fish and wildlife; hunting and fishing.

Sec. 108. Fire, insects, and diseases.

Sec. 109. Land reclassification.

Sec. 110. Valid existing rights and withdrawal.

Sec. 111. Maintenance and replacement of foot bridges in wilderness areas.

TITLE II—DESIGNATION OF STREAMS FOR WILD AND SCENIC RIVER PROTECTION IN THE MOUNT HOOD AREA

Sec. 201. Purpose.

Sec. 202. Wild and Scenic River designations, Mount Hood National Forest.

Sec. 203. Impact on water rights and flow requirements.

Sec. 204. Culvert replacement.

Sec. 205. Protection for Hood River, Oregon.
TITLE III—MOUNT HOOD NATIONAL
RECREATION AREA

Sec. 301. Designation.

TITLE IV—TRANSPORTATION AND COMMUNICATION SYSTEMS

Sec. 401. Definition of Mount Hood region.

Sec. 402. Transportation plan.

Sec. 403. Study relating to gondola connection and intermodal transportation center.

Sec. 404. Burial of power lines.

Sec. 405. Clarification of treatment of State highways.

#### TITLE V—LAND EXCHANGE

Subtitle A—Cooper Spur-Government Camp Land Exchange

Sec. 501. Purposes.

Sec. 502. Definitions.

Sec. 503. Cooper Spur-Government Camp land exchange.

Sec. 504. Concessionaires at the Inn at Cooper Spur and the Cooper Spur Ski Area.

Subtitle B—Port of Cascade Locks Land Exchange

Sec. 511. Definitions.

Sec. 512. Land exchange, Port of Cascade Locks-Pacific Crest National Scenic Trail.

Subtitle C—Hunchback Mountain Land Exchange and Boundary Adjustment

Sec. 521. Definitions.

Sec. 522. Hunchback Mountain land exchange, Clackamas County.

Sec. 523. Boundary adjustment.

# TITLE VI—MOUNT HOOD NATIONAL FOREST AND WATERSHED STEWARDSHIP

Sec. 601. Findings and purpose.

Sec. 602. Forest stewardship assessment.

Sec. 603. Sustainable biomass utilization study.

Sec. 604. Watershed management memoranda of understanding.

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TITLE VII—CRYSTAL SPRINGS WATER-SHED SPECIAL RESOURCES MANAGE-MENT UNIT

Sec. 701. Findings and purpose.

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#### TITLE IX—RECREATION

Sec. 901. Findings and purpose.

Sec. 902. Retention of Mount Hood National Forest land use fees from special use authorizations.

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reational Working Group. Sec. 906. Consideration of conversion of forest roads to recreational uses.

Sec. 907. Improved trail access for persons with disabilities.

# TITLE X—AUTHORIZATION OF APPROPRIATIONS

Sec. 1001. Authorization of appropriations. **SEC. 2. DEFINITIONS.** 

In this Act:

(1) INDIAN TRIBE.—The term "Indian tribe" has the meaning given the term in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b).

(2) MOUNTAIN BIKE.—The term "mountain bike" does not include a motorized vehicle.

(3) SECRETARY.—The term "Secretary" means—

(A) when used in reference to Forest Service land, the Secretary of Agriculture; and

(B) when used in reference to Bureau of Land Management land, the Secretary of the Interior.

(4) STATE.—The term "State" means the State of Oregon.

# TITLE I—DESIGNATION OF WILDERNESS AREAS

# SEC. 101. DESIGNATION OF LEWIS AND CLARK MOUNT HOOD WILDERNESS AREAS.

In accordance with the Wilderness Act (16 U.S.C. 1131 et seq.), the following areas in the State are designated as wilderness areas and as components of the National Wilderness Preservation System:

(1) BADGER CREEK WILDERNESS ADDITIONS.—
Certain Federal land managed by the Forest Service, comprising approximately 4,139 acres, as generally depicted on the maps entitled "Badger Creek" and "Bonney Butte", dated February 2007, which are incorporated in, and considered to be a part of, the Badger Creek Wilderness, as designated by section 3(3) of the Oregon Wilderness Act of 1984 (16 U.S.C. 1132 note; 98 Stat. 273).

(2) BULL OF THE WOODS WILDERNESS ADDITION.—Certain Federal land managed by the

Forest Service, comprising approximately 9,814 acres, as generally depicted on the map entitled "Bull of the Woods', dated February 2007, which is incorporated in, and considered to be a part of, the Bull of the Woods Wilderness, as designated by section 3(4) of the Oregon Wilderness Act of 1984 (16 U.S.C. 1132 note; 98 Stat. 273).

(3) CLACKAMAS WILDERNESS.—Certain Federal land managed by the Forest Service and Bureau of Land Management, comprising approximately 11,532 acres, as generally depicted on the maps entitled "Clackamas Canyon", "Big Bottom", "Memaloose Lake", "South Fork Clackamas", "Sisi Butte", and "Upper Big Bottom", dated February 2007, which shall be known as the "Clackamas Wilderness".

(4) Mark O. Hatfield Wilderness additions.—Certain Federal land managed by the Forest Service, comprising approximately 25,807 acres, as generally depicted on the maps entitled "Gorge Face" and "Larch Mountain", dated February 2007, which shall be known as the "Mark O. Hatfield Wilderness Additions".

(5) Mount hood wilderness additions.— Certain Federal land managed by the Forest Service, comprising approximately 20.230 acres, as generally depicted on the maps en-"Elk Cove/Mazama", "Sandy Addi-, "Tilly Jane", "Sand Canyon", "Twin titled tions" Lakes", "Barlow Butte", "White River", and "Richard L. Kohnstamm Memorial Area" dated February 2007, which are incorporated in, and considered to be a part of, the Mount Hood Wilderness as designated under section 3(a) of the Wilderness Act (16 U.S.C. 1132(a)). and enlarged by section 3(d) of the Endangered American Wilderness Act of 1978 (16 U.S.C. 1132 note; 92 Stat. 43).

(6) ROARING RIVER WILDERNESS.—Certain Federal land managed by the Forest Service, comprising approximately 37,590 acres, as generally depicted on the map entitled "Roaring River Wilderness", dated February 2007, which shall be known as the "Roaring River Wilderness".

(7) SALMON-HUCKLEBERRY WILDERNESS ADDITIONS.—Certain Federal land managed by the Forest Service, comprising approximately 16,704 acres, as generally depicted on the maps entitled "Alder Creek Addition", "Eagle Creek Addition", "Mirror Lake", "Inch Creek", "Salmon River Meadows", and "Hunchback Mountain", dated February 2007, which are incorporated in, and considered to be a part of, the Salmon-Huckleberry Wilderness, as designated by section 3(2) of the Oregon Wilderness Act of 1984 (16 U.S.C. 1132 note; 98 Stat. 273).

(8) LOWER WHITE RIVER WILDERNESS.—Certain Federal land managed by the Forest Service and Bureau of Land Management, comprising approximately 2,844 acres, as generally depicted on the map entitled "Lower White River", dated February 2007, which shall be known as the "Lower White River Wilderness".

# SEC. 102. RICHARD L. KOHNSTAMM MEMORIAL AREA.

(a) DESIGNATION.—Certain Federal land managed by the Forest Service, as generally depicted on the map entitled "Richard L. Kohnstamm Wilderness", dated February 2007, and including approximately 157 acres of designated wilderness, as generally depicted on the map entitled "Richard L. Kohnstamm Wilderness", dated February 2007, shall be known and designated as the "Richard L. Kohnstamm Wilderness".

(b) REFERENCES.—Any reference in a law, map, regulation, document, paper, or other record of the United States to an area described in subsection (a) shall be deemed to be a reference to the Richard L. Kohnstamm Wilderness

(c) BOUNDARY.—

(1) IN GENERAL.—The memorial area shall consist of land located within the boundary depicted on the map entitled "Richard L. Kohnstamm Wilderness", dated February 2007.

(2) AVAILABILITY OF MAP.—The map shall be on file and available for public inspection in the appropriate offices of the Forest Service.

#### SEC. 103. MAP AND LEGAL DESCRIPTIONS.

(a) IN GENERAL.—As soon as practicable after the date of enactment of this Act, the Secretary shall file a map entitled "Lewis and Clark Mount Hood Wilderness Additions of 2007", dated February 2007, and a legal description of each wilderness area designated by this title, with—

(1) the Committee on Energy and Natural Resources of the Senate; and

(2) the Committee on Natural Resources of the House of Representatives.

(b) FORCE OF LAW.—The map and legal descriptions filed under subsection (a) shall have the same force and effect as if included in this Act, except that the Secretary may correct typographical errors in the map and each legal description.

(c) PUBLIC AVAILABILITY.—Each map and legal description filed under subsection (a) shall be on file and available for public inspection in the appropriate offices of the Forest Service and Bureau of Land Management.

(d) DESCRIPTION OF LANDS.—The boundaries of the areas designated as wilderness by section 101 where generally depicted on the map as immediately adjacent to a utility right of way or a Federal Energy Regulatory Commission project boundary shall be 100 feet from the boundary of the right of way.

#### SEC. 104. ADMINISTRATION.

(a) IN GENERAL.—Subject to valid existing rights, each area designated as wilderness by this Act shall be administered by the Secretary in accordance with the Wilderness Act (16 U.S.C. 1131 et seq.), except that—

(1) any reference in that Act to the effective date shall be considered to be a reference to the date of enactment of this Act; and

(2) any reference in that Act to the Secretary of Agriculture shall be considered to be a reference to the Secretary that has jurisdiction over the wilderness.

(b) CONSISTENT INTERPRETATION TO THE PUBLIC.—Notwithstanding their separate jurisdictions, the Secretary of Agriculture and the Secretary of the Interior shall collaborate to ensure that the wilderness areas designated by this title, if appropriate, are interpreted for the public as an overall complex related by—

(1) common location in the Mount Hood-Columbia River Gorge region;

(2) the abundant history of Native American use;

(3) the epic journey of Lewis and Clark;

(4) the pioneer settlement and growth of the State; and

(5) water sources for more than 40 percent of the residents of the State.

(c) INCORPORATION OF ACQUIRED LAND AND INTERESTS.—Any land within the boundary of a wilderness area designated by this Act that is acquired by the Federal Government shall—

(1) become part of the wilderness area in which the land is located; and

(2) be managed in accordance with this Act, the Wilderness Act (16 U.S.C. 1131 et seq.), and any other applicable law.

(d) WILDERNESS AREAS DESIGNATED IN NATIONAL RECREATION AREAS.—Any portion of a wilderness area designated by section 101(a) that is located within a national recreation area shall be administrated in accordance with the Wilderness Act (16 U.S.C. 1131 et sea.).

#### SEC. 105, BUFFER ZONES.

(a) IN GENERAL.—As provided in the Oregon Wilderness Act of 1984 (16 U.S.C. 1132 note; Public Law 98-328), Congress does not intend for designation of wilderness areas in the State under this title to lead to the creation of protective perimeters or buffer zones around each wilderness area

around each wilderness area.
(b) ACTIVITIES OR USES UP TO BOUND-ARIES.—The fact that nonwilderness activities or uses can be seen or heard from within a wilderness area shall not, of itself, preclude the activities or uses up to the boundary of the wilderness area.

#### SEC. 106. FIRE SAFE COMMUNITY ZONES.

Consistent with the Mount Hood National Forest Management Plan and the Healthy Forests Restoration Act of 2003 (16 U.S.C. 6501 et seq.), the Secretary shall construct strategic system of defensible fuel profile zones (including shaded fuelbreaks, thinning, individual tree selection, and other methods of vegetation management) between the wilderness boundary and the community boundary around Cascade Locks and Government Camp.

## SEC. 107. FISH AND WILDLIFE; HUNTING AND FISHING.

As provided in section 4(d)(7) of the Wilderness Act (16 U.S.C. 1133(d)(7)), nothing in this section shall be construed as affecting the jurisdiction or responsibilities of the State with respect to fish and wildlife in the State. SEC. 108. FIRE, INSECTS, AND DISEASES.

As provided in section 4(d)(1) of the Wilderness Act (16 U.S.C. 1133(d)(1)), within the wilderness areas designated by this Act, the Secretary of Agriculture (in collaboration with the Secretary of the Interior, where appropriate) may take such measures as are necessary to control fire, insects, and diseases, subject to such terms and conditions as the Secretary of Agriculture (in collaboration with the Secretary of the Interior where appropriate) determines to be desirable and appropriate.

#### SEC. 109. LAND RECLASSIFICATION.

- (a) OREGON AND CALIFORNIA RAILROAD LAND.—Not later than 180 days after the date of enactment of this Act, the Secretary of Agriculture and the Secretary of the Interior shall identify any Oregon and California Railroad Land that is subject to section 201 of the Act of August 28, 1937 (43 U.S.C. 1181f), within the boundary of the Clackamas Wilderness, as generally depicted on the map entitled "South Fork Clackamas", dated February 2007.
- (b) Public Domain Land.—
- (1) DEFINITION OF PUBLIC DOMAIN LAND.—In this section, the term "public domain land"—
- (A) has the meaning given the term "public land" in section 103 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1702); and
- (B) does not include any land managed under the Act of August 28, 1937 (43 U.S.C. 1181a et seq.).
- (2) IDENTIFICATION.—Not later than 180 days after the date of enactment of this Act, the Secretary of the Interior shall identify public domain land within the State that—
- (A) is approximately equal in acreage of land described in subsection (a); and
- (B) would be appropriate for administration in accordance with the Act of August 28, 1937 (43 U.S.C. 1181a et seq.).
- (3) MAPS.—Not later than 180 days after the date of enactment of this Act, the Secretary of the Interior shall submit to Congress and publish in the Federal Register, 1 or more maps depicting the land identified under subsections (a) and this subsection.
- (4) RECLASSIFICATION.—After providing an opportunity for public comment, the Secretary of the Interior shall administratively reclassify—

- (A) the land described in subsection (a) as public domain land that is not subject to section 201 of the Act of August 28, 1937 (43 U.S.C. 1181f); and
- (B) the land described in this subsection as Oregon and California Railroad Land that is subject to the Act of August 28, 1937 (43 U.S.C. 1181a et seq.).

### SEC. 110. VALID EXISTING RIGHTS AND WITHDRAWAL.

Subject to valid rights in existence on the date of enactment of this Act, the Federal land designated as wilderness by this Act is withdrawn from all forms of—

- (1) entry, appropriation, or disposal under the public land laws:
- (2) location, entry, and patent under the mining laws; and
- (3) disposition under all laws pertaining to mineral and geothermal leasing or mineral materials

#### SEC. 111. MAINTENANCE AND REPLACEMENT OF FOOT BRIDGES IN WILDERNESS AREAS.

- (a) IN GENERAL.—In the case of each wilderness area designated or expanded by section 102, it is the intent of Congress that the Secretary be able to provide for—
- (1) the maintenance of any foot bridge crossing located in a wilderness area; and
- (2) when needed, the replacement of the foot bridge crossings to ensure public access and safety.
- (b) MINIMUM TOOL POLICIES.—The Secretary shall carry out foot bridge replacement and maintenance work under subsection (a) subject to the minimum requirement for the administration of the area.

# TITLE II—DESIGNATION OF STREAMS FOR WILD AND SCENIC RIVER PROTECTION IN THE MOUNT HOOD AREA

#### SEC. 201. PURPOSE.

The purpose of this title is to designate approximately 81 miles of waterways in the Mount Hood National Forest as additions to the National Wild and Scenic Rivers System.

SEC. 202. WILD AND SCENIC RIVER DESIGNA-

#### SEC. 202. WILD AND SCENIC RIVER DESIGNA-TIONS, MOUNT HOOD NATIONAL FOREST.

Section 3(a) of the Wild and Scenic Rivers Act (16 U.S.C. 1274(a)) is amended—

- (1) by redesignating paragraph (167) (relating to the Musconetcong River, New Jersey) as paragraph (169);
- (2) by designating the undesignated paragraph relating to the White Salmon River, Washington, as paragraph (167);
- (3) by designating the undesignated paragraph relating to the Black Butte River, California, as paragraph (168); and
  - (4) by adding at the end the following:
- "(170) SOUTH FORK CLACKAMAS RIVER.—The 4.2-mile segment of the South Fork Clackamas River from its confluence with the East Fork of the South Fork Clackamas to its confluence with the Clackamas River, to be administered by the Secretary as a wild river.
- "(171) EAGLE CREEK.—The 8.3-mile segment of Eagle Creek from its headwaters to the Mount Hood National Forest boundary, to be administered by the Secretary of Agriculture as a wild river.
- "(172) MIDDLE FORK HOOD RIVER.—The 3.7-mile segment of the Middle Fork Hood River from the confluence of Clear and Coe Branches to the north section line of section 11, township 1 south, range 9 east, to be administered by the Secretary of Agriculture as a scenic river.
- "(173) SOUTH FORK ROARING RIVER.—The 4.6mile segment of the South Fork Roaring River from its headwaters to its confluence with Roaring River, to be administered by the Secretary of Agriculture as a wild river.

"(174) ZIG ZAG RIVER.—The 2.9-mile segment of the Zig Zag River from its head-

waters to the Mount Hood Wilderness boundary, to be administered by the Secretary of Agriculture as a wild river.

"(175) FIFTEENMILE CREEK.—

"(A) IN GENERAL.—The 11.1-mile segment of Fifteenmile Creek from its source at Senecal Spring to the eastern edge of the northwest quarter of section 20, township 2 south, range 12 east, to be administered by the Secretary of Agriculture in the following classes:

"(i) the 2.6-mile segment from its source at Senecal Spring to the Badger Creek Wilderness boundary, as a wild river;

"(ii) the 0.4-mile segment from the Badger Creek Wilderness boundary to the point 0.4 miles downstream, as a scenic river;

"(iii) the 7.9-mile segment from the point 0.4 miles downstream of the Badger Creek Wilderness boundary to the western edge of section 20, township 2 south, range 12 east as a wild river; and

"(iv) the 0.2-mile segment from the western edge of section 20, township 2 south, range 12 east, to the eastern edge of the northwest quarter of the northwest quarter of section 20, township 2 south, range 12 east as a scenic river.

"(B) INCLUSIONS.—Notwithstanding section 3(b) of this Act, the lateral boundaries of both the wild river area and the scenic river area along Fifteenmile Creek shall include an average of not more than 640 acres per mile measured from the ordinary high water mark on both sides of the river.

"(176) EAST FORK HOOD RIVER.—The 13.5-mile segment of the East Fork Hood River from Oregon State Highway 35 to the Mount Hood National Forest boundary, to be administered by the Secretary of Agriculture as a recreational river.

"(177) COLLAWASH RIVER.—The 17.8-mile segment of the Collawash River from the headwaters of the East Fork Collawash to the confluence of the mainstream of the Collawash River with the Clackamas River, to be administered in the following classes:

- "(A) the 11.0-mile segment from the headwaters of the East Fork Collawash River to Buckeye Creek, as a scenic river; and
- "(B) the 6.8-mile segment from Buckeye Creek to the Clackamas River, as a recreational river.
- "(178) FISH CREEK.—The 13.5-mile segment of Fish Creek from its headwaters to the confluence with the Clackamas River, to be administered by the Secretary of Agriculture as a recreational river."

# SEC. 203. IMPACT ON WATER RIGHTS AND FLOW REQUIREMENTS.

- (a) RELATION TO EXISTING REQUIREMENTS.—Congress does not intend for the designation of any portion of the Hood River under section 3(a) of the Wild and Scenic Rivers Act (16 U.S.C. 1274(a)), as amended by this Act, to have any impact on any water right or flow requirement relating to—
- (1) the Middle Fork Irrigation District;
- (2) the East Fork Irrigation District; or
- (3) the Mt. Hood Meadows Ski Resort.
- (b) EXCLUSION OF OPERATIONAL AREAS.—Congress does not intend for the designation of any portion of the Hood River under section 3(a) of the Wild and Scenic Rivers Act (16 U.S.C. 1274(a)), as amended by this Act, to include any portion of the operational area of—
- (1) the Middle Fork Irrigation District;
- (2) the East Fork Irrigation District; or
- (3) the Mt. Hood Meadows Ski Resort.

#### SEC. 204. CULVERT REPLACEMENT.

Culvert replacement carried out by the Forest Service or the Bureau of Land Management to improve fish passage and the ecology of the wilderness designated by this Act shall not be considered water and resource development.

#### SEC. 205. PROTECTION FOR HOOD RIVER, OR-EGON.

Section 13(a)(4) of the "Columbia River Gorge National Scenic Area Act" (16 U.S.C. 544k(a)(4)) is amended by striking "for a period not to exceed twenty years from the date of enactment of this Act.

#### TITLE III-MOUNT HOOD NATIONAL RECREATION AREA

#### SEC, 301, DESIGNATION.

- (a) Designation.—In order to best provide for the protection, preservation, and enhancement of its recreational, ecological, scenic, watershed, and fish and wildlife values, there is hereby established the Mount Hood National Recreation Area within the Mount Hood National Forest.
- (b) BOUNDARY.—The Mount Hood National Recreation Area shall consist of land located within the boundary depicted on the map entitled "Mount Hood National Recreation Area" and dated February 2007.

(c) AVAILABILITY OF MAP.—The map shall be on file and available for public inspection in the appropriate offices of the Forest Service and Bureau of Land Management.

- (d) Administration.—The Secretary shall administer the Mount Hood National Recreation Area in accordance with the laws, rules and regulations applicable to the national forests and the purposes and values identified in subsection (a). The Secretary shall only allow such uses as are consistent with the purposes and values identified in subsection (a).
- (e) TIMBER.—The cutting, sale, or removal of timber within the Mount Hood National Recreation Area may be permitted-
- (1) to the extent necessary to improve the health of the forest in a manner that-
- (A) maximizes the retention of large trees as appropriate to the forest type, to the extent that those trees promote stands that are fire-resilient and healthy;
- (B) improves the habitats of threatened, endangered, proposed, or sensitive species; or
- (C) maintains or restores the composition and structure of the ecosystem by reducing the risk of uncharacteristic wildfire effects;
- (2) to accomplish an approved management activity in furtherance of the purposes established by this subsection, if the cutting, sale, or removal of timber is incidental to the management activity; or
- (3) for de minimus personal or administrative use within the Mount Hood National Recreation Area, where such use will not impair the purposes established by this subsection.
- (f) ROAD CONSTRUCTION.—No new or temporary roads are to be constructed or reconstructed except where it is required-
- (1) to protect the health and safety of individuals in cases of an imminent threat of flood, fire, or any other catastrophic event that, without intervention, would cause the loss of life or property;
- (2) to conduct environmental cleanup required by the Federal Government:
- (3) to allow for reserved or outstanding rights provided for by a statute or treaty:
- (4) to prevent irreparable resource damage by an existing road:
- (5) to rectify a hazardous road condition; or
- (6) in conjunction with—
- (A) the continuation, extension, or renewal of a mineral lease on land that is under lease: or
- (B) a new mineral lease that is issued immediately after the expiration of an existing mineral lease.

#### TITLE IV—TRANSPORTATION AND COMMUNICATION SYSTEMS

#### SEC. 401. DEFINITION OF MOUNT HOOD REGION.

In this title, the term "Mount Hood region" means-

- (1) Mount Hood and the other land located adjacent to the mountain;
- (2) any segment of the Oregon State Highway 26 corridor that is located in or near Mount Hood National Forest;
- (3) any segment of the Oregon State Highway 35 corridor that is located in or near Mount Hood National Forest;
- (4) each other road of the Forest Service, State, or county that is located in and near Mount Hood National Forest; and
- (5) any gateway community located adjacent to any highway or road described in paragraph (2), (3), or (4).

#### SEC. 402. TRANSPORTATION PLAN.

- (a) IN GENERAL.—The Secretary shall participate with the State, local governments, and other Federal agencies in the development of an integrated, multimodal transportation plan for the Mount Hood region to achieve comprehensive solutions to transportation challenges in the Mount Hood region-
- (1) to promote appropriate economic development;
- (2) to preserve the landscape of the Mount Hood region; and
- (3) to enhance public safety.
  (b) PLANNING PROCESS.—The tation plan under subsection (a) shall-
- (1) conform with Federal and Oregon transportation planning requirements; and
- (2) be developed through a collaborative process, preferably through the use of a commission composed of interested persons appointed by the State, with representation from the Forest Service and local governments in the Mount Hood region.
- (c) Scope of Plan.—The transportation plan under subsection (a) shall address issues relating to-
- (1) the transportation of individuals to and from areas outside the Mount Hood region on major corridors traversing that region; and
- (2) the transportation of individuals to and from locations that are located within the Mount Hood region.
- (d) CONTENTS OF PLAN.—At a minimum, the transportation plan under subsection (a) shall consider-
- (1) transportation alternatives between and among recreation areas and gateway communities that are located within the Mount Hood region;
- (2) establishing park-and-ride facilities that shall be located at gateway communities;
- (3) establishing intermodal transportation centers to link public transportation, parking, and recreation destinations;
- (4) creating a new interchange on Oregon State Highway 26 that shall be located adjacent to or within Government Camp;
- (5) designating, maintaining, and improving alternative routes using Forest Service or State roads for-
- (A) providing emergency routes; or
- (B) improving access to, and travel within, the Mount Hood region;
- (6) reconstructing the segment of Oregon State Highway 35 that is located between Mineral Creek and Baseline Road to address ongoing debris flow locations; and
- (7) creating mechanisms for funding the implementation of the transportation plan under subsection (a), including-
- (A) funds provided by the Federal Government:
- (B) public-private partnerships:
- (C) incremental tax financing; and
- (D) other financing tools that link transportation infrastructure improvements with development.
- (e) COMPLETION OF PLAN.—Not later than 2 years after the date on which funds are first made available to carry out this section, the Secretary shall complete the transportation plan under subsection (a).

(f) AUTHORIZATION OF APPROPRIATIONS.-There is authorized to be appropriated to carry out this section \$2,000,000.

#### SEC. 403. STUDY RELATING TO GONDOLA CON-NECTION AND INTERMODAL TRANS-PORTATION CENTER.

- (a) FEASIBILITY STUDY.—The Oregon Department of Transportation, along with the participation of the Secretary, shall carry out a study of the feasibility of establishing-
  - (1) a gondola connection that-
- (A) connects Timberline Lodge to Government Camp; and
- (B) is located in close proximity to the site of the historic gondola corridor; and
- (2) an intermodal transportation center to be located in close proximity to Government Camp.
- (b) Consideration of Multiple Sites.—In carrying out the feasibility study under subsection (a), the Secretary may consider 1 or more sites.
- (c) RELIANCE ON PAST STUDIES -To the extent that prior studies have been completed that can assist in the assessment of the Gondola connection, those may be utilized.

#### SEC. 404. BURIAL OF POWER LINES.

Because of the incongruent presence of power lines adjacent to wilderness areas, the Secretary may provide to Cascade Locks and Hood River County funds through the Forest Service State and Private Forestry program to bury ground power lines adjacent to the Mount Hood wilderness areas, including wilderness areas designated by this Act.

#### SEC. 405. CLARIFICATION OF TREATMENT OF STATE HIGHWAYS.

- (a) EXCLUSION.—Any part of Oregon State Highway 35 or other any other State highway in existence on the date of enactment of this Act (including all existing rights-of-way and 150 feet on each side of the centerline, whichever is greater, that is adjacent to wilderness areas in the Mount Hood National Forest, including wilderness areas designated by this Act) shall be excluded from wilderness under this Act.
- (b) No NET EFFECT.—The designation of wilderness or wild and scenic rivers under this Act or an amendment made by this Act shall not limit or restrict the ability of the State, and in consultation with the Forest Service-
- (1) to operate, maintain, repair, reconstruct, protect, realign, expand capacity, or make any other improvement to Oregon State Highway 35 or any other State highway in existence on the date of enactment of this Act:
- (2) to use any site that is not within a highway right-of-way to operate, maintain, repair, reconstruct, protect, realign, expand capacity, or make any other improvement to those highways; or
- (3) to take any action outside of a highway right-of-way that is necessary to operate, maintain, repair, reconstruct, protect, realign, expand capacity, or make any other improvement to those highways.
- (c) FLOOD PLAIN.—Congress encourages the carrying out of projects that will reduce the impact of Oregon State Highway 35 on the flood plain of the East Fork Hood River.

#### TITLE V-LAND EXCHANGE

#### Subtitle A-Cooper Spur-Government Camp Land Exchange

#### SEC. 501. PURPOSES.

The purposes of this subtitle are-

- (1) to recognize the years of work by local residents and political and business leaders from throughout the States of Oregon and Washington to protect the north side of Mount Hood; and
- (2) to authorize the exchange of the Federal land and non-Federal land.

#### SEC. 502. DEFINITIONS.

In this subtitle:

- (1) COUNTY.—The term "County" means Hood River County, Oregon.
- (2) EXCHANGE MAP.—The term "exchange map" means the map entitled "Cooper Spur-Government Camp Land Exchange" and dated September 2006.
- (3) FEDERAL LAND.—The term "Federal land" means—
- (A) the parcel of approximately 80 acres of National Forest System land in Mount Hood National Forest in Government Camp, Clackamas County, Oregon, as depicted on the exchange map; and
- (B) the parcel of approximately 40 acres of National Forest System land in Mount Hood National Forest in Government Camp, Clackamas County, Oregon, as depicted on the exchange map.
- (4) Mt. Hood Meadows.—The term "Mt. Hood Meadows" means the Mt. Hood Meadows Oreg., Limited Partnership.
- (5) NON-FEDERAL LAND.—The term "non-Federal land" means—
- (A) the parcel of approximately 770 acres of private land at Cooper Spur, as depicted on the exchange map:
- (B) any buildings, furniture, fixtures, and equipment at the Inn at Cooper Spur and the Cooper Spur Ski Area covered by an appraisal described in section 503(d).
- (6) SECRETARY.—The term "Secretary" means the Secretary of Agriculture.
- (7) TRAIL MAP.—The term "trail map" means the map entitled "Government Camp Trail Map" and dated September 2006.

### SEC. 503. COOPER SPUR-GOVERNMENT CAMP LAND EXCHANGE.

- (a) CONVEYANCE OF FEDERAL LAND.—Subject to the provisions of this section, if Mt. Hood Meadows offers to convey to the United States all right, title, and interest of Mt. Hood Meadows in and to the non-Federal land, the Secretary shall convey to Mt. Hood Meadows all right, title, and interest of the United States in and to the Federal land (other than any easements reserved under subsection (g)).
- (b) CONDITIONS ON ACCEPTANCE.—Title to the non-Federal land to be acquired by the Secretary under this section must be acceptable to the Secretary, and the conveyances shall be subject to valid existing rights of record and such terms and conditions the Secretary may prescribe. The non-Federal land shall conform with the title approval standards applicable to Federal land acquisitions.
- (c) APPLICABLE LAW.—Except as otherwise provided in this section, the Secretary shall carry out the land exchange under this section in accordance with section 206 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1716).
  - (d) Appraisals.—
- (1) IN GENERAL.—As soon as practicable after the date of enactment of this Act, the Secretary shall select an appraiser to conduct an appraisal of the Federal land and non-Federal land.
- (2) REQUIREMENTS.—An appraisal under paragraph (1) shall—
- (A) be conducted in accordance with nationally recognized appraisal standards, including—
- (i) the Uniform Appraisal Standards for Federal Land Acquisitions developed by the Interagency Land Acquisition Conference;
- (ii) the Uniform Standards of Professional Appraisal Practice;
- (B) incorporate the dates of the appraisals of the Federal land and non-Federal land performed in 2005 by Appraiser Steven A. Hall, MAI, CCIM; and
- (C) be approved by the Secretary, the County, and Mt. Hood Meadows.

- (e) SURVEYS .-
- (1) IN GENERAL.—The exact acreage and legal description of the Federal land and non-Federal land shall be determined by surveys approved by the Secretary.
- (2) Costs.—The responsibility for the costs of any surveys conducted under paragraph (1), and any other administrative costs of carrying out the land exchange, shall be determined by the Secretary and the County.
- (f) DEADLINE FOR COMPLETION OF LAND EXCHANGE.—It is the intent of Congress that, not later than 16 months after the date of enactment of this Act. the Secretary shall—
- (1) complete all legal and regulatory processes required for the exchange of the Federal land and the non-Federal land; and
- (2) close on the Federal land and the non-Federal land.
- (g) RESERVATION OF EASEMENTS.—As a condition of the conveyance of the Federal land, the Secretary shall reserve—
- (1) a conservation easement to the Federal land to protect existing wetland on the conveyed parcels, as identified by the Oregon Department of State Lands, that allows equivalent wetland mitigation measures to compensate for minor wetland encroachments necessary for the orderly development of the Federal land; and
- (2) a trail easement to the Federal land that allows—
- (A) the nonmotorized functional use by the public of identified existing trails located on the Federal land, as depicted on the trail map:
- (B) roads, utilities, and infrastructure facilities to cross the trails; and
- (C) improvement or relocation of the trails to accommodate development of the Federal land.

# SEC. 504. CONCESSIONAIRES AT THE INN AT COOPER SPUR AND THE COOPER SPUR SKI AREA.

- (a) PROSPECTUS.—Not later than 60 days after the date on which the land exchange is completed under section 503, the Secretary shall publish in the Federal Register a proposed prospectus to solicit 1 or more new concessionaires for the Inn at Cooper Spur and the Cooper Spur Ski Area, as reconfigured in accordance with the exchange map.
- (b) COMPETITIVE PROCESS.—Prospective concessionaires shall submit bids to compete for the right to operate the Inn at Cooper Spur, the Cooper Spur Ski Area, or both the Inn and the Ski Area.
- (c) CONSIDERATIONS.—In selecting a concessionaire, the Secretary shall consider—
- (1) which bid is highest in terms of monetary value; and
- (2) other attributes of the bids submitted. (d) CONSULTATION.—The Secretary shall consult with Mt. Hood Meadows, Meadows North, LLC, North Face Inn, LLC, the Hood River Valley Residents Committee, the Cooper Spur Wild and Free Coalition, and the Hood River County Commission—
- (1) in selecting a new concessionaire for the Inn at Cooper Spur and the Cooper Spur Ski Area; and
- (2) in preparing for the orderly and smooth transition of the operation of the Inn at Cooper Spur and the Cooper Spur Ski Area to the new concessionaire.

  PROCEEDS.—Any
- (e) Treatment of Proceeds.—Any amounts received under a concession contract under this section shall—
- (1) be deposited in the fund established under Public Law 90-171 (commonly known as the "Sisk Act") (16 U.S.C. 484a); and
- (2) remain available to the Secretary until expended, without further appropriation, for use in the Mount Hood National Forest, with priority given to using amounts in the Hood River Ranger District for restoration projects on the North side of Mount Hood.
- (f) ALTERNATIVE CONVEYANCE AND SPECIAL USE PERMIT.—

- (1) IN GENERAL.—If the Secretary has not selected a concessionaire for the Inn at Cooper Spur and the Cooper Spur Ski Area by the date that is 1 year after the date on which the prospectus is published under subsection (a), the Secretary may—
- (A) convey to the County, without consideration, the improvements described in section 502(5)(B): or
- (B) continue to allow Mt. Hood Meadows to operate as the concessionaire while the Secretary continues to seek an alternate concessionaire.
- (2) SPECIAL USE PERMIT.—If the Secretary conveys improvements to the County under paragraph (1)(A), the Secretary shall issue to the County a special use permit that would allow reasonable access to, and management of, the improvements under terms similar to the Cooper Spur Ski Area Special Use Permit.

#### Subtitle B—Port of Cascade Locks Land Exchange

#### SEC. 511. DEFINITIONS.

In this subtitle:

- (1) EXCHANGE MAP.—The term "exchange map" means the map entitled "Port of Cascade Locks-Pacific Crest National Scenic Trail Land Exchange" and dated June 2006.
- (2) FEDERAL LAND.—The term "Federal land" means the parcel of land consisting of approximately 10 acres of National Forest System land in the Columbia River Gorge National Scenic Area, as depicted on the exchange map.
- (3) Non-Federal Land.—The term "non-Federal land" means the parcel of land consisting of approximately 40 acres, as depicted on the exchange map.
- (4) PORT.—The term "Port" means the Port of Cascade Locks, Cascade Locks, Oregon.
- (5) SECRETARY.—The term "Secretary" means the Secretary of Agriculture.

# SEC. 512. LAND EXCHANGE, PORT OF CASCADE LOCKS-PACIFIC CREST NATIONAL SCENIC TRAIL.

- (a) CONVEYANCE REQUIRED.—Subject to the provisions of this section, if the Port offers to convey to the United States all right, title, and interest of the Port in and to the non-Federal land, the Secretary shall convey to the Port all right, title, and interest of the United States in and to the Federal land.
- (b) COMPLIANCE WITH EXISTING LAW.—Except as otherwise provided in this section, the Secretary shall carry out the land exchange under this section in the manner provided in section 206 of the Federal Land Policy Management Act of 1976 (43 U.S.C. 1716).
- (c) CONDITIONS ON ACCEPTANCE.—Title to the non-Federal land to be acquired by the Secretary under this section must be acceptable to the Secretary, and the conveyances shall be subject to valid existing rights of record and such terms and conditions the Secretary may prescribe. The non-Federal land shall conform with the title approval standards applicable to Federal land acquisitions.
  - (d) Surveys.—
- (1) IN GENERAL.—The exact acreage and legal description of the Federal land and non-Federal land shall be determined by surveys approved by the Secretary.
- (2) Costs.—The responsibility for the costs of any surveys conducted under paragraph (1), and any other administrative costs of carrying out the land exchange, shall be determined by the Secretary and the Port.
- (e) DEADLINE FOR COMPLETION OF LAND EXCHANGE.—It is the intent of Congress that, not later than 16 months after the date of enactment of this Act, the Secretary shall—
- (1) complete all legal and regulatory processes required for the exchange of the Federal land and the non-Federal land; and

(2) close on the Federal land and the non-Federal land.

#### Subtitle C—Hunchback Mountain Land Exchange and Boundary Adjustment

#### SEC. 521. DEFINITIONS.

- In this subtitle:
- (1) BOUNDARY EXTENSION MAP.—The term "boundary extension map" means the map entitled "Mount Hood National Forest Hunchback Exchange Boundary Adjustment" and dated January 2007.
- (2) COUNTY.—The term "County" means Clackamas County, Oregon.
- (3) EXCHANGE MAP.—The term "exchange map" means the map entitled "Hunchback Mountain Land Exchange-Clackamas County" and dated June 2006.
- (4) FEDERAL LAND.—The term "Federal land" means the parcel of land consisting of approximately 160 acres of National Forest System land in the Mount Hood National Forest, as depicted on the exchange map.
- (5) NON-FEDERAL LAND.—The term "non-Federal land" means the parcel of land consisting of approximately 160 acres, as depicted on the exchange map.
- (6) SECRETARY.—The term "Secretary" means the Secretary of Agriculture.

#### SEC. 522. HUNCHBACK MOUNTAIN LAND EX-CHANGE, CLACKAMAS COUNTY.

- (a) CONVEYANCE REQUIRED.—Subject to the provisions of this section, if the County offers to convey to the United States all right, title, and interest of the County in and to the non-Federal land, the Secretary shall convey to the County all right, title, and interest of the United States in and to the Federal land.
- (b) COMPLIANCE WITH EXISTING LAW.—Except as otherwise provided in this section, the Secretary shall carry out the land exchange under this section in the manner provided in section 206 of the Federal Land Policy Management Act of 1976 (43 U.S.C. 1716).
- (c) CONDITIONS ON ACCEPTANCE.—Title to the non-Federal land to be acquired by the Secretary under this section must be acceptable to the Secretary, and the conveyances shall be subject to valid existing rights of record and such terms and conditions the Secretary may prescribe. The non-Federal land shall conform with the title approval standards applicable to Federal land acquisitions.
  - (d) Surveys.—
- (1) IN GENERAL.—The exact acreage and legal description of the Federal land and non-Federal land shall be determined by surveys approved by the Secretary.
- (2) COSTS.—The responsibility for the costs of any surveys conducted under paragraph (1), and any other administrative costs of carrying out the land exchange, shall be determined by the Secretary and the County.
- (e) DEADLINE FOR COMPLETION OF LAND EXCHANGE.—It is the intent of Congress that, not later than 16 months after the date of enactment of this Act, the Secretary shall—
- (1) complete all legal and regulatory processes required for the exchange of the Federal land and the non-Federal land; and
- (2) close on the Federal land and the non-Federal land.

#### SEC. 523. BOUNDARY ADJUSTMENT.

- (a) IN GENERAL.—The boundary of the Mount Hood National Forest is adjusted as depicted on the map entitled "Boundary extension map", dated January 2007.
- (b) AVAILABILITY OF BOUNDARY EXTENSION MAP.—The boundary extension map shall be on file and available for public inspection in the office of the Chief of the Forest Service.
- (c) CORRECTION AUTHORITY.—The Secretary may make minor corrections to the boundary extension map.
- (d) ADDITIONS TO THE NATIONAL FOREST SYSTEM.—The Secretary shall administer

- any land that is conveyed to the United States and is located in the Mount Hood National Forest in accordance with—
- (1) the Act of March 1, 1911 (commonly known as the "Weeks Law") (16 U.S.C. 480 et seg.); and
- (2) any laws (including regulations) applicable to the National Forest System.
- (e) AUTHORITY OF SECRETARY TO ADJUST BOUNDARIES.—Nothing in this Act shall limit the authority or responsibility of the Secretary to adjust the boundaries of the Mount Hood National Forest under section 11 of the Act of March 1, 1911 (16 U.S.C. 521).
- (f) LAND AND WATER CONSERVATION FUND.—For the purposes of section 7 of the Land and Water Conservation Fund Act of 1965 (16 U.S.C. 460l-9), the boundaries of the Mount Hood National Forest modified by this Act shall be considered to be the boundaries of the Mount Hood National Forest in existence as of January 1, 1965.

# TITLE VI—MOUNT HOOD NATIONAL FOREST AND WATERSHED STEWARDSHIP

#### SEC. 601. FINDINGS AND PURPOSE.

The purpose of this title is to direct the Forest Service to prepare an assessment to promote forested landscapes resilient to catastrophic fire, insects, and disease, to protect homes and communities from property damage and threats to public safety, and to protect and enhance existing community or municipal watersheds. It is the intent of Congress that site-specific forest health projects undertaken pursuant to this assessment shall be completed in accordance with existing law.

#### SEC. 602. FOREST STEWARDSHIP ASSESSMENT.

- (a) PREPARATION OF ASSESSMENT.—The Secretary of Agriculture shall prepare an assessment to identify the forest health needs in those areas of the Mount Hood National Forest with a high incidence of insect or disease infestation (or both), heavily overstocked tree stands, or moderate-to-high risk of unnatural catastrophic wildfire for the purpose of improving condition class, which significantly improves the forest health and water quality. The Secretary may utilize existing information to complete the assessment. The assessment shall also identify specific projects to address these issues.
- (b) IMPROVED MAPPING.—The assessment will include peer reviewed mapping of condition class 2 and condition class 3 areas and other areas identified in subsection (a) in Mount Hood National Forest.
- (c) COMPLETION.—The Secretary of Agriculture shall complete the assessment not later than 1 year after the date of enactment of this Act.
- (d) DURATION OF STUDY.—The assessment shall cover a 10-year period.
- (e) IMPLEMENTATION.—Not later than 1 year after completion of the assessment, the Secretary shall commence implementation of projects to address the needs identified in the assessment. These projects shall be implemented using authorities available to the Secretary to manage the Mount Hood National Forest to achieve the purpose specified in subsection (a).
- (f) DELAY.—During development of the assessment under this section, a forest management project that is unaffiliated with the assessment and has completed review as required under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.) in accordance with existing law, need not be dealing the event the Secretary fails to meet the deadline specified in subsection (c).
- (g) RELATION TO EXISTING LAW AND PLANS.—Nothing in this section grants the Secretary any authority to manage the Mount Hood National Forest contrary to existing law. The assessment conducted by the Secretary under this section shall not super-

sede, be considered a supplement or amendment to, or in any way affect the legal or regulatory authority of the Mount Hood National Forest Land and Resource Management Plan or the collection of documents entitled "Final Supplemental Environmental Impact Statement and Record of Decision for Amendments to Forest Service and Bureau of Land Management Planning Documents Within the Range of the Northern Spotted Owl" and "Standards and Guidelines for Management of Habitat for Late-Successional and Old-Growth Forest-Related Species Within the Range of the Northern Spotted Owl".

(h) Public Participation.—The Secretary shall provide an opportunity for interested persons to be involved in development of the assessment conducted by the Secretary under this section.

### SEC. 603. SUSTAINABLE BIOMASS UTILIZATION STUDY.

- (a) STUDY REQUIRED.—The Secretary of Agriculture shall conduct a study to assess the amount of long-term sustainable biomass available in the Mount Hood National Forest that, consistent with applicable law, could be made available as a raw material for—
- (1) the production of electric energy, sensible heat, transportation fuel, or substitutes for petroleum-based products;
- (2) dimensional lumber, fencing, framing material, poles, firewood, furniture, chips, or pulp for paper; or
  - (3) other commercial purposes.
- (b) DEFINITION.—In this section, the term "biomass" means small diameter trees and understory vegetation that is removed from forested land as a by-product of forest restoration efforts.

### SEC. 604. WATERSHED MANAGEMENT MEMORANDA OF UNDERSTANDING.

- (a) COMPLETION OF MEMORANDA OF UNDERSTANDING.—To the extent that memoranda of understanding or other legal agreements involving watersheds of Mount Hood National Forest do not exist between irrigation districts or municipalities and the Forest Service, the Secretary of Agriculture may complete memoranda of understanding that outline stewardship goals to manage the watersheds for water quality and water quantity.
- (b) ELEMENTS OF MEMORANDUM.—A memorandum of understanding involving a watershed of Mount Hood National Forest shall encourage adaptability, establish benchmarks regarding water quality and water quantity, and require monitoring to determine progress in meeting such benchmarks. The memorandum of understanding may restrict public access to areas of the watershed where appropriate.
  - (c) Public Process Required.—
- (1) COLLABORATION AND CONSULTATION.—
  The Secretary of Agriculture shall ensure that the process by which the Secretary enters into a memorandum of understanding with an irrigation district, local government, or other entity involving a watershed of Mount Hood National Forest is based on collaboration and cooperation between the Forest Service and local jurisdictions and other interested persons.
- (2) PUBLIC MEETING REQUIRED.—The Secretary and the other party or parties to the proposed memorandum of understanding shall hold at least 1 joint public meeting before completing a final draft of the memorandum of understanding.
- (3) PUBLIC COMMENT.—A draft memorandum of understanding shall also be open to public comment before being finalized.

#### SEC. 605. TERMINATION OF AUTHORITY.

The authority provided by this title shall terminate on the date that is 10 years after the date of enactment of this Act.

#### TITLE VII—CRYSTAL SPRINGS WATER-SHED SPECIAL RESOURCES MANAGE-MENT UNIT

#### SEC. 701. FINDINGS AND PURPOSE.

The purpose of this title is to establish a special resources management unit to ensure protection of the quality and quantity of the Crystal Springs watershed as a clean drinking water source for the residents of Hood River County, Oregon, while also allowing visitors to enjoy its special scenic, natural, cultural, and wildlife values.

#### SEC. 702. ESTABLISHMENT OF CRYSTAL SPRINGS WATERSHED SPECIAL RESOURCES MANAGEMENT UNIT.

- (a) ESTABLISHMENT.—Effective as provided by section 705, the Secretary of Agriculture shall establish a special resources management unit in the State consisting of all National Forest System land that is located within 200 yards from any point on the perimeter of the Crystal Springs Zone of Contribution, as determined by the Crystal Springs Water District, and other National Forest System land in and around the Inn at Cooper Spur and the Cooper Spur Ski Area, as depicted on the map entitled "Crystal Springs Watershed Special Resources Management Unit" and dated June 2006 (in this subtitle referred to as the "official map").
- (b) DESIGNATION.—The special resources management unit established pursuant to subsection (a) shall be known as the Crystal Springs Watershed Special Resources Management Unit, in this title referred to as the "Management Unit".
- (c) EXCLUSION OF CERTAIN LAND.—The Management Unit does not include any National Forest System land otherwise covered by subsection (a) that is designated as wilderness by title I.
- (d) WITHDRAWAL.—Subject to valid existing rights, National Forest System land included in the Management Unit are permanently withdrawn from all forms of appropriation under the public land laws, including the mining laws and mineral and geothermal leasing laws.
  - (e) MAPS AND LEGAL DESCRIPTION.-
- (1) SUBMISSION OF LEGAL DESCRIPTIONS.—As soon as practicable after the effective date specified in section 705, the Secretary shall prepare and submit to Congress a legal description of the Management Unit.
- (2) FORCE OF LAW.—The map referred to in subsection (a) and the legal descriptions prepared under paragraph (1) shall have the same force and effect as if included in this Act, except that the Secretary may correct technical errors in the map and legal descriptions. The map of the Crystal Springs Zone of Contribution is incorporated in this Act to delineate the boundaries of the Management Unit, and the delineation of these boundaries is not intended to affect the specific uses that may occur on private land within the boundaries of the Management Unit.
- (3) PUBLIC AVAILABILITY.—The map referred to in subsection (a) and the legal descriptions prepared under paragraph (1) shall be filed and made available for public inspection in the appropriate offices of the Forest Service.

## SEC. 703. ADMINISTRATION OF MANAGEMENT UNIT.

- (a) GENERAL APPLICABILITY OF EXISTING LAWS.—Except as provided in this title, all other laws and regulations affecting National Forest System lands shall continue to apply to the National Forest System lands included in the Management Unit.
  - (b) AUTHORIZED ACTIVITIES.-
- (1) PROCESS FOR ALLOWING ACTIVITIES.— Only activities described in this subsection may occur in the Management Unit, and the Secretary of Agriculture may permit an ac-

- tivity described in this subsection to occur in the Management Unit only after the Secretary—
- (A) obtains the review and opinions of the Crystal Springs Water District regarding the effect of the activity on the purposes of the Management Unit:
- (B) complies with all applicable Federal law regarding development and implementation of the activity; and
- (C) when appropriate, provides to the general public advance notice of the activity, an opportunity to comment on the activity, and appeal rights regarding the activity.
  - (2) RECREATION.—The Secretary may-
- (A) continue to maintain recreational opportunities and trails, in existence in the Management Unit as of the effective date specified in section 705, within their existing and historic footprints or at an alternative location; and
- (B) develop new footpaths or cross-county skiing trails in the Management Unit.
- (3) LEASE OF CERTAIN IMPROVEMENTS.—The Secretary may lease improvements and facilities, in existence in the Management Unit as of the effective date specified in section 705, within their existing and designated footprints to 1 or more concessionaires.
- (4) ROAD MAINTENANCE.—Subject to subsection (d), the Secretary may maintain National Forest System roads, in existence in the Management Unit as of the effective date specified in section 705 or as directed by the management plan required by subsection (d). Maintenance may include the installation of culverts and drainage improvements and other similar activities.
- (5) FUEL REDUCTION IN PROXIMITY TO IMPROVEMENTS AND PRIMARY PUBLIC ROADS.—To protect the water quality, water quantity, scenic, cultural, historic, natural, and wild-life values of the Management Unit, the Secretary may permit fuel reduction on National Forest System land in the Management Unit—
- (A) extending up to 400 feet from structures on National Forest System land or structures on adjacent private land; and
- (B) extending up to 400 feet from the Cooper Spur Road, the Cloud Cap Road, and the Cooper Spur ski area loop road.
- (6) Other fuel reduction and forest HEALTH ACTIVITIES -The Secretary may conduct fuel reduction and forest health management activities in the Management Unit. with priority given to activities that restore previously harvested stands, including the removal of logging slash, smaller diameter material, and ladder fuels. The purpose of any fire risk reduction or forest health management activity conducted in the Management Unit shall be the maintenance and restoration of fire-resilient forest structures containing late successional forest structure characterized by large trees and multi-storied canopies (where ecologically appropriate) and the protection of the water quality, water quantity, scenic, cultural, historic, natural, and wildlife values of the Management Unit.
- (c) SPECIFICALLY PROHIBITED ACTIVITIES.— The following activities may not occur on National Forest System land in the Management Unit, whether separately or, except as provided in paragraph (2), as part of an activity authorized by subsection (b):
- (1) New road construction or renovation of existing non-System roads.
- (2) Projects undertaken for the purpose of harvesting commercial timber. The harvest of merchantable products that are by-products of activities conducted pursuant to subsection (b)(6) and carried out pursuant to a stewardship contract are not prohibited by this subsection.
  - (3) Commercial livestock grazing.

- (4) The placement or maintenance of fuel storage tanks.
- (5) The application of any toxic chemicals, including pesticides, rodenticides, herbicides, or retardants, for any purpose, except with the consent of the Crystal Springs Water District.
  - (d) MANAGEMENT PLAN.-
- (1) PLAN REQUIRED.—Within 9 months after the effective date specified in section 605, the Secretary of Agriculture shall adopt a management plan for the Management Unit that, while providing for the limited activities specifically authorized by subsection (b), protects the watershed from illegal dumping, human waste, fires, vandalism, and other risks to water quality.
- (2) CONSULTATION AND PUBLIC PARTICIPATION.—The Secretary shall prepare the management plan in consultation with the Crystal Springs Water District, the Cooper Spur Wild and Free Coalition, and Hood River County and provide for public participation as described in subsection (b)(1)(C).
- (e) FOREST ROAD CLOSURES.—As part of the management plan required by subsection (d), the Secretary of Agriculture may provide for the closure or gating to the general public of any Forest Service road within the Management Unit, except for the road commonly known as Cloud Cap Road.
- (f) PRIVATE LAND.—Nothing in this section affects the use of, or access to, any private property within the Crystal Springs Zone of Contribution by the owners of the private property and their guests. The Secretary is encouraged to work with interested private landowners who have voluntarily agreed to cooperate with the Secretary to further the purposes of this title.
- (g) RELATIONSHIP WITH WATER DISTRICT.— Except as provided in this section, the Crystal Springs Water District has no authorities over management or use of National Forest System land included in the Management Unit.

## SEC. 704. ACQUISITION OF LANDS.

- (a) Acquisition Authority.—The Secretary of Agriculture may acquire from willing landowners any lands located in the Crystal Springs Zone of Contribution within the boundaries of Mount Hood National Forest. Lands so acquired shall automatically be added to the Management Unit.
- (b) Prohibition on Subsequent Conveyance.—The Secretary may not sell, trade, or otherwise transfer ownership of any land within the Management Unit, including any of the land acquired under subsection (a) or received by the Secretary as part of the Cooper Spur-Government Camp land exchange authorized by subtitle A of title V and included within the Management Unit, to any person.

## SEC. 705. EFFECTIVE DATE.

The Secretary of Agriculture shall establish the Management Unit as soon as practicable after the final closing of the Cooper Spur-Government Camp land exchange authorized by subtitle A of title V, but in no case later than 30 days after the date of the final closing of such land exchange. The Management Unit may not be established before final closing of the land exchange.

## TITLE VIII—LOCAL AND TRIBAL RELATIONSHIPS

## SEC. 801. FINDINGS AND PURPOSE.

The purpose of this title is to recognize and support the ability of Native Americans to continue to gather first foods in the Mount Hood National Forest using traditional methods and the central role of the State and local governments in management of issues dealing with natural and developed environments in the vicinity of the national forest.

#### SEC. 802. FIRST FOODS GATHERING AREAS.

- (a) PRIORITY USE AREAS.—The Secretary of Agriculture shall identify, establish, develop, and manage priority-use areas in Mount Hood National Forest for the gathering of first foods by members of Indian tribes with treaty-reserved gathering rights on lands encompassed by the national forest. The priority-use areas shall be identified, established, developed, and managed in a manner consistent with the memorandum of understanding entered into between the Department of Agriculture, the Bureau of Land Management, the Bureau of Indian Affairs, and the Confederated Tribes of the Warm Springs Reservation of Oregon (in this section referred to as the "Warm Springs Tribe") and dated April 23, 2003, and such further agreements as are necessary between the Secretary of Agriculture and the Warm Springs Tribe to carry out the purposes of this section.
- (b) PRIORITY USE.—Members of Indian tribes with treaty-reserved gathering rights on lands encompassed by Mount Hood National Forest shall, in cooperation with the Mount Hood National Forest, gather first foods in the priority-use areas established pursuant to subsection (a).
- (c) APPLICABLE LAW.—In considering and selecting National Forest System land for inclusion in a priority-use area under subsection (a), the Secretary of Agriculture shall comply with the land and resource management plan for Mount Hood National Forest and applicable laws.
- (d) DEFINITION.—In this section, the term "first foods" means roots, berries, and plants on National Forest System land in Mount Hood National Forest that have been gathered for traditional and cultural purposes by members of Indian tribes with treaty-reserved gathering rights on lands encompassed by Mount Hood National Forest.

## SEC. 803. FOREST SERVICE COORDINATION WITH STATE AND LOCAL GOVERNMENTS.

Congress encourages the Secretary of Agriculture to cooperate with the State, local communities, counties, and Indian tribes in the vicinity of Mount Hood National Forest, and the heads of other Federal agencies to identify common ground, coordinate planning efforts around the national forest, and make the Federal Government a better partner in building cooperative and lasting solutions for management of Mount Hood National Forest and non-Federal land in the vicinity of the national forest.

### SEC. 804. SAVINGS PROVISIONS REGARDING RE-LATIONS WITH INDIAN TRIBES.

- (a) TREATY RIGHTS.—Nothing in this Act is intended to alter, modify, enlarge, diminish, or extinguish the treaty rights of any Indian tribe, including the off-reservation reserved rights established by the Treaty of June 25, 1855, with the Tribes and Bands of Middle Oregon (12 Stat. 963). Section 702 is consistent with and intended to implement the gathering rights reserved by such treaty.
- (b) TRIBAL LANDS.—Nothing in this Act is intended to affect lands held in trust by the Secretary of the Interior for Indian tribes or individual members of Indian tribes or other lands acquired by the Army Corps of Engineers and administered by the Secretary of the Interior for the benefit of Indian tribes and individual members of Indian tribes.
- (c) HUNTING AND FISHING.—Nothing in this Act is intended to affect the laws, rules, and regulations pertaining to hunting and fishing under existing State and Federal laws and Indian treaties.

#### SEC. 805. IMPROVED NATURAL DISASTER PRE-PAREDNESS.

(a) IMPOSITION OF STANDARDS.—New development occurring on land conveyed by the Secretary of Agriculture under title V or un-

dertaken or otherwise permitted by the Secretary of Agriculture on National Forest System land in Mount Hood National Forest after the date of the enactment of this Act shall be constructed or altered in compliance with—

(1) 1 of—

- (A) the nationally recognized model building codes; and
- (B) nationally recognized wildland-urban interface codes and standards; or
- (2) 1 of the other applicable nationally recognized codes and standards relating to—
- (A) fire protection infrastructure in the wildland urban interface;
- (B) land development in wildland areas; or
- (C) wild fire hazard mitigation.
- (b) INCLUSION OF STANDARDS IN LAND CONVEYANCES.—In the case of each of the land conveyances described in title V, the Secretary shall impose the requirements of subsection (a) as a condition on the conveyance of the Federal land under the conveyance.
- (c) EFFECT ON STATE AND LOCAL LAW.—To the maximum extent feasible, the codes imposed pursuant to subsection (a) shall be consistent with the nationally recognized codes and development standards adopted or referenced by the State or political subdivisions of the State. This section shall not be construed to limit the power of the State or a political subdivision of the State to implement or enforce any law, rule, regulation, or standard concerning fire prevention and control.
- (d) ENFORCEMENT.—The codes imposed pursuant to subsection (a) may be enforced by the same entities otherwise enforcing codes, ordinances, and standards relating to new development occurring on land conveyed by the Secretary of Agriculture under title V.

### TITLE IX—RECREATION

### SEC. 901. FINDINGS AND PURPOSE.

The purpose of this title is to recognize and support recreation as a dynamic social and economic component of the legacy and future of the Mount Hood National Forest.

# SEC. 902. RETENTION OF MOUNT HOOD NATIONAL FOREST LAND USE FEES FROM SPECIAL USE AUTHORIZATIONS.

- (a) Special Account.—The Secretary of the Treasury shall establish a special account in the Treasury for Mount Hood National Forest.
- (b) DEPOSITS.—Except as provided in section 7 of the Act of April 24, 1950 (commonly known as the Granger-Thye Act; 16 U.S.C. 580d), the National Forest Organizational Camp Fee Improvement Act of 2003 (title V of division F of Public Law 108-107; 16 U.S.C. 6231 et seq.), Public Law 106-206 (commonly known as the Commercial Filming Act: 16 U.S.C. 4601-d), and the Federal Lands Recreation Enhancement Act (title VIII of division J of Public Law 108-477; 16 U.S.C. 6801 et seq.), all land use fees received after the date which is 6 months after the date of enactment of this Act from special use authorizations, such as recreation residences, resorts, winter recreation resorts, communication uses, and linear rights-of-way, and all other special use types issued with regard to Mount Hood National Forest shall be deposited in the special account established under subsection (a).
- (c) AVAILABILITY.—Subject to subsection (d), amounts in the special account established under subsection (a) shall remain available, without further appropriation and until expended, for expenditure as provided in section 903. Upon request of the Secretary of Agriculture, the Secretary of the Treasury shall transfer to the Secretary of Agriculture from the special account such funds as the Secretary of Agriculture may request. The Secretary shall accept and use the funds in accordance with section 903.

(d) TERMINATION OF SPECIAL ACCOUNT.—The special account required by subsection (a) shall terminate at the end of the 10-year period beginning on the date of enactment of this Act. Any amounts remaining in the special account at the end of such period shall be transferred to the general fund of the Treasury.

## SEC. 903. USE OF FUNDS IN SPECIAL ACCOUNT TO SUPPORT RECREATION.

- (a) AUTHORIZED USES.—The Secretary of Agriculture shall use funds received from the special account under section 902(c) for the following purposes related to Mount Hood National Forest:
- (1) Installation, repair, maintenance, and facility enhancement related directly to visitor enjoyment, visitor access, and health and safety, such as—
- (A) the improvement and maintenance of trails, including trails used for hiking, biking, snowmobiling, horseback riding, cross-country skiing, and off-highway vehicles:
  - (B) water system improvements; and
- (C) personal sanitation facilities improvements.
- (2) Interpretive programs, visitor information, visitor services, visitor needs assessments, mapping, signage, Leave-No-Trace materials, and wilderness rangers.
- (3) Habitat restoration directly related to recreation.
- (4) Cooperative environmental restoration projects with non-Federal partnership groups and associations, including groups and associations that work with youth.
- (5) Law enforcement and rescue and recovery efforts related to public use and recreation, such as law enforcement at recreation events, search and rescue operations, illegal recreation activities investigations, and enforcement.
- (6) Improving administration of special use authorizations.
- (7) Preparation of documents required under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.) in connection with the improvement or development of recreational opportunities.
- (8) Other projects or partnerships recommended by the Mount Hood National Forest Recreation Working Group established by section 905.
- (b) ALLOCATION REQUIREMENTS.—Of the total funds received by the Secretary of Agriculture from the special account under section 902(c) for a fiscal year, the Secretary shall allocate the funds as follows:
- (1) 95 percent of the funds to Mount Hood National Forest.
- (2) 5 percent of the funds to the Regional Office for the Pacific Northwest Region of the Forest Service to develop needed policy and training to support programs in wilderness areas, special uses, trails, developed and dispersed recreation, and interpretation related to Mount Hood National Forest.

## SEC. 904. ANNUAL REPORTING REQUIREMENT.

The Secretary of Agriculture shall submit to Congress an annual report specifying—

- (1) the total funds received by the Secretary from the special account under section 902(c) for the preceding fiscal year;
- (2) how the funds were allocated and expended; and
- (3) the results from such expenditures.

## SEC. 905. MOUNT HOOD NATIONAL FOREST RECREATIONAL WORKING GROUP.

(a) ESTABLISHMENT AND PURPOSE.—The Secretary of Agriculture shall establish the Mount Hood National Forest Recreational Working Group for the purpose of providing advice and recommendations to the Forest Service on planning and implementing recreation enhancements in Mount Hood National Forest, including advice and recommendations regarding how the funds in the special

account established under section 902 should be requested and expended.

- (b) DUTIES.—The Working Group shall—
- (1) review projects proposed by the Secretary for Mount Hood National Forest under section 903(a);
- (2) propose projects under section 903(a) to the Secretary;
- (3) recommend the amount of funds from the special account established under section 902 to be used to fund projects under section 903; and
- (4) provide opportunities for citizens, organizations, Indian tribes, the Forest Service, and other interested parties to participate openly and meaningfully, beginning at the early stages of the development of projects under section 903(a).
  - (c) Appointment.—
- (1) APPOINTMENT AND TERM.—The Regional Forester, acting on behalf of the Secretary of Agriculture, shall appoint the members of the Working Group for a term of 3 years beginning on the date of appointment. A member may be reappointed to subsequent 3-year terms.
- (2) INITIAL APPOINTMENT.—The Regional Forester shall make initial appointments to the Working Group not later than 180 days after the date of enactment of this Act.
- (3) VACANCIES.—The Regional Forester shall make appointments to fill vacancies on the Working Group as soon as practicable after the vacancy has occurred.
- (4) COMPENSATION.—Members of the Working Group shall not receive any compensation for their service on the Working Group.
- (5) NOMINATIONS.—The State, county, and Tribal governments for each county directly adjacent to or containing any portion of Mount Hood National Forest may submit a nomination to the Regional Forester for each activity or interest group category described in subsection (d).
- (6) Broad and balanced representa-TION.—In appointing the members of the Working Group, the Regional Forester shall provide for a balanced and broad representation from the recreation community.
- (d) COMPOSITION OF WORKING GROUP.—The Working Group shall be composed of 15 members, selected so that the following activities and interest groups are represented:
- (1) Summer non-mechanized recreation, such as hiking.
- (2) Winter non-motorized recreation, such as snowshoeing and backcountry skiing.
  - (3) Mountain biking.
  - (4) Hunting and fishing.
- (5) Summer motorized recreation, such as off-highway vehicle use.
- (6) Local environmental groups.
- (7) Winter motorized recreation, such as snowmobiling.
  - (8) Permitted ski areas.
  - (9) Forest products industry.
- (10) Affected Indian tribes.
- (11) Local holder of a recreation residence permit.
- (12) Local government interests, such as a county commissioner or city mayor in an elected position representing a county or city directly adjacent or containing any portion of Mount Hood National Forest.
- (13) A resident of Government Camp.
- (14) The State.
- (15) Operators of campground facilities open to the general public.
- (e) CHAIRPERSON.—The chairperson of the Working Group shall be selected by a majority of the Working Group.
- (f) OTHER WORKING GROUP AUTHORITIES AND REQUIREMENTS.—
- (1) STAFF ASSISTANCE.—The Secretary of Agriculture shall provide staff assistance to the Working Group from Federal employees under the jurisdiction of the Secretary.

- (2) MEETINGS.—All meetings of the Working Group shall be announced at least 1 week in advance in a local newspaper of record and shall be open to the public.
- (3) RECORDS.—The Working Group shall maintain records of the meetings of the Working Group and make the records available for public inspection.
- (g) LIMITATION ON ADMINISTRATIVE ASSISTANCE.—Not more than 5 percent of the funds allocated under section 903(b) to Mount Hood National Forest for a fiscal year may be used to provide administrative assistance to the Working Group during that fiscal year.
- (h) FEDERAL ADVISORY COMMITTEE ACT.— The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the Working Group.
- (i) TERMINATION OF WORKING GROUP.—The Working Group shall terminate at the end of the 10-year period beginning on the date of enactment of this Act.

## SEC. 906. CONSIDERATION OF CONVERSION OF FOREST ROADS TO RECREATIONAL USES.

- (a) EVALUATION OF CURRENTLY CLOSED ROADS.—
- (1) CONSIDERATION FOR RECREATIONAL USE.—The Secretary of Agriculture may make a determination regarding whether the Forest Service roads in Mount Hood National Forest that were selected before the date of enactment of this Act for closure and decommissioning, but have not yet been decommissioned, should be converted to recreational uses to enhance recreational opportunities in the national forest, such as conversion to single-track trails for mountain bikes and trails for snowmobiling, off-road vehicle use, horseback riding, hiking, cross-country skiing, and other recreational uses.
- (2) CONSIDERATION OF ENVIRONMENTAL AND ECONOMIC IMPACTS.—In evaluating the feasibility and suitability of converting Forest Service roads under this subsection to recreational uses, and the types of recreational uses to be authorized, the Secretary shall take into account the environmental and economic impacts of implementing the conversion and of the resulting recreational uses.
- (3) Public Process.—The consideration and selection of Forest Service roads under this subsection for conversion to recreational uses, and the types of recreational uses to be authorized, shall be a public process, including consultation by the Secretary of Agriculture with the Mount Hood National Forest Recreational Working Group.
- (b) FUTURE CLOSURE CONSIDERATIONS.—Whenever the Secretary of Agriculture considers a Forest Service road in Mount Hood National Forest for possible closure and decommissioning after the date of enactment of this Act, the Secretary shall include, as an alternative to decommissioning the road, consideration of converting the road to recreational uses to enhance recreational opportunities in the Mount Hood National Forest.

  SEC. 907. IMPROVED TRAIL ACCESS FOR PER-

## SEC. 907. IMPROVED TRAIL ACCESS FOR PER-SONS WITH DISABILITIES. (a) CONSTRUCTION OF TRAIL.—The Sec-

- retary of Agriculture may enter into a contract with a partner organization or other person to design and construct a trail at a location selected by the Secretary in Mount Hood National Forest suitable for use by persons with disabilities.
- (b) PUBLIC PROCESS.—The selection of the trail location under subsection (a) and the preparation of the design of the trail shall be a public process, including consultation by the Secretary of Agriculture with the Mount Hood National Forest Recreational Working Group.
- (c) FUNDING.—The Secretary of Agriculture may use funds in the special account established under section 902 to carry out this section.

## TITLE X—AUTHORIZATION OF APPROPRIATIONS

#### SEC. 1001. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated such sums as are necessary to carry out this Act

## By Mr. REID:

S. 650. A bill to amend the Energy Employees Occupational Illness Compensation Program Act of 2000 to provide for certain nuclear weapons program workers to be included in the Special Exposure Cohort under the compensation program established by that Act; to the Committee on Health, Education, Labor and Pensions.

Mr. REID. Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

#### S. 650

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.

#### SECTION 1. SHORT TITLE.

This Act may be cited as the "Nevada Test Site Veterans' Compensation Act of 2007".

#### SEC. 2. FINDINGS.

Congress makes the following findings:

- (1) The contribution of the State of Nevada to the security of the United States throughout the Cold War and since has been unparalleled.
- (2) In 1950, President Harry S Truman designated what would later be called the Nevada Test Site as the country's nuclear proving grounds and, a month later, the first atmospheric test at the Nevada Test Site was detonated.
- (3) The United States conducted 100 aboveground and 828 underground nuclear tests at the Nevada Test Site from 1951 to 1992.
- (4) Out of the 1,054 nuclear tests conducted in the United States, 928, or 88 percent, were conducted at the Nevada Test Site.
- (5) The Nevada Test Site has served, and continues to serve, as the premier research, testing, and development site for the nuclear defense capabilities of the United States.
- (6) The Nevada Test Site and its workers are an essential and irreplaceable part of the Nation's defense capabilities.
- (7) Individuals working on Cold War-era nuclear weapons programs were employed in facilities owned by the Federal Government and the private sector producing and testing nuclear weapons and engaging in related atomic energy defense activities for the national defense beginning in the 1940s.
- (8) These Cold War atomic energy veterans helped to build and test the nuclear arsenal that served as a deterrent during the Cold War, sacrificing their personal health and well-being in service to the United States.
- (9) During the Cold War, many of these workers were exposed to radiation, beryllium, and silica, and were placed in harm's way by the Department of Energy and contractors, subcontractors, and vendors of the Department without the workers' knowledge or consent, without adequate radiation monitoring, and without necessary protections from internal or external occupational radiation exposure.
- (10) The Energy Employees Occupational Illness Compensation Program Act of 2000 (42 U.S.C. 7384 et seq.) (in this section referred to as "EEOICPA") was enacted to ensure fairness and equity for the men and women who, during the past 60 years, performed duties uniquely related to the nuclear weapons

production and testing programs of the Department of Energy, its predecessor agencies, and its contractors by establishing a program that would provide timely, uniform, and adequate compensation for beryllium-and radiation-related health conditions.

- (11) Research by the Department of Energy, the National Institute for Occupational Safety and Health (NIOSH), NIOSH contractors, the President's Advisory Board on Radiation and Worker Health, and congressional committees indicates that at certain nuclear weapons facilities—
- (A) workers were not adequately monitored for internal or external exposure to ionizing radiation; and
- (B) records were not maintained, are not reliable, are incomplete, or fail to indicate the radioactive isotopes to which workers were exposed.
- (12) Due to the inequities posed by the factors described above and the resulting harm to the workers, Congress designated classes of atomic weapons employees at the Paducah, Kentucky, Portsmouth, Ohio, Oak Ridge K-25, Tennessee, and the Amchitka Island, Alaska, sites as members of the Special Exposure Cohort under EEOICPA.
- (13) It has become evident that it is not feasible to estimate with sufficient accuracy in a timely manner the radiation dose received by employees at the Department of Energy facility at the Nevada Test Site for many reasons, including the following:
- (A) The NIOSH Technical Basis Document, the threshold document for radiation dose reconstruction under EEOICPA, has incomplete radionuclide lists.
- (B) NIOSH has not demonstrated that it can estimate dose from exposure to large, nonrespirable hot particles.
- (C) There are significant gaps in environmental measurement and exposure data.
- (D) Resuspension doses have been seriously underestimated.
- (E) NIOSH has not been able to estimate accurately exposures to bomb assembly workers and radon levels.
- (F) NIOSH has not demonstrated that it can accurately sample tritiated water vapor.
- (G) External dose records lack integrity.
- (H) There are no beta dose data from before 1966.
- (I) There are no neutron dose data from before 1966 and only partial data after such date.
- (J) There are no internal dose data from before late 1955 or 1956, and limited data until well into the 1960s.
- (K) NIOSH has ignored exposure from more than a dozen underground tests that vented, including Blanca, Des Moines, Baneberry, Camphor, Diagonal Line, Riola, Agrini, Midas Myth. Misty Rain, and Mighty Oak.
- (L) Instead of monitoring individuals, groups were monitored, resulting in unreliable personnel monitoring.
- (14) Some Nevada Test Site workers, despite having worked with significant amounts of radioactive materials and having known exposures leading to serious health effects, have been denied compensation under EEOICPA as a result of flawed calculations based on records that are incomplete or in error, or based on faulty assumptions and incorrect models.
- (15) Although basal cell carcinoma and chronic lymphocytic leukemia are both radiogenic cancers that employees at the Nevada Test Site may have contracted in the scope of their work, EEOICPA currently will not include individuals with basal cell carcinoma as members of the Special Exposure Cohort, nor does it provide for compensation for employees with chronic lymphocytic leukemia.

- SEC. 3. INCLUSION OF CERTAIN NUCLEAR WEAPONS PROGRAM WORKERS IN SPECIAL EXPOSURE COHORT UNDER
  ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION
  PROGRAM.
- (a) IN GENERAL.—Section 3621 of the Energy Employees Occupational Illness Compensation Program Act of 2000 (42 U.S.C. 7384) is amended—
- (1) in paragraph (9), by adding at the end the following new subparagraph:
- "(C) An individual described in paragraph (14)(D)."; and
- (2) in paragraph (14), by adding at the end the following new subparagraph:
- "(D) The employee was so employed at the Nevada Test Site or other similar sites located in Nevada during the period beginning on January 1, 1950, and ending on December 31, 1993, and contracted an occupational illness, basal cell carcinoma, or chronic lymphocytic leukemia, and, during such employment—
- "(i) was present during an atmospheric or underground nuclear test or performed drillbacks, tunnel re-entry, or clean-up work following such a test (without regard to the duration of employment);
- "(ii) was present at an event involving the venting of an underground test or during a planned or unplanned radiation release (without regard to the duration of employment):
- "(iii) was present during testing or posttest activities related to nuclear rocket or ramjet engine testing at the Nevada Test Site (without regard to the duration of employment):
- "(iv) was assigned to work at Area 51 or other classified program areas of the Nevada Test Site (without regard to the duration of employment); or
- "(v) was employed at the Nevada Test Site, and was employed in a job activity that—
- "(I) was monitored for exposure to ionizing radiation: or
- "(II) was comparable to a job that is, was, or should have been monitored for exposure to ionizing radiation at the Nevada Test Site.".
- (b) DEADLINE FOR CLAIMS ADJUDICATION.—Claims for compensation under section 3621(14)(D) of the Energy Employees Occupational Illness Compensation Program Act of 2000, as added by subsection (a), shall be adjudicated and a final decision issued—
- (1) in the case of claims pending as of the date of the enactment of this Act, not later than 30 days after such date; and
- (2) in the case of claims filed after the date of the enactment of this Act, not later than 30 days after the date of such filing.

## By Mr. HARKIN (for himself and Mrs. CLINTON):

S. 651. A bill to help promote the national recommendation of physical activity to kids, families, and communities across the United States; to the Committee on Health, Education, Labor, and Pensions.

Mr. HARKIN. Mr. President, as you may have heard, today we are launching the Partnership for Play Every Day and it has been spearheaded by three terrific organizations: the YMCA, the National Recreation and Park Association, and the National Association for Sport and Physical Education. Together, they have 350 years of experience in helping our kids to be physically active or, to use the old-fashioned word, "to play."

More than a century ago, these groups came together to support the

Playground Movement, which took kids out of factories and coal mines, and gave them parks and playgrounds where they could be children again.

Well, today we face a different challenge. As we confront an epidemic of childhood obesity, as many new elementary schools are built without playgrounds, as recess and PE are phased out of so many of our schools, we need a 21st century Playground Movement. And that's what we are launching this morning.

On a personal note, I have been a lifelong admirer of the YMCA. When I was in my early 20s and aspiring to join the Navy as a fighter pilot, they told me: First you've got to learn how to swim. So what did I do? I signed up at the Y in downtown Des Moines for swimming lessons.

Well, the Y was there for me, just as the Y is there for millions of American families, giving them the facilities and tools to stay fit and healthy.

You know, there is something fundamentally wrong when kids spend their free time parked in front of the TV instead of playing in parks.

I mentioned the childhood obesity epidemic. "Epidemic" is not my word. That's what the Centers for Disease Control and Prevention call it. Today, nearly 15 percent of American children and teenagers are obese. A quarter of the children between the ages of 5 and 10 already show the early warning signs of heart disease. Cases of adultonset diabetes in children—which used to be almost unheard of—have exploded tenfold in the last two decades.

Add it all up, and experts say there is a very real prospect that today's kids could be the first generation in American history to have a shorter lifespan than their parent's generation.

And that is unacceptable. We are not going to let that happen. And that is why we have set the goal of ensuring that every child in America gets 60 minutes of play and physical activity every day.

Hand in hand with this important new initiative, today I am honored to introduce with Senator HILLARY CLINTON a bill called the PLAY Every Day Act. That first word, PLAY, is an acronym for "Promoting Lifelong Active Communities."

The PLAY Every Day Act will help to promote the national physical-activity standards for both children and adults.

To that end, the legislation will do two things:

One, it will mandate the development of a well-validated assessment tool called the "community play index," to identify barriers preventing young people from being physically active in a given community.

And two, it will help local coalitions to use this "community play index" as they craft plans to promote physical activity and wellness in their communities.

My vision is to have every community in America focused on promoting health and preventing disease—instead of just dealing with the bad consequences of obesity, diabetes, and heart disease.

By the way, I am grateful to the good corporate citizens that are joining in the Partnership for Play Every Day, including PepsiCo, Toyota, Kellogg Company, General Mills, PlayCore, and Landscape Structures. Your support of this legislation and new initiative is going to be critical to the Partnership's success.

So, again, I salute all the players in this new Partnership. Together, we can build a better, healthier future for America's children.

By Mr. DURBIN (for himself and Mr. Schumer):

S. 654. A bill to establish the Food Safety Administration to protect the public health by preventing food-borne illness, ensuring the safety of food, improving research on contaminants leading to food-borne illness, and improving security of food from intentional contamination, and for other purposes; to the Committee on Agriculture, Nutrition, and Forestry.

Mr. DURBIN. Mr. President, years ago, a friend from Chicago went out and bought hamburger meat at a local grocery store. She took it home, cooked it, and gave it to her five-year-old boy. That poor boy was exposed to E. coli and died a few days later, a gruesome, horrible death.

In 1992, four children died and 700 people were sickened by an E. coli outbreak that was traced to hamburgers served at Jack in the Box restaurants. That outbreak proved to be a pivotal moment in the history of the beef industry. The Federal Government revamped the meat inspection program which has led a decline in the number of illnesses from beef since 2000.

The E. coli outbreaks from fresh produce that occurred at the end of 2006 may prove to be the critical events for the produce industry as the Jack in the Box outbreak was for the meat industry. Three people died and nearly 200 were sickened in 26 States due to E. coli that was traced back to packaged spinach

The breadth of the problem of foodborne illness is stunning. The Centers for Disease Control and Prevention estimate that as many as 76 million people suffer from food poisoning each year. Of those individuals, approximately 325,000 will be hospitalized and more than 5,000 will die. Children and the elderly are especially vulnerable to foodborne pathogens. Despite these statistics, our food supply is still the safest in the world; however, there are widening gaps in our food safety system due to the fact that food safety oversight has evolved over time and is spread across several agencies.

As the number of foods imported from outside the United States continues to increase so do concerns that terrorists could easily attack our food supply and distribute a harmful product widely. It is more important now then ever to reinforce any potential weak spots in our food safety system.

Last month, the Government Accountability Office (GAO) designated the Federal oversight of food safety as a high-risk area. In order to achieve greater effectiveness and accountability, there needs to be a broad-based transformation of our federal food safety oversight. GAO concluded that the fragmented federal system, with 15 agencies collectively administering at least 30 laws, has caused inconsistent oversight and an inefficient use of resources. An accidental or deliberate contamination of the food supply could undermine consumer confidence and cause severe economic consequences. It is not a surprise that GAO placed food safety oversight on its high-risk list this year. GAO has been calling for a single food safety agency for the past 30 years.

Here is one example of where our current food safety system doesn't make sense. Take a pre-packaged ham and cheese sandwich that's available at your local convenience store. The way the sandwich is regulated depends on how it is presented. USDA has jurisdiction if the sandwich is a packaged open-face meat or poultry sandwich that contains one slice of bread. If the sandwich is a closed-face meat or poultry sandwich, meaning it has two slices of bread, FDA inspects it. USDA inspects the open-face sandwiches that are sold in interstate commerce on a daily basis while FDA inspects closedface sandwiches an average of once every five years.

Here's another example that illustrates the inefficient use of resources. The U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) both inspect shipments of imported food at 18 U.S. ports-ofentry; however the two agencies do not share inspection resources at these ports. USDA import inspectors are assigned to USDA-approved import inspection facilities at these ports and some of the ports also handle FDA-regulated products. USDA does not have jurisdiction over the FDA-regulated products. USDA has inspectors assigned to these facilities every day while the FDA-regulated products may remain at the facilities for some time awaiting FDA inspection. In fiscal year 2003, USDA spent nearly \$16 million on imported food inspections and FDA spent over \$115 million. This is just one example of where millions of dollars could have been saved if one agency oversaw the inspection process.

Please join me in sponsoring the Safe Food Act of 2007, which addresses our Nation's fractured food safety system. The Safe Food Act of 2007 would create a single, independent Federal food safety agency to administer all aspects of Federal food safety efforts, including inspections, enforcement, standards-setting and research, in order to protect public health. The agencies and sub-agencies now charged with pro-

tecting the food supply, primarily housed at the Food and Drug Administration and the Department of Agriculture, would be transferred to this new agency.

A single food safety agency with authority based on sound scientific principles would provide this country with the greatest hope of reducing foodborne illness, and would also prevent or minimize the harm of a bioterrorist attack on our food supply. The Safe Food Act of 2007 would put authority for imported and domestic food in the hands of one Food Safety Administrator. The Administrator would oversee one science-based food safety law that would harmonize the various authorities that currently govern food safety regulation.

Our food distribution system has undergone many changes over the years. For example, in the past, it was likely that produce that ended up in a local grocery store came from a farm not too far from the retailer. Fast forward to today produce grown on a single farm in one state could end up on dinner tables in many states across the country. We cannot continue trying to use a 1950s food safety model to oversee a 21st Century food distribution system. That's like asking a propeller plane to keep up with an F-18. We need to change, to shed the old bureaucratic shackles that have tied us to the overlapping and inefficient ad hoc food safety system of the past and create a system fit for the 21st Century.

I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the Record, as follows:

S. 654

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.

## SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

- (a) Short Title.—This Act may be cited as the "Safe Food Act of 2007".
- (b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:
- Sec. 1. Short title; table of contents.
- Sec. 2. Findings; purposes.
- Sec. 3. Definitions.

## TITLE I—ESTABLISHMENT OF FOOD SAFETY ADMINISTRATION

- Sec. 101. Establishment of Food Safety Administration.
- Sec. 102. Consolidation of separate food safety and inspection services and agencies
- Sec. 103. Additional duties of the Administration.

## TITLE II—ADMINISTRATION OF FOOD SAFETY PROGRAM

- Sec. 201. Administration of national program.
- Sec. 202. Registration of food establishments and foreign food establishments.
- Sec. 203. Preventative process controls to reduce adulteration of food.
- Sec. 204. Performance standards for contaminants in food.
- Sec. 205. Inspections of food establishments.
- Sec. 206. Food production facilities.
- Sec. 207. Federal and State cooperation.

- Sec. 208. Imports.
- Sec. 209. Resource plan.
- Sec. 210. Traceback.

#### TITLE III—RESEARCH AND EDUCATION

- Sec. 301. Public health assessment system.
- Sec. 302. Public education and advisory sys
  - tem.

## Sec. 303. Research.

## TITLE IV—ENFORCEMENT

- Sec. 401. Prohibited Acts.
- Sec. 402. Food detention, seizure, and condemnation.
- Sec. 403. Notification and recall.
- Sec. 404. Injunction proceedings.
- Sec. 405. Civil and criminal penalties.
- Sec. 406. Presumption.
- Sec. 407. Whistleblower protection.
- Sec. 408. Administration and enforcement.
- Sec. 409. Citizen civil actions.

#### TITLE V—IMPLEMENTATION

- Sec. 501. Definition.
- Sec. 502. Reorganization plan.
- Sec. 503. Transitional authorities.
- Sec. 504. Savings provisions.
- Sec. 505. Conforming amendments.
- Sec. 506. Additional technical and conforming amendments.
- Sec. 507. Regulations.
- Sec. 508. Authorization of appropriations.
- Sec. 509. Limitation on authorization of appropriations.

Sec. 510. Effective date.

### SEC. 2. FINDINGS; PURPOSES.

- (a) FINDINGS.—Congress finds that—
- (1) the safety of the food supply of the United States is vital to the public health, to public confidence in the food supply, and to the success of the food sector of the Nation's economy:
- (2) lapses in the protection of the food supply and loss of public confidence in food safety are damaging to consumers and the food industry, and place a burden on interstate commerce;
- (3) the safety and security of the food supply requires an integrated, system-wide approach to preventing food-borne illness, a thorough and broad-based approach to basic and applied research, and intensive, effective, and efficient management of the Nation's food safety program;
- (4) the task of preserving the safety of the food supply of the United States faces tremendous pressures with regard to—
- (A) emerging pathogens and other contaminants and the ability to detect all forms of contamination;
- (B) an aging and immune compromised population, with a growing number of people at high-risk for food-borne illnesses, including infants and children;
- (C) an increasing volume of imported food, without adequate monitoring and inspection; and
- (D) maintenance of rigorous inspection of the domestic food processing and food service industries:
- (5) Federal food safety standard setting, inspection, enforcement, and research efforts should be based on the best available science and public health considerations and food safety resources should be systematically deployed in ways that most effectively prevent food-borne illness;
- (6) the Federal food safety system is fragmented, with at least 12 Federal agencies sharing responsibility for food safety, and operates under laws that do not reflect current conditions in the food system or current scientific knowledge about the cause and prevention of food-borne illness;
- (7) the fragmented Federal food safety system and outdated laws preclude an integrated, system-wide approach to preventing food-borne illness, to the effective and efficient operation of the Nation's food safety

program, and to the most beneficial deployment of food safety resources;

- (8) the National Academy of Sciences recommended in the report "Ensuring Safe Food from Production to Consumption" that Congress establish by statute a unified and central framework for managing Federal food safety programs, and recommended modifying Federal statutes so that inspection, enforcement, and research efforts are based on scientifically supportable assessments of risks to public health; and
- (9) the lack of a single focal point for food safety leadership in the United States undercuts the ability of the United States to exert food safety leadership internationally, which is detrimental to the public health and the international trade interests of the United States.
- (b) Purposes.—The purposes of this Act are—
- (1) to establish a single agency to be known as the "Food Safety Administration" to—
- (A) regulate food safety and labeling to strengthen the protection of the public health;
- (B) ensure that food establishments fulfill their responsibility to produce food in a manner that protects the public health of all people in the United States;
- (C) lead an integrated, system-wide approach to food safety and to make more effective and efficient use of resources to prevent food-borne illness:
- (D) provide a single focal point for food safety leadership, both nationally and internationally; and
- (E) provide an integrated food safety research capability, utilizing internally-generated, scientifically and statistically valid studies, in cooperation with academic institutions and other scientific entities of the Federal and State governments, to achieve the continuous improvement of research on food-borne illness and contaminants;
- (2) to transfer to the Food Safety Administration the food safety, labeling, inspection, and enforcement functions that, as of the day before the effective date of this Act, are performed by other Federal agencies; and
- (3) to modernize and strengthen the Federal food safety laws to achieve more effective application and efficient management of the laws for the protection and improvement of public health.

## SEC. 3. DEFINITIONS.

- In this Act:
- (1) Administration.—The term "Administration" means the Food Safety Administration established under section 101(a)(1).
- (2) ADMINISTRATOR.—The term "Administrator" means the Administrator of Food Safety appointed under section 101(a)(3).
- (3) Adulterated.—
- (A) IN GENERAL.—The term "adulterated" has the meaning described in subsections (a) through (c) of section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342).
- (B) INCLUSION.—The term "adulterated" includes bearing or containing a contaminant that causes illness or death among sensitive populations.
- (4) AGENCY.—The term "agency" has the meaning given that term in section 551 of title 5, United States Code.
- (5) CATEGORY 1 FOOD ESTABLISHMENT.—The term "category 1 food establishment" means a food establishment that slaughters animals for food.
- (6) CATEGORY 2 FOOD ESTABLISHMENT.—The term "category 2 food establishment" means a food establishment that processes raw meat, poultry, seafood products, regardless of whether the establishment also has a kill step, and animal feed and other products that the Administrator determines by regu-

- lation to be at high risk of contamination and the processes of which do not include a step validated to destroy contaminants.
- (7) CATEGORY 3 FOOD ESTABLISHMENT.—The term "category 3 food establishment" means a food establishment that processes meat, poultry, seafood products, and other products that the Administrator determines by regulation to be at high risk of contamination and whose processes include a step validated to destroy contaminants.
- (8) CATEGORY 4 FOOD ESTABLISHMENT.—The term "category 4 food establishment" means a food establishment that processes all other categories of food products not described in paragraphs (5) through (7).
- (9) CATEGORY 5 FOOD ESTABLISHMENT.—The term "category 5 food establishment" means a food establishment that stores, holds, or transports food products prior to delivery for retail sale
- (10) CONTAMINANT.—The term "contaminant" includes a bacterium, chemical, natural or manufactured toxin, virus, parasite, prion, physical hazard, or other human pathogen that when found on or in food can cause human illness, injury, or death.
- (11) CONTAMINATION.—The term "contamination" refers to a presence of a contaminant in food.
  - (12) FOOD.—
- (A) IN GENERAL.—The term "food" means a product intended to be used for food or drink for a human or an animal.
- (B) INCLUSIONS.—The term "food" includes any product (including a meat food product, as defined in section 1(j) of the Federal Meat Inspection Act (21 U.S.C. 601(j))), capable for use as human food that is made in whole or in part from any animal, including cattle, sheep, swine, or goat, or poultry (as defined in section 4 of the Poultry Products Inspection Act (21 U.S.C. 453)), and animal feed.
- (C) EXCLUSION.—The term "food" does not include dietary supplements, as defined in section 201(ff) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)).
  - (13) FOOD ESTABLISHMENT.—
- (A) IN GENERAL.—The term "food establishment" means a slaughterhouse, factory, warehouse, or facility owned or operated by a person located in any State that processes food or a facility that holds, stores, or transports food or food ingredients.
- (B) EXCLUSIONS.—For the purposes of registration, the term "food establishment" does not include a farm, restaurant, other retail food establishment, nonprofit food establishment in which food is prepared for or served directly to the consumer, or fishing vessel (other than a fishing vessel engaged in processing, as that term is defined in section 123 3 of title 21 Code of Federal Regulations)
- (14) FOOD PRODUCTION FACILITY.—The term "food production facility" means any farm, ranch, orchard, vineyard, aquaculture facility, or confined animal-feeding operation.
- (15) FOOD SAFETY LAW.—The term "food safety law" means—
- (A) the provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) related to and requiring the safety, labeling, and inspection of food, infant formulas, food additives, pesticide residues, and other substances present in food under that Act;
- (B) the provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and of any other Act that are administered by the Center for Veterinary Medicine of the Food and Drug Administration;
- (C) the Poultry Products Inspection Act (21 U.S.C. 451 et seq.);
- (D) the Federal Meat Inspection Act (21  $U.S.C.\ 601$  et seq.);
- (E) the Egg Products Inspection Act (21 U.S.C. 1031 et seq.);
- (F) the Sanitary Food Transportation Act of 1990 (49 U.S.C. App. 2801 et seq.);

- (G) the amendments made by the Sanitary Food Transportation Act of 2005 (subtitle B of title VII of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users) (21 U.S.C. 301 note);
- (H) the provisions of the Humane Methods of Slaughter Act of 1978 (21 U.S.C. 601 note) administered by the Food Safety and Inspection Service:
- (I) the provisions of this Act; and
- (J) such other provisions of law related to and requiring food safety, labeling, inspection, and enforcement as the President designates by Executive order as appropriate to include within the jurisdiction of the Administration.
- (16) FOREIGN FOOD ESTABLISHMENT.—The term "foreign food establishment" means a slaughterhouse, factory, warehouse, or facility located outside the United States that processes food for consumption that is imported into the United States or food ingredients.
- INTERSTATE COMMERCE.—The term (17)"interstate commerce" has the meaning given that term in section 201(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(b))
- (18) MISBRANDED.—The term "misbranded" has the meaning given that term in section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343).
- (19) PROCESS.—The term "process" or "processing" means the commercial harvesting, slaughter, packing, preparation, or manufacture of food.
- (20) SAFE.—The term "safe" refers to human and animal health.
- (21) STATE.—The term "State" means-
- (A) a State:

ling the hazard.

- (B) the District of Columbia;
- (C) the Commonwealth of Puerto Rico; and (D) any other territory or possession of the United States.
- (22) Validation.—The term "validation" means the obtaining of evidence that the food hygiene control measure or measures selected to control a hazard in food is capable of effectively and consistently control-
- (23) STATISTICALLY VALID.—With respect to a study, the term "statistically valid" means evaluated and conducted under standards set by the National Institute of Standards and Technology.

## TITLE I—ESTABLISHMENT OF FOOD SAFETY ADMINISTRATION

## SEC. 101. ESTABLISHMENT OF FOOD SAFETY AD-MINISTRATION.

- (a) Establishment.—
- (1) IN GENERAL —There is established in the executive branch an agency to be known as the "Food Safety Administration"
- (2) STATUS.—The Administration shall be an independent establishment (as defined in section 104 of title 5, United States Code).
- (3) HEAD OF ADMINISTRATION.—The Administration shall be headed by the Administrator of Food Safety, who shall be appointed by the President, by and with the advice and consent of the Senate.
- (b) DUTIES OF ADMINISTRATOR.—The Administrator shall-
- (1) administer and enforce the food safety law:
- (2) serve as a representative to international food safety bodies and discussions;
- (3) promulgate regulations to ensure the security of the food supply from all forms of contamination, including intentional contamination; and
  - (4) oversee-
- (A) implementation of Federal food safety inspection, enforcement, and research efforts, to protect the public health;
- (B) development of consistent and sciencebased standards for safe food;

- (C) coordination and prioritization of food safety research and education programs with other Federal agencies;
- (D) prioritization of Federal food safety efforts and deployment of Federal food safety resources to achieve the greatest possible benefit in reducing food-borne illness;
- (E) coordination of the Federal response to food-borne illness outbreaks with other Federal and State agencies; and
- (F) integration of Federal food safety activities with State and local agencies.

#### SEC. 102. CONSOLIDATION OF SEPARATE FOOD SAFETY AND INSPECTION SERVICES AND AGENCIES.

- (a) TRANSFER OF FUNCTIONS.—For each Federal agency specified in subsection (b). there are transferred to the Administration all functions that the head of the Federal agency exercised on the day before the effective date of this Act (including all related functions of any officer or employee of the Federal agency) that relate to administration or enforcement of the food safety law, as determined by the President.
- (b) TRANSFERRED AGENCIES.—The Federal agencies referred to in subsection (a) are-
- (1) the Food Safety and Inspection Service of the Department of Agriculture;
- (2) the Center for Food Safety and Applied Nutrition of the Food and Drug Administra-
- (3) the part of the Agriculture Marketing Service that administers shell egg surveillance services established under the Egg Products Inspection Act (21 U.S.C. 1031 et seq.);
- (4) the resources and facilities of the Office of Regulatory Affairs of the Food and Drug Administration that administer and conduct inspections of food establishments and imports:
- (5) the resources and facilities of the Office of the Commissioner of the Food and Drug Administration that support—
- (A) the Center for Food Safety and Applied Nutrition:
- (B) the Center for Veterinary Medicine; and
- (C) the Office of Regulatory Affairs facilities and resources described in paragraph (4);
- (6) the Center for Veterinary Medicine of the Food and Drug Administration; (7) the resources and facilities of the Envi-
- ronmental Protection Agency that control and regulate pesticide residues in food;
- (8) the part of the Research, Education, and Economics mission area of the Department of Agriculture related to food safety and animal feed research;
- (9) the part of the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration of the Department of Commerce that administers the seafood inspection program:
- (10) the Animal and Plant Inspection Health Service of the Department of Agriculture: and
- (11) such other offices, services, or agencies as the President designates by Executive order to carry out this Act.

### SEC. 103. ADDITIONAL DUTIES OF THE ADMINIS-TRATION.

- (a) OFFICERS AND EMPLOYEES.—The Administrator may-
- (1) appoint officers and employees for the Administration in accordance with the provisions of title 5, United States Code, relating to appointment in the competitive service: and
- (2) fix the compensation of those officers and employees in accordance with chapter 51 and with subchapter III of chapter 53 of that title, relating to classification and General Schedule pay rates.
- (b) EXPERTS AND CONSULTANTS.—The Administrator may-

- (1) procure the services of temporary or intermittent experts and consultants as authorized by section 3109 of title 5, United States Code; and
- (2) pay in connection with those services the travel expenses of the experts and consultants, including transportation and per diem in lieu of subsistence while away from the homes or regular places of business of the individuals, as authorized by section 5703 of that title.
- (c) Bureaus, Offices, and Divisions.—The Administrator may establish within the Administration such bureaus, offices, and divisions as the Administrator determines are necessary to perform the duties of the Administrator.
  - (d) ADVISORY COMMITTEES .-
- (1) IN GENERAL.—The Administrator shall establish advisory committees that consist of representatives of scientific expert bodies, academics, industry specialists, and con-
- (2) DUTIES.—The duties of an advisory committee established under paragraph (1) may include developing recommendations with respect to the development of new processes, communications, research, performance standards, and inspection.

### TITLE II—ADMINISTRATION OF FOOD SAFETY PROGRAM

#### SEC. 201. ADMINISTRATION OF NATIONAL PRO-GRAM.

- (a) ĪΝ GENERAL.—The Administrator shall-
- (1) administer a national food safety program (referred to in this section as the "program") to protect public health; and
- (2) ensure that persons who produce or process food meet their responsibility to prevent or minimize food safety hazards related to their products.
- (b) Comprehensive Analysis.—The program shall be based on a comprehensive analysis of the hazards associated with different food and with the processing of different food, including the identification and evaluation of-
- (1) the severity of the potential health risks:
- (2) the sources and specific points of potential contamination extending from the farm or ranch to the consumer that may render food unsafe:
- (3) the potential for persistence, multiplication, or concentration of naturally occurring or added contaminants in food;
- (4) opportunities across the food production, processing, distribution, and retail system to reduce potential health risks; and
- (5) opportunities for intentional contamination
- (c) Program Elements.—In carrying out the program, the Administrator shall-
- (1) adopt and implement a national system for the registration of food establishments and foreign food establishments and regular unannounced inspection of food establishments:
- (2) enforce the adoption of process controls in food establishments, based on best available scientific and public health considerations and best available technologies;
- (3) establish and enforce science-based standards for-
- (A) substances that may contaminate food; and
- (B) safety and sanitation in the processing and handling of food;
- (4) implement a statistically valid sampling program to ensure that industry programs and procedures that prevent food contamination are effective on an ongoing basis and that food meets the standards established under this Act;
- (5) implement procedures and requirements to ensure the safety and security of imported food:

- (6) coordinate with other agencies and State or local governments in carrying out inspection, enforcement, research, and monitoring:
- (7) have access to the surveillance data of the Centers for Disease Control and Prevention, and other Federal Government agencies, in order to implement a national surveillance system to assess the health risks associated with the human consumption of food or to create surveillance data and studies:
- (8) develop public education risk communication and advisory programs;
- (9) implement a basic and applied research program to further the purposes of this Act; and
- (10) coordinate and prioritize food safety research and educational programs with other agencies, including State or local agencies.

#### SEC. 202. REGISTRATION OF FOOD ESTABLISH-MENTS AND FOREIGN FOOD ESTAB-LISHMENTS.

- (a) IN GENERAL.—The Administrator shall by regulation require that any food establishment or foreign food establishment engaged in processing food in the United States be registered with the Administrator.
  - (b) REGISTRATION REQUIREMENTS.—
- (1) IN GENERAL.—To be registered under subsection (a)—
- (A) in the case of a food establishment, the owner, operator, or agent in charge of the food establishment shall submit a registration to the Administrator; and
- (B) in the case of a foreign food establishment, the owner, operator, or agent in charge of the foreign food establishment
- (i) submit a registration to the Administrator; and
- (ii) provide the name, address, and emergency contact information of the United States agent for the foreign food establishment.
- (2) Registration.—A food establishment or foreign food establishment shall submit a registration under paragraph (1) to the Administrator that—
- (A) identifies the name, address, and emergency contact information of each food establishment or foreign food establishment that the registrant operates under this Act and all trade names under which the registrant conducts business relating to food;
- (B) lists the primary purpose and business activity of each food establishment or foreign food establishment, including the dates of operation if the food establishment or foreign food establishment is seasonal;
- (C) lists the types of food processed or sold at each food establishment or, for foreign food establishments selling food for consumption in the United States, identifies the specific food categories of that food as listed under section 170.3 of title 21, Code of Federal Regulations; and
- (D) not later than 30 days after a change in the products, function, or legal status of the food establishment or foreign food establishment (including cessation of business activities), notifies the Administrator of the change.
- (3) PROCEDURE.—Upon receipt of a completed registration described in paragraph (1), the Administrator shall notify the registrant of the receipt of the registration, designate each establishment as a category 1, 2, 3, 4, or 5 food establishment, and assign a registration number to each food establishment and foreign food establishment.
- (4) LIST.—The Administrator shall compile and maintain an up-to-date list of food establishments and foreign food establishments that are registered under this section. The Administrator may establish regula-

- tions by which such list may be shared with other governmental authorities.
- (5) DISCLOSURE EXEMPTION.—The disclosure requirements under section 552 of title 5, United States Code, shall not apply to—
- (A) the list compiled under paragraph (4);
- (B) information derived from the list under paragraph (4), to the extent that it discloses the identity or location of a specific registered person.
  - (6) SUSPENSION OF REGISTRATION.—
- (A) IN GENERAL.—The Administrator may suspend the registration of a food establishment or foreign food establishment, including the facility of an importer, for violation of a food safety law.
- (B) NOTICE AND OPPORTUNITY FOR HEARING.—The Administrator shall provide notice to a registrant immediately upon the suspension of the registration of the facility and provide registrant with an opportunity for a hearing within 3 days of the suspension.
- (7) REINSTATEMENT.—A registration that is suspended under this section may be reinstated pursuant to criteria published in the Federal Register by the Administrator.

## SEC. 203. PREVENTATIVE PROCESS CONTROLS TO REDUCE ADULTERATION OF FOOD.

- (a) IN GENERAL.—The Administrator shall, upon the basis of best available public health, scientific, and technological data, promulgate regulations to ensure that food establishments carry out their responsibilities to—
- (1) process food in a sanitary manner so that it is free of dirt and filth;
- (2) limit the presence of potentially harmful contaminants in food;
- (3) implement appropriate measures of preventative process control to minimize and reduce the presence and growth of contaminants in food and meet the performance standards established under section 204;
- (4) process all fully processed or ready-toeat food in a sanitary manner, using reasonably available techniques and technologies to eliminate any potentially harmful contaminants; and
- (5) label food intended for final processing outside commercial food establishments with instructions for handling and preparation for consumption that will destroy contaminants.
- (b) REGULATIONS.—Not later than 1 year after the effective date of this Act, the Administrator shall promulgate regulations that—
- (1) require all food establishments to adopt preventative process controls that are—
- (A) adequate to protect the public health; (B) meet relevant regulatory and food safety standards; and
- (C) limit the presence and growth of contaminants in food prepared in a food establishment:
- (2) set standards for sanitation;
- (3) meet any performance standards for contaminants established under section 204;
- (4) require recordkeeping to monitor compliance:
- (5) require sampling and testing at a frequency and in a manner sufficient to ensure that process controls are effective on an ongoing basis and that regulatory standards are being met; and
- (6) provide for agency access to records kept by food establishments and submission of copies of the records to the Administrator, as the Administrator determines appropriate.
- (c) Processing Controls.—The Administrator may require any person with responsibility for or control over food or food ingredients to adopt process controls, if the process controls are needed to ensure the protection of the public health.

## SEC. 204. PERFORMANCE STANDARDS FOR CONTAMINANTS IN FOOD.

- (a) IN GENERAL.—To protect the public health, the Administrator shall establish by regulation and enforce performance standards that define, with respect to specific food-borne contaminants and foods, the level of food safety performance that a person responsible for producing, processing, or selling food shall meet.
- (b) IDENTIFICATION OF CONTAMINANTS; PERFORMANCE STANDARDS.—
- (1) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, the Administrator shall identify the food-borne contaminants and food that contribute significantly to the risk of food-borne illness.
- (2) PERFORMANCE STANDARDS.—As soon as practicable after the identification of the contaminants under paragraph (1), the Administrator shall establish appropriate performance standards to protect against all food-borne contaminants.
- (3) SIGNIFICANT CONTAMINANTS.—The Administrator shall establish performance standards for the 5 contaminants that contribute to the greatest number of illnesses or deaths associated with raw meat, poultry, and seafood not later than 3 years after the date of enactment of this Act. The Administrator shall revise such standards not less often than every 3 years.
  - (c) Performance Standards.-
- (1) IN GENERAL.—The performance standards established under this section shall include—
- (A) health-based standards that set the level of a contaminant that can safely and lawfully be present in food;
- (B) zero tolerances, including zero tolerances for fecal matter, in addition to any zero-tolerance standards in effect on the day before the date of enactment of this Act, when necessary to protect against significant adverse health outcomes;
- (C) process standards, such as log reduction criteria for cooked products, when sufficient to ensure the safety of processed food; and
- (D) in the absence of data to support a performance standard described in subparagraph (A), (B), or (C), standards that define required performance in terms of "best reasonably achievable performance", using best available technologies, interventions, and practices.
- (2) BEST REASONABLY ACHIEVABLE PERFORMANCE STANDARDS.—In developing best reasonably achievable performance standards, the Administrator shall collect, or contract for the collection of, data on current best practices and food safety outcomes related to the contaminants and foods in question, as the Administrator determines necessary.
- (3) REVOCATION BY ADMINISTRATOR.—All performance standards, tolerances, action levels, or other similar standards in effect on the date of enactment of this Act shall remain in effect until revised or revoked by the Administrator.
  - (d) Enforcement.-
- (1) IN GENERAL.—Not later than 1 year after the promulgation of a performance standard under this section, the Administrator shall implement a statistically significant sampling program to determine whether food establishments are complying with the performance standards promulgated under this section. The program established under this paragraph shall be at least as stringent as the Hazard Analysis and Critical Control Point System requirements established under part 417 of title 9, Code of Federal Regulations (or successor regulation).
- (2) INSPECTIONS.—If the Administrator determines that a food establishment fails to meet a standard promulgated under this section, and such establishment fails to take

appropriate corrective action as determined by the Administrator, the Administrator shall, as appropriate—

- (A) detain, seize, or condemn food from the food establishment under section 402;
- (B) order a recall of food from the food establishment under section 403;
- (C) increase the inspection frequency for the food establishment;
- (D) withdraw the mark of inspection from the food establishment, if in use; or
- (E) take other appropriate enforcement action concerning the food establishment, including withdrawal of registration.
- (e) Newly Identified Contaminants.—Notwithstanding any other provision of this section, the Administrator shall promulgate interim performance standards for newly identified contaminants as necessary to protect the public health.

#### SEC. 205. INSPECTIONS OF FOOD ESTABLISH-MENTS.

- (a) IN GENERAL.—The Administrator shall establish an inspection program, which shall include sampling and testing of food and food establishments, to determine if each food establishment—
  - (1) is operating in a sanitary manner:
- (2) has continuous systems, interventions, and processes in place to minimize or eliminate contaminants in food:
- (3) is in compliance with applicable performance standards established under section 204, and other regulatory requirements;
- (4) is processing food that is safe and not adulterated or misbranded:
- (5) maintains records of process control plans under section 203, and other records related to the processing, sampling, and handling of food; and
- (6) is in compliance with the requirements of the food safety law.
- (b) ESTABLISHMENT CATEGORIES AND IN-SPECTION FREQUENCIES.—The resource plan required under section 209, including the description of resources required to carry out inspections of food establishments, shall be based on the following categories and inspection frequencies, subject to subsections (c), (d), and (e):
- (1) CATEGORY 1 FOOD ESTABLISHMENTS.—A category 1 food establishment shall be subject to antemortem, postmortem, and continuous inspection of each slaughter line during all operating hours, and other inspection on a daily basis, sufficient to verify that—
- (A) diseased animals are not offered for slaughter;
- (B) the food establishment has successfully identified and removed from the slaughter line visibly defective or contaminated carcasses, has avoided cross-contamination, and destroyed or reprocessed them in a manner acceptable to the Administrator; and
- (C) that applicable performance standards and other provisions of the food safety law, including those intended to eliminate or reduce pathogens, have been satisfied.
- (2) CATEGORY 2 FOOD ESTABLISHMENTS.—A category 2 food establishment shall be randomly inspected at least daily.
- (3) CATEGORY 3 FOOD ESTABLISHMENTS.—A category 3 food establishment shall—
- (A) have ongoing verification that its processes are controlled; and
- (B) be randomly inspected at least monthly.
- (4) CATEGORY 4 FOOD ESTABLISHMENTS.—A category 4 food establishment shall be randomly inspected at least quarterly.
- (5) CATEGORY 5 FOOD ESTABLISHMENTS.—A category 5 food establishment shall be randomly inspected at least annually.
- (c) ESTABLISHMENT OF INSPECTION PROCE-DURES.—The Administrator shall establish procedures under which inspectors or safety officers shall take random samples, photo-

- graphs, and copies of records in food establishments.
- (d) ALTERNATIVE INSPECTION FREQUENCIES.—With respect to a category 2, 3, 4, or 5 food establishment, the Administrator may establish alternative increasing or decreasing inspection frequencies for subcategories of food establishments or individual establishments, to foster risk-based allocation of resources, subject to the following criteria and procedures:
- (1) Subcategories of food establishments and their alternative inspection frequencies shall be defined by regulation, subject to paragraphs (2) and (3).
- (2) Regulations of alternative inspection frequencies for subcategories of food establishments under paragraph (1) and for a specific food establishment under paragraph (4) shall provide that—
- $\overline{\rm (A)}$  category 2 food establishments shall be inspected at least monthly; and
- (B) category 3, 4, and 5 food establishments shall be inspected at least annually.
- (3) In defining subcategories of food establishments and their alternative inspection frequencies under paragraphs (1) and (2), the Administrator shall consider—
- (A) the nature of the food products being processed, stored, or transported;
- (B) the manner in which food products are processed, stored, or transported;
- (C) the inherent likelihood that the products will contribute to the risk of food-borne illness:
- (D) the best available evidence concerning reported illnesses associated with the foods produced in the proposed subcategory of establishments; and
- (E) the overall record of compliance with the food safety law among establishments in the proposed subcategory, including compliance with applicable performance standards and the frequency of recalls.
- (4) The Administrator may adopt alternative inspection frequencies for increased or decreased inspection for a specific establishment, subject to paragraphs (2) and (5) and shall periodically publish a list of establishments subject to alternative inspections.
- (5) In adopting alternative inspection frequencies for a specific establishment, the Administrator shall consider—
  - (A) the criteria in paragraph (3);
- (B) whether products from the specific establishment have been associated with a case or an outbreak of food-borne illness; and
- (C) the record of the establishment of compliance with the food safety law, including compliance with applicable performance standards and the frequency of recalls.
- (6) Before establishing decreased alternative inspection frequencies for subcategories of establishments or individual establishments, the Administrator shall—
- (A) determine, based on the best available evidence, that the alternative uses of the resources required to carry out the inspection activity would make a greater contribution to protecting the public health and reducing the risk of food-borne illness than the use of resources described in subsection (b);
- (B) describe the alternative uses of resources in general terms when issuing the regulation or order that establishes the alternative inspection frequency;
- (C) consider the supporting evidence that an individual food establishment shall submit related to whether an alternative inspection frequency should be established for such establishment by the Administrator; and
- (D) include a description of the alternative uses in the annual resource plan required in section 209.
- (e) INSPECTION TRANSITION.—The Administrator shall manage the transition to the inspection system described in this Act as follows:

- (1) In the case of a category 1 or 2 food establishment, the Administrator shall continue to implement the applicable inspection mandates of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) until—
- (A) regulations required to implement this section have been promulgated;
- (B) the performance standards required by section 204(c) have been promulgated and implemented for 1 year; and
- (C) the establishment has achieved compliance with the other applicable provisions of the food safety law.
- (2) In the case of a category 1 or 2 food establishment that, within 2 years after the promulgation of the performance standards required by section 204(c), has not achieved compliance with the food safety law, the Administrator shall—
- (A) issue an order prohibiting the establishment from operating pending a demonstration by the establishment that sufficient changes in facilities, procedures, personnel, or other aspects of the process control system have been made such that the Administrator determines that compliance with the food safety law is achieved; and
- (B) following the demonstration required in subparagraph (A), issue an order authorizing the food establishment to operate subject, at a minimum, to—
- (i) the inspection requirement applicable to the establishment under subsection (b) (1) or (2); and
- (ii) such other inspection or compliance measures determined by the Administrator necessary to assure compliance with the applicable food safety law.
- (3) In the case of a category 3 food establishment, the Administrator shall continue to implement the applicable inspection mandates of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) until—
- (A) the regulations required to implement this section have been promulgated;
- (B) the first resource plan under section 209 has been submitted; and
- (C) for individual establishments, compliance with the food safety law has been demonstrated.
- (4) In the case of a category 3 food establishment that, within 1 year after the promulgation of the regulations required to implement this section, have not demonstrated compliance with the food safety law, the Administrator shall—
- (A) issue an order prohibiting the establishment from operating, pending a demonstration by the establishment that sufficient changes in facilities, procedures, personnel, or other aspects of the process control system have been made such that the Administrator determines that compliance with the food safety law is achieved; and
- (B) following the demonstration required in subparagraph (A), issue an order authorizing the establishment to operate subject, at a minimum, to—
- (i) the inspection requirement applicable to the establishment under subsection (b)(3); and
- (ii) such other inspection or compliance measures determined by the Administrator necessary to assure compliance with the food safety law.
- (5) In the case of a category 4 or 5 food establishment, the inspection requirements of this Act shall be implemented as soon as possible after—
- (A) the promulgation of the regulations required to implement this section;

- (B) the publication of the first resource plan under section 209; and
- (C) the commencement of the first fiscal year in which the Administration is operating with budgetary resources that Congress has appropriated following consideration of the resource plan under section 209.
  - (f) Official Mark.—
  - (1) In general.—
- (A) ESTABLISHMENT.—Before the completion of the transition process under paragraphs (1) through (3) of subsection (e), the Administrator shall by regulation establish an official mark that shall be affixed to a food product produced in a category 1, 2, or 3 establishment, subject to subparagraph (B).
- (B) PREREQUISITE.—The official mark required under subparagraph (A) shall be affixed to a food product by the Administrator if the establishment has been inspected by the Administrator in accordance with the inspection frequencies under this section and the establishment is in compliance with the food safety law.
- (C) REMOVAL OF OFFICIAL MARK.—The Administrator shall promulgate regulations that provide for the removal of the official mark under this subsection if the Administrator makes a finding that the establishment is not in compliance with the food safety law.
- (2) CATEGORY 1, 2, OR 3 FOOD ESTABLISH-MENTS.—In the case of products produced in a category 1, 2, or 3 food establishment—
- (A) products subject to Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) as of the date of enactment of this Act shall remain subject to the requirement under those Acts that they bear the mark of inspection pending completion of the transition process under paragraphs (1) through (3) of subsection (e);
- (B) the Administrator shall publicly certify on a monthly basis that the inspection frequencies required under this Act have been achieved; and
- (C) a product from an establishment that has not been inspected in accordance with the required frequencies under this section shall not bear the official mark and shall not be shipped in interstate commerce.
- (3) CATEGORY 4 AND 5 FOOD ESTABLISHMENTS.—In the case of a product produced in a category 4 or 5 food establishment the Administrator shall provide by regulation for the voluntary use of the official mark established under paragraph (1), subject to—
- (A) such minimum inspection frequencies as determined appropriate by the Administrator:
- (B) compliance with applicable performance standards and other provisions of the food safety law and
- (C) such other requirements the Administrator considers appropriate.
- (g) IMPLEMENTATION.—Not later than 1 year after the effective date of this Act, the Administrator shall issue regulations to implement subsections (b) through (e).
- (h) MAINTENANCE AND INSPECTION OF RECORDS.—
- (1) In general.
- (A) RECORDS.—A food establishment shall—
- (i) maintain such records as the Administrator shall require by regulation, including all records relating to the processing, distributing, receipt, or importation of any food and
- (ii) permit the Administrator, in addition to any authority of the food safety agencies in effect on the day before the date of enactment of this Act, upon presentation of appropriate credentials and at reasonable times and in a reasonable manner, to have access

- to and copy all records maintained by or on behalf of such food establishment representative in any format (including paper or electronic) and at any location, that are necessary to assist the Administrator—
- (I) to determine whether the food is contaminated or not in compliance with the food safety law; or
  - (II) to track the food in commerce.
- (B) REQUIRED DISCLOSURE.—A food establishment shall have an affirmative obligation to disclose to the Administrator the results of testing or sampling of food, equipment, or material in contact with food, that is positive for any contaminant.
- (2) MAINTENANCE OF RECORDS.—The records in paragraph (1) shall be maintained for a reasonable period of time, as determined by the Administrator.
- (3) REQUIREMENTS.—The records in paragraph (1) shall include records describing—
- (A) the origin, receipt, delivery, sale, movement, holding, and disposition of food or ingredients:
- (B) the identity and quantity of ingredients used in the food;
- (C) the processing of the food;
- (D) the results of laboratory, sanitation, or other tests performed on the food or in the food establishment;
- (E) consumer complaints concerning the food or packaging of the food:
- (F) the production codes, open date codes, and locations of food production; and
- (G) other matters reasonably related to whether food is unsafe, is adulterated or misbranded, or otherwise fails to meet the requirements of this Act.
- (i) PROTECTION OF SENSITIVE INFORMATION.—
- (1) IN GENERAL.—The Administrator shall develop and maintain procedures to prevent the unauthorized disclosure of any trade secret or confidential information obtained by the Administrator.
- (2) LIMITATION.—The requirement under this subsection does not—
- (A) limit the authority of the Administrator to inspect or copy records or to require the establishment or maintenance of records under this Act;
- (B) have any legal effect on section 1905 of title 18, United States Code;
- (C) extend to any food recipe, financial data, pricing data, personnel data, or sales data (other than shipment dates relating to sales);
- (D) limit the public disclosure of distribution records or other records related to food subject to a voluntary or mandatory recall under section 403; or
- (E) limit the authority of the Administrator to promulgate regulations to permit the sharing of data with other governmental authorities.
- (j) BRIBERY OF OR GIFTS TO INSPECTOR OR OTHER OFFICERS AND ACCEPTANCE OF GIFTS.—Section 22 of the Federal Meat Inspection Act (21 U.S.C. 622) shall apply under this Act. SEC. 206. FOOD PRODUCTION FACILITIES.
- In carrying out the duties of the Administrator and the purposes of this Act, the Administrator shall have the authority, with respect to food production facilities, to—
- (1) visit and inspect food production facilities in the United States and in foreign countries to investigate bioterrorism threats and for other critical food safety purposes;
- (2) review food safety records as required to be kept by the Administrator to carry out traceback and for other critical food safety purposes:
- (3) set good practice standards to protect the public and animal health and promote food safety:
- (4) conduct monitoring and surveillance of animals, plants, products, or the environment, as appropriate; and

(5) collect and maintain information relevant to public health and farm practices.

#### SEC. 207. FEDERAL AND STATE COOPERATION.

- (a) IN GENERAL.—The Administrator shall work with the States to carry out activities and programs that create a national food safety program so that Federal and State programs function in a coordinated and cost-effective manner.
- (b) STATE ACTION.—The Administrator shall work with States to—
- (1) continue, strengthen, or establish State food safety programs, especially with respect to the regulation of retail commercial food establishments, transportation, harvesting, and fresh markets;
- (2) continue, strengthen, or establish inspection programs and requirements to ensure that food under the jurisdiction of the State is safe; and
- (3) support recall authorities at the State and local levels.
- (c) ASSISTANCE.—To assist in planning, developing, and implementing a food safety program, the Administrator may provide and continue to a State—
  - (1) advisory assistance;
- (2) technical and laboratory assistance and training (including necessary materials and equipment); and
  - (3) financial, in kind, and other aid.
  - (d) SERVICE AGREEMENTS.-
- (1) IN GENERAL.—The Administrator may, under agreements entered into with Federal, State, or local agencies, use on a reimbursable basis or otherwise, the personnel and services of those agencies in carrying out this Act.
- (2) TRAINING.—Agreements with a State under this subsection may provide for training of State employees.
- (3) MAINTENANCE OF AGREEMENTS.—The Administrator shall maintain any agreement that is in effect on the day before the date of enactment of this Act until the Administrator evaluates such agreement and determines whether to maintain or substitute such agreement.
  - (e) AUDITS.-
- (1) IN GENERAL.—The Administrator shall annually conduct a comprehensive review of each State program that provides services to the Administrator in carrying out the responsibilities under this Act, including mandated inspections under section 205.
  - (2) REQUIREMENTS.—The review shall—
- (A) include a determination of the effectiveness of the State program; and
- (B) identify any changes necessary to ensure enforcement of Federal requirements under this Act.
- (f) No Federal Preemption.—Nothing in this Act shall be construed to preempt the enforcement of State food safety laws and standards that are at least as stringent as those under this Act.

## SEC. 208. IMPORTS.

- (a) IN GENERAL.—Not later than 2 years after the effective date of this Act, the Administrator shall establish a system under which a foreign government or foreign food establishment seeking to import food to the United States shall submit a request for certification to the Administrator.
- (b) CERTIFICATION STANDARD.—A foreign government or foreign food establishment requesting a certification to import food to the United States shall demonstrate, in a manner determined appropriate by the Administrator, that food produced under the supervision of a foreign government or by the foreign food establishment has met standards for food safety, inspection, labeling, and consumer protection that are at least equivalent to standards applicable to food produced in the United States.
  - (c) CERTIFICATION APPROVAL.—

- (1) REQUEST BY FOREIGN GOVERNMENT.— Prior to granting the certification request of a foreign government, the Administrator shall review, audit, and certify the food safety program of a requesting foreign government (including all statutes, regulations, and inspection authority) as at least equivalent to the food safety program in the United States, as demonstrated by the foreign government.
- (2) REQUEST BY FOREIGN FOOD ESTABLISH-MENT.—Prior to granting the certification request of a foreign food establishment, the Administrator shall certify, based on an onsite inspection, the food safety programs and procedures of a requesting foreign firm as at least equivalent to the food safety programs and procedures of the United States.
- (d) LIMITATION.—A foreign government or foreign firm approved by the Administrator to import food to the United States under this section shall be certified to export only the approved food products to the United States for a period not to exceed 5 years.
- (e) WITHDRAWAL OF CERTIFICATION.—The Administrator may withdraw certification of any food from a foreign government or foreign firm—
- (1) if such food is linked to an outbreak of human illness;
- (2) following an investigation by the Administrator that finds that the foreign government programs and procedures or foreign food establishment is no longer equivalent to the food safety programs and procedures in the United States: or
- (3) following a refusal to allow United States officials to conduct such audits and investigations as may be necessary to fulfill the requirements under this section.
- (f) RENEWAL OF CERTIFICATION.—The Administrator shall audit foreign governments and foreign food establishments at least every 5 years to ensure the continued compliance with the standards set forth in this section.
- (g) REQUIRED ROUTINE INSPECTION.—The Administrator shall routinely inspect food and food animals (via a physical examination) before it enters the United States to ensure that it is—
- (1) safe;
- (2) labeled as required for food produced in the United States; and
- (3) otherwise meets requirements under the food safety law.
- (h) ENFORCEMENT.—The Administrator is authorized to—
- (1) deny importation of food from any foreign government that does not permit United States officials to enter the foreign country to conduct such audits and inspections as may be necessary to fulfill the requirements under this section;
- (2) deny importation of food from any foreign government or foreign firm that does not consent to an investigation by the Administration when food from that foreign country or foreign firm is linked to a foodborne illness outbreak or is otherwise found to be adulterated or mislabeled; and
- (3) promulgate rules and regulations to carry out the purposes of this section, including setting terms and conditions for the destruction of products that fail to meet the standards of this Act.
- (i) DETENTION AND SEIZURE.—Any food imported for consumption in the United States may be detained, seized, or condemned pursuant to section 402.

## SEC. 209. RESOURCE PLAN.

(a) IN GENERAL.—The Administrator shall prepare and update annually a resource plan describing the resources required, in the best professional judgment of the Administrator, to develop and fully implement the national food safety program established under this Act.

- (b) CONTENTS OF PLAN.—The resource plan shall—
- (1) describe quantitatively the personnel, financial, and other resources required to carry out the inspection of food establishments under section 205 and other requirements of the national food safety program;
- (2) allocate inspection resources in a manner reflecting the distribution of risk and opportunities to reduce risk across the food supply to the extent feasible based on the best available information, and subject to section 205; and
- (3) describe the personnel, facilities, equipment, and other resources needed to carry out inspection and other oversight activities, at a total resource level equal to at least 50 percent of the resources required to carry out inspections in food establishments under section 205—
  - (A) in foreign establishments;
  - (B) at the point of importation; and
- (C) at the point of production on farms, ranches, and feedlots.
- (c) GRANTS.—The resource plan shall include recommendations for funding to provide grants to States and local governments to carry out food safety activities in retail and food service facilities and the required inspections in food establishments.
- (d) Submission of Plan.—The Administrator shall submit annually to the Committee on Appropriations of the Senate, the Committee on Appropriations of the House of Representatives, and other relevant committees of Congress, the resource plan required under this section.

#### SEC. 210. TRACEBACK.

- (a) IN GENERAL.—The Administrator, in order to protect the public health, shall establish requirements for a national system for tracing food and food producing animals from point of origin to retail sale, subject to subsection (b).
- (b) APPLICABILITY.—Traceability requirements shall—
- (1) be established in accordance with regulations and guidelines issued by the Administrator; and
- (2) apply to food production facilities and food establishments.
  (c) RELATIONSHIP TO COUNTRY OF ORIGIN
- (c) RELATIONSHIP TO COUNTRY OF ORIGIN LABELING.—Nothing contained in this section prevents or interferes with implementation of the country of origin labeling requirements of subtitle D of the Agricultural Marketing Act of 1946 (7 U.S.C. 1638 et seq.).

## TITLE III—RESEARCH AND EDUCATION

- SEC. 301. PUBLIC HEALTH ASSESSMENT SYSTEM.
- (a) IN GENERAL.—The Administrator, acting in coordination with the Director of the Centers for Disease Control and Prevention and with the Research Education and Economics mission area of the Department of Agriculture, shall—
- (1) have access to the applicable data systems of the Centers for Disease Control and Prevention and to the databases made available by a State:
- (2) maintain an active surveillance system of food, food products, and epidemiological evidence submitted by States to the Centers for Disease Control and Prevention based on a representative proportion of the population of the United States;
- (3) assess the frequency and sources of human illness in the United States associated with the consumption of food;
- (4) maintain a state-of-the-art DNA matching system and epidemiological system dedicated to food-borne illness identification, outbreaks, and containment; and
- (5) have access to the surveillance data created via monitoring and statistical studies conducted as part of its own inspection.
  - (b) PUBLIC HEALTH SAMPLING.—
- (1) IN GENERAL.—Not later than 1 year after the effective date of this Act, the Adminis-

- trator shall establish guidelines for a sampling system under which the Administrator shall take and analyze samples of food—
- (A) to assist the Administrator in carrying out this Act; and
- (B) to assess the nature, frequency of occurrence, and quantities of contaminants in food.
- (2) REQUIREMENTS.—The sampling system described in paragraph (1) shall provide—
- (A) statistically valid monitoring, including market-based studies, on the nature, frequency of occurrence, and quantities of contaminants in food available to consumers; and
- (B) at the request of the Administrator, such other information, including analysis of monitoring and verification samples, as the Administrator determines may be useful in assessing the occurrence of contaminants in food.
  - (c) Assessment of Health Hazards.-
- (1) IN GENERAL.—Through the surveillance system referred to in subsection (a) and the sampling system described in subsection (b), the Administrator shall—
- (A) rank food categories based on the hazard to human health presented by the food category;
- (B) identify appropriate industry and regulatory approaches to minimize hazards in the food supply; and
- (C) assess the public health environment for emerging diseases, including zoonosis, for their risk of appearance in the United States food supply.
- (2) COMPONENTS OF ANALYSIS.—The analysis under subsection (b)(1) may include—
- (A) a comparison of the safety of commercial processing with the health hazards associated with food that is harvested for recreational or subsistence purposes and prepared noncommercially;
- (B) a comparison of the safety of food that is domestically processed with the health hazards associated with food that is processed outside the United States;
- (C) a description of contamination originating from handling practices that occur prior to or after the sale of food to consumers: and
- (D) use of comparative risk assessments.

## SEC. 302. PUBLIC EDUCATION AND ADVISORY SYSTEM.

- (a) Public Education.—
- (1) In GENERAL.—The Administrator, in cooperation with private and public organizations, including the cooperative extension services and building on the efforts of appropriate State and local entities, shall establish a national public education program on food safety.
- (2) REQUIREMENTS.—The program shall provide—
- (A) information to the public regarding Federal standards and best practices and promotion of public awareness, understanding, and acceptance of those standards and practices;
- (B) information for health professionals—
- (i) to improve diagnosis and treatment of food-related illness; and
- $\left( \mathrm{ii} \right)$  to advise individuals at special risk for food-related illnesses; and
- (C) such other information or advice to consumers and other persons as the Administrator determines will promote the purposes of this Act.
- (b) HEALTH ADVISORIES.—The Administrator, in consultation with other Federal departments and agencies as the Administrator determines necessary, shall work with the States and other appropriate entities—
- (1) to develop and distribute regional and national advisories concerning food safety;
- (2) to develop standardized formats for written and broadcast advisories;

- (3) to incorporate State and local advisories into the national public education program established under subsection (a); and
- (4) to present prompt, specific information regarding foods found to pose a threat to the public health.

### SEC. 303. RESEARCH.

- (a) IN GENERAL.—The Administrator shall conduct research to carry out this Act, including studies to—
- (1) improve sanitation and food safety practices in the processing of food;
- (2) develop improved techniques to monitor and inspect food;
- (3) develop efficient, rapid, and sensitive methods to detect contaminants in food;
- (4) determine the sources of contamination of contaminated food;
  - (5) develop food consumption data;
- (6) identify ways that animal production techniques could improve the safety of the food supply;
- (7) draw upon research and educational programs that exist at the State and local level;
- (8) utilize the DNA matching system and other processes to identify and control pathogens;
- (9) address common and emerging zoonotic diseases;
- (10) develop methods to reduce or destroy harmful pathogens before, during, and after processing;
- (11) analyze the incidence of antibiotic resistence as it pertains to the food supply and develop new methods to reduce the transfer of antibiotic resistance to humans; and
- (12) conduct other research that supports the purposes of this Act.
- (b) CONTRACT AUTHORITY.—The Administrator may enter into contracts and agreements with any State, university, Federal Government agency, or person to carry out this section.

## TITLE IV—ENFORCEMENT

## SEC. 401. PROHIBITED ACTS.

- It is prohibited—
- (1) to manufacture, introduce, deliver for introduction, or receive into interstate commerce any food that is adulterated, misbranded, or otherwise unsafe:
- (2) to adulterate or misbrand any food in interstate commerce;
- (3) for a food establishment or foreign food establishment to fail to register under section 202, or to operate without a valid registration:
- (4) to refuse to permit access to a food establishment for the inspection and copying of a record as required under section 205(h);
- (5) to fail to establish or maintain any record or to make any report as required under section 205(h);
- (6) to refuse to permit entry to or inspection of a food establishment as required under section 205;
- (7) to fail to provide to the Administrator the results of a testing or sampling of a food, equipment, or material in contact with contaminated food under section 205(i);
- (8) to fail to comply with a provision, regulation, or order of the Administrator under section 202, 203, 204, or 208;
- (9) to slaughter an animal that is capable for use in whole or in part as human food at a food establishment processing any such food for commerce, except in compliance with the food safety law:
- (10) to transfer food in violation of an administrative detention order under section 402 or to remove or alter a required mark or label identifying the food as detained;
- (11) to fail to comply with a recall or other order under section 403; or
- (12) to otherwise violate the food safety law.

## SEC. 402. FOOD DETENTION, SEIZURE, AND CONDEMNATION.

- (a) Administrative Detention of Food.-
- (1) EXPANDED AUTHORITY.—The Administrator shall have authority under section 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334) to administratively detain and seize any food that the Administrator has reason to believe is unsafe, is adulterated or misbranded, or otherwise fails to meet the requirements of the food safety law.
- (2) DETENTION AUTHORITY.—If, during an inspection conducted in accordance with section 205 or 208, an officer, employee, or agent of the Administration making the inspection has reason to believe that a domestic food, imported food, or food offered for import is unsafe, is adulterated or misbranded, or otherwise fails to meet the requirements of this Act, the officer or employee may order the food detained
  - (3) PERIOD OF DETENTION.—
- (A) IN GENERAL.—A food may be detained for a reasonable period, not to exceed 20 days, unless a longer period, not to exceed 30 days, is necessary for the Administrator to institute a seizure action.
- (B) PERISHABLE FOOD.—The Administrator shall provide by regulation for procedures to institute a seizure action on an expedited basis with respect to perishable food.
  - (4) SECURITY OF DETAINED FOOD.—
  - (A) IN GENERAL.—A detention order—
- (i) may require that the food be labeled or marked as detained; and
- (ii) shall require that the food be removed to a secure facility, if appropriate.
- (B) FOOD SUBJECT TO AN ORDER.—A food subject to a detention order shall not be transferred by any person from the place at which the food is removed, until released by the Administrator or until the expiration of the detention period applicable under the order, whichever occurs first.
- (C) DELIVERY OF FOOD.—This subsection does not authorize the delivery of a food in accordance with execution of a bond while the article is subject to the order.
  - (b) APPEAL OF DETENTION ORDER.—
- (1) IN GENERAL.—A person who would be entitled to be a claimant for a food subject to a detention order if the food were seized under section 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334), may appeal the order to the Administrator.
- (2) ACTION BY THE ADMINISTRATOR.—Not later than 5 days after an appeal is filed under paragraph (1), the Administrator, after providing an opportunity for an informal hearing, shall confirm, modify, or terminate the order involved.
- (3) FINAL AGENCY ACTION.—Confirmation, modification, or termination by the Administrator under paragraph (2) shall be considered a final agency action for purposes of section 702 of title 5, United States Code.
- (4) TERMINATION.—The order shall be considered to be terminated if, after 5 days, the Administrator has failed—
- (A) to provide an opportunity for an informal hearing; or
- (B) to confirm, modify, or terminate the order.
- (5) EFFECT OF INSTITUTING COURT ACTION.—
  If the Administrator initiates an action under section 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332) or section 304(a) of that Act (21 U.S.C. 334(a)), the process for the appeal of the detention order shall terminate.
  - (c) CONDEMNATION OF FOOD.—
- (1) IN GENERAL.—After confirming a detention order, the Administrator may order the food condemned.
- (2) DESTRUCTION OF FOOD.—Any food condemned shall be destroyed under the supervision of the Administrator.

- (3) Release of food.—If the Administrator determines that, through reprocessing, relabeling, or other action, a detained food can be brought into compliance with this Act, the food may be released following a determination by the Administrator that the relabeling or other action as specified by the Administrator has been performed.
- (d) Temporary Holds at Ports of Entry.—
- (1) IN GENERAL.—If an officer or qualified employee of the Administration has reason to believe that a food is unsafe, is adulterated or misbranded, or otherwise fails to meet the requirements of this Act, and the officer or qualified employee is unable to inspect, examine, or investigate the food when the food is offered for import at a port of entry into the United States, the officer or qualified employee shall request the Secretary of Homeland Security to hold the food at the port of entry for a reasonable period of time, not to exceed 24 hours, to enable the Administrator to inspect or investigate the food as appropriate.
- (2) REMOVAL TO SECURE FACILITY.—The Administrator shall work in coordination with the Secretary of Homeland Security to remove a food held in accordance with paragraph (1) to a secure facility as appropriate.
- (3) PROHIBITION ON TRANSFER.—During the period in which the food is held, the food shall not be transferred by any person from the port of entry into the United States, or from the secure facility to which the food has been removed.
- (4) DELIVERY IN ACCORDANCE WITH A BOND.— The delivery of the food in accordance with the execution of a bond while the food is held is not authorized.
- (5) PROHIBITION ON REEXPORT.—A food found unfit for human or animal consumption shall be prohibited from reexport without further processing to remove the contamination and reinspection by the Administration.

## SEC. 403. NOTIFICATION AND RECALL.

- (a) NOTICE TO ADMINISTRATOR OF VIOLATION.—
- (1) In general.—A person that has reason to believe that any food introduced into or in interstate commerce, or held for sale (whether or not the first sale) after shipment in interstate commerce, may be in violation of the food safety law shall immediately notify the Administrator of the identity and location of the food.
- (2) MANNER OF NOTIFICATION.—Notification under paragraph (1) shall be made in such manner and by such means as the Administrator may require by regulation.
  - (b) RECALL AND CONSUMER NOTIFICATION.—
- (1) VOLUNTARY ACTIONS.—If the Administrator determines that food is in violation of the food safety law when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce and that there is a reasonable probability that the food, if consumed, would present a threat to public health, as determined by the Administrator, the Administrator shall give the appropriate persons (including the manufacturers, importers, distributors, or retailers of the food) an opportunity to—
- (A) cease distribution of the food;
- (B) notify all persons-
- (i) processing, distributing, or otherwise handling the food to immediately cease such activities with respect to the food; or
- (ii) to which the food has been distributed, transported, or sold, to immediately cease distribution of the food;
  - (C) recall the food;
- (D) in conjunction with the Administrator, provide notice of the finding of the Administrator—

- (i) to consumers to whom the food was, or may have been, distributed; and
- (ii) to State and local public health officials; or
- (E) take any combination of the measures described in this paragraph, as determined by the Administrator to be appropriate in the circumstances.
- (2) MANDATORY ACTIONS.—If a person referred to in paragraph (1) refuses to or does not adequately carry out the actions described in that paragraph within the time period and in the manner prescribed by the Administrator, the Administrator shall—
- (A) have authority to control and possess the food, including ordering the shipment of the food from the food establishment to the Administrator—
- (i) at the expense of the food establishment; or
- (ii) in an emergency (as determined by the Administrator), at the expense of the Administration; and
- (B) by order, require, as the Administrator determines to be necessary, the person to immediately—
  - (i) cease distribution of the food; and
  - (ii) notify all persons—
- (I) processing, distributing, or otherwise handling the food to immediately cease such activities with respect to the food; or
- (II) if the food has been distributed, transported, or sold, to immediately cease distribution of the food.
- (3) NOTIFICATION TO CONSUMERS BY ADMINISTRATOR.—The Administrator shall, as the Administrator determines to be necessary, provide notice of the finding of the Administrator under paragraph (1)—
- (A) to consumers to whom the food was, or may have been, distributed; and
- (B) to State and local public health officials
- (4) NONDISTRIBUTION BY NOTIFIED PERSONS.—A person that processes, distributes, or otherwise handles the food, or to which the food has been distributed, transported, or sold, and that is notified under paragraph (1)(B) or (2)(B) shall immediately cease distribution of the food.
- (5) AVAILABILITY OF RECORDS TO ADMINISTRATOR.—Each person referred to in paragraph (1) that processed, distributed, or otherwise handled food shall make available to the Administrator information necessary to carry out this subsection, as determined by the Administrator, regarding—
- (A) persons that processed, distributed, or otherwise handled the food; and
- (B) persons to which the food has been transported, sold, distributed, or otherwise handled.
  - (c) INFORMAL HEARINGS ON ORDERS.—
- (1) IN GENERAL.—The Administrator shall provide any person subject to an order under subsection (b) with an opportunity for an informal hearing, to be held as soon as practicable but not later than 2 business days after the issuance of the order.
- (2) SCOPE OF THE HEARING.—In a hearing under paragraph (1), the Administrator shall consider the actions required by the order and any reasons why the food that is the subject of the order should not be recalled.
  - (d) Post-Hearing Recall Orders.—
- (1) AMENDMENT OF ORDER.—If, after providing an opportunity for an informal hearing under subsection (c), the Administrator determines that there is a reasonable probability that the food that is the subject of an order under subsection (b), if consumed, would present a threat to the public health, the Administrator, as the Administrator determines to be necessary, may—
- (A) amend the order to require recall of the food or other appropriate action;
- (B) specify a timetable in which the recall shall occur;

- (C) require periodic reports to the Administrator describing the progress of the recall; and
- (D) provide notice of the recall to consumers to whom the food was, or may have been distributed.
- (2) VACATION OF ORDERS.—If, after providing an opportunity for an informal hearing under subsection (c), the Administrator determines that adequate grounds do not exist to continue the actions required by the order, the Administrator shall vacate the order.
- (e) REMEDIES NOT EXCLUSIVE.—The remedies provided in this section shall be in addition to, and not exclusive of, other remedies that may be available.

#### SEC. 404. INJUNCTION PROCEEDINGS.

- (a) JURISDICTION.—The district courts of the United States, and the United States courts of the territories and possessions of the United States, shall have jurisdiction, for cause shown, to restrain a violation of section 202, 203, 204, 207, or 401 (or a regulation promulgated under that section).
- (b) TRIAL.—In a case in which violation of an injunction or restraining order issued under this section also constitutes a violation of the food safety law, trial shall be by the court or, upon demand of the accused, by a jury.

## SEC. 405. CIVIL AND CRIMINAL PENALTIES.

- (a) CIVIL SANCTIONS.—
- (1) CIVIL PENALTY.—
- (A) IN GENERAL.—Any person that commits an act that violates the food safety law (including a regulation promulgated or order issued under a Federal food safety law) may be assessed a civil penalty by the Administrator of not more than \$10,000 for each such act.
- (B) SEPARATE OFFENSE.—Each act described in subparagraph (A) and each day during which that act continues shall be considered a separate offense.
  - (2) OTHER REQUIREMENTS.—
- (A) WRITTEN ORDER.—The civil penalty described in paragraph (1) shall be assessed by the Administrator by a written order, which shall specify the amount of the penalty and the basis for the penalty under subparagraph (B) considered by the Administrator.
- (B) AMOUNT OF PENALTY.—Subject to paragraph (1)(A), the amount of the civil penalty shall be determined by the Administrator, after considering—
  - (i) the gravity of the violation;
- (ii) the degree of culpability of the person; (iii) the size and type of the business of the
- person; and
  (iv) any history of prior offenses by the
- person under the food safety law.
  (C) REVIEW OF ORDER.—The order may be
- (C) REVIEW OF ORDER.—The order may be reviewed only in accordance with subsection (c).
- (b) CRIMINAL SANCTIONS.—
- (1) IN GENERAL.—Except as provided in paragraphs (2) and (3), a person that knowingly produces or introduces into commerce food that is unsafe or otherwise adulterated or misbranded shall be imprisoned for not more than 1 year or fined not more than \$10,000, or both.
- (2) SEVERE VIOLATIONS.—A person that commits a violation described in paragraph (1) after a conviction of that person under this section has become final, or commits such a violation with the intent to defraud or mislead, shall be imprisoned for not more than 3 years or fined not more than \$100,000, or both.
- (3) EXCEPTION.—No person shall be subject to the penalties of this subsection—
- (A) for having received, proffered, or delivered in interstate commerce any food, if the receipt, proffer, or delivery was made in good faith, unless that person refuses to furnish

- (on request of an officer or employee designated by the Administrator)—
- (i) the name, address and contact information of the person from whom that person purchased or received the food;
- (ii) copies of all documents relating to the person from whom that person purchased or received the food; and
- (iii) copies of all documents pertaining to the delivery of the food to that person; or
- (B) if that person establishes a guaranty signed by, and containing the name and address of, the person from whom that person received in good faith the food, stating that the food is not adulterated or misbranded within the meaning of this Act.
  - (c) Judicial Review.—
- (1) In general.—An order assessing a civil penalty under subsection (a) shall be a final order unless the person—
- (A) not later than 30 days after the effective date of the order, files a petition for judicial review of the order in the United States court of appeals for the circuit in which that person resides or has its principal place of business or the United States Court of Appeals for the District of Columbia; and
- (B) simultaneously serves a copy of the petition by certified mail to the Administrator.
- (2) FILING OF RECORD.—Not later than 45 days after the service of a copy of the petition under paragraph (1)(B), the Administrator shall file in the court a certified copy of the administrative record upon which the order was issued.
- (3) STANDARD OF REVIEW.—The findings of the Administrator relating to the order shall be set aside only if found to be unsupported by substantial evidence on the record as a whole.
- (d) Collection Actions for Failure To Pay.—
- (1) IN GENERAL.—If any person fails to pay a civil penalty assessed under subsection (a) after the order assessing the penalty has become a final order, or after the court of appeals described in subsection (b) has entered final judgment in favor of the Administrator, the Administrator shall refer the matter to the Attorney General, who shall institute in a United States district court of competent jurisdiction a civil action to recover the amount assessed.
- (2) LIMITATION ON REVIEW.—In a civil action under paragraph (1), the validity and appropriateness of the order of the Administrator assessing the civil penalty shall not be subject to judicial review.
- (e) PENALTIES PAID INTO ACCOUNT.—The Administrator—
- (1) shall deposit penalties collected under this section in an account in the Treasury;
- (2) may use the funds in the account, without further appropriation or fiscal year limitation—
- (A) to carry out enforcement activities under food safety law; or
- (B) to provide assistance to States to inspect retail commercial food establishments or other food or firms under the jurisdiction of State food safety programs.
- (f) DISCRETION OF THE ADMINISTRATOR TO PROSECUTE.—Nothing in this Act requires the Administrator to report for prosecution, or for the commencement of an action, the violation of the food safety law in a case in which the Administrator finds that the public interest will be adequately served by the assessment of a civil penalty under this section.
- (g) REMEDIES NOT EXCLUSIVE.—The remedies provided in this section may be in addition to, and not exclusive of, other remedies that may be available.

#### SEC. 406. PRESUMPTION.

In any action to enforce the requirements of the food safety law, the connection with interstate commerce required for jurisdiction shall be presumed to exist.

#### SEC. 407. WHISTLEBLOWER PROTECTION.

- (a) In General.—No Federal employee, employee of a Federal contractor or subcontractor, or any individual employed by a company (referred to in this section as a "covered individual"), may be discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against, because of any lawful act done by the covered individual to—
- (1) provide information, cause information to be provided, or otherwise assist in an investigation regarding any conduct that the covered individual reasonably believes constitutes a violation of any law, rule, or regulation, or that the covered individual reasonably believes constitutes a threat to the public health, when the information or assistance is provided to, or the investigation is conducted by—
- (A) a Federal regulatory or law enforcement agency;
- (B) a Member or committee of Congress; or (C) a person with supervisory authority over the covered individual (or such other individual who has the authority to inves-
- tigate, discover, or terminate misconduct);
  (2) file, cause to be filed, testify, participate in, or otherwise assist in a proceeding or action filed or about to be filed relating to
- or action filed or about to be filed relating to a violation of any law, rule, or regulation; or (3) refused to violate or assist in the viola-
- tion of any law, rule, or regulation.
- (b) Enforcement Action.—
- (1) IN GENERAL.—A covered individual who alleges discharge or other discrimination by any person in violation of subsection (a) may seek relief under subsection (c) by filing a complaint with the Secretary of Labor. If the Secretary of Labor has not issued a final decision within 180 days after the date on which the complaint is filed and there is no showing that such delay is due to the bad faith of the claimant, the claimant may bring an action at law or equity for de novo review in the appropriate district court of the United States, which shall have jurisdiction over such an action without regard to the amount in controversy
  - (2) Procedure.—
- (A) IN GENERAL.—An action under paragraph (1) shall be governed under the rules and procedures set forth in section 42121(b) of title 49, United States Code.
- (B) EXCEPTION.—Notification under section 42121(b)(1) of title 49, United States Code, shall be made to the person named in the complaint and to the person's employer.
- (C) BURDENS OF PROOF.—An action brought under paragraph (1) shall be governed by the legal burdens of proof set for in section 42121(b) of title 49, United States Code.
- (D) STATUTE OF LIMITATIONS.—An action under paragraph (1) shall be commenced not later than 90 days after the date on which the violation occurs.
- (c) Remedies.-
- (1) IN GENERAL.—A covered individual prevailing in any action under subsection (b)(1) shall be entitled to all relief necessary to make the covered individual whole.
- (2) COMPENSATORY DAMAGES.—Relief for any action described in paragraph (1) shall include—
- (A) reinstatement with the same seniority status that the covered individual would have had, but for the discrimination;
- (B) the amount of any back pay, with interest; and
- (C) compensation for any special damages sustained as a result of the discrimination, including litigation costs, expert witness fees, and reasonable attorney's fees.

(d) RIGHTS RETAINED BY THE COVERED INDIVIDUAL.—Nothing in this section shall be construed to diminish the rights, privileges, or remedies of any covered individual under any Federal or State law, or under any collective bargaining agreement.

### SEC. 408. ADMINISTRATION AND ENFORCEMENT.

- (a) IN GENERAL.—For the efficient administration and enforcement of the food safety law, the provisions (including provisions relating to penalties) of sections 6, 8, 9, and 10 of the Federal Trade Commission Act (15 U.S.C. 46, 48, 49, and 50) (except subsections (c) through (h) of section 6 of that Act), relating to the jurisdiction, powers, and duties of the Federal Trade Commission and the Attorney General to administer and enforce that Act, and to the rights and duties of persons with respect to whom the powers are exercised, shall apply to the jurisdiction, powers, and duties of the Administrator and the Attorney General in administering and enforcing the provisions of the food safety law and to the rights and duties of persons with respect to whom the powers are exercised, respectively.
  - (b) INQUIRIES AND ACTIONS.—
- (1) IN GENERAL.—The Administrator, in person or by such agents as the Administrator may designate, may prosecute any inquiry necessary to carry out the duties of the Administrator under the food safety law in any part of the United States.
- (2) POWERS.—The powers conferred by sections 9 and 10 of the Federal Trade Commission Act (15 U.S.C. 49 and 50) on the United States district courts may be exercised for the purposes of this chapter by any United States district court of competent jurisdiction

### SEC. 409. CITIZEN CIVIL ACTIONS.

- (a) CIVIL ACTIONS.—A person may commence a civil action against—
- (1) a person that violates a regulation (including a regulation establishing a performance standard), order, or other action of the Administrator to ensure the safety of food; or
- (2) the Administrator (in his or her capacity as the Administrator), if the Administrator fails to perform an act or duty to ensure the safety of food that is not discretionary under the food safety law.
  - (b) Court.
- (1) IN GENERAL.—The action shall be commenced in the United States district court for the district in which the defendant resides, is found, or has an agent.
- (2) JURISDICTION.—The court shall have jurisdiction, without regard to the amount in controversy, or the citizenship of the parties, to enforce a regulation (including a regulation establishing a performance standard), order, or other action of the Administrator, or to order the Administrator to perform the act or duty.
- (3) DAMAGES.—The court may-
- (A) award damages, in the amount of damages actually sustained; and
- (B) if the court determines it to be in the interest of justice, award the plaintiff the costs of suit, including reasonable attorney's fees, reasonable expert witness fees, and penalties.
- (c) REMEDIES NOT EXCLUSIVE.—The remedies provided for in this section shall be in addition to, and not exclusive of, other remedies that may be available.

## TITLE V—IMPLEMENTATION

## SEC. 501. DEFINITION.

For purposes of this title, the term "transition period" means the 12-month period beginning on the effective date of this Act.

## SEC. 502. REORGANIZATION PLAN.

(a) SUBMISSION OF PLAN.—Not later than 180 days after the effective date of this Act,

- the President shall transmit to the appropriate congressional committees a reorganization plan regarding the following:
- (1) The transfer of agencies, personnel, assets, and obligations to the Administration pursuant to this Act.
- (2) Any consolidation, reorganization, or streamlining of agencies transferred to the Administration pursuant to this Act.
- (b) PLAN ELEMENTS.—The plan transmitted under subsection (a) shall contain, consistent with this Act, such elements as the President determines appropriate, including the following:
- (1) Identification of any functions of agencies designated to be transferred to the Administration pursuant to this Act that will not be transferred to the Administration under the plan.
- (2) Specification of the steps to be taken by the Administrator to organize the Administration, including the delegation or assignment of functions transferred to the Administration among the officers of the Administration in order to permit the Administration to carry out the functions transferred under the plan.
- (3) Specification of the funds available to each agency that will be transferred to the Administration as a result of transfers under the plan.
- (4) Specification of the proposed allocations within the Administration of unexpended funds transferred in connection with transfers under the plan.
- (5) Specification of any proposed disposition of property, facilities, contracts, records, and other assets and obligations of agencies transferred under the plan.
- (6) Specification of the proposed allocations within the Administration of the functions of the agencies and subdivisions that are not related directly to ensuring the safety of food.
- (c) Modification of Plan.—The President may, on the basis of consultations with the appropriate congressional committees, modify, or revise any part of the plan until that part of the plan becomes effective in accordance with subsection (d).
  - (d) Effective Date.—
- (1) IN GENERAL.—The reorganization plan described in this section, including any modifications or revisions of the plan under subsection (c), shall become effective for an agency on the earlier of—
- (A) the date specified in the plan (or the plan as modified pursuant to subsection (c)), except that such date may not be earlier than 90 days after the date the President has transmitted the reorganization plan to the appropriate congressional committees pursuant to subsection (a); or
  - (B) the end of the transition period.
- (2) STATUTORY CONSTRUCTION.—Nothing in this subsection may be construed to require the transfer of functions, personnel, records, balances of appropriations, or other assets of an agency on a single date.
- (3) SUPERCEDES EXISTING LAW.—Paragraph (1) shall apply notwithstanding section 905(b) of title 5, United States Code.

## SEC. 503. TRANSITIONAL AUTHORITIES.

- (a) Provision of Assistance by Officials.—Until the transfer of an agency to the Administration, any official having authority over or function relating to the agency immediately before the effective date of this Act shall provide the Administrator such assistance, including the use of personnel and assets, as the Administrator may request in preparing for the transfer and integration of the agency to the Administration.
- (b) SERVICES AND PERSONNEL.—During the transition period, upon the request of the Administrator, the head of any executive

agency may, on a reimbursable basis, provide services or detail personnel to assist with the transition.

- (c) ACTING OFFICIALS.—
- (1) IN GENERAL.—During the transition period, pending the advice and consent of the Senate to the appointment of an officer required by this Act to be appointed by and with such advice and consent, the President may designate any officer whose appointment was required to be made by and with such advice and consent and who was such an officer immediately before the effective date of this Act (and who continues to be in office) or immediately before such designation, to act in such office until the same is filled as provided in this Act.
- (2) COMPENSATION.—While acting pursuant to paragraph (1), such officers shall receive compensation at the higher of—
- (A) the rates provided by this Act for the respective offices in which they act; or
- $(\bar{\mathbf{B}})$  the rates provided for the offices held at the time of designation.
- (3) LIMITATION.—Nothing in this Act shall be construed to require the advice and consent of the Senate to the appointment by the President to a position in the Administration of any officer whose agency is transferred to the Administration pursuant to this Act and whose duties following such transfer are germane to those performed before such transfer.
- (d) Transfer of Personnel, Assets, Obligations, and Function.—
- (1) IN GENERAL.—Consistent with section 1531 of title 31, United States Code, the personnel, assets, liabilities, contracts, property, records, and unexpended balances of appropriations, authorizations, allocations, and other funds that relate to the functions transferred under subsection (a) from a Federal agency shall be transferred to the Administration.
- (2) UNEXPENDED FUNDS.—Unexpended funds transferred under this subsection shall be used by the Administration only for the purposes for which the funds were originally authorized and appropriated.

## SEC. 504. SAVINGS PROVISIONS.

- (a) COMPLETED ADMINISTRATIVE ACTIONS.—
  The enactment of this Act or the transfer of functions under this Act shall not affect any order, determination, rule, regulation, permit, personnel action, agreement, grant, contract, certificate, license, registration, privilege, or other administrative action issued, made, granted, or otherwise in effect or final with respect to that agency on the day before the transfer date with respect to the transferred functions.
- (b) PENDING PROCEEDINGS.—Subject to the authority of the Administrator under this Act—
- (1) pending proceedings in an agency, including notices of proposed rulemaking, and applications for licenses, permits, certificates, grants, and financial assistance, shall continue notwithstanding the enactment of this Act or the transfer of the agency to the Administration, unless discontinued or modified under the same terms and conditions and to the same extent that such discontinuance could have occurred if such enactment or transfer had not occurred; and
- (2) orders issued in such proceedings, and appeals therefrom, and payments made pursuant to such orders, shall issue in the same manner on the same terms as if this Act had not been enacted or the agency had not been transferred, and any such order shall continue in effect until amended, modified, superceded, terminated, set aside, or revoked by an officer of the United States or a court of competent jurisdiction, or by operation of law.
- (c) PENDING CIVIL ACTIONS.—Subject to the authority of the Administrator under this

Act, any civil action commenced with regard to that agency pending before that agency on the day before the transfer date with respect to the transferred functions shall continue notwithstanding the enactment of this Act or the transfer of an agency to the Administration.

- (d) References.-
- (1) In GENERAL.—After the transfer of functions from a Federal agency under this Act, any reference in any other Federal law, Executive order, rule, regulation, directive, document, or other material to that Federal agency or the head of that agency in connection with the administration or enforcement of the food safety laws shall be deemed to be a reference to the Administration or the Administrator, respectively.
- (2) STATUTORY REPORTING REQUIREMENTS.—Statutory reporting requirements that applied in relation to such an agency immediately before the effective date of this Act shall continue to apply following such transfer if they refer to the agency by name.

#### SEC. 505. CONFORMING AMENDMENTS.

- (a) EXECUTIVE SCHEDULE.—Section 5313 of title 5, United States Code, is amended by inserting at the end the following new item: "Administrator of Food Safety.".
- (b) REPEAL OF CERTAIN PROVISIONS.—Section 18 of the Poultry Products Inspection Act (21 U.S.C. 467), section 401 of the Federal Meat Inspection Act (21 U.S.C. 671), and section 18 of the Egg Products Inspection Act (21 U.S.C. 1047) are repealed.

## SEC. 506. ADDITIONAL TECHNICAL AND CONFORMING AMENDMENTS.

Not later than 60 days after the submission of the reorganization plan under section 502, the President shall prepare and submit proposed legislation to Congress containing necessary and appropriate technical and conforming amendments to the Acts listed in section 3(15) of this Act to reflect the changes made by this Act.

## SEC. 507. REGULATIONS.

The Administrator may promulgate such regulations as the Administrator determines are necessary or appropriate to perform the duties of the Administrator.

## SEC. 508. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated such sums as are necessary to carry out this Act.

## SEC. 509. LIMITATION ON AUTHORIZATION OF APPROPRIATIONS.

For the fiscal year that includes the effective date of this Act, the amount authorized to be appropriated to carry out this Act shall not exceed—

- (1) the amount appropriated for that fiscal year for the Federal agencies identified in section 102(b) for the purpose of administering or enforcing the food safety law; or
- (2) the amount appropriated for those agencies for that purpose for the preceding fiscal year, if, as of the effective date of this Act, appropriations for those agencies for the fiscal year that includes the effective date have not yet been made.

## SEC. 510. EFFECTIVE DATE.

This Act takes effect on the date of enactment of this Act.  $\,$ 

## SUBMITTED RESOLUTIONS

SENATE RESOLUTION 82—DESIGNATING AUGUST 16, 2007 AS "NATIONAL AIRBORNE DAY"

Mr. HAGEL (for himself, Mr. REED, Mrs. CLINTON, Mr. BURR, Mr. REID, Ms. SNOWE, Mr. KERRY, Mr. GREGG, and Mrs. BOXER) submitted the following

resolution; which was referred to the Committee on the Judiciary.

### S. RES. 82

Whereas the airborne forces of the Armed Forces have a long and honorable history as units of adventuresome, hardy, and fierce warriors who, for the national security of the United States and the defense of freedom and peace, project the effective ground combat power of the United States by Air Force air transport to the far reaches of the battle area and, indeed, to the far corners of the world:

Whereas August 16, 2007 marks the anniversary of the first official Army parachute jump on August 16, 1940, an event that validated the innovative concept of inserting United States ground combat forces behind the battle line by means of a parachute;

Whereas the United States experiment of airborne infantry attack began on June 25, 1940, when the Army Parachute Test Platoon was first authorized by the Department of War, and was launched when 48 volunteers began training in July 1940;

Whereas the success of the Parachute Test Platoon in the days immediately preceding the entry of the United States into World War II led to the formation of a formidable force of airborne units that have served with distinction and have had repeated success in armed hostilities;

Whereas among those airborne units are the former 11th, 13th, and 17th Airborne Divisions, the venerable 82nd Airborne Division (Air Assault), and the airborne regiments and battalions (some as components of those divisions, some as separate units) that achieved distinction as the elite 75th Ranger Regiment, the 173rd Airborne Brigade, the 187th Infantry (Airborne) Regiment, the 503rd, 507th, 508th, 517th, 541st, and 542nd Parachute Infantry Regiments, the 88th Glider Infantry Regiment, the 509th, 551st, and 555th Parachute Infantry Battalions, and the 550th Airborne Infantry Battalions, and the 550th Airborne Infantry Battalion;

Whereas the achievements of the airborne forces during World War II prompted the evolution of those forces into a diversified force of parachute and air assault units that, over the years, have fought in Korea, Vietnam, Grenada, Panama, the Persian Gulf region, and Somalia, and have engaged in peace-keeping operations in Lebanon, the Sinai Peninsula, the Dominican Republic, Haiti, Bosnia, and Kosovo;

Whereas the modern-day airborne force that has evolved from those World War II beginnings is an agile, powerful force that, in large part, is composed of the 82nd Airborne Division, the 101st Airborne Division (Air Assault), and the 75th Ranger Regiment;

Whereas those units, together with additional units, comprise the quick reaction force of the Army's XVIII Airborne Corps when not operating separately under a regional combatant commander;

Whereas that modern-day airborne force also includes other elite forces composed entirely of airborne trained and qualified special operations warriors, including Army Special Forces, Marine Corps Reconnaissance units, Navy SEALs, and Air Force combat control teams, all or most of which comprise the forces of the United States Special Operations Command:

Whereas in the aftermath of the terrorist attacks on the United States on September 11, 2001, the 75th Ranger Regiment, special forces units, and units of the 82nd Airborne Division and the 101st Airborne Division (Air Assault), together with other units of the Armed Forces, have been prosecuting the