(Mrs. FEINSTEIN), the Senator from Massachusetts (Mr. KENNEDY), the Senator from New York (Mrs. CLINTON), the Senator from Hawaii (Mr. INOUYE), the Senator from Hawaii (Mr. AKAKA), the Senator from Illinois (Mr. DURBIN) and the Senator from Nevada (Mr. ENSIGN) were added as cosponsors of S. 2681, a bill to require the issuance of medals to recognize the dedication and valor of Native American code talkers.

S. 2689

At the request of Mr. SMITH, the name of the Senator from Oregon (Mr. WYDEN) was added as a cosponsor of S. 2689, a bill to amend section 411h of title 37, United States Code, to provide travel and transportation allowances for family members of members of the uniformed services with serious inpatient psychiatric conditions.

S. 2719

At the request of Mrs. DOLE, the names of the Senator from Mississippi (Mr. WICKER) and the Senator from Oklahoma (Mr. COBURN) were added as cosponsors of S. 2719, a bill to provide that Executive Order 13166 shall have no force or effect, and to prohibit the use of funds for certain purposes.

S. 2722

At the request of Mrs. DOLE, the name of the Senator from Oklahoma (Mr. COBURN) was added as a cosponsor of S. 2722, a bill to prohibit aliens who are repeat drunk drivers from obtaining legal status or immigration benefits.

S. 2742

At the request of Mr. COCHRAN, the name of the Senator from North Carolina (Mrs. DOLE) was added as a cosponsor of S. 2742, a bill to reduce the incidence, progression, and impact of diabetes and its complications and establish the position of National Diabetes Coordinator.

S. 2756

At the request of Mr. BIDEN, the names of the Senator from North Carolina (Mrs. DOLE) and the Senator from California (Mrs. FEINSTEIN) were added as cosponsors of S. 2756, a bill to amend the National Child Protection Act of 1993 to establish a permanent background check system.

S. 2764

At the request of Mr. KERRY, the name of the Senator from Illinois (Mr. OBAMA) was added as a cosponsor of S. 2764, a bill to amend the Servicemembers Civil Relief Act to enhance protections for servicemembers relating to mortgages and mortgage foreclosures, and for other purposes.

S. 2785

At the request of Ms. STABENOW, the name of the Senator from North Carolina (Mrs. DOLE) was added as a cosponsor of S. 2785, a bill to amend title XVIII of the Security Act to preserve access to physicians' services under the Medicare program.

S. 2790

At the request of Ms. LANDRIEU, the name of the Senator from Maryland (Mr. CARDIN) was added as a cosponsor of S. 2790, a bill to amend title XVIII of the Social Security Act to provide for coverage of comprehensive cancer care planning under the Medicare program and to improve the care furnished to individuals diagnosed with cancer by establishing a Medicare hospice care demonstration program and grants programs for cancer palliative care and symptom management programs, provider education, and related research.

S. 2819

At the request of Mr. ROCKEFELLER, the name of the Senator from Illinois (Mr. DURBIN) was added as a cosponsor of S. 2819, a bill to preserve access to Medicaid and the State Children's Health Insurance Program during an economic downturn, and for other purposes.

S. 2839

At the request of Mr. CORNYN, the name of the Senator from Maine (Ms. COLLINS) was added as a cosponsor of S. 2839, a bill to provide emergency relief for United States businesses and industries currently employing temporary foreign workers and for other purposes.

S. 2874

At the request of Mrs. FEINSTEIN, the name of the Senator from Georgia (Mr. ISAKSON) was added as a cosponsor of S. 2874, a bill to amend titles 5, 10, 37, and 38, United States Code, to ensure the fair treatment of a member of the Armed Forces who is discharged from the Armed Forces, at the request of the member, pursuant to the Department of Defense policy permitting the early discharge of a member who is the only surviving child in a family in which the father or mother, or one or more siblings, served in the Armed Forces and, because of hazards incident to such service, was killed, died as a result of wounds, accident, or disease, is in a captured or missing in action status, or is permanently disabled, and for other purposes.

S. 2904

At the request of Mrs. MCCASKILL, the name of the Senator from Delaware (Mr. CARPER) was added as a cosponsor of S. 2904, a bill to improve Federal agency awards and oversight of contracts and assistance and to strengthen accountability of the Government-wide suspension and debarment system.

S. 2916

At the request of Mr. BAYH, his name was added as a cosponsor of S. 2916, a bill to ensure greater transparency in the Federal contracting process, and to help prevent contractors that violate criminal laws from obtaining Federal contracts.

S. 2938

At the request of Mr. GRAHAM, the name of the Senator from Louisiana (Mr. VITTER) was added as a cosponsor of S. 2938, a bill to amend titles 10 and 38, United States Code, to improve educational assistance for members of the Armed Forces and veterans in order to enhance recruitment and retention for the Armed Forces, and for other purposes.

S. 2958

At the request of Mr. DOMENICI, the names of the Senator from Kansas (Mr. ROBERTS), the Senator from Idaho (Mr. CRAIG) and the Senator from Mississippi (Mr. COCHRAN) were added as cosponsors of S. 2958, a bill to promote the energy security of the United States, and for other purposes.

S. 2971

At the request of Mr. BAYH, his name was added as a cosponsor of S. 2971, a bill to amend the Internal Revenue Code of 1986 to provide for a suspension of the highway fuel tax, and for other purposes.

S. 2973

At the request of Mr. DOMENICI, the name of the Senator from Kentucky (Mr. MCCONNELL) was added as a cosponsor of S. 2973, a bill to promote the energy security of the United States, and for other purposes.

S. 2979

At the request of Mr. KERRY, the name of the Senator from New York (Mr. SCHUMER) was added as a cosponsor of S. 2979, a bill to exempt the African National Congress from treatment as a terrorist organization, and for other purposes.

S. RES. 512

At the request of Mr. DEMINT, the name of the Senator from Georgia (Mr. ISAKSON) was added as a cosponsor of S. Res. 512, a resolution honoring the life of Charlton Heston.

AMENDMENT NO. 4705

At the request of Ms. LANDRIEU, the names of the Senator from Missouri (Mrs. MCCASKILL), the Senator from North Dakota (Mr. CONRAD) and the Senator from North Dakota (Mr. DORGAN) were added as cosponsors of amendment No. 4705 proposed to S. 2284, an original bill to amend the National Flood Insurance Act of 1968, to restore the financial solvency of the flood insurance fund, and for other purposes.

AMENDMENT NO. 4709

At the request of Mr. NELSON of Florida, the name of the Senator from Illinois (Mr. OBAMA) was added as a cosponsor of amendment No. 4709 proposed to S. 2284, an original bill to amend the National Flood Insurance Act of 1968, to restore the financial solvency of the flood insurance fund, and for other purposes.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Ms. LANDRIEU:

S. 2985. A bill to amend the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users to correct a reference relating to a transit project in Orleans Parish, Louisiana; to the Committee on Environment and Public Works.

Ms. LANDRIEU. Mr. President, I rise today to ask that the Senate support technical corrections to a few highway bill projects in Louisiana. Specifically,

a modified alignment to a project in Lake Charles, an expanded project area for Jefferson Parish and expanded use for a project in New Orleans.

These limited technical corrections will improve transportation in Louisiana and get the dollars previously directed toward this work into the economy. Notably, the corrections do not change the previously authorized level of spending, nor do they fundamentally alter the scope of the project.

I look forward to working with the Environment and Public Works Committee to address these technical corrections.

Mr. LIEBERMAN:

S. 2988. A bill to amend the Public Health Service Act to enhance public and private research efforts to develop new tools and therapies that prevent, detect, and cure diseases; to the Committee on Health, Education, Labor, and Pensions.

Mr. LIEBERMAN. Mr. President, I rise today to introduce a new bill, the Accelerating Cures Act of 2008, to enhance public and private research efforts to develop new tools and therapies that prevent, detect, and cure diseases more quickly from bench to bedside. I introduced an earlier version of this legislation in December 2005, the American Center for Cures Act of 2005, S. 2104. Fundamentally, the Accelerating Cures Act of 2008 has the same intent to promote clinical and translational research within the National Institutes of Health while incorporating many of the recommendations made from the 2003 National Academy of Sciences Report, ''Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges.''

The NIH is a successful, worldwide leader in biomedical research whose mission is to support ''science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability.'' Our national investment in NIH is integral to our Nation's capacity to respond safely and effectively to public and population health threats, chronic disease prevention and management, and burdensome orphan diseases. The 2006 NIH reauthorization strengthened the agency even further, and also brought a greater focus on clinical and translational research to its mission.

The Accelerating Cures Act of 2008 would build upon the progress of NIH reauthorization and further enhance the ability of the agency to address clinical and translational research barriers. For example, it is estimated to take up to 17 years for a scientific discovery to be translated into a clinical application. This gap will not be resolved unless we take serious action to implement clinical and translational research initiatives, critically evaluate the impact of health care delivery, promote multi- and cross-disciplinary collaboration, increase the number of clinicians engaged in clinical and translational research, and foster efforts that streamline the translational development process to result in product commercialization.

The Accelerating Cures Act of 2008 would address these issues by creating new programs that fund high-risk, high-reward research, to oversee and direct promising avenues of translational research, to increase the translational and clinical research workforce, and to provide new funds and authorities to evaluate the clinical effectiveness of various treatments and procedures at the NIH. The bill expands upon existing infrastructure in the Office of Portfolio Analysis and Strategic Initiatives and encourages intra- and inter-agency collaboration to build on strengths of NIH's 27 institutes and centers and other Federal agencies such as the Department of Defense, Food and Drug Administration, and the Agency for Healthcare Research and Quality. Lastly, the Accelerating Cures Act of 2008 uniquely adds resources to guide researchers through the 'Valley of Death,' a stage in biomedical development between research and commercialization where the success of an initiative is dependent on feasibility and profitability that can only be established by a market that, by definition, has not yet developed. With the bill's strengthening and broadening of the Small Business Innovation Research and Small Business Technology Transfer programs and making available resources such as the Rapid Access to Intervention Development and Translational Development programs, investigators, institutions, small businesses, and other entities, will be better suited to navigate the regulatory and commercialization processes.

To summarize, the NIH has been and continues to be our Nation's premier biomedical research investment in areas of basic science and clinical and translational research. My legislation seeks to expand upon existing clinical and translational research efforts not only to meet the healthcare needs of this Nation, but to maintain the NIH's status as the most respected research institution in the World. This bill will not only increase our overall Federal investment in the NIH, but enhance our translational and clinical research capacities overall. I urge my Senate colleagues, patient advocacy groups, and researchers to work together to bring new hope to Americans that we can fight and conquer disease.

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. 2988

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 ''Accelerating Cures Act of 2008''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

SEC. 3. FINDINGS; PURPOSE.

(a) FINDINGS.—Congress finds the following:

(1) The National Institutes of Health (referred to in this section as the ''NIH'') is the United States premier biomedical research investment with annual appropriations exceeding $29,200,000,000.

(2) The goals of the NIH are to—

(A) foster fundamental creative discoveries, innovative research strategies, and their applications as a basis to significantly advance the Nation's capacity to protect and improve health;

(B) develop, maintain, and renew scientific human and physical resources that will ensure the Nation's capacity to prevent disease;

(C) expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and

(D) exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

(3) Thus, the NIH is tasked with applying basic science discoveries to protect and improve health. This includes, translational research, which is the scientific work necessary to develop a clinical application from a basic science discovery.

(4) The United States translational research investment will be key to the Nation responding effectively—

(A) to public and population health threats;

(B) to the complex nature of chronic diseases, which are responsible for 7 out of 10 deaths in the United States, for 75 percent of

the $2,300,000,000,000 spent annually on healthcare in the United States, and for 16 percent of gross domestic product;

(C) to research and development vacuums in the private for-profit market, such as in the fields of vaccine and antibiotic production, drugs for Third World diseases, orphan drugs, and medical tools for pediatric populations; and

(D) to facilitate the process of converting medical innovations into commercial products.

(5) Key components of the translational research process include research prioritization, a strengthening and maintenance of an expert workforce, multidisciplinary collaborative work, strategic risk taking, support of small innovative businesses caught along common pathways in the research and development Valley of Death, simplification and promotion of the clinical research endeavor, and early involvement of private entities that are skilled in the manufacturing and marketing process in the translational research endeavor.

(6) A National Academy of Sciences/Institute of Medicine report made recommendations for reorganizing NIH to meet new challenges facing the biomedical research endeavor. The committee report contained specific recommendations aimed at strengthening clinical and translational research including: increasing trans-NIH research, promoting innovation and risk taking in intramural research, creating a ''special projects'' program, and increasing funding for research management and support.

(7) The Government Accountability Office reported that although the pharmaceutical industry has increased its research and development investment by 147 percent from 1993 to 2004, new drug applications to the Food and Drug Administration have only increased by 39 percent; thus, the productivity of the industry's research and development expenditures is declining. The report cited that a limited scientific understanding of how to translate research discoveries into safe and effective drugs is contributing to the problem and recommended that training researchers who can translate drug discoveries into effective medicines is necessary.

(8) It is estimated to take 17 years for a science discovery to be translated from the point of proof of concept to clinical application. The percent of physicians engaged in research has declined steadily from a peak of 4.6 percent in 1985 to 1.8 percent in 2003.

(9) A report by the Infectious Disease Society of America cited concerns with the lack of new antibiotics to treat infectious diseases. The report commended the NIH Roadmap, but also recommended that NIH aggressively expand the translational research components of the Roadmap, increase grants to small businesses, universities, and nonprofits working in antibiotics research and development, and seek more opportunities to partner with pharmaceutical and biotech companies.

(10) Clinical effectiveness results provide patients, payers, and clinicians with tools to evaluate the benefits versus risks of the ever evolving number of prevention, diagnosis, and treatment strategies available.

(11) The Common Fund is an annual set aside account created from an agreed upon percentage of the annual budget that supports innovative and trans-NIH initiatives to improve and accelerate research to impact health.

(12) The ''Valley of Death'' is a stage in biomedical development between research and commercialization where the success of a product is dependent on its profitability.

(b) PURPOSE.—The purpose of this Act is to create a new pathway to curing disease by enhancing public and private research to translate new discoveries from bench to bedside.

SEC. 4. ACCELERATING CURES ACT OF 2008.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following:

''PART J—ACCELERATING CURES

''Subpart 1—Pathways to Cures Subcommittee

''SEC. 499A. PATHWAYS TO CURES SUBCOMMITTEE.

''(a) DEFINITION OF TRANSLATIONAL RESEARCH.—In this section, the term 'translational research' means research that transforms scientific discoveries arising from laboratory, clinical, or population studies into clinical application to reduce disease incidence, morbidity, and mortality.

''(b) ESTABLISHMENT OF PATHWAYS TO CURES SUBCOMMITTEE.—There is established a Pathways to Cures Subcommittee within the Council of Councils of the Office of Portfolio Analysis and Strategic Initiatives of the National Institutes of Health that shall convene not less frequently than twice a year to help advise and direct the translational research priorities of the Office of Portfolio Analysis and Strategic Initiatives (referred to in this part as the 'OPASI').

''(c) MEMBERSHIP.—

''(1) IN GENERAL.—The subcommittee established under subsection (b) may be composed of the following members:

''(A) The Director of NIH and the Director of OPASI who shall be subcommittee cochairs.

''(B) The heads of the institutes and centers of the National Institutes of Health.

''(C) Heads from Federal agencies, including—

''(i) the Administrator for the Substance Abuse and Mental Health Services Administration;

''(ii) the Under Secretary for Science and Technology of the Department of Homeland Security;

''(iii) the Commanding General for the United States Army Medical Research and Materiel Command;

''(iv) the Director of the Centers for Disease Control and Prevention;

''(v) the Commissioner of Food and Drugs;

''(vi) the Director of the Office of Science of the Department of Energy;

''(vii) the President of the Institute of Medicine;

''(viii) the Director of the Agency for Healthcare Research and Quality; and

''(ix) the Director of the Defense Advanced Research Projects Agency.

''(2) OTHER MEMBERS.—The subcommittee established under subsection (b) shall also include not fewer than 3 leaders from the small business medical research community, 3 leaders from large pharmaceutical or biotechnology companies, and 3 leaders from academia and patient advocacy organizations, all of whom shall be appointed by the Director of NIH.

''(d) RECOMMENDATIONS; COORDINATION; FUNDING.—

''(1) SETTING PRIORITIES.—The subcommittee established under subsection (b) shall make recommendations to assist the Director of OPASI in setting translational research priorities.

''(2) RECOMMENDATIONS.—In making recommendations, the subcommittee shall—

''(A) consider risk and burden of disease as well as lines of research uniquely poised to deliver effective diagnostics and therapies; and

''(B) be mission-driven and identify research that shows specific promise for a new treatment or cure for a disease.

''(3) COORDINATION.—The subcommittee shall ensure sharing of research agendas among the institutes and centers of the National Institutes of Health for the purpose of coordinating translational research priorities, where appropriate, across such institutes and centers.

''(4) FUNDING.—The subcommittee and the Director of OPASI—

''(A) shall identify research with application or commercialization potential; and

''(B) may fund such research.

''(e) REPORT.—The subcommittee established under subsection (b) shall submit an annual report to Congress on progress towards finding new treatments and cures.

''Subpart 2—Clinical Effectiveness; FFRDC

''SEC. 499B. FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTER.

''(a) ESTABLISHMENT OF CENTER.—

''(1) IN GENERAL.—The Director of NIH, in conjunction with the Director of the Agency for Healthcare Research and Quality (referred to in this subpart as the 'AHRQ'), shall establish a Federally Funded Research and Development Center (referred to in this subpart as the 'FFRDC') on clinical effectiveness research.

''(2) DEFINITION OF CLINICAL EFFECTIVENESS RESEARCH.—In this section, the term 'clinical effectiveness research' means research that—

''(A) provides information for health care decision makers, including patients, providers, and public and private payers, to make evidence-based decisions about the delivery of health care; and

''(B) considers specific subpopulations.

''(3) DIRECTOR OF THE FFRDC.—The Director of NIH, in conjunction with the Director of the AHRQ, shall appoint a Director of the FFRDC.

''(b) DUTIES OF THE DIRECTOR OF THE FFRDC.—The Director of the FFRDC shall—

''(1) review, synthesize, and disseminate clinical effectiveness research;

''(2) set priorities for, and fund, trials, such as randomized controlled trials, adaptive trials, and practical trials, observational studies, secondary data analysis in areas of clinical effectiveness research where evidence is lacking, systematic reviews of existing research, as necessary, and cost-effectiveness studies;

''(3) make recommendations regarding the findings of paragraphs (1) and (2);

''(4) study the differential outcomes of interventions on subpopulations within diseases;

''(5) use competitive award processes, including, but not solely, competitive peer review, and examine methods of rapid review cycles to reduce delays in funding decisions;

''(6) encourage the development and use of electronic health data to conduct clinical effectiveness research for the goal of improving clinical care delivery;

''(7) support the development of methodological standards to be used when conducting studies of clinical effectiveness and value in order to help ensure accurate and effective comparisons and update such standards not less frequently than annually;

''(8) include, and collaborate and consult with, as necessary, the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, the Department of Defense, the Department of Veterans Affairs, and other Federal agencies, and the Institute of Medicine, as well as private payers, insurers, pharmaceutical and device companies, patient advocacy and public interest groups, professional societies, hospitals, academic institutions, and health foundations;

''(9) establish a public review or hearing process, which includes the Food and Drug Administration, to examine findings of studies;

''(10) determine the best approach to make available the findings resulting from subparagraphs (A) and (B) to relevant Federal agencies, private and public stakeholders in the health care system, and consumers;

''(11) provide a public forum for addressing conflicting guidelines and recommendations; and

''(12) submit annual reports to Congress on the research activities and findings of the FFRDC.

''(c) CLINICAL EFFECTIVENESS ADVISORY BOARD.—

''(1) ESTABLISHMENT AND FUNCTION.—The Director of the FFRDC shall establish, in conjunction with the Director of NIH and the Director of the AHRQ, an independent Clinical Effectiveness Advisory Board (referred to in this section as the 'Advisory Board'), to include not more than 20 appointed members, in order to provide expert advice and guidance on the research priorities of the FFRDC.

''(2) MEMBERSHIP.—

''(A) IN GENERAL.—Membership on the Advisory Board shall be comprised of—

''(i) representatives of the National Institutes of Health, the AHRQ, the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, the Department of Defense, the Department of Veterans Affairs, and other Federal agencies, and the Institute of Medicine; and

''(ii) private payers, insurers, pharmaceutical and device companies, patient advocacy and public interest groups, professional societies, hospitals, academic institutions, and health foundations.

''(B) EXPERTS.—Membership on the Advisory Board shall consist of leading experts from diverse disciplinary areas, including physicians, social scientists, statisticians, health services researchers, economists, and other health care professionals.

''(C) TERMS.—Terms for members of the Advisory Board shall be fixed, multiyear, and staggered.

''(D) APPOINTMENT.—The members of the Advisory Board who are described in subparagraph (A)(ii) shall be appointed by the Director of the FFRDC, the Director of NIH, and the Director of the AHRQ.

''(E) CHAIR.—The Director of the AHRQ shall be chair of the Advisory Board.

''(3) CONFLICTS OF INTEREST.—Members of the Advisory Board shall disclose any financial, political, or organizational conflicts of interest in conducting the work of the Advisory Board.

''(4) DUTIES.—The Advisory Board shall—

''(A) recommend priorities for clinical effectiveness research to be undertaken by the FFRDC, taking into consideration significant gaps in clinical effectiveness research, including research needs for information on subpopulations and diverse populations, including women, children, and racial and ethnic minorities, and on individuals with comorbid diseases;

''(B) identify existing and novel research designs and methods that may be considered by the FFRDC in conducting clinical effectiveness research;

''(C) review clinical effectiveness research methods;

''(D) review the FFRDC processes to determine whether the research conducted is objective, credible, developed through a transparent process that includes consultations with appropriate stakeholders, including consumers, patient organizations, and the public, and is clinically relevant;

''(E) make recommendations to the AHRQ and the National Institutes of Health for the effective dissemination of the findings of the FFRDC supported research to clinicians, payers, and consumers, and patient organizations; and

''(F) following the first year, review current and previous research agendas and make recommendations regarding research agendas.

''(5) INITIAL MEETING.—The initial meeting of the Advisory Board shall be no later than 6 months after the date of enactment of the Accelerating Cures Act of 2008.

''(6) ADVISORY NATURE OF BOARD.—The recommendations of the Advisory Board shall not be binding, but shall be considered by the Director of the FFRDC when developing the clinical effectiveness research agenda.

''(d) RESEARCH AGENDA.—The Director of the FFRDC shall establish the research agenda of the FFRDC, based on the priorities established by the Advisory Board, and shall update such agenda not less frequently than annually, and shall—

''(1) focus on—

''(A) identifying gaps in clinical effectiveness research relating to medical procedures, medical technologies, pharmaceuticals, health information technologies, and other relevant services and products that significantly contribute to health care outcomes and expenditures;

''(B) funding trials, studies, and reviews, and coordinating these efforts with ongoing research efforts in the Federal Government, academic institutions, and private entities to fill gaps identified under subparagraph (A);

''(C) synthesizing and reviewing clinical effectiveness research to fill gaps identified under subparagraph (A); and

''(D) supporting the development of an evidence base for the development of clinical care guidelines based on the results of clinical effectiveness research;

''(2) convene such working groups on clinical effectiveness research as the Director of the FFRDC determines necessary;

''(3) meet with members representing the National Institutes of Health, the AHRQ, the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, the Department of Defense, the Department of Veterans Affairs, and other Federal agencies, and the Institute of Medicine, as well as private payers, insurers, pharmaceutical and device companies, patient advocacy and public interest groups, professional societies, hospitals, academic institutions, practice based research networks health foundations, and the general public to promote communication and transparency; and

''(4) notify the public well in advance of any public meetings.

''(e) REPORTS.—

''(1) GUIDANCE OR RECOMMENDATIONS.—The Director of the FFRDC, in conjunction with the Director of NIH and the Director of the AHRQ, shall provide, not less frequently than annually, guidance or recommendations to health care providers, payers, and consumers, and Congressional committees of jurisdiction on the comparative effectiveness of health care services.

''(2) STATUS REPORTS.—The Director of the FFRDC shall provide annual status reports on the work of the FFRDC to Congressional committees of jurisdiction.

''(f) AVAILABILITY OF RESEARCH FINDINGS.—The Director of the FFRDC shall develop and identify efficient and effective methods of disseminating the findings of the clinical effectiveness assessments of medical procedures, technologies, and therapeutics, including by making these available on the Internet. Any relevant reports (including interim progress reports, draft final clinical effectiveness reviews, and final progress reports on new research submitted for publication) on the results of clinical effectiveness research supported by the FFRDC shall be made available on the Internet, not later than 90 days after the report is completed.

''(g) EVALUATIONS AND REPORTS OF FFRDC.—The Director of NIH, in conjunction with the Director of the AHRQ, shall enter into regular agreements with entities, such as the Institute of Medicine, to—

''(1) evaluate the FFRDC and its functioning; and

''(2) produce reports on priority setting for the FFRDC, and on research methods developed and employed by the FFRDC, among other purposes.

''Subpart 3—Health Advanced Research Projects Program

''SEC. 499C. HEALTH ADVANCED RESEARCH PROJECTS PROGRAM.

''(a) ESTABLISHMENT.—There is established within the OPASI, a Health Advanced Research Projects Program (referred to in this section as the 'Research Projects Program') that shall be headed by a Director of the Research Projects Program who is appointed by the Director of NIH.

''(b) COMPOSITION.—The Research Projects Program shall be composed of portfolio managers in key health areas, which are determined by the Director of the Research Projects Program in conjunction with the Director of OPASI, the Director of NIH, and the Pathways to Cures Subcommittee established under section 499A.

''(c) GUIDANCE.—The Research Projects Program shall be guided by and shall undertake grand challenges that encourage innovative, multidisciplinary, and collaborative research across institutes and centers of the National Institutes of Health, across Federal agencies, and between public and private partners of the National Institutes of Health.

''(d) MANAGEMENT GUIDANCE.—The Research Projects Program shall be guided by the following management and organizing principles in directing the Research Projects Program:

''(1) Keep the Research Projects Program small, flexible, entrepreneurial, and nonhierarchical, and empower portfolio managers with substantial autonomy to foster research opportunities with freedom from bureaucratic impediments in administering the manager's portfolios.

''(2) Seek to employ the strongest scientific and technical talent in the Nation in research fields in which the Research Projects Program is working.

''(3) Rotate a significant portion of the staff after 3 to 5 years of experience to ensure continuous entry of new talent into the Research Projects Program.

''(4) Use, whenever possible, research and development investments by the Research Projects Program to leverage comparable matching investment and coordinated research from other institutes and centers of the National Institutes of Health, from other Federal agencies, and from the private and nonprofit research sectors.

''(5) Utilize supporting technical, contracting, and administrative personnel from other institutes and centers of the National Institutes of Health in administering and implementing research efforts to encourage participation, collaboration, and cross-fertilization of ideas across the National Institutes of Health.

''(6) Utilize a challenge model in Research Projects Program research efforts, creating a translational research model that supports fundamental research breakthroughs, early and late stage applied development, prototyping, knowledge diffusion, and technology deployment.

''(7) Establish metrics to evaluate research success and periodically revisit ongoing research efforts to carefully weigh new research opportunities against ongoing research.

''(8) Support risk-taking in research pursuits and tolerate productive failure.

''(9) Ensure that revolutionary and breakthrough technology research dominates the Research Projects Program's research agenda and portfolio.

''(e) ACTIVITIES.—Using the funds and authorities provided to the Director of NIH, the Research Projects Program shall carry out the following activities:

''(1) The Research Projects Program shall support basic and applied health research to promote revolutionary technology changes that promote health.

''(2) The Research Projects Program shall advance the development, testing, evaluation, prototyping, and deployment of critical health products.

''(3) The Research Projects Program, consistent with recommendations of the Pathways to Cures Subcommittee established under section 499A, with the priorities of OPASI, and with the grand challenges that encourage innovative, multidisciplinary, and collaborative research, shall emphasize—

''(A) translational research efforts, including efforts conducted through collaboration with the private sector, that pursue—

''(i) innovative health products that could address acute health threats such as a flu pandemic, spread of antibiotic resistant hospital acquired infections, or other comparable problems;

''(ii) remedies for diseases afflicting lesser developed countries;

''(iii) remedies for orphan diseases for which the for-profit sector is not finding new treatments;

''(iv) alternative technologies with significant health promise that are not well-supported in the system of health research, such as adjuvant technology or technologies for vaccines based on the innate immunological response; and

''(v) fast track development, including development through accelerated completion of animal and human clinical trials, for emerging remedies for significant public health problems; and

''(B) other appropriate translational research efforts for critical health issues.

''(4) The Research Projects Program shall utilize funds to provide support to outstanding research performers in all sectors and encourage cross-disciplinary research collaborations that will allow scientists from fields such as information and computer sciences, nanotechnology, chemistry, physics, and engineering to work alongside top researchers with more traditional biomedical backgrounds.

''(5) The Research Projects Program shall provide selected research projects with single-year or multiyear funding and require researchers for such projects to provide interim progress reports, including milestones on progress, to the Research Projects Program on not less frequently than a biannual basis.

''(6) The Research Projects Program shall award competitive, merit-reviewed grants, cooperative agreements, or contracts to public or private entities, including businesses, federally-funded research and development centers, and universities.

''(7) The Research Projects Program shall provide advice to the Director of OPASI concerning funding priorities.

''(8) The Research Projects Program may solicit proposals for competitions to address specific health vulnerabilities identified by the Director of NIH and the Director of OPASI and award prizes for successful outcomes.

''(9) The Research Projects Program shall periodically hold health research and technology demonstrations to improve contact among researchers, technology developers, vendors, and acquisition personnel.

''(10) The Research Projects Program shall carry out other activities determined appropriate by the Director of NIH.

''(f) EMPLOYEES.—

''(1) HIRING.—The Director of the Research Projects Program, in hiring employees for positions with the Research Projects Program, shall have the same hiring and management authorities as described in section 1101 of the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999 (5 U.S.C. 3104 note).

''(2) TERM.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the term of such appointments for employees of the Research Projects Program may not exceed 5 years.

''(B) EXTENSION.—The Director of the Research Projects Program may, in the case of a particular employee of the Research Projects Program, extend the term to which employment is limited under subparagraph (A) by not more than 2 years if the Director of the Research Projects Program determines that such action is necessary to promote the efficiency of the Research Projects Program.

''(g) FLEXIBILITY.—The Director of the Research Projects Program shall have the authority to flexibly fund projects, including the prompt awarding, releasing, enhancing, or withdrawal of monies in accordance with the assessment of the Research Projects Program and project manager.

''Subpart 4—Clinical Trials

''SEC. 499D. GRANTS FOR QUALITY CLINICAL TRIAL DESIGN AND EXECUTION.

''The Director of OPASI—

''(1) shall award grants for clinical trial design and execution to academic centers and practice-based research networks to fund multidisciplinary clinical research teams, which clinical research teams may be composed of members who include project managers, clinicians, epidemiologists, social scientists, and clinical research coordinators; and

''(2) may award grants for clinical trial design and execution to researchers.

''SEC. 499D–1. STREAMLINING THE REGULATORY PROCESS GOVERNING CLINICAL RESEARCH.

''(a) ESTABLISHMENT OF CENTRALIZED INSTITUTIONAL REVIEW BOARDS.—

''(1) IN GENERAL.—

''(A) ESTABLISHMENT AND OVERSIGHT.—The Director of OPASI shall appoint a Director of Centralized Institutional Review Boards (referred to in this part as the 'Director of CIRBs') who shall establish and oversee the functioning and progress of a series of Centralized Institutional Review Boards (referred to in this part as 'CIRBs') to serve as human subject safety and well-being custodians for multi-institutional clinical trials that are funded partially or in full by public research dollars.

''(B) WORK WITH FDA.—The Director of CIRBs shall work with the Commissioner of Food and Drugs to make regulations governing multi-site clinical trials and the regulatory requirements of the Food and Drug Administration more consistent in order to reduce barriers to commercialization of new treatments.

''(2) EXISTING GUIDELINES AND BEST PRACTICES.—CIRBs shall be established in accordance with professional best practices and Good Clinical Practice (GCP) guidelines so that institutions involved in multi-institutional studies may—

''(A) use joint review;

''(B) rely upon the review of another qualified institutional review board; or

''(C) use similar arrangements to avoid duplication of effort and to assure a high-quality of expert oversight.

''(b) HOUSED.—Each CIRB shall be housed—

''(1) at the institute or center of the National Institutes of Health with expertise on the subject of the clinical trial; or

''(2) at a public or private institution with comparable organizational capacity, such as the Department of Veterans Affairs.

''(c) SERVICE.—The use of CIRBs shall be available, as appropriate, at the request of public or private institutions and shall be funded through user fees of the CIRBs or the National Institutes of Health's funds.

''(d) REVIEW PROCESS.—

''(1) IN GENERAL.—Each CIRB shall review research protocols and subject informed consent forms to ensure the protection of safety and well-being of research participants enrolled in multi-institutional clinical trials.

''(2) PROCESS.—The CIRB review process shall consist of contractual agreements between the CIRB and the study sites of multi-institutional clinical trials. The CIRB shall act on behalf, in whole or in part, of the bodies ordinarily responsible for the safety of research subjects in a locality. In the case in which a locality does not have such a body, the locality shall depend solely on the CIRB to oversee the protection of human subjects and the CIRB shall assume responsibility for ensuring adequate assessment of the local research context.

''(e) RESEARCH APPLICATIONS.—

''(1) IN GENERAL.—Each CIRB shall review and package research applications for facilitated electronic review by local institutional review boards participating in a multi-institutional clinical trial.

''(2) CIRB REVIEW.—A local institutional review board may accept or reject a CIRB review. In the case in which a local institutional review board accepts a CIRB review, the CIRB shall assume responsibility for annual, amendment, and adverse event reviews. If a local institutional review board elects to decline participation in the CIRB, the local institutional review board shall appoint a liaison to the CIRB.

''(f) WORK IN CONCERT.—In the case in which a local institutional review board works in concert with a CIRB, the local institutional review board shall be responsible for taking into consideration local characteristics (including ethnicity, educational level, and other demographic characteristics) of the population from which research subjects will be drawn, which influence, among other things, whether there is sound selection of research subjects or whether adequate provision is made to minimize risks to vulnerable populations.

''(g) COMMUNICATION OF IMPORTANT INFORMATION.—Each CIRB shall regularly communicate important information in electronic form to the local institutional review boards or, in cases where a local institutional review board does not exist, to the principal investigator, including regular safety updates or requirements to change a research protocol in order to improve safety.

''(h) COORDINATION.—Each CIRB shall fully coordinate with the institute or center of the National Institutes of Health that has specialized knowledge of the research area of the clinical trial. Other Federal agencies and private entities undertaking clinical trials may contract with the National Institutes of Health to use a CIRB.

''SEC. 499D–2. CLINICAL RESEARCH STUDY AND CLINICAL TRIAL.

''(a) IN GENERAL.—The Director of NIH shall—

''(1) commission the Institute of Medicine to study the rules that protect patient safety

and anonymity so that in a contemporary clinical research context, a better balance can be achieved between clinical research promotion and regulatory requirements governing research subject safety and privacy;

''(2) examine informed consent processes; and

''(3) request that the Institute of Medicine issue a written report not later than 18 months after the date of enactment of the Accelerating Cures Act of 2008 that shall—

''(A) consider changes to the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191) and the amendments made by such Act that further promote the clinical research endeavor; and

''(B) include recommendations for changes that shall not be limited to legislation but shall include changes to healthcare systems, including health information technology, and to researcher practice that facilitate the clinical research endeavor.

''Subpart 5—Training Clinical and Translational Researchers of the Future

''SEC. 499E. TRAINING TRANSLATIONAL AND CLINICAL RESEARCHERS OF THE FUTURE.

''(a) IN GENERAL.—

''(1) ESTABLISHMENT OF PROGRAM.—The Director of OPASI shall establish training programs to increase the number of, and maintain existing, translational and clinical researchers, including researchers trained in community-based research.

''(2) PURPOSE.—The purpose of the training programs described in paragraph (1) shall be to train a cadre of researchers in core competencies in the translational and clinical sciences for the ultimate goal of improving healthcare delivery, healthcare options to the public, the use of healthcare by patients, and healthcare outcomes.

''(b) GRANTS.—

''(1) IN GENERAL.—The Director of OPASI shall award grants to, and enter into contracts with, public and nonprofit educational entities to establish, strengthen, or expand training programs for researchers to be trained in the translational and clinical sciences.

''(2) AWARDING OF GRANTS.—The Director of OPASI shall award grants to, and enter into contracts with, applicants that—

''(A) support multidisciplinary approaches in training;

''(B) utilize collaborative strategies for conducting research across various disciplines to translate basic science discoveries; and

''(C) train researchers focused on improving care and patient outcomes.

''(3) REQUIRED USE OF FUNDS.—The Director of OPASI shall award grants to, and enter into contracts with, entities for the following purposes:

''(A) To establish training programs for M.D. and Ph.D. researchers in translational or clinical research.

''(B) To establish training programs for individuals at predoctoral levels, including those in medical school, and for allied health professionals, in translational or clinical research.

''(C) To establish training programs for nurses in translational and clinical research.

''(D) To strengthen or expand existing training programs for translational or clinical researchers.

''(E) To establish a wide range of training programs, including one-year training programs, summer programs, pre- and postdoctoral clinical or translational research fellowships, and advanced research training programs for mid-career researchers and clinicians.

''(F) To provide stipends and allowances, including for travel and subsistence expenses, in amounts the Director of OPASI determines appropriate, to support the training of translational or clinical researchers.

''(G) To provide financial assistance to public and nonprofit educational entities for the purpose of supporting the training of translational or clinical researchers, through clinical education, curricula, and technological support, and other measures.

''(H) To measure the impact of the translational and clinical research training programs on the biomedical sciences and on clinical practice.

''(c) FUNDS AVAILABLE.—The Director of OPASI may make funds available to support training programs for translational or clinical researchers at the National Institutes of Health for entities awarded grants or contracts under subsection (b).

''(d) NOVEL AND BEST PRACTICES.—The Director of OPASI shall convene, on not less frequently than a biannual basis, members of training institutions to share novel and best practices in training translational or clinical researchers.

''(e) TRAINING.—A trainee of a program funded under a grant or contract awarded under this section may conduct part of the trainee's training at the Health Advanced Research Projects Program.

''(f) CONSISTENT DEFINITIONS AND METHODOLOGIES.—For the purposes of funding training programs for clinical researchers, the Director of NIH shall develop consistent definitions and methodologies to classify and report clinical research.

''SEC. 499E–1. TRANSLATIONAL RESEARCH TRAINING PROGRAM.

''The Director of NIH shall ensure that each institute and center of the National Institutes of Health has established, or contracted for the establishment of, a translational research training program at the institute or center.

''Subpart 6—The 'Valley of Death'

''SEC. 499F. SMALL BUSINESS PARTNERSHIPS.

''(a) IN GENERAL.—An independent advisory board shall be established at the National Academy of Sciences to conduct periodic evaluations of the Small Business Innovation Research program (referred to in this subpart as the 'SBIR program') and the Small Business Technology Transfer program (referred to in this subpart as the 'STTR program') of the Office of Extramural Research in the Office of the Director of the National Institutes of Health for the purpose of improving management of the programs through data-driven assessment. The advisory board shall consist of the Director of NIH, the Director of the SBIR program, senior National Institutes of Health agency managers, university and industry experts, and program stakeholders.

''(b) SBIR AND STTR GRANTS AND CONTRACTS.—

''(1) IN GENERAL.—

''(A) PROGRAM MANAGERS WITH SUFFICIENT EXPERTISE.—Not less than 25 percent of the grants and contracts awarded by each of the SBIR and STTR programs shall be awarded on a competitive basis by an SBIR or STTR program manager who has sufficient managerial, technical, and translational research expertise to expertly assess the quality of a SBIR or STTR proposal.

''(B) EXPERIENCE OF PROGRAM MANAGERS.—In hiring new SBIR or STTR program managers, the Director of NIH shall consider experience in commercialization or industry.

''(C) EMPHASIS ON GRANT AND CONTRACT AWARDS.—In awarding grants and contracts under the SBIR program and the STTR program—

''(i) each SBIR and STTR program manager shall place an emphasis on applications that identify from the onset products with commercial potential to prevent, diagnose, and treat diseases, as well as promote health and well-being; and

''(ii) risk-taking shall be supported and productive failure shall be tolerated.

''(2) EXAMINATION OF COMMERCIALIZATION AND OTHER METRICS.—The independent advisory board described in subsection (a) shall evaluate the success of the requirement under paragraph (1)(A) by examining increased commercialization and other metrics, to be determined and collected by SBIR and STTR programs.

''(3) SUCCESS.—Each recipient of a SBIR or STTR grant or contract, as a condition of receiving such grant or contract, shall report to the SBIR or STTR program—

''(A) whether there was eventual commercial success of the product developed with the assistance of the grant or contract; and

''(B) on other metrics as determined by the SBIR or STTR program to capture broader measures of success.

''(c) POTENTIAL PURCHASERS OR INVESTORS.—The SBIR and STTR programs shall administer nonpeer review grants and contracts pursuant to this section through program managers who shall place special emphasis on partnering grantees and entities awarded contracts from the very beginning of the research and development process with potential purchasers or investors of the product, including large pharmaceutical or biotechnology companies, venture capital firms, and Federal agencies (including the National Institutes of Health).

''(d) PHASE I AND II.—The SBIR and STTR programs shall reduce the time period between Phase I and Phase II funding of grants and contracts under the SBIR and STTR programs to—

''(1) 6 months; or

''(2) less than 6 months if the grantee or entity awarded a contract demonstrates that the grantee or entity awarded a contract has interest from third parties to buy or fund the product development with the grant or contract.

''(e) PHASE III.—A SBIR or STTR program manager may petition the Director of NIH for Phase III funding of a grant or contract for a project that requires a boost to finalize procurement of a product. The maximum funding for Phase III funding shall be $2,000,000 for each of a maximum of 2 years. Such Phase III funding may come from the Common Fund of the NIH.

''(f) EVALUATION AND REPORTING REQUIREMENTS.—In order to enhance the evidence base guiding SBIR and STTR program decisions and changes, the SBIR and STTR programs shall—

''(1) conduct regular internal and external evaluations of the program;

''(2) review current data collection methods for the purpose of identifying gaps and deficiencies, and develop a formal plan for evaluation and assessment of program success, including operational benchmarks for success; and

''(3) conduct a review on the number of SBIR and STTR awards made to women and minorities and develop outreach and review strategies to increase the number of awards to women and minorities.

''(g) PILOT PROGRAMS.—

''(1) IN GENERAL.—The SBIR and STTR programs may initiate pilot programs, based on the development of a formal mechanism for designing, implementing, and evaluating pilot programs, to spur innovation and to test new strategies that may enhance the effectiveness of the program.

''(2) CONSIDERATIONS.—The SBIR and STTR programs shall consider, among other issues, conducting pilot programs on including individuals with commercialization experience

in study sections, hiring individuals with industry experience for staff positions, separating the commercial and scientific review processes, and examining the impact of the trend toward larger awards on the overall program.

''(h) ELECTRONIC RECORDS.—

''(1) IN GENERAL.—The SBIR and STTR programs shall keep a publicly accessible electronic record of all SBIR or STTR investments in research and development.

''(2) CONTENT OF RECORD.—The record described in paragraph (1) shall include, at a minimum, the following information:

''(A) The grantee or entity awarded a grant or contract.

''(B) A description of the research being funded.

''(C) The amount of money awarded in each phase of SBIR or STTR funding.

''(D) If applicable, the purchaser of the product, current use of the product, and estimated annual revenue resulting from the procurement.

''(E) Dates of Phases I, II, and III awards, as applicable.

''(F) Other metrics as determined by the SBIR or STTR programs.

''(i) MEETING.—The Director of NIH shall convene a meeting, not less frequently than annually, consisting of the National Institutes of Health SBIR/STTR program coordinator or manager and each institute and center of the National Institutes of Health to share best practices, report on program activities, and review existing policies.

''(j) REPORT TO CONGRESS.—The Director of NIH shall submit an annual report to Congress and the independent advisory board described in subsection (a) on the SBIR and STTR programs' activities.

''SEC. 499F–1. RAPID ACCESS TO INTERVENTION DEVELOPMENT.

''(a) IN GENERAL.—The Director of OPASI shall expand the existing Rapid Access to Intervention Development Program (referred to in this subpart as the 'RAID') that—

''(1) is designed to assist the translation of promising, novel, and scientifically meritorious therapeutic interventions to clinical use by helping investigators navigate the product development pipeline;

''(2) shall aim to remove barriers between laboratory discoveries and clinical trials of new molecular therapies, technologies, and other clinical interventions;

''(3) shall aim to progress, augment, and complement the innovation and research conducted in private entities to reduce duplicative and redundant work using public funds;

''(4) shall coordinate with the offices of the National Institutes of Health that promote translational research in the pre-clinical phase across the National Institutes of Health;

''(5) shall identify, for the OPASI, those research projects with promise for clinical application or commercialization; and

''(6) shall, in collaboration with the Translational Development Program for New Innovations, facilitate the translation of new innovations through the development process.

''(b) PROJECTS.—

''(1) IN GENERAL.—The RAID, in collaboration with the Director of OPASI, shall carry out a program that shall select, in accordance with paragraph (2), projects of eligible entities to receive access to laboratories, facilities, and other support resources of the National Institutes of Health for the preclinical development of drugs, biologics, diagnostics, and devices.

''(2) SELECTION.—Not less than 25 percent of the projects selected under paragraph (1) shall be selected on a competitive basis—

''(A) by a program manager with sufficient managerial, technical, and translational research expertise to adequately assess the quality of a project proposal; or

''(B) from a peer review process.

''(3) ELIGIBLE ENTITIES.—In this subsection, the term 'eligible entity' means—

''(A) a university researcher;

''(B) a nonprofit research organization; or

''(C) a firm of less than 100 employees in collaboration with 1 or more universities or nonprofit organizations such as a community health center.

''(4) DISCONTINUE SUPPORT.—The RAID may discontinue support of a project if the project fails to meet commercialization success criteria established by the RAID.

''(c) DISCOVERIES FROM LAB TO CLINICAL PRACTICE.—The program under subsection (b) shall accelerate the process of bringing discoveries in medical technology and drugs from the laboratory to the clinic.

''(d) ONGOING REVIEW.—The RAID shall review, on an ongoing basis, potential products and may not support products past the proof-of-principle stage.

''SEC. 499F–2. TRANSLATIONAL DEVELOPMENT PROGRAM FOR NEW INNOVATIONS.

''(a) IN GENERAL.—The Director of OPASI shall develop a Translational Development Program for New Innovations to guide institutions of higher education, small businesses, for-profits, nonprofits, or other such entities through the translational research development process by facilitating the following:

''(1) Triage screening of applications for promising innovations expected to reduce disease incidence, morbidity, and mortality.

''(2) Outlining the tasks, timelines, and costs required to navigate and complete the development process for such innovations.

''(3) Providing project management support for the recommended development tasks.

''(4) Interfacing with the Food and Drug Administration and the entity to devise a plan that safely and rapidly brings new drugs, biologics devices, diagnostics, and other interventions to approval.

''(b) COORDINATION.—The Translational Development Program for New Innovations shall—

''(1) collaborate with the RAID; and

''(2) be comprised of personnel with extensive experience with investigational new drug applications and in commercialization.

''Subpart 7—Translational Research Fund

''SEC. 449G. TRANSLATIONAL RESEARCH FUND.

''(a) ACCOUNT.—There is established an account to be known as the Translational Research Fund that shall consist of amounts appropriated for translational research priorities as described in subsection (b). Such account shall not be funded from amounts otherwise provided to the National Institutes of Health.

''(b) AUTHORIZATION OF APPROPRIATIONS.—For each fiscal year, there is authorized to be appropriated for the Translational Research Fund to carry out the activities under this part an amount equal to the amount set aside for the Common Fund for such fiscal year.

''(c) ALLOTMENT TO HEALTH ADVANCED RESEARCH PROJECTS PROGRAM.—Not less than half of the annual amount appropriated for the Translational Research Fund shall be allotted to the Health Advanced Research Projects Program.''.

SEC. 5. APPLICATION OF RESEARCH REQUIREMENT.

Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following:

''SEC. 404I. APPLICATION OF RESEARCH REQUIREMENT.

''Each application for, and summary of, a project, grant, or contract from the National Institutes of Health, shall include a statement on the possible application of the research for detecting, treating, or curing a health condition or disease state.''.

By Mrs. MURRAY (for herself and Mr. DOMENICI):

S. 2989. A bill to direct the Secretary of Health and Human Services to implement a National Neurotechnology Initiative, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

Mrs. MURRAY. Mr. President, it is estimated that 199 million Americans—or one in three—suffer from some kind of brain or nervous system illness, injury or disorder. Among these illnesses are debilitating diseases and conditions, including: Alzheimer's, multiple sclerosis, epilepsy, Parkinson's disease, and traumatic brain injury. These diseases are challenging for the patients and for their loved ones, who often have intense caretaker burdens.

In addition, our men and women fighting overseas are suffering from these conditions in record numbers. The signature injuries of the current conflicts in Iraq and Afghanistan are brain and spinal cord injuries, such as traumatic brain injury, post-traumatic stress disorder, and paralysis. For example, it is estimated that as many as 12 percent to 20 percent of servicemembers who have served in Iraq suffer from PTSD alone.

The combined economic burden of these illnesses and disorders is estimated at $1 trillion annually—and this cost is rising quickly as our population ages and our military conflicts continue. Recent discoveries are revolutionizing our understanding of the human brain, and new uses for these discoveries are emerging almost every day. At the same time, researchers still have a limited understanding of the human brain and how best to diagnose, treat, and cure its diseases. The current research system for neurological diseases is disjointed and often limits this life altering research from reaching the patients in need. For example, compared to the average drug, it costs nearly $100 million more—and takes 2 years longer—to bring a drug that treats a neurological disease to the market.

We need a targeted, coordinated, national effort to support the development of neurotechnology. It is vitally important that public infrastructure be developed to ensure that today's neurotechnology discoveries quickly become tools to improve the human condition. This research has the potential to transform highly specialized areas of medicine, computing, and defense. It could dramatically change Americans' everyday lives.

The National Neurotechnology Initiative Act addresses each of these issues. I am proud to be an original cosponsor with my colleague from New Mexico. Under this proposal, the National Institutes of Health would receive funds to coordinate research and

move research into innovative companies developing the next generation of treatments.

This legislation will also accelerate research and treatment of neurological diseases by removing key bottlenecks in the system. It will coordinate neurological research across Federal agencies, create a coordinated blueprint for neuroscience at the NIH, and streamline the FDA approval process for life changing neuro drugs—without sacrificing safety. All of this will mean more treatments faster for millions of Americans.

This act is an investment in America's neurological health. Investigation into the mechanisms and functions of the brain will lead to vastly improved understanding of brain disease and injuries and human behavior. It will give us an unprecedented ability to treat and heal those in need. The act also will dramatically reduce healthcare costs while expanding the American neurotechnology industry and creating good American jobs. Finally, this bill will help us honor our debt to the brave men and women of America's armed forces.

Today, I am proud to introduce this legislation with Senator DOMENICI. I thank him for his leadership on this issue, and I look forward to working with him and my other colleagues to pass this important legislation.

Mr. DOMENICI. Mr. President, I rise today to join my colleague, Senator MURRAY, to introduce the National Neurotechnology Initiative Act of 2008. Our bill will coordinate and accelerate federal brain and nervous system research, and will help move that research from the laboratory into the hands of patients.

It is estimated that approximately 100 million Americans—one in three—suffer from some kind of neurological illness, disorder, or injury. These include some of the most debilitating illnesses, such as Alzheimer's disease, Parkinson's disease, multiple sclerosis, autism, schizophrenia, and stroke. They include issues with a neurological basis that often goes unnoticed, such as obesity and hearing loss. They also include issues of particular importance to Senator MURRAY and me: traumatic brain injury, spinal cord injury, posttraumatic stress disorder, and other neurological effects suffered by the brave men and women of our armed forces as they execute their missions throughout the world.

The total economic burden of these neurological illnesses, disorders, and injuries is estimated to be more than one trillion dollars every year. These costs include direct medical treatment, long-term care for senior citizens who have been incapacitated by a neurological disease, addiction-related costs, secondary medical costs related to obesity, and so on.

As the baby boom generation ages, the cost associated with these illnesses will increase rapidly, straining our healthcare resources even further than they already are. Now is the time to act to promote the development of diagnostics, treatments, and cures that will restore health and reduce costs.

Our armed forces too often suffer from a traumatic brain injury, which is among the primary types of casualty that disables our service members. Some soldiers also suffer from posttraumatic stress disorder as well. We owe it to these heroic warriors to help them heal as quickly and as completely as possible.

The National Neurotechnology Initiative Act is designed to address four key issues currently slowing the development of neurological treatments, and to rapidly accelerate R&D for only three percent of the annual NIH brain research budget. The first is a lack of coordination between the many agencies that conduct brain research. The bill creates a coordinating office that will help ensure that the Department of Defense, the Department of Veterans Affairs, the National Institutes of Health, and other agencies know what every other agency is doing, and that they work together toward common goals.

The second issue is insufficient coordination within the National Institutes of Health. Sixteen different Institutes, Centers, and offices within NIH conduct research on the brain and nervous system, and they have begun to work together through a program called the Blueprint for Neuroscience Research. This bill authorizes and fully funds that program.

The third issue is the need to translate basic research into treatments. Advances in neurotechnology are useless if they merely sit in the lab. This bill boosts neuroscience-related technology transfer through the SBIR and STTR programs.

The fourth issue is regulatory approval of new neurotechnology drugs, diagnostics, and devices. Brain-related treatments take much longer and cost much more to approve than other treatments. This bill will increase the timeliness and safety of the neurotechnology review process by allowing the FDA to hire and train neuroscience experts and to work with industry to develop neurotechnology standards.

The bill also supports the analysis of societal implications of neuroscience and neurotechnology, so that we know we are proceeding thoughtfully and carefully in our research.

Brain and nervous system research is an issue that has been extremely important to me throughout my time in the Senate. I have long been a supporter of the MIND Research Network, which does amazing work on these issues in New Mexico; and I have worked hard to advance our ability to treat and cure brain and nervous system diseases and disorders. I hope that this legislation will be part of my legacy in this area.

I want to thank my good friend Senator MURRAY for asking me to join her on this very important issue. I appreciate her commitment to advancing this important research and I look forward to working with her to pass this legislation this Congress.

By Mr. KERRY (for himself, Mr. ALEXANDER, and Ms. STABENOW):

S 2990. A bill to amend title XVIII of the Social Security Act to improve access of Medicare beneficiaries to intravenous immune globulines; to the Committee on Finance.

Mr. KERRY. Mr. President, we have the opportunity this year to help a group of Medicare beneficiaries who are currently subject to costly, bureaucratic red tape which is delaying essential, life-saving treatments to some of our most vulnerable citizens. Addressing this problem will increase the quality of life for many patients and ease financial burdens for their medical providers.

Between 6,000 and 10,000 Medicare beneficiaries have primary immunodeficiency diseases, PIDD, and require intravenous immunoglobulin, IVIG treatment to maintain a healthy immune system.

Primary Immunodeficiency Diseases are disorders in which part of the body's immune system is missing or does not function properly. These disorders are caused by intrinsic or genetic defects in the immune system. Untreated primary immune deficiencies result in frequent life-threatening infections and debilitating illnesses. Even illnesses such as the common cold or the flu, while unpleasant for most of us, can be deadly for someone with PIDD.

Because of advances in our medical understanding and treatment of primary immune deficiency diseases, individuals who in the past would not have survived childhood are now able to live nearly normal lives. While there is still no cure for PIDD, there are effective treatments available. Nearly 70 percent of primary immune deficient patients use intravenous immunoglobulin to maintain their health.

Immunoglobulin is a naturally occurring collection of highly specialized proteins, known as antibodies, which strengthen the body's immune response. It is derived from human plasma donations and is administered through an IV to the patient every three to four weeks.

Currently, Medicare beneficiaries needing IVIG treatments are experiencing access problems—an unintended result of the way Medicare has determined the payment for IVIG. The current IVIG access and care issue began in January 2005 as a result of the Medicare Modernization Act under Part B, which changed the way physicians and hospital outpatient departments were paid under Medicare. The law reduced IVIG reimbursement rates such that most physicians in outpatient settings could no longer afford to treat Medicare patients requiring IVIG. In addition, access to home based infusion

therapy is limited since Medicare currently pays only for the cost of IVIG, and not nursing services and supplies required for infusion.

As a result, patients are experiencing delays in receiving this life saving treatment and are being shifted to more expensive care settings such as inpatient hospitals. In addition to incurring extra expenses, hospital-based care results in patients being in close proximity to countless microorganisms, an unsafe prospect for those who have suppressed immune systems.

In April 2007, the U.S. Department of Health and Human Services Office of the Inspector General, OIG,reported that Medicare reimbursement for IVIG was inadequate to cover the cost many providers must pay for the product. In fact, the OIG found that 44 percent of hospitals and 41 percent of physicians were unable to purchase IVIG at the Medicare reimbursements rate during the 3rd quarter of 2006. The previous quarter had been even worse—77.2 percent of hospitals and 96.5 percent of physicians were unable to purchase IVIG at the Medicare reimbursement rate.

We have a rare opportunity to fix this very real problem with a compassionate and common sense solution. We can improve the quality of life for PIDD patients and cut inpatient expenses by improving reimbursement procedures for IVIG treatments for physicians and outpatient facilities and allowing for home treatments and coverage for related services.

Today, I am introducing—along with Senators ALEXANDER and STABENOW—the bipartisan Medicare IVIG Access Act, a bill that will grant the Secretary of Health & Human Services temporary authority to update the payment for IVIG, if necessary based on new or existing data, and to provide coverage for related items and services currently excluded from the existing Medicare home infusion therapy benefit. This bill is endorsed by several national organizations from the patient and physician communities, including the Immune Deficiency Foundation, IDF, GBS/CIDP Foundation International, the Jeffrey Modell Foundation JMF, the Platelet Disorder Support Association, PDSA, the National Patient Advocate Foundation, NPAF, and the Clinical Immunology Society, CIS.

The patients, physicians, caretakers, researchers, and plasma donors have all done their part—now it's time for us to do ours.

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. 2990

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 ''Medicare IVIG Access Act of 2008''.

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

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Intravenous immune globulin (IVIG) is a human blood plasma derived product, which over the past 25 years has become an invaluable therapy for many primary immunodeficiency diseases, as well as a number of neurological, autoimmune, and other chronic conditions and illnesses. For many of these disorders, IVIG is the most effective and viable treatment available, and has dramatically improved the quality of life for persons with these conditions and has become a life-saving therapy for many.

(2) The Food and Drug Administration recognizes each IVIG brand as a unique biologic. The differences in basic fractionation and the addition of various modifications for further purification, stabilization, and virus inactivation/removal yield clearly different biological products. As a result, IVIG therapies are not interchangeable, with patient tolerance differing from one IVIG brand to another.

(3) The report of the Office of the Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services, ''Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV)'', that was issued in May 2007, found that IVIG manufacturing is complex and requires substantial up-front cash outlay and planning and takes between 7 and 12 months from plasma collection at donor centers to lot release by the Food and Drug Administration.

(4) The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2066) changed Medicare's reimbursement methodology for IVIG from average wholesale price (AWP) to average sales price plus 6 percent (ASP+6 percent), effective January 1, 2005, for physicians, and January 1, 2006, for hospital outpatient departments, thereby reducing reimbursement rates paid to those providers of IVIG on behalf of Medicare beneficiaries.

(5) An April 2007 report of the Office of Inspector General of the Department of Health and Human Services, ''Intravenous Immune Globulin: Medicare Payment and Availability'', found that Medicare reimbursement for IVIG was inadequate to cover the cost many providers must pay for the product. During the third quarter of 2006, 44 percent of IVIG sales to hospitals and 41 percent of sales to physicians by the 3 largest distributors occurred at prices above Medicare payment amounts.

(6) The report of the Office of the Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services, ''Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV)'' notes that, after the new reimbursement rules for physicians were instituted in 2005, 42 percent of Medicare beneficiaries who had received their IVIG treatment in their physician's office at the end of 2004 were shifted to the hospital outpatient setting by the beginning of 2006. This shift in site of care has resulted in a lack of continuity of care and has had an adverse impact on health outcomes and quality of life.

(7) The Office of Inspector General of the Department of Health and Human Services also reported that 61 percent of responding physicians indicated that they had sent patients to hospitals for IVIG treatment, largely because of their inability to purchase IVIG at prices below the Medicare payment amounts. In addition, the Office of Inspector General found that some physicians had stopped providing IVIG to Medicare beneficiaries altogether.

(8) The Office of Inspector General's 2007 report concluded that whatever improvement some providers saw in the relationship of Medicare reimbursement for IVIG to prices paid during the first 3 quarters of 2006 would be eroded if manufacturers were to increase prices for IVIG in the future.

(9) The Centers for Medicare & Medicaid Services, in recognition of dislocations experienced by patients and providers in obtaining IVIG since the change to the ASP+6 reimbursement methodology, has provided a temporary additional payment during 2006 and 2007 for IVIG preadministration-related services to compensate physicians and hospital outpatient departments for the extra resources they have had to expend in locating and obtaining appropriate IVIG products and in scheduling patient infusions.

(10) Approximately 10,000 Medicare beneficiaries receive IVIG treatment for their primary immunodeficiency disease in a variety of different settings. Those beneficiaries have no other effective treatment for their condition.

(11) The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established an IVIG home infusion benefit for persons with primary immune deficiency disease, paying only for IVIG and specifically excluding coverage of items and services related to administration of the product.

(12) The report of the Office of the Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services, ''Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV)'', noted that, because of limitations in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provision, Medicare's IVIG home infusion benefit is not designed to provide reimbursement for more than the cost of IVIG and does not cover the cost of infusion services (such as nursing and clinical services and supplies) in the home. As a consequence, the report found that home infusion providers generally do not accept new patients who have primary immune deficiency disease and only have Medicare coverage. These limitations in service are caused by health care providers—

(A) not being able to acquire IVIG at prices at or below the Medicare part B reimbursement level; and

(B) not being reimbursed for the infusion services provided by a nurse.

(13) Access to home infusion of IVIG for patients with primary immune deficiency disease, who have a genetic or intrinsic defect in their human immune system, will reduce their exposure to infections at a time when their antibodies are compromised and will improve the quality of care and health of the patient.

SEC. 3. MEDICARE PAYMENT FOR INTRAVENOUS IMMUNE GLOBULINS.

(a) IN GENERAL.—Section 1842(o) of the Social Security Act (42 U.S.C. 1395u(o)) is amended—

(1) in paragraph (1)(E)(ii), by inserting '', plus an additional amount (if applicable) under paragraph (7)'' before the period at the end;

(2) by redesignating paragraph (7) as paragraph (8); and

(3) by inserting after paragraph (6) the following new paragraph:

''(7)(A) Not later than 6 months after the date of enactment of the Medicare IVIG Access Act of 2008, the Secretary shall—

''(i) collect data on the differences, if any, between payments to physicians for intravenous immune globulin under paragraph (1)(E)(ii) and costs incurred by physicians for furnishing such products; and

''(ii) review available data, including survey and pricing data collected by the Federal Government and data presented by members of the intravenous immune globulin community on the access of individuals eligible for services under this part to intravenous immune globulin and the differences described in clause (i).

''(B) Subject to subparagraph (C), in the case of intravenous immune globulin furnished on or after the date of enactment of this paragraph, the Secretary shall continue the IVIG preadministration-related services payment established under the final rule promulgated by the Secretary in the Federal Register on November 27, 2007 (72 Fed. Reg. 66254), until such time as the Secretary determines that payment for intravenous immune globulin is adequate.

''(C) Upon collection of data and completion of the review under subparagraph (A), the Secretary shall, during a 2-year period beginning not later than 7 months after such date of enactment, provide, if appropriate, to physicians furnishing intravenous immune globulins, a payment, in addition to the payment under paragraph (1)(E)(ii) and instead of the IVIG preadministration-related services payment under subparagraph (B), for all items related to the furnishing of intravenous immune globulin, in an amount the Secretary determines to be appropriate.''.

(b) AS PART OF HOSPITAL OUTPATIENT SERVICES.—Section 1833(t)(14) of such Act (42 U.S.C. 1395l(t)(14)) is amended—

(1) in subparagraph (A)(iii), by striking ''subparagraph (E)'' and inserting ''subparagraphs (E) and (I)''; and

(2) by adding at the end the following new subparagraph:

''(I) ADDITIONAL PAYMENT FOR INTRAVENOUS IMMUNE GLOBULIN.—

''(i) DATA COLLECTION AND REVIEW.—Not later than 6 months after the date of enactment of the Medicare IVIG Access Act of 2008, the Secretary shall—

''(I) collect data on the differences, if any, between payments of intravenous immune globulin under subparagraph (A)(iii) and costs incurred by a hospital for furnishing such products; and

''(II) review available data, including survey and pricing data collected by the Federal Government and data presented by members of the intravenous immune globulin community on the access of individuals eligible for services under this part to intravenous immune globulin and the differences described in subclause (I).

''(ii) CONTINUATION OF SPECIAL PAYMENT RULE.—Subject to clause (iii), in the case of intravenous immune globulin furnished on or after the date of enactment of this subparagraph, the Secretary shall continue the IVIG preadministration-related services payment established under the final rule promulgated by the Secretary in the Federal Register on November 27, 2007 (72 Fed. Reg. 66697), until such time as the Secretary determines that payment for intravenous immune globulin is adequate.

''(iii) ADDITIONAL PAYMENT AUTHORITY.—Upon collection of data and completion of the review under clause (i), the Secretary shall, during a 2-year period beginning not later than 7 months after such date of enactment, provide, if appropriate, to hospitals furnishing intravenous immune globulin as part of a covered OPD service, in addition to the payment under subparagraph (A)(iii) and instead of the IVIG preadministration-related services payment under clause (ii), for all items related to the furnishing of intravenous immune globulin, in an amount the Secretary determines to be appropriate.''.

SEC. 4. COVERAGE AND PAYMENT OF INTRAVENOUS IMMUNE GLOBULIN IN THE HOME.

(a) IN GENERAL.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended—

(1) in subsection (s)(2)(Z), by inserting ''and items and services related to the administration of intravenous immune globulin'' after ''globulin''; and

(2) in subsection (zz), by striking ''but not including items or services related to the administration of the derivative,''.

(b) PAYMENT FOR INTRAVENOUS IMMUNE GLOBULIN ADMINISTRATION IN THE HOME.—Section 1842(o) of the Social Security Act (42 U.S.C. 1395u(o), as amended by section 3, is amended—

(1) in paragraph (1)(E)(ii), by striking ''paragraph (7)'' and inserting ''paragraph (7) or (8)'';

(2) by redesignating paragraph ''(8)'' as paragraph ''(9)''; and

(3) by inserting after paragraph (7) the following new paragraph:

''(8)(A) Subject to subparagraph (B), in the case of intravenous immune globulins described in section 1861(s)(2)(Z) that are furnished on or after January 1, 2008, the Secretary shall provide for a separate payment for items and services related to the administration of such intravenous immune globulins in an amount that the Secretary determines to be appropriate based on a review of available published and unpublished data and information, including the Study of Intravenous Immune Globulin Administration Options: Safety, Access, and Cost Issues conducted by the Secretary (CMS Contract #500–95–0059). Such payment amount may take into account the following:

''(i) Pharmacy overhead and related expenses.

''(ii) Patient service costs.

''(iii) Supply costs.

''(B) The separate payment amount provided under this paragraph for intravenous immune globulins furnished in 2009 or a subsequent year shall be equal to the separate payment amount determined under this paragraph for the previous year increased by the percentage increase in the medical care component of the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year.''.

SEC. 5. REPORTS.

(a) REPORT BY THE SECRETARY.—Not later than 7 months after the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall submit a report to Congress on the following:

(1) The results of the data collection and review conducted by the Secretary under subparagraph (A) of section 1842(o)(7) of the Social Security Act, as added by section 3(a), and clause (i) of section 1833(t)(14)(I) of such Act, as added by section 3(b).

(2) Whether the Secretary plans to use the authority under subparagraph (C) of such section 1842(o)(7) and clause (iii) of such section 1833(t)(14)(I) to provide an additional payment to physicians furnishing intravenous immune globulins.

(b) MEDPAC REPORT.—Not later than 2 years after the date of enactment of this Act, the Medicare Payment Advisory Commission shall submit a report to the Secretary and to Congress that contains the following:

(1) In the case where the Secretary has used the authority under sections 1842(o)(7)(C) and 1833(t)(14)(I)(iii) of the Social Security Act, as added by subsections (a) and (b), respectively, of section 3 to provide an additional payment to physicians furnishing intravenous immune globulins during the preceding year, an analysis of whether beneficiary access to intravenous immune globulins under the Medicare program under title XVIII of the Social Security Act has improved as a result of the Secretary's use of such authority.

(2) An analysis of the appropriateness of implementing a new methodology for payment for intravenous immune globulins under part B of title XVIII of the Social Security Act (42 U.S.C. 1395k et seq.).

(3) An analysis of the feasibility of reducing the lag time with respect to data used to determine average sales price under section 1847A of the Social Security Act (42 U.S.C. 1395w–3a).

(4) Recommendations for such legislation and administrative action as the Medicare Payment Advisory Commission determines appropriate, including recommendations for such legislation and administrative action as the Commission determines is necessary to implement any methodology analyzed under paragraph (2).

SEC. 6. OFFSET.

Section 1861(n) of the Social Security Act (42 U.S.C. 1395x(n)) is amended by adding at the end the following: ''Such term includes disposable drug delivery systems, including elastomeric infusion pumps, for the treatment of colorectal cancer.''.

By Mr. REID (for himself, Mr. SCHUMER, Mr. LEVIN, Mr. WYDEN, Mr. INOUYE, Mr. CARDIN, Ms. STABENOW, Mr. BROWN, Mr. WHITEHOUSE, Mrs. FEINSTEIN, Mr. JOHNSON, Mr. KENNEDY, Ms. KLOBUCHAR, Mr. LAUTENBERG, Mr. LEAHY, Ms. MIKULSKI, Mrs. MURRAY, Mr. REED, Mrs. MCCASKILL, and Mr. DURBIN):

S. 2991. A bill to provide energy price relief and hold oil companies and other entities accountable for their actions with regard to high energy prices, and for other purposes; read the first time.

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 placed in the RECORD, as follows:

S. 2991

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 ''Consumer-First Energy Act of 2008''.

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

SEC. 2. FINDINGS.

Congress finds that—

(1) excessive prices for petroleum products have created, or imminently threaten to create, severe economic dislocations and hardships, including the loss of jobs, business failures, disruption of economic activity, curtailment of vital public services, and price increases throughout the economy;

(2) those hardships and dislocations jeopardize the normal flow of commerce and constitute a national energy and economic crisis that is a threat to the public health, safety, and welfare of the United States;

(3) consumers, workers, small businesses, and large businesses of the United States are particularly vulnerable to those price increase due to the failure of the President to aggressively develop alternatives to petroleum and petroleum products and to promote efficiency and conservation;

(4) reliable and affordable supplies of crude oil and products refined from crude oil (including gasoline, diesel fuel, heating oil, and jet fuel) are vital to the economic and national security of the United States given current energy infrastructure and technology;

(5) the price of crude oil and products refined from crude oil (including gasoline, diesel fuel, heating oil, and jet fuel) have skyrocketed to record levels and are continuing to rise;

(6) since 2001, oil prices have increased from $29 per barrel to levels near $120 per barrel and gasoline prices have more than doubled from $1.47 per gallon to more than $3.50 per gallon;

(7) the record prices for crude oil and products refined from crude oil (including gasoline, diesel fuel, heating oil, and jet fuel)—

(A) are hurting millions of consumers, workers, small businesses, and large businesses of the United States, and threaten long-term damage to the economy and security of the United States;

(B) are partially due to—

(i) the declining value of the dollar and a widespread lack of confidence in the management of economic and foreign policy by the President;

(ii) the accumulation of national debt and growing budget deficits under the failed economic policies of the President; and

(iii) high levels of military expenditures under the failed policies of the President in Iraq; and

(C) are no longer justified by traditional forces of supply and demand;

(8) rampant speculation in the markets for crude oil and products refined from crude oil has magnified the price increases and market volatility resulting from those underlying causes of price increases; and

(9) Congress must take urgent action to protect consumers, workers, and businesses of the United States from rampant speculation in the energy markets and the price increases resulting from the failed domestic and foreign policies of the President.

TITLE I—TAX PROVISIONS RELATED TO OIL AND GAS

SEC. 101. DENIAL OF DEDUCTION FOR MAJOR INTEGRATED OIL COMPANIES FOR INCOME ATTRIBUTABLE TO DOMESTIC PRODUCTION OF OIL, GAS, OR PRIMARY PRODUCTS THEREOF.

(a) IN GENERAL.—Subparagraph (B) of section 199(c)(4) (relating to exceptions) is amended by striking ''or'' at the end of clause (ii), by striking the period at the end of clause (iii) and inserting '', or'', and by inserting after clause (iii) the following new clause:

''(iv) in the case of any major integrated oil company (as defined in section 167(h)(5)(B)), the production, refining, processing, transportation, or distribution of oil, gas, or any primary product thereof during any taxable year described in section 167(h)(5)(B).''.

(b) PRIMARY PRODUCT.—Section 199(c)(4)(B) is amended by adding at the end the following flush sentence:

''For purposes of clause (iv), the term 'primary product' has the same meaning as when used in section 927(a)(2)(C), as in effect before its repeal.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2008.

SEC. 102. ELIMINATION OF THE DIFFERENT TREATMENT OF FOREIGN OIL AND GAS EXTRACTION INCOME AND FOREIGN OIL RELATED INCOME FOR PURPOSES OF THE FOREIGN TAX CREDIT.

(a) IN GENERAL.—Subsections (a) and (b) of section 907 of the Internal Revenue Code of 1986 (relating to special rules in case of foreign oil and gas income) are amended to read as follows:

''(a) REDUCTION IN AMOUNT ALLOWED AS FOREIGN TAX UNDER SECTION 901.—In applying section 901, the amount of any foreign oil and gas taxes paid or accrued (or deemed to have been paid) during the taxable year which would (but for this subsection) be taken into account for purposes of section 901 shall be reduced by the amount (if any) by which the amount of such taxes exceeds the product of—

''(1) the amount of the combined foreign oil and gas income for the taxable year,

''(2) multiplied by—

''(A) in the case of a corporation, the percentage which is equal to the highest rate of tax specified under section 11(b), or

''(B) in the case of an individual, a fraction the numerator of which is the tax against which the credit under section 901(a) is taken and the denominator of which is the taxpayer's entire taxable income.

''(b) COMBINED FOREIGN OIL AND GAS INCOME; FOREIGN OIL AND GAS TAXES.—For purposes of this section—

''(1) COMBINED FOREIGN OIL AND GAS INCOME.—The term 'combined foreign oil and gas income' means, with respect to any taxable year, the sum of—

''(A) foreign oil and gas extraction income, and

''(B) foreign oil related income.

''(2) FOREIGN OIL AND GAS TAXES.—The term 'foreign oil and gas taxes' means, with respect to any taxable year, the sum of—

''(A) oil and gas extraction taxes, and

''(B) any income, war profits, and excess profits taxes paid or accrued (or deemed to have been paid or accrued under section 902 or 960) during the taxable year with respect to foreign oil related income (determined without regard to subsection (c)(4)) or loss which would be taken into account for purposes of section 901 without regard to this section.''.

(b) RECAPTURE OF FOREIGN OIL AND GAS LOSSES.—Paragraph (4) of section 907(c) of the Internal Revenue Code of 1986 (relating to recapture of foreign oil and gas extraction losses by recharacterizing later extraction income) is amended to read as follows:

''(4) RECAPTURE OF FOREIGN OIL AND GAS LOSSES BY RECHARACTERIZING LATER COMBINED FOREIGN OIL AND GAS INCOME.—

''(A) IN GENERAL.—The combined foreign oil and gas income of a taxpayer for a taxable year (determined without regard to this paragraph) shall be reduced—

''(i) first by the amount determined under subparagraph (B), and

''(ii) then by the amount determined under subparagraph (C).

The aggregate amount of such reductions shall be treated as income (from sources without the United States) which is not combined foreign oil and gas income.

''(B) REDUCTION FOR PRE-2008 FOREIGN OIL EXTRACTION LOSSES.—The reduction under this paragraph shall be equal to the lesser of—

''(i) the foreign oil and gas extraction income of the taxpayer for the taxable year (determined without regard to this paragraph), or

''(ii) the excess of—

''(I) the aggregate amount of foreign oil extraction losses for preceding taxable years beginning after December 31, 1982, and before January 1, 2008, over

''(II) so much of such aggregate amount as was recharacterized under this paragraph (as in effect before and after the date of the enactment of the Consumer-First Energy Act of 2008) for preceding taxable years beginning after December 31, 1982.

''(C) REDUCTION FOR POST-2008 FOREIGN OIL AND GAS LOSSES.—The reduction under this paragraph shall be equal to the lesser of—

''(i) the combined foreign oil and gas income of the taxpayer for the taxable year (determined without regard to this paragraph), reduced by an amount equal to the reduction under subparagraph (A) for the taxable year, or

''(ii) the excess of—

''(I) the aggregate amount of foreign oil and gas losses for preceding taxable years beginning after December 31, 2008, over

''(II) so much of such aggregate amount as was recharacterized under this paragraph for preceding taxable years beginning after December 31, 2008.

''(D) FOREIGN OIL AND GAS LOSS DEFINED.—

''(i) IN GENERAL.—For purposes of this paragraph, the term 'foreign oil and gas loss' means the amount by which—

''(I) the gross income for the taxable year from sources without the United States and its possessions (whether or not the taxpayer chooses the benefits of this subpart for such taxable year) taken into account in determining the combined foreign oil and gas income for such year, is exceeded by

''(II) the sum of the deductions properly apportioned or allocated thereto.

''(ii) NET OPERATING LOSS DEDUCTION NOT TAKEN INTO ACCOUNT.—For purposes of clause (i), the net operating loss deduction allowable for the taxable year under section 172(a) shall not be taken into account.

''(iii) EXPROPRIATION AND CASUALTY LOSSES NOT TAKEN INTO ACCOUNT.—For purposes of

clause (i), there shall not be taken into account—

''(I) any foreign expropriation loss (as defined in section 172(h) (as in effect on the day before the date of the enactment of the Revenue Reconciliation Act of 1990)) for the taxable year, or

''(II) any loss for the taxable year which arises from fire, storm, shipwreck, or other casualty, or from theft,

to the extent such loss is not compensated for by insurance or otherwise.

''(iv) FOREIGN OIL EXTRACTION LOSS.—For purposes of subparagraph (B)(ii)(I), foreign oil extraction losses shall be determined under this paragraph as in effect on the day before the date of the enactment of the Consumer-First Energy Act of 2008.''.

(c) CARRYBACK AND CARRYOVER OF DISALLOWED CREDITS.—Section 907(f) of the Internal Revenue Code of 1986 (relating to carryback and carryover of disallowed credits) is amended—

(1) by striking ''oil and gas extraction taxes'' each place it appears and inserting ''foreign oil and gas taxes'', and

(2) by adding at the end the following new paragraph:

''(4) TRANSITION RULES FOR PRE-2009 AND 2009 DISALLOWED CREDITS.—

''(A) PRE-2009 CREDITS.—In the case of any unused credit year beginning before January 1, 2009, this subsection shall be applied to any unused oil and gas extraction taxes carried from such unused credit year to a year beginning after December 31, 2008—

''(i) by substituting 'oil and gas extraction taxes' for 'foreign oil and gas taxes' each place it appears in paragraphs (1), (2), and (3), and

''(ii) by computing, for purposes of paragraph (2)(A), the limitation under subparagraph (A) for the year to which such taxes are carried by substituting 'foreign oil and gas extraction income' for 'foreign oil and gas income' in subsection (a).

''(B) 2009 CREDITS.—In the case of any unused credit year beginning in 2009, the amendments made to this subsection by the Consumer-First Energy Act of 2008 shall be treated as being in effect for any preceding year beginning before January 1, 2009, solely for purposes of determining how much of the unused foreign oil and gas taxes for such unused credit year may be deemed paid or accrued in such preceding year.''.

(d) CONFORMING AMENDMENT.—Section 6501(i) of the Internal Revenue Code of 1986 is amended by striking ''oil and gas extraction taxes'' and inserting ''foreign oil and gas taxes''.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2008.

SEC. 103. WINDFALL PROFITS TAX.

(a) IN GENERAL.—Subtitle E of the Internal Revenue Code of 1986 (relating to alcohol, tobacco, and certain other excise taxes) is amended by adding at the end thereof the following new chapter:

''CHAPTER 56—WINDFALL PROFITS ON CRUDE OIL

''SEC. 5896. IMPOSITION OF TAX.

''(a) IN GENERAL.—In addition to any other tax imposed under this title, there is hereby imposed on any applicable taxpayer an excise tax in an amount equal to 25 percent of the excess of—

''(1) the windfall profit of such taxpayer, over

''(2) the amount of the qualified investment of such applicable taxpayer.

''(b) APPLICABLE TAXPAYER.—For purposes of this chapter, the term 'applicable taxpayer' means any major integrated oil company (as defined in section 167(h)(5)(B)).

''SEC. 5897. WINDFALL PROFIT; QUALIFIED INVESTMENT.

''(a) GENERAL RULE.—For purposes of this chapter, the term 'windfall profit' means the excess of the adjusted taxable income of the applicable taxpayer for the taxable year over the reasonably inflated average profit for such taxable year.

''(b) ADJUSTED TAXABLE INCOME.—For purposes of this chapter, with respect to any applicable taxpayer, the adjusted taxable income for any taxable year is equal to the taxable income for such taxable year (within the meaning of section 63 and determined without regard to this subsection)—

''(1) increased by any interest expense deduction, charitable contribution deduction, and any net operating loss deduction carried forward from any prior taxable year, and

''(2) reduced by any interest income, dividend income, and net operating losses to the extent such losses exceed taxable income for the taxable year.

In the case of any applicable taxpayer which is a foreign corporation, the adjusted taxable income shall be determined with respect to such income which is effectively connected with the conduct of a trade or business in the United States.

''(c) REASONABLY INFLATED AVERAGE PROFIT.—For purposes of this chapter, with respect to any applicable taxpayer, the reasonably inflated average profit for any taxable year is an amount equal to the average of the adjusted taxable income of such taxpayer for taxable years beginning during the 2001–2005 taxable year period (determined without regard to the taxable year with the highest adjusted taxable income in such period) plus 10 percent of such average.

''(d) QUALIFIED INVESTMENT.—For purposes of this chapter—

''(1) IN GENERAL.—The term 'qualified investment' means, with respect to any applicable taxpayer, means any amount paid or incurred with respect to—

''(A) section 263(c) costs,

''(B) qualified refinery property (as defined in section 179C(c) and determined without regard to any termination date),

''(C) any qualified facility described in paragraph (1), (2), (3), or (4) of section 45(d) (determined without regard to any placed in service date), or

''(D) any facility for the production renewable fuel or advanced biofuel (as defined in section 211(o) of the Clean Air Act 942 U.S.C. 7545).

''(2) SECTION 263(c) COSTS.—For purposes of this subsection, the term 'section 263(c) costs' means intangible drilling and development costs incurred by the taxpayer which (by reason of an election under section 263(c)) may be deducted as expenses for purposes of this title (other than this paragraph). Such term shall not include costs incurred in drilling a nonproductive well.

''SEC. 5898. SPECIAL RULES AND DEFINITIONS.

''(a) WITHHOLDING AND DEPOSIT OF TAX.—The Secretary shall provide such rules as are necessary for the withholding and deposit of the tax imposed under section 5896.

''(b) RECORDS AND INFORMATION.—Each taxpayer liable for tax under section 5896 shall keep such records, make such returns, and furnish such information as the Secretary may by regulations prescribe.

''(c) RETURN OF WINDFALL PROFIT TAX.—The Secretary shall provide for the filing and the time of such filing of the return of the tax imposed under section 5896.

''(d) CRUDE OIL.—The term 'crude oil' includes crude oil condensates and natural gasoline.

''(e) BUSINESSES UNDER COMMON CONTROL.—For purposes of this chapter, all members of the same controlled group of corporations (within the meaning of section 267(f)) and all persons under common control (within the meaning of section 52(b) but determined by treating an interest of more than 50 percent as a controlling interest) shall be treated as 1 person.

''(f) REGULATIONS.—The Secretary shall prescribe such regulations as may be necessary or appropriate to carry out the purposes of this chapter.''.

(b) CLERICAL AMENDMENT.—The table of chapters for subtitle E of the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

(c) DEDUCTIBILITY OF WINDFALL PROFIT TAX.—The first sentence of section 164(a) of the Internal Revenue Code of 1986 (relating to deduction for taxes) is amended by inserting after paragraph (5) the following new paragraph:

''(6) The windfall profit tax imposed by section 5896.''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2007.

SEC. 104. ENERGY INDEPENDENCE AND SECURITY TRUST FUND.

(a) ESTABLISHMENT.—Subchapter A of chapter 98 of the Internal Revenue Code of 1986 (relating to trust fund code) is amended by adding at the end the following new section:

''SEC. 9511. ENERGY INDEPENDENCE AND SECURITY TRUST FUND.

''(a) CREATION OF TRUST FUND.—There is established in the Treasury of the United States a trust fund to be known as 'Energy Independence and Security Trust Fund' (referred to in this section as the 'Trust Fund'), consisting of such amounts as may be appropriated or credited to the Trust Fund as provided in this section or section 9602(b).

''(b) TRANSFERS TO TRUST FUND.—There is hereby appropriated to the Trust Fund an amount equivalent to the increase in the revenues received in the Treasury as the result of the amendments made by sections 101, 102, and 103 of the Consumer-First Energy Act of 2008.

''(c) DISTRIBUTION OF AMOUNTS IN TRUST FUND.—Amounts in the Trust Fund shall be available, as provided by appropriation Acts, for the purposes of reducing the dependence of the United States on foreign and unsustainable energy sources and reducing the risks of global warming through programs and measures that—

''(1) reduce the burdens on consumers of rising energy prices;

''(2) diversify and expand the use of secure, efficient, and environmentally-friendly energy supplies and technologies;

''(3) result in net reductions in emissions of greenhouse gases; and

''(4) prevent energy price gouging, profiteering, and market manipulation.''.

(b) CLERICAL AMENDMENT.—The table of sections for subchapter A of chapter 98 of such Code is amended by adding at the end the following new item:

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of the enactment of this Act.

TITLE II—PRICE GOUGING

SEC. 201. SHORT TITLE.

This title may be cited as the ''Petroleum Consumer Price Gouging Protection Act''.

SEC. 202. DEFINITIONS.

In this title:

(1) AFFECTED AREA.—The term ''affected area'' means an area covered by a Presidential declaration of energy emergency.

(2) SUPPLIER.—The term ''supplier'' means any person engaged in the trade or business of selling or reselling, at retail or wholesale, or distributing crude oil, gasoline, petroleum distillates, or biofuel.

(3) PRICE GOUGING.—The term ''price gouging'' means the charging of an unconscionably excessive price by a supplier in an affected area.

(4) UNCONSCIONABLY EXCESSIVE PRICE.—The term ''unconscionably excessive price'' means an average price charged during an energy emergency declared by the President in an area and for a product subject to the declaration, that—

(A)(i)(I) constitutes a gross disparity from the average price at which it was offered for sale in the usual course of the supplier's business during the 30 days prior to the President's declaration of an energy emergency; and

(II) grossly exceeds the prices at which the same or similar crude oil, gasoline, petroleum distillates, or biofuel was readily obtainable by purchasers from other suppliers in the same relevant geographic market within the affected area; or

(ii) represents an exercise of unfair leverage or unconscionable means on the part of the supplier, during a period of declared energy emergency; and

(B) is not attributable to increased wholesale or operational costs, including replacement costs, outside the control of the supplier, incurred in connection with the sale of crude oil, gasoline, petroleum distillates, or biofuel, and is not attributable to local, regional, national, or international market conditions.

(5) COMMISSION.—The term ''Commission'' means the Federal Trade Commission.

SEC. 203. ENERGY EMERGENCY AND ADDITIONAL PRICE GOUGING ENFORCEMENT.

(a) IN GENERAL.—During any energy emergency declared by the President under section 204 of this title, it is unlawful for any supplier to sell, or offer to sell crude oil, gasoline, petroleum distillates, or biofuel subject to that declaration in, or for use in, the area to which that declaration applies at an unconscionably excessive price.

(b) FACTORS CONSIDERED.—In determining whether a violation of subsection (a) has occurred, there shall be taken into account, among other factors, whether—

(1) the price charged was a price that would reasonably exist in a competitive and freely functioning market; and

(2) the amount of gasoline, other petroleum distillates, or biofuel the seller produced, distributed, or sold during the period the Proclamation was in effect increased over the average amount during the preceding 30 days.

SEC. 204. PRESIDENTIAL DECLARATION OF ENERGY EMERGENCY.

(a) IN GENERAL.—If the President finds that the health, safety, welfare, or economic well-being of the citizens of the United States is at risk because of a shortage or imminent shortage of adequate supplies of crude oil, gasoline, petroleum distillates, or biofuel due to a disruption in the national distribution system for crude oil, gasoline, petroleum distillates, or biofuel (including such a shortage related to a major disaster (as defined in section 102(2) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5122(2))), or significant pricing anomalies in national energy markets for crude oil, gasoline, petroleum distillates, or biofuel the President may declare that a Federal energy emergency exists.

(b) SCOPE AND DURATION.—The emergency declaration shall specify—

(1) the period, not to exceed 30 days, for which the declaration applies;

(2) the circumstance or condition necessitating the declaration; and

(3) the area or region to which it applies which may not be limited to a single State; and

(4) the product or products to which it applies.

(c) EXTENSIONS.—The President may—

(1) extend a declaration under subsection (a) for a period of not more than 30 days;

(2) extend such a declaration more than once; and

(3) discontinue such a declaration before its expiration.

SEC. 205. ENFORCEMENT BY THE FEDERAL TRADE COMMISSION.

(a) ENFORCEMENT.—This title shall be enforced by the Federal Trade Commission in the same manner, by the same means, and with the same jurisdiction as though all applicable terms of the Federal Trade Commission Act were incorporated into and made a part of this title. In enforcing section 203 of this title, the Commission shall give priority to enforcement actions concerning companies with total United States wholesale or retail sales of crude oil, gasoline, petroleum distillates, and biofuel in excess of $500,000,000 per year but shall not exclude enforcement actions against companies with total United States wholesale sales of $500,000,000 or less per year.

(b) VIOLATION IS TREATED AS UNFAIR OR DECEPTIVE ACT OR PRACTICE.—The violation of any provision of this title shall be treated as an unfair or deceptive act or practice proscribed under a rule issued under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a)(1)(B)).

(c) COMMISSION ACTIONS.—Following the declaration of an energy emergency by the President under section 204 of this title, the Commission shall—

(1) maintain within the Commission—

(A) a toll-free hotline that a consumer may call to report an incident of price gouging in the affected area; and

(B) a program to develop and distribute to the public informational materials to assist residents of the affected area in detecting, avoiding, and reporting price gouging;

(2) consult with the Attorney General, the United States Attorney for the districts in which a disaster occurred (if the declaration is related to a major disaster), and State and local law enforcement officials to determine whether any supplier in the affected area is charging or has charged an unconscionably excessive price for crude oil, gasoline, petroleum distillates, or biofuel in the affected area; and

(3) conduct investigations as appropriate to determine whether any supplier in the affected area has violated section 203 of this title, and upon such finding, take any action the Commission determines to be appropriate to remedy the violation.

SEC. 206. ENFORCEMENT BY STATE ATTORNEYS GENERAL.

(a) IN GENERAL.—A State, as parens patriae, may bring a civil action on behalf of its residents in an appropriate district court of the United States to enforce the provisions of section 203 of this title, or to impose the civil penalties authorized by section 207 for violations of section 203, whenever the attorney general of the State has reason to believe that the interests of the residents of the State have been or are being threatened or adversely affected by a supplier engaged in the sale or resale, at retail or wholesale, or distribution of crude oil, gasoline, petroleum distillates, or biofuel in violation of section 203 of this title.

(b) NOTICE.—The State shall serve written notice to the Commission of any civil action under subsection (a) prior to initiating the action. The notice shall include a copy of the complaint to be filed to initiate the civil action, except that if it is not feasible for the State to provide such prior notice, the State shall provide such notice immediately upon instituting the civil action.

(c) AUTHORITY TO INTERVENE.—Upon receiving the notice required by subsection (b), the Commission may intervene in the civil action and, upon intervening—

(1) may be heard on all matters arising in such civil action; and

(2) may file petitions for appeal of a decision in such civil action.

(d) CONSTRUCTION.—For purposes of bringing any civil action under subsection (a), nothing in this section shall prevent the attorney general of a State from exercising the powers conferred on the Attorney General by the laws of such State to conduct investigations or to administer oaths or affirmations or to compel the attendance of witnesses or the production of documentary and other evidence.

(e) VENUE; SERVICE OF PROCESS.—In a civil action brought under subsection (a)—

(1) the venue shall be a judicial district in which—

(A) the defendant operates;

(B) the defendant was authorized to do business; or

(C) where the defendant in the civil action is found;

(2) process may be served without regard to the territorial limits of the district or of the State in which the civil action is instituted; and

(3) a person who participated with the defendant in an alleged violation that is being litigated in the civil action may be joined in the civil action without regard to the residence of the person.

(f) LIMITATION ON STATE ACTION WHILE FEDERAL ACTION IS PENDING.—If the Commission has instituted a civil action or an administrative action for violation of this title, a State attorney general, or official or agency of a State, may not bring an action under this section during the pendency of that action against any defendant named in the complaint of the Commission or the other agency for any violation of this title alleged in the Commission's civil or administrative action.

(g) NO PREEMPTION.—Nothing contained in this section shall prohibit an authorized State official from proceeding in State court to enforce a civil or criminal statute of that State.

SEC. 207. PENALTIES.

(a) CIVIL PENALTY.—

(1) IN GENERAL.—In addition to any penalty applicable under the Federal Trade Commission Act, any supplier—

(A) that violates section 203 of this title is punishable by a civil penalty of not more than $1,000,000; and

(B) that violates section 203 of this title is punishable by a civil penalty of—

(i) not more than $500,000, in the case of an independent small business marketer of gasoline (within the meaning of section 324(c) of the Clean Air Act (42 U.S.C. 7625(c))); and

(ii) not more than $5,000,000 in the case of any other supplier.

(2) METHOD.—The penalties provided by paragraph (1) shall be obtained in the same manner as civil penalties imposed under section 5 of the Federal Trade Commission Act (15 U.S.C. 45).

(3) MULTIPLE OFFENSES; MITIGATING FACTORS.—In assessing the penalty provided by subsection (a)—

(A) each day of a continuing violation shall be considered a separate violation; and

(B) the court shall take into consideration, among other factors, the seriousness of the violation and the efforts of the person committing the violation to remedy the harm caused by the violation in a timely manner.

(b) CRIMINAL PENALTY.—Violation of section 203 of this title is punishable by a fine of not more than $5,000,000, imprisonment for not more than 5 years, or both.

SEC. 208. EFFECT ON OTHER LAWS.

(a) OTHER AUTHORITY OF THE COMMISSION.—Nothing in this title shall be construed to limit or affect in any way the Commission's authority to bring enforcement actions or take any other measure under the Federal Trade Commission Act (15 U.S.C. 41 et seq.) or any other provision of law.

(b) STATE LAW.—Nothing in this title preempts any State law.

TITLE III—STRATEGIC PETROLEUM RESERVE

SEC. 301. SUSPENSION OF PETROLEUM ACQUISITION FOR STRATEGIC PETROLEUM RESERVE.

(a) IN GENERAL.—Except as provided in subsection (b) and notwithstanding any other provision of law, during the period beginning on the date of enactment of this Act and ending on December 31, 2008—

(1) the Secretary of the Interior shall suspend acquisition of petroleum for the Strategic Petroleum Reserve through the royalty-in-kind program; and

(2) the Secretary of Energy shall suspend acquisition of petroleum for the Strategic Petroleum Reserve through any other acquisition method.

(b) RESUMPTION.—Not earlier than 30 days after the date on which the President notifies Congress that the President has determined that the weighted average price of petroleum in the United States for the most recent 90-day period is $75 or less per barrel—

(1) the Secretary of the Interior may resume acquisition of petroleum for the Strategic Petroleum Reserve through the royalty-in-kind program; and

(2) the Secretary of Energy may resume acquisition of petroleum for the Strategic Petroleum Reserve through any other acquisition method.

(c) EXISTING CONTRACTS.—In the case of any oil scheduled to be delivered to the Strategic Petroleum Reserve pursuant to a contract entered into by the Secretary of Energy prior to, and in effect on, the date of enactment of this Act, the Secretary shall, to the maximum extent practicable, negotiate a deferral of the delivery of the oil for a period of not less than 1 year, in accordance with procedures of the Department of Energy in effect on the date of enactment of this Act for deferrals of oil.

TITLE IV—NO OIL PRODUCING AND EXPORTING CARTELS

SEC. 401. NO OIL PRODUCING AND EXPORTING CARTELS ACT OF 2008.

(a) SHORT TITLE.—This section may be cited as the ''No Oil Producing and Exporting Cartels Act of 2008'' or ''NOPEC''.

(b) SHERMAN ACT.—The Sherman Act (15 U.S.C. 1 et seq.) is amended by adding after section 7 the following:

''SEC. 7A. OIL PRODUCING CARTELS.

''(a) IN GENERAL.—It shall be illegal and a violation of this Act for any foreign state, or any instrumentality or agent of any foreign state, to act collectively or in combination with any other foreign state, any instrumentality or agent of any other foreign state, or any other person, whether by cartel or any other association or form of cooperation or joint action—

''(1) to limit the production or distribution of oil, natural gas, or any other petroleum product;

''(2) to set or maintain the price of oil, natural gas, or any petroleum product; or

''(3) to otherwise take any action in restraint of trade for oil, natural gas, or any petroleum product;

when such action, combination, or collective action has a direct, substantial, and reasonably foreseeable effect on the market, supply, price, or distribution of oil, natural gas, or other petroleum product in the United States.

''(b) SOVEREIGN IMMUNITY.—A foreign state engaged in conduct in violation of subsection (a) shall not be immune under the doctrine of sovereign immunity from the jurisdiction or judgments of the courts of the United States in any action brought to enforce this section.

''(c) INAPPLICABILITY OF ACT OF STATE DOCTRINE.—No court of the United States shall decline, based on the act of state doctrine, to make a determination on the merits in an action brought under this section.

''(d) ENFORCEMENT.—The Attorney General of the United States may bring an action to enforce this section in any district court of the United States as provided under the antitrust laws.''.

(c) SOVEREIGN IMMUNITY.—Section 1605(a) of title 28, United States Code, is amended—

(1) in paragraph (6), by striking ''or'' after the semicolon;

(2) in paragraph (7), by striking the period and inserting ''; or''; and

(3) by adding at the end the following:

''(8) in which the action is brought under section 7A of the Sherman Act.''.

TITLE V—MARKET SPECULATION

SEC. 501. SPECULATIVE LIMITS AND TRANSPARENCY FOR OFF-SHORE OIL TRADING.

Section 4 of the Commodity Exchange Act (7 U.S.C. 6) is amended by adding at the end the following:

''(e) FOREIGN BOARDS OF TRADE.—

''(1) IN GENERAL.—In the case of any foreign board of trade for which the Commission has granted or is considering an application to grant a board of trade located outside of the United States relief from the requirement of subsection (a) to become a designated contract market, derivatives transaction execution facility, or other registered entity, with respect to an energy commodity that is physically delivered in the United States, prior to continuing to or initially granting the relief, the Commission shall determine that the foreign board of trade—

''(A) applies comparable principles or requirements regarding the daily publication of trading information and position limits or accountability levels for speculators as apply to a designated contract market, derivatives transaction execution facility, or other registered entity trading energy commodities physically delivered in the United States; and

''(B) provides such information to the Commission regarding the extent of speculative and nonspeculative trading in the energy commodity that is comparable to the information the Commission determines necessary to publish a Commitment of Traders report for a designated contract market, derivatives transaction execution facility, or other registered entity trading energy commodities physically delivered in the United States.

''(2) EXISTING FOREIGN BOARDS OF TRADE.—During the period beginning 1 year after the date of enactment of this subsection and ending 18 months after the date of enactment of this subsection, the Commission shall determine whether to continue to grant relief in accordance with paragraph (1) to any foreign board of trade for which the Commission granted relief prior to the date of enactment of this subsection.''.

SEC. 502. MARGIN LEVEL FOR CRUDE OIL.

(a) IN GENERAL.—Section 2(a)(1) of the Commodity Exchange Act (7 U.S.C. 2(a)(1)) is amended by adding at the end the following:

''(G) MARGIN LEVEL FOR CRUDE OIL.—Not later than 90 days after the date of enactment of this subparagraph, the Commission shall promulgate regulations to set a substantial increase in margin levels for crude oil traded on any trading facility or as part of any agreement, contract, or transaction covered by this Act in order to reduce excessive speculation and protect consumers.''.

(b) STUDIES.—

(1) STUDY RELATING TO EFFECT OF CERTAIN REGULATIONS.—Not later than 1 year after the date of enactment of this Act, the Commodity Futures Trading Commission shall submit to the appropriate committees of Congress a report describing the effect of the amendment made by subsection (a) on any trading facilities and agreements, contracts, and transactions covered by the Commodity Exchange Act (7 U.S.C. 1 et seq.).

(2) STUDY RELATING TO EFFECTS OF CHANGES IN MARGIN LEVELS.—Not later than 180 days after the date of enactment of this Act, the Comptroller General of the United States shall submit to the appropriate committees of Congress a report describing the effect (including any effect relating to trade volume or volatility) of any change of a margin level that occurred during the 10-year period ending on the date of enactment of this Act.

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 554—EXPRESSING THE SENSE OF THE SENATE ON HUMANITARIAN ASSISTANCE TO BURMA AFTER CYCLONE NARGIS

Mr. KERRY (for himself, Mr. LUGAR, Mr. BIDEN, Mr. MCCONNELL, Mrs. FEINSTEIN, Mr. DURBIN, Mr. DODD, Mr. OBAMA, Mr. WEBB, Ms. MURKOWSKI, Mr. KENNEDY, Mr. MENENDEZ, Mr. FEINGOLD, Mr. LIEBERMAN, Mr. HAGEL, Mrs. BOXER, Mrs. CLINTON, Mrs. DOLE, Mr. MCCAIN, and Mr. COLEMAN) submitted the following resolution; which was considered and agreed to:

S. RES. 554

Whereas, on May 3, 2008, Cyclone Nargis devastated Burma, leaving an estimated 22,500 people dead, 41,000 missing, and 1,000,000 homeless;

Whereas, on May 5, 2008, the United States embassy in Burma issued a disaster declaration authorizing $250,000 in immediate humanitarian assistance to the people of Burma;

Whereas, on May 5, 2008, First Lady Laura Bush stated that the United States will ''work with the U.N. and other international nongovernmental organizations to provide water, sanitation, food, and shelter. More assistance will be forthcoming'';

Whereas, on May 5, 2008, Department of State Deputy Spokesman Tom Casey stated that the United States has ''a disaster assistance response team that is standing by and ready to go in to Burma to help try to assess need there'';

Whereas, on May 6, 2008, President George W. Bush said, ''The United States has made an initial aid contribution, but we want to do a lot more. We're prepared to move U.S. Navy assets to help find those who've lost their lives, to help find the missing, to help stabilize the situation. But in order to do so, the military junta must allow our disaster assessment teams into the country.'';