human rights, ethnic cleansing, and genocide documented in the United States record relating to the Armenian Genocide.

S. RES. 134

At the request of Mr. DURBIN, the names of the Senator from Mississippi (Mr. COCHRAN) and the Senator from Hawaii (Mr. INOUYE) were added as cosponsors of S. Res. 134, a resolution designating September 2007 as ''Adopt a School Library Month''.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

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

S. 1138. A bill to enhance nuclear safeguards and to provide assurances of nuclear fuel supply to countries that forgo certain fuel cycle activities; to the Committee on Foreign Relations.

Mr. LUGAR. Mr. President, I rise today with my colleague from Indiana, Senator BAYH, to introduce the Nuclear Safeguards and Supply Act of 2007.

The future of the Nuclear Non-Proliferation Treaty and the larger nonproliferation system it supports is in doubt. The existing safeguards regime used by the International Atomic Energy Agency (IAEA) has succeeded in forestalling nuclear weapons programs in the world's advanced industrial states, several of which were weighing the nuclear option 40 years ago. Unfortunately, this regime has failed to keep pace with the increase in the global availability of nuclear weapons technology, especially the technology and equipment for uranium enrichment and spent nuclear reactor fuel reprocessing, which can produce fissile material for weapons. Now the road to nuclear weapons can be traveled by determined countries with only a minimal industrial base. While the number of recognized nuclear weapon states has not dramatically increased over the years, the dangers of proliferation have become all too apparent as demonstrated by the A.Q. Khan network, the Iranian, North Korean, and Libyan examples.

The construction of facilities for the enrichment of uranium and reprocessing of spent nuclear fuel in new states, even for ostensibly peaceful purposes, poses an unacceptable long-term risk to the national security of the United States. The enrichment technology intended to produce fuel for reactors can also be used to create highly-enriched uranium for a nuclear weapon, and the plutonium that is produced from reprocessing spent fuel is also suitable for nuclear weapons and susceptible to diversion to terrorists. The spread of enrichment and reprocessing capabilities will dangerously increase the chances that new nations will develop nuclear weapons and that terrorists might obtain fissile or radiological materials for crude devices. It is therefore incumbent on the United States to lead an international effort to halt the expansion of enrichment and reprocessing to new countries.

We know President Bush shares our assessment of this situation. On February 11, 2004, he stated, ''The world's leading nuclear exporters should ensure that states have reliable access at reasonable cost to fuel for civilian reactors, so long as those states renounce enrichment and reprocessing. Enrichment and reprocessing are not necessary for nations seeking to harness nuclear energy for peaceful purposes.''

The threats posed by new nuclear fuel cycle facilities in new states are made worse by the fact that the use of nuclear power is likely to increase, both in developed and developing countries. As energy costs have soared in recent years, many states are reexamining nuclear power as a potential source of electricity. Importantly, however, the expansion of nuclear power does not require—either technically or economically—the construction of enrichment or reprocessing facilities in countries that do not currently have them.

Senator BAYH and I believe the United States should adopt as a basic nonproliferation principle that countries who give up their own enrichment and reprocessing programs have an assurance, either bilateral or multilateral or both, of nuclear reactor fuel at reasonable prices. Today, the market provides the basic framework for commerce in and access to nuclear fuel, and should not be interrupted by government action, but the exchange of nuclear fuel and fuel services for enrichment and reprocessing capabilities is not currently explicit. This would also require that states agreeing to accept fuel services and leasing of fuel, in return for giving up joining the group of states possessing reprocessing and enrichment capabilities, would also consent to wide access and close monitoring of their nuclear energy activities, exceeding the requirements of the IAEA Additional Protocol. Related efforts in this area should also move forward in the [Nuclear Suppliers Group, where various nations have advocated a criteria-based approach to nuclear fuel supply.

Unfortunately, as the world looks to increase the number of civilian nuclear power plants, the IAEA, charged with ensuring that energy programs do not stray into weapons efforts through the verification of safeguards agreements, operates on a shortsighted budget with old equipment. This situation threatens the institution, and to some degree the nuclear stability that the IAEA's safeguards verification mandate supports. The IAEA is responsible for verifying that states do not violate their obligations under the Nuclear Nonproliferation Treaty (NPT). The IAEA monitors states' nuclear programs through safeguards agreements and additional protocols to ensure that nuclear material, equipment, and technology are used for declared, peaceful purposes.

Last November, I visited the IAEA and its Safeguards Analytical Laboratory (SAL), located just outside Vienna, Austria. Samples collected by IAEA inspectors during inspections are brought to the SAL to verify that safeguards obligations are being met and that there are no undeclared materials and activities. Unfortunately the laboratory's aging equipment and dangerous working conditions will hamper the important work done there, particularly as more samples arrive there and as more states expand their nuclear power infrastructure. Such a situation could, in the future, shut down a critical nonproliferation facility. The IAEA's nuclear materials analysis capability is vulnerable to a single point of failure given the situation at SAL. Laboratory staff is also severely limited in the time they can spend analyzing evidence in the ''hot'' or nuclear part of SAL because of the dilapidated air purification system in one part of the laboratory. Equally disturbing, SAL is still using equipment manufactured in the 1970's. If the IAEA is supposed to be the world's nuclear watchdog, the least we can do is to provide the people who work there with appropriate and effective tools to do their job.

Absent refurbishment of SAL, or the construction of a new IAEA facility with modem equipment, President Ronald Reagan's charge ''trust but verify'' will be abandoned because we have not taken action.

The SAL helped to discover the inconsistencies in Iran's cover-up of its nuclear weapons program. The analysis and questioning by inspectors prompted stonewalling by Tehran. The Iranian failure to provide information and access led the IAEA Board of Governors to refer the matter to the United Nations Security Council. While I wish this might have happened more quickly, the fact is that SAL, the network of laboratories in other Member States, and the IAEA's inspectors provided the evidence necessary to build consensus on Iranian violations.

The Lugar-Bayh legislation works to create both bilateral and multilateral assurances of nuclear fuel supply by specifically authorizing the President to pursue such mechanisms. Importantly, our legislation takes note of the fact that merely ensuring fuel supply is not enough to truly deal with the potential proliferation that could arise as a result of many more nuclear reactors being built around the world. Proliferation of fuel cycle technologies may continue, regardless of the ability of our Nation and others to craft layers of assurance in fuel supply. Our bill makes an important point—that fuel supply for new nuclear power is as important as the safeguards applied to nuclear power.

The Lugar-Bayh legislation makes it the policy of the United States to discourage the development of enrichment and reprocessing capabilities in additional countries, and to encourage the creation of bilateral and multilateral assurances of nuclear fuel supply,

and ensure that all supply mechanisms operate in strict accordance with the IAEA safeguards system and do not result in any additional unmet verification burdens for the system. To ensure that SAL does not cease to function, we authorize an additional $10,000,000 for the refurbishment or possible replacement of the IAEA Safeguards Analytical Laboratory. We also authorize the Secretary of State, in cooperation with the Secretary of Energy and the Directors of the National Laboratories, and in consultation with the Secretary of Defense and the Director of National Intelligence, to pursue a program that will improve nuclear safeguards technology development.

With regard to fuel supply, our bill authorizes the President to create, consistent with existing law, bilateral and multilateral mechanisms to provide a reliable supply of nuclear fuel to those countries and groups of countries that adhere to policies designed to prevent the proliferation of nuclear weapons and that decide to forgo a national uranium enrichment program and spent nuclear fuel reprocessing facilities. Such mechanisms must confront the challenges of international politics, thus the authority contained in the bill is designed to provide a flexible framework, rather than a final set of requirements, for such mechanisms. The bill embraces both bilateral and multilateral fuel supply mechanisms, and calls for a report on the establishment of an International Nuclear Fuel Authority.

The United States cannot fix the IAEA's problems alone, but we must lead. An international diplomatic effort is required to raise the funds necessary to ensure that the IAEA has the resources and leadership it needs to continue its important mission. But the IAEA, its Member States and Board of Governors must also act. The Board must review and revise SAL staffing policies as they apply to professional staff working at SAL to ensure that it attracts and retains key personnel. Current policies are self-defeating and force experts out just as they are accumulating the level of experience and expertise necessary to succeed.

Not only is the existing IAEA infrastructure in desperate need of modernization, but a global nuclear power expansion will require a commensurate increase in IAEA capability. We must strengthen the organization to ensure that multiplying nuclear power facilities are not diverted to weapons work. This can and should be accompanied by better support to our own efforts in verification activities and technologies, such as through the Key Assets Verification Fund at the Department of State and the U.S. Program of Technical Assistance to IAEA Safeguards or POTAS.

If the world is at the dawn of a new nuclear power age, then there will be more facilities and materials for the IAEA to inspect and verify. The IAEA is not prepared for such a future, but there is still time to put the necessary investments in place to ensure that it continues its important role. The United States and other Member States have the ability to plan and make decisions now that will ensure a safer nuclear power option in the future. It is incumbent upon the United States to assist in the construction of the best possible safeguards system to provide for international peace and security. Peaceful uses of nuclear energy are only as good as the means to verify them.

The current budget of the IAEA cannot sustain further stress, nor can the world afford to allow another state to develop nuclear weapons in secret. The IAEA is underfunded to perform its current tasks and would be required to do much more should nuclear energy become more widespread. The Bush Administration must significantly increase funding to the IAEA to improve its ability to exercise its rights and meet its obligations. We hope this legislation will begin that process.

I look forward to working with my colleagues on the Committee on Foreign Relations on these important matters. I thank Senator BAYH for his partnership in this endeavor.

By Mr. BINGAMAN (for himself, Mr. SALAZAR, Ms. CANTWELL, and Mr. SANDERS):

S. 1139. A bill to establish the National Landscape Conservation System; to the Committee on Energy and Natural Resources.

Mr. BINGAMAN. Mr. President, together with Senators SALAZAR, CANTWELL, and SANDERS, I am pleased today to introduce legislation to codify the National Landscape Conservation System, the collection of national monuments, national conservation areas, wilderness areas, wild and scenic rivers and other remarkable landscapes on our public lands administered by the Bureau of Land Management.

The National Landscape Conservation System was established administratively by the Department of the Interior in 2000 and consists of all areas the BLM administers for conservation purposes. The concept behind grouping all of these areas into one system was to increase public awareness of the importance of these lands and to highlight the BLM's conservation of these areas and their cultural, historical, scientific, and ecological significance to the Nation.

Within my own State of New Mexico, the National Landscape Conservation System encompasses several nationally significant areas, including the rugged lava flows of El Malpais National Conservation Area, the unique cone-shaped rock formations of the Kasha-Katuwe Tent Rocks National Monument, the Rio Grande Wild and Scenic River, the Continental Divide National Scenic Trail and the El Camino Real de Tierra Adentro and Old Spanish Trail National Historic Trails, as well as over one million acres of wilderness and wilderness study areas.

However, because the NLCS was established administratively, it does not have the permanence that it would have if enacted legislatively. In addition, legislative enactment of the NLCS will help increase the attention to these important, congressionally protected areas, and hopefully will help ensure that the system remains a high priority within the BLM and the Department of the Interior. The bill does not create any new management authority and does not change the authorities for any of the previously designated areas within the system.

Given the broad public support for these areas, I expect this bill to be noncontroversial and it is my hope that it will be able to move quickly through the Congress and enactment into law.

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. 1139

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 ''National Landscape Conservation System Act''.

SEC. 2. DEFINITIONS.

In this Act:

(1) SECRETARY.—The term ''Secretary'' means the Secretary of the Interior.

(2) SYSTEM.—The term ''system'' means the National Landscape Conservation System established by section 3(a).

SEC. 3. ESTABLISHMENT OF THE NATIONAL LANDSCAPE CONSERVATION SYSTEM.

(a) ESTABLISHMENT.—In order to conserve, protect, and restore nationally significant landscapes that have outstanding cultural, ecological, and scientific values for the benefit of current and future generations, there is established in the Bureau of Land Management the National Landscape Conservation System.

(b) COMPONENTS.—The system shall include each of the following areas administered by the Bureau of Land Management:

(1) Each area that is designated as—

(A) a national monument;

(B) a national conservation area;

(C) an outstanding natural area;

(D) a wilderness study area;

(E) a component of the National Trails System;

(F) a component of the National Wild and Scenic Rivers System; or

(G) a component of the National Wilderness Preservation System.

(2) Any area designated by Congress to be administered for conservation purposes, including—

(A) the Steens Mountain Cooperative Management and Protection Area, as designated under section 101(a) of the Steens Mountain Cooperative Management and Protection Act of 2000 (16 U.S.C. 460nnn–11(a));

(B) the Headwaters Forest Reserve; and

(C) any additional area designated by Congress for inclusion in the system.

(c) MANAGEMENT.—The Secretary shall manage the system—

(1) in accordance with any applicable law (including regulations) relating to any component of the system included under subsection (b); and

(2) in a manner that protects the values for which the components of the system were designated.

SEC. 4. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated such sums as are necessary to carry out this Act.

Mr. SALAZAR. Mr. President, today Senator BINGAMAN and I are introducing the National Landscape Conservation System Act, a bill that will help protect some of our Nation's most treasured landscapes.

This bill, which we are introducing with Senators Cantwell and Sanders, will make permanent a system of management for the 26 million most spectacular acres of the 260 million acres that the Bureau of Land Management oversees.

The National Landscape Conservation System was created administratively in 2000 to guide the management of the national monuments, national conservation areas, national wild and scenic rivers, wilderness areas, wilderness study areas, and national historic and scenic trails that are under the BLM's authority.

Many of these lands are on par with our national parks in their beauty and value to the American people. Unfortunately, the National Landscape Conservation System has taken a backseat in our country's land conservation efforts. The NLCS has been shortchanged in funding in the President's budget year in and year out. There are not enough resources or staff to properly manage these lands, and we are hearing a growing number of reports that natural, cultural, and archaeological sites on NLCS lands are being overrun or destroyed. Last year, a report by the National Trust for Historic Preservation painted a disappointing portrait of how cultural resources are being managed on BLM lands.

At Colorado's Canyons of the Ancients National Monument, home to the highest density of cultural sites in America, 47 ancestral Puebloan sites were looted in the first half of 2006. With only one law enforcement officer for the entire monument, it is almost impossible to prevent this type of vandalism.

At McInnis Canyon National Conservation Area, also in Colorado, the one law enforcement officer splits his time with other lands overseen by the BLM field office. How is one officer to be expected to protect 1.3 million acres of BLM land?

This same unit of the NLCS shares an archaeologist with the Grand Junction, CO, field office. There is no way that an individual can oversee the archaeological surveys under way in the area's booming oil and gas fields while still ensuring that the conservation area's petroglyphs, fossils, and archaeological treasures are documented and protected.

The Secretary of the Interior took a good step in 2000 when he established the National Landscape Conservation System. The BLM should have additional resources and tools for the management of lands that the American people have determined to be of exceptional natural, cultural, recreational, scenic, or historic value. Unfortunately, this system has not come far in the last 7 years.

The administration provides no line item in the President's budget for the system, NLCS units have endured repeated funding cuts, and there are meager plans for where the system is going over the coming decades.

The bill that Senator BINGAMAN and I are introducing today takes the first step in improving the stewardship of these crown jewel BLM lands. It is a straightforward bill: it simply writes the National Landscape Conservation System into law, making it permanent for the enjoyment of future generations.

The bill does not change how any of the units in the system are managed. Grazing rights, water rights, and public access to the national monuments, the wilderness areas, and the conservation areas are unchanged.

The bill does, however, recognize that these landscapes are of great interest to the American people and should be managed to protect their values.

Over the coming decades, these lands will become more widely used and known. Americans are already coming to see these landscapes—places like canyons of the Ancients National Monument or Gunnison Gorge National Conservation Area—as treasures that match our great national parks and wildlife refuges.

This bill is a logical and needed step toward improving the management of the units that comprise the National Landscape Conservation. I thank Chairman BINGAMAN for his leadership on this issue, and I hope we will have an opportunity to move this bill through the Senate as quickly as possible.

By Mr. GREGG (for himself, Mr. LAUTENBERG, Mr. COCHRAN, Mr. WARNER, Mr. WYDEN, Mr. LIEBERMAN, Ms. SNOWE, Mrs. BOXER, Mr. KERRY, Mr. MENENDEZ, Ms. CANTWELL, Mrs. FEINSTEIN, Mr. REED, Mrs. MURRAY, Ms. COLLINS, and Mr. SUNUNU):

S. 1142. A bill to authorize the acquisition of interests in undeveloped coastal areas in order better to ensure their protection from development; to the Committee on Commerce, Science, and Transportation.

Mr. GREGG. Mr. President, I rise today along with Senator LAUTENBERG to introduce the Coastal and Estuarine Land Protection Act. We are introducing this much needed coastal protection act along with Senators COCHRAN, WARNER, WYDEN, KENNEDY, LIEBERMAN, SNOWE, BOXER, KERRY, MENENDEZ, CANTWELL, FEINSTEIN, REED, MURRAY, COLLINS, and SUNUNU. In addition, this legislation is supported by the Trust for Public Land, The Nature Conservancy, Association of Fish and Wildlife Agencies, the Land Trust Alliance, The Conservation Fund, Restore America's Estuaries, The Ocean Conservancy, American Fly Fishing Trade Association, Society for the Protection of New Hampshire Forests, National Estuarine Research Reserve Association, Association of National Estuary Programs, Coastal States Organization, New Jersey Audubon Society, and the NY/NJ Baykeeper.

The Coastal and Estuarine Land Protection Act promotes coordinated land acquisition and protection efforts in coastal and estuarine areas by fostering partnerships between non-governmental organizations and Federal, State, and local governments. As clearly outlined by the U.S. Commission of Ocean Policy, these efforts are urgently needed. With Americans rapidly moving to the coast, pressures to develop critical coastal ecosystems are increasing. There are fewer and fewer undeveloped and pristine areas left in the Nation's coastal and estuarine watersheds. These areas provide important nursery habitat for two-thirds of the Nation's commercial fish and shellfish, provide nesting and foraging habitat for coastal birds, harbor significant natural plant communities, and serve to facilitate coastal flood control and pollutant filtration.

The Coastal and Estuarine Land Protection Act pairs willing sellers through community-based initiatives with sources of federal funds to enhance environmental protection. Lands can be acquired in full or through easements, and none of the lands purchased through this program would be held by the Federal Government. This bill puts land conservation initiatives in the hands of State and local communities. This new program, administered by the National Oceanic and Atmospheric Administration, would provide Federal matching funds to states with approved coastal management programs or to National Estuarine Research Reserves through a competitive grant process. Federal matching funds may not exceed 75 percent of the cost of a project under this program, and non-Federal sources may count in-kind support toward their portion of the cost share.

This coastal land protection program provides much needed support for local coastal conservation initiatives throughout the country. In New Hampshire, we have worked collaboratively with local communities, environmental groups, willing sellers, and the State to conserve lands around Great Bay, Sagamore Creek, Massacre Marsh, Hurd Farm, Moose Mountain, Winnicut Headwaters, Marden Woods, Sleeper Wetlands, and the Piscassic River Greenway. These lands are home to a wide variety of plants and animal species that are particularly threatened by encroaching development and environmental pollutants. By working with local communities to purchase lands or easements on these valuable parcels of land, New Hampshire has been able to successfully conserve the natural and scenic heritage of this vital estuary.

Programs like the Coastal and Estuarine Land Protection program will further enable other states to participate in these community-based conservation efforts in coastal areas. This program was modeled after the U.S. Department of Agriculture's successful Forest Legacy Program, which has conserved millions of acres of productive and ecologically significant forest land around the country.

I welcome the opportunity to offer this important legislation, with my good friend from New Jersey, Senator LAUTENBERG. I am thankful for his leadership on this issue, and look forward to working with him to make the vision for this legislation a reality, and to successfully conserve our coastal lands for their ecological, historical, recreational, and aesthetic values.

Mr. LAUTENBERG. Mr. President, I rise today to join Senator GREGG in our introduction of legislation that would help protect and preserve the valuable coastal and estuarine lands of our Nation.

Development of the Nation's coastal and estuarine areas poses an increasing threat to water quality, wildlife habitat, flood protection, and recreational opportunities. The U.S. Commission on Ocean Policy emphasized that intact coastal lands are vital to ensuring the ecological and economic health of coastal communities. However, as these areas are fragmented and disappear, so do the benefits they provide. The Coastal and Estuarine Land Protection Act (CELP) would authorize the National Oceanic and Atmospheric Administration (NOAA) as the lead Federal agency supporting State, local or private acquisition of land or conservation easements in undeveloped coastal areas in order to ensure their protection from development. The Joint Ocean Commission Initiative has identified enactment of the Coastal and Estuarine Land Protection Act as a high priority for improving our coastal resource management. This legislation builds upon the existing Coastal and Estuarine Land Conservation Program (CELCP) within NOAA. The Program allows States to compete for matching funds to acquire land or easements for the protection of sensitive coastal ecosystems. The Federal funds provided through this program help leverage additional State, local and private funding.

The CELCP complements private, Federal and State conservation programs. This program is based on the highly successful Forest Legacy program which is a Federal-State partnership program that supports efforts to protect environmentally sensitive forest lands. Permanent protection of lands in the coastal zone is also necessary to maintain and enhance coastal and estuarine areas for the benefit of the Nation, including protecting water quality, keeping public beachfront accessible, conserving wildlife habitat, and sustaining sport and commercial fisheries.

Coastal and estuarine areas are some of the most productive ecosystems on earth. They are home to countless plants, animals, birds, and fish. These are complex ecosystems that provide a foundation for marine life as well as protection of inland areas from storm damage. Over the last 150 years the national system of estuaries has decreased in size because of our growing coastal populations and short-sighted land-use planning. Today our coastal areas are home to over 150 million Americans, about 53 percent of the U.S. population, and over 180 million people visit the coasts each year. Due to the increasing pressures from development in low-lying areas, NOAA has estimated 80 percent of our Nations' coastal waters are impaired for human use and marine life.

The National Estuarine Research Reserve System (NERRS) established under the Coastal Zone Management Act is a network of 27 protected estuaries throughout the United States, including the Jacques Cousteau NERRS site in New Jersey. These are pristine areas that provide public education and conservation awareness, and serve as living laboratories for scientific research. The funds provided through the CELP program established by our legislation would promote the expansion of these estuarine areas and assist in keeping coastal ecosystems healthy and productive.

Federal funds help make New Jersey conservation possible. New Jersey's treasured natural resources—from the Meadowlands to the marshlands of Barnegat Bay—have substantially benefited from Federal support. The existing CELCP has aided in securing protection for over a thousand acres in New Jersey including lands for Gunning Island, Tuckerton Creek, and the Harbor Herons project. This week there will be a formal dedication of a 115-acre property, acquired with the aid of CELCP, on Potter Creek in Berkeley Township for public use and recreation. Lands have been protected in the Manahawkin Marsh, for wildlife habitat, including migratory birds along the Atlantic Flyway. In Ocean County, the CELCP helped secure the acquisition of 800 acres on Tuckerton Creek in Little Egg Harbor which is vital to protecting Atlantic white cedar stands and improving the water quality of the Barnegat Bay. These projects have successfully protected our coasts while sustaining human activity.

The coastal zone is essential to our country's prosperity and well-being. The coastal and estuarine lands are areas of national importance and they are vulnerable to human activities. From 2002 through 2006 twenty-five States have benefited from the CELCP. Now is the time for Congress to authorize this program to conserve lands that are vital to our Nation.

The bill Senator GREGG and I are introducing today, the Coastal and Estuarine Land Protection Act, will ensure an ongoing partnership between Federal, State, and local governments to support the economic and natural resource base of communities through the acquisition of coastal and estuarine lands. This legislation offers the opportunity for States to protect coastal and estuarine areas that have significant conservation, recreation, ecological, historical, or aesthetic values and are threatened by conversion to other uses.

The organizations supporting this legislation include The Trust for Public Land, The American Littoral Society, NY/NJ Baykeeper, Association of Fish and Wildlife Agencies, Land Trust Alliance, Restore America's Estuaries, American Fly Fishing Trade Association, Society for the Protection of New Hampshire's Forests, National Estuarine Research Reserve Association, Association of National Estuary Programs, The Ocean Conservancy, Coastal States Organization, The Conservation Fund, The Nature Conservancy, and the New Jersey Audubon Society. I ask unanimous consent that a letter of support from these groups be printed in the RECORD.

I would like to thank Senator GREGG for his long-time leadership on this issue. I would also like to thank Senator MIKULSKI for her many years of support for this legislation. I look forward to continuing to work with Senator GREGG and my colleagues in the Senate to ensure its passage so that we can fill this vital need for coastal and estuarine protection.

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

APRIL 16, 2007.

Hon. JUDD GREGG,
Russell Senate Office Building,
Washington, DC.
Hon. FRANK LAUTENBERG,
Hart Senate Office Building,
Washington, DC.

DEAR SENATORS GREGG AND LAUTENBERG: On behalf of the organizations listed below, we would like to thank you for your long-standing support of coastal zone management and coastal land conservation. We are writing today in support of the Coastal and Estuarine Land Protection Act (CELP), which would formally codify the Coastal and Estuarine Land Conservation Program. This program was created by Congress in FY 2002 in order to ''protect those coastal and estuarine areas with significant conservation, recreation, ecological, historical or aesthetic values, or that are threatened by conversion from their natural or recreational states to other uses.'' Thus far, this program has invested over $177 million towards 119 conservation projects in 25 of the nation's 35 coastal states. This federal investment has leveraged more than an equal amount of state, local and private funding, demonstrating the importance of coastal protection throughout the nation and the critical role of federal funding to its success.

Our nation's coastal zone is under significant pressures from unplanned development. In fact, it is estimated that by 2025, nearly 75 percent of the nation's population will live within 50 miles of the coast, in addition to millions more who enjoy America's storied coastlines. Across the nation, beaches and waterfronts have always been the destination of choice for Americans. Fully one-half of the nation's gross domestic product, $4.5

trillion annually, is generated in coastal watershed counties, inexorably linking our coastal zone with the economic health of the nation.

As a result of this economic boom, rapid, unplanned development has marred the once-pristine viewshed and substantially reduced public access to the coast. The resulting increase in impervious surfaces has correspondingly increased non-point source pollution and seriously degraded coastal and estuarine waters. The loss of coastal wetlands has drastically impaired estuaries, some of the most productive habitat on earth, and has exacerbated damage from coastal storms. The U.S. Commission on Ocean Policy has also stressed the importance of land conservation as part of its broader recommendations to Congress and the nation.

From our first-hand experience at the local level, we know that CELP will significantly leverage ongoing community-based conservation, and will provide a much needed boost to local efforts. Given the importance of healthy, productive and accessible coastal areas, a federal commitment to state and local coastal protection is a sound investment. The new legislation codifies the existing investment that Congress has already made to coastal protection and authorizes the program formally. We believe this is an important and necessary step to enhance efforts to ensure safe and accessible coastal waters.

We thank you for introducing this legislation, and look forward to working with you towards its enactment.

Sincerely,

Gary J. Taylor, Legislative Director, Association of Fish and Wildlife Agencies; Russell Shay, Director of Public Policy, Land Trust Alliance; Alan Front, Senior Vice President, The Trust for Public Land; Steven Bosak, Vice President for External Affairs, Restore America's Estuaries; Robert Ramsay, President, American Fly Fishing Trade Association; Jane A. Difley, President-Forester, Society for the Protection of New Hampshire's Forests; Angela Corridore, Executive Director, National Estuarine Research Reserve Association; Rich Innes, Executive Director, Association of National Estuary Programs; David Hoskins, Vice President for Government Affairs and General Counsel, The Ocean Conservancy; Kacky Andrews, Executive Director, Coastal States Organization; Lawrence A. Selzer, President, The Conservation Fund; Jimmie Powell, Director of Government Relations, The Nature Conservancy; Eric Stiles, Vice President for Conservation and Stewardship, New Jersey Audubon Society; Tim Dillingham, Executive Director, American Littoral Society (NJ).

By Mr. NELSON of Florida:

S. 1143. A bill to designate the Jupiter Inlet Lighthouse and the surrounding Federal land in the State of Florida as an Outstanding Natural Area and as a unit of the National Landscape System, and for other purposes; to the Committee on Energy and Natural Resources.

Mr. NELSON of Florida. Mr. President, today I am introducing a bill designating the Jupiter Inlet Lighthouse and the 126 surrounding acres in Jupiter, Florida, as an ''Outstanding Natural Area.'' The Jupiter Lighthouse is a local and regional icon, full of rich history and home to many endangered plant and animal species. Designating the lighthouse as an ''Outstanding Natural Area'' will preserve the rich cultural heritage and important ecological value of the site. This designation would give the Jupiter Inlet the distinction of being the sole East Coast representative of the National Landscape Conservation System—the eastern counterpart to the Yaquina Head Lighthouse in Oregon.

This bill is the product of the hard work and cooperation of many people in Florida, including the Town of Jupiter Island, the Town of Jupiter, the Board of County Commissioners of Palm Beach County, the Loxahatchee River Historical Society, and numerous others. I am also pleased that Representative TIM MAHONEY is introducing similar legislation in the House of Representatives.

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. 1143

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 ''Jupiter Inlet Lighthouse Outstanding Natural Area Act of 2007''.

SEC. 2. FINDINGS.

Congress finds that—

(1) the area surrounding the Jupiter Inlet Lighthouse in the State of Florida—

(A) is at the confluence of the Loxahatchee River and the Indian River Lagoon; and

(B) supports significant ecological values, including—

(i) endangered species of flora and fauna; and

(ii) imperiled natural communities rapidly vanishing in south Florida;

(2) the area surrounding the Lighthouse was first used by Native Americans over 4,000 years ago;

(3) Europeans made contact with the area surrounding the Lighthouse in the 17th century;

(4) the Lighthouse and the associated Oil House, which was constructed in 1860, are nationally recognized historical structures that should be preserved for present and future generations of people in the United States;

(5) the Lighthouse tells an important story about—

(A) the maritime history of southeast Florida;

(B) the prehistory and history of southeast Florida; and

(C) the role of southeast Florida in the Civil War, World War II, and the creation of the National Weather Service;

(6) the Lighthouse is listed on the National Register of Historic Places;

(7) the Lighthouse has been, and continues to be, a physical manifestation of the commitment of the Federal Government to maritime safety and security;

(8) the current operations and activities of the Coast Guard at Jupiter Inlet perpetuate the commitment described in paragraph (7);

(9) the Jupiter Inlet Lighthouse Outstanding Natural Area—

(A) would make a significant addition to the National Landscape Conservation System administered by the Bureau of Land Management; and

(B) would be the only unit of the National Landscape Conservation System located east of the Mississippi River;

(10) statutory protection is needed for the Lighthouse and the Federal land surrounding the Lighthouse to ensure that the natural and cultural resources continue to be—

(A) a part of the historic, cultural, and natural heritage of the United States; and

(B) a source of inspiration for the people of the United States;

(11) the actions of the Federal Government to protect and conserve the land and historic structures associated with the Outstanding Natural Area should not be construed, interpreted, or allowed to diminish or control ongoing or future Coast Guard operations or activities; and

(12) the Lighthouse and the Federal land surrounding the Lighthouse represent a true partnership of the highest order in which collaboration is, and would continue to be, an everyday reality leading to successful management and land stewardship by the Bureau of Land Management, Palm Beach County, Florida, the Town of Jupiter, Florida, the Village of Tequesta, Florida, the Loxahatchee River Historical Society, and the Coast Guard (collectively known as the ''Jupiter Working Group'') and other partners.

SEC. 3. DEFINITIONS.

In this Act:

(1) COMMANDANT.—The term ''Commandant'' means the Commandant of the Coast Guard.

(2) LIGHTHOUSE.—The term ''Lighthouse'' means the Jupiter Inlet Lighthouse located in Palm Beach County, Florida.

(3) LOCAL PARTNERS.—The term ''Local Partners'' includes—

(A) Palm Beach County, Florida;

(B) the Town of Jupiter, Florida;

(C) the Village of Tequesta, Florida; and

(D) the Loxahatchee River Historical Society.

(4) MANAGEMENT PLAN.—The term ''management plan'' means the management plan developed under section 5(a).

(5) MAP.—The term ''map'' means the map entitled ''Jupiter Inlet Lighthouse: Outstanding Natural Area'' and dated February 2007.

(6) OUTSTANDING NATURAL AREA.—The term ''Outstanding Natural Area'' means the Jupiter Inlet Lighthouse Outstanding Natural Area established by section 4(a).

(7) PUBLIC LAND.—The term ''public land'' has the meaning given the term ''public lands'' in section 103(e) of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1702(e)).

(8) SECRETARY.—The term ''Secretary'' means the Secretary of the Interior.

(9) STATE.—The term ''State'' means the State of Florida.

SEC. 4. ESTABLISHMENT OF THE JUPITER INLET LIGHT HOUSE OUTSTANDING NATURAL AREA.

(a) ESTABLISHMENT.—Subject to valid existing rights, there is established for the purposes described in subsection (b) the Jupiter Inlet Lighthouse Outstanding Natural Area, the boundaries of which are depicted on the map.

(b) PURPOSES.—The purposes of the Outstanding Natural Area are to protect, conserve, and enhance the unique and nationally important historic, natural, cultural, scientific, educational, scenic, and recreational values of the Federal land surrounding the Lighthouse for the benefit of present generations and future generations of people in the United States, while—

(1) allowing certain recreational and research activities to continue in the Outstanding Natural Area; and

(2) ensuring that Coast Guard operations and activities are unimpeded within the boundaries of the Outstanding Natural Area.

(c) AVAILABILITY OF MAP.—The map shall be on file and available for public inspection in—

(1) the Office of the Director of the Bureau of Land Management; and

(2) the Eastern States Office of the Bureau of Land Management in the State of Virginia.

(d) WITHDRAWAL.—

(1) IN GENERAL.—Subject to valid existing rights, section 7, and any existing withdrawals under the Executive orders and public land order described in paragraph (2), the Federal land and any interests in the Federal land included in the Outstanding Natural Area are withdrawn from—

(A) all forms of entry, appropriation, or disposal under the public land laws;

(B) location, entry, and patent under the public land mining laws; and

(C) operation of the mineral leasing and geothermal leasing laws and the mineral materials laws.

(2) DESCRIPTION OF EXECUTIVE ORDERS.—The Executive orders and public land order described in paragraph (1) are—

(A) the Executive Order dated October 22, 1854;

(B) Executive Order No. 4254 (June 12, 1925); and

(C) Public Land Order No. 7202 (61 Fed. Reg. 29758).

SEC. 5. MANAGEMENT PLAN.

(a) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Secretary, in consultation with the Commandant, shall develop a comprehensive management plan in accordance with section 202 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1712) to—

(1) provide long-term management guidance for the public land in the Outstanding Natural Area; and

(2) ensure that the Outstanding Natural Area fulfills the purposes for which the Outstanding Natural Area is established.

(b) CONSULTATION; PUBLIC PARTICIPATION.—The management plan shall be developed—

(1) in consultation with appropriate Federal, State, county, and local government agencies, the Commandant, the Local Partners, the Loxahatchee River Historical Society, and other partners; and

(2) in a manner that ensures full public participation.

(c) EXISTING PLANS.—The management plan shall, to the maximum extent practicable, be consistent with existing resource plans, policies, and programs.

(d) INCLUSIONS.—The management plan shall include—

(1) objectives and provisions to ensure—

(A) the protection and conservation of the resource values of the Outstanding Natural Area; and

(B) the restoration of native plant communities and estuaries in the Outstanding Natural Area, with an emphasis on the conservation and enhancement of healthy, functioning ecological systems in perpetuity;

(2) objectives and provisions to maintain or recreate historic structures;

(3) an implementation plan for a program of interpretation and public education about the natural and cultural resources of the Lighthouse, the public land surrounding the Lighthouse, and associated structures;

(4) a proposal for administrative and public facilities to be developed or improved that—

(A) are compatible with achieving the resource objectives for the Outstanding Natural Area described in section 6(a)(1)(B); and

(B) would accommodate visitors to the Outstanding Natural Area;

(5) natural and cultural resource management strategies for the Outstanding Natural Area, to be developed in consultation with appropriate departments of the State, the Local Partners, and the Commandant, with an emphasis on resource conservation in the Outstanding Natural Area and the interpretive, educational, and long-term scientific uses of the resources; and

(6) recreational use strategies for the Outstanding Natural Area, to be prepared in consultation with the Local Partners, appropriate departments of the State, and the Coast Guard, with an emphasis on passive recreation.

(e) INTERIM PLAN.—Until a management plan is adopted for the Outstanding Natural Area, the Jupiter Inlet Coordinated Resource Management Plan (including any updates or amendments to the Jupiter Inlet Coordinated Resource Management Plan) shall be in effect.

SEC. 6. MANAGEMENT OF THE JUPITER INLET LIGHTHOUSE OUTSTANDING NATURAL AREA.

(a) MANAGEMENT.—

(1) IN GENERAL.—The Secretary, in consultation with the Local Partners and the Commandant, shall manage the Outstanding Natural Area—

(A) as part of the National Landscape Conservation System; and

(B) in a manner that conserves, protects, and enhances the unique and nationally important historical, natural, cultural, scientific, educational, scenic, and recreational values of the Outstanding Natural Area, including an emphasis on the restoration of native ecological systems.

(2) LIMITATION.—In managing the Outstanding Natural Area, the Secretary shall not take any action that precludes, prohibits, or otherwise affects the conduct of ongoing or future Coast Guard operations or activities on lots 16 and 18, as depicted on the map.

(b) USES.—Subject to valid existing rights and section 7, the Secretary shall only allow uses of the Outstanding Natural Area that the Secretary, in consultation with the Commandant and Local Partners, determines would likely further—

(1) the purposes for which the Outstanding Natural Area is established;

(2) the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 et seq.); and

(3) other applicable laws.

(c) COOPERATIVE AGREEMENTS.—To facilitate implementation of the management plan and to continue the successful partnerships with local communities and other partners, the Secretary shall, in accordance with section 307(b) of the Federal Land Management Policy and Management Act of 1976 (43 U.S.C. 1737(b)), enter into cooperative agreements with the appropriate Federal, State, county, other local government agencies, and other partners (including the Loxahatchee River Historical Society) for the long-term management of the Outstanding Natural Area

(d) RESEARCH ACTIVITIES.—To continue successful research partnerships, pursue future research partnerships, and assist in the development and implementation of the management plan, the Secretary may, in accordance with section 307(a) of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1737(a)), authorize the conduct of appropriate research activities in the Outstanding Natural Area for the purposes described in section 4(b).

(e) ACQUISITION OF LAND.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary may acquire for inclusion in the Outstanding Natural Area any State or private land or any interest in State or private land that is—

(A) adjacent to the Outstanding Natural Area; and

(B) identified in the management plan as appropriate for acquisition.

(2) MEANS OF ACQUISITION.—Land or an interest in land may be acquired under paragraph (1) only by—

(A) donation;

(B) exchange with a willing party; or

(C) purchase from a willing seller.

(3) ADDITIONS TO THE OUTSTANDING NATURAL AREA.—Any land or interest in land adjacent to the Outstanding Natural Area acquired by the United States after the date of enactment of this Act under paragraph (1) shall be added to, and administered as part of, the Outstanding Natural Area.

(f) LAW ENFORCEMENT ACTIVITIES.—Nothing in this Act, the management plan, or the Jupiter Inlet Coordinated Resource Management Plan (including any updates or amendments to the Jupiter Inlet Coordinated Resource Management Plan) precludes, prohibits, or otherwise affects—

(1) any maritime security, maritime safety, or environmental protection mission or activity of the Coast Guard;

(2) any border security operation or law enforcement activity by the Department of Homeland Security or the Department of Justice; or

(3) any law enforcement activity of any Federal, State, or local law enforcement agency in the Outstanding Natural Area.

(g) FUTURE DISPOSITION OF COAST GUARD FACILITIES.—If the Commandant determines, after the date of enactment of this Act, that Coast Guard facilities within the Outstanding Natural Area exceed the needs of the Coast Guard, the Commandant may relinquish the facilities to the Secretary without removal, subject only to any environmental remediation that may be required by law.

SEC. 7. EFFECT ON ONGOING AND FUTURE COAST GUARD OPERATIONS.

Nothing in this Act, the management plan, or the Jupiter Inlet Coordinated Resource Management Plan (including updates or amendments to the Jupiter Inlet Coordinated Resource Management Plan) precludes, prohibits, or otherwise affects ongoing or future Coast Guard operations or activities in the Outstanding Natural Area, including—

(1) the continued and future operation of, access to, maintenance of, and, as may be necessitated for Coast Guard missions, the expansion, enhancement, or replacement of, the Coast Guard High Frequency antenna site on lot 16;

(2) the continued and future operation of, access to, maintenance of, and, as may be necessitated for Coast Guard missions, the expansion, enhancement, or replacement of, the military family housing area on lot 18;

(3) the continued and future use of, access to, maintenance of, and, as may be necessitated for Coast Guad missions, the expansion, enhancement, or replacement of, the pier on lot 18;

(4) the existing lease of the Jupiter Inlet Lighthouse on lot 18 from the Coast Guard to the Loxahatchee River Historical Society; or

(5) any easements or other less-than-fee interests in property appurtenant to existing Coast Guard facilities on lots 16 and 18.

SEC. 8. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated such sums as are necessary to carry out this Act.

By Ms. SNOWE:

S. 1144. A bill to provide for an assessment of the achievements by the Government of Iraq of benchmarks for

political settlement and national reconciliation in Iraq; to the Committee on Foreign Relations.

Ms. SNOWE. Mr. President, I rise to speak to the monumental and consequential matter regarding the future course of the United States and our courageous men and women in uniform in Iraq.

Today, we are at a profoundly challenging moment in time, and at a critical crossroads with respect to our direction in this war. I know that none of us arrive at this question lightly. In my 28-year tenure in Congress, I have witnessed and participated in debates on such vital matters as Lebanon, Panama, the Persian Gulf, Somalia, Bosnia, and Kosovo. And indisputably, myriad, deeply-held beliefs and arguments were expressed on those pivotal matters—some in concert, some complementary, some in conflict. Yet, without question, all were rooted in mutual concern for—and love of—our great Nation. And there was—and should not be today—no question about our support for our brave and extraordinary troops.

It is therefore with the utmost respect for our troops that I today introduce a bill which allows them the ability to complete the mission they have selflessly undertaken, while assuring them that their valor shall not be unconditionally expended upon an Iraqi government which fails to respond in kind. This amendment requires that government to actually achieve previously agreed political and security benchmarks while the Baghdad Security Plan—commonly referred to as the ''surge''—is in effect, or face the redeployment of those U.S. troops dedicated to that plan.

Specifically, this legislation would require that, 120 days after enactment—a point in time at which our military commanders have stated that they should know whether the surge will succeed—the Commander of Multi-National Forces, Iraq would report to Congress as to whether the Iraqi government has met each of six political and security-related benchmarks which it has already agreed to meet by that time. These six benchmarks are:

Iraqi assumption of control of its military . . .

Enactment of a Militia Law to disarm and demobilize militias and to ensure that such security forces are accountable only to the central government and loyal to the constitution of Iraq . . .

Completion of the constitutional review and a referendum held on special amendments to the Iraqi Constitution that ensure equitable participation in the government of Iraq without regard to religious sect or ethnicity . . .

Completion of provincial election law and preparation for the conduct of provincial elections that ensures equitable constitution of provincial representative bodies without regard to religious sect or ethnicity . . .

Enactment and implementation of legislation to ensure that the energy resources of Iraq benefit Sunni Arabs, Shia Arabs, Kurds, and other Iraqi citizens in an equitable manner; and

Enactment and implementation of legislation that equitably reforms the de-Ba'athification process in Iraq.

The Iraqi Government must know that any opportunity gained from our increased troop levels in Baghdad is a window that we will soon close if it fails to take urgent action and show tangible results in tandem. If, at the end of 120 days, the Commander of Multi-National Forces, Iraq reports the Iraqi Government has not met the benchmarks, then the Commander should plan for the phased redeployment of the troops we provided for the Baghdad Security Plan, period.

That is why, under this amendment, after 120 days, should the Commander report that the Iraqi Government has failed to meet the benchmarks listed, he will then be required to present a plan for the phased redeployment of those combat troops sent to Iraq in support of the Baghdad Security Plan and to provide plans detailing the transition of the mission of the U.S. forces remaining in Iraq to one of logistical support, training, force protection, and targeted counter-terrorism operations—i.e., those functions set forth in the Iraq Study Group Report. As General Petraeus stated in March, ''I have an obligation to the young men and women in uniform out here, that if I think it's not going to happen, to tell them that it's not going to happen, and there needs to be a change.''

The message must be loud and clear—the Iraqi government must understand in no uncertain terms that our presence is neither open-ended nor unconditional, and I support setting conditions for a phased withdrawal. My concern with the supplemental appropriations bill stems from the fact that it mandates a specific date for troop withdrawal by requiring it to occur within 120 days of passage. This arbitrary timeline would telegraph a precise and immediate departure date to our enemies that I believe would jeopardize the security of our men and women remaining on the ground.

Moreover, this mandated, 120-day timetable does not place the necessary pressure and conditions on the Iraqi government to implement national reconciliation and solidify their own security. Rather, we should require that the Iraqi government complete work within 120 days on the specific, concrete benchmarks they have already agreed to that would lead to national reconciliation. If the Iraqis cannot meet these benchmarks within this 120-day period, our commanders should begin planning for the phased redeployment of the troops we deployed for the Baghdad Security Plan.

My colleagues may recall that I opposed the surge because I did not—and still do not—believe that additional troops are a substitute for political will and capacity. General Petraeus said last month that a political resolution is crucial because that is what will determine in the long run the success of this effort. I could not agree more. The fact is, America and the world require more than Iraq's commitment to accomplishing the benchmarks that will lead to a true national reconciliation—we must see actual results. The Iraqi Government must find the will to ensure that it represents and protects the rights of every Iraqi.

After our four-year commitment, Iraq's Government should not doubt that we must observe more than incremental steps toward political reconciliation we require demonstrable changes. While limited progress has been made on necessary legislative initiatives such as the Hydrocarbon Law, it is in fact a sheaf of laws and not just a single measure that must pass to ensure that all Iraqis have a share and stake in their government. Chief among these are constitutional amendments which will permit Iraqis of all ethnicities and confessions to be represented at the local level of government. Yet, so far, the review committee has yet to even finish drafts of these critical amendments.

I believe we were all encouraged by the recent Ambassadorial meetings in Baghdad and the follow-on ministerial conference called at the Iraqi government's request. These talks are vital to securing Iraq's border, reversing the flow of refugees, and stemming the foreign interference which exacerbates sectarian divisions. But we also look for the Iraqi government's leadership in dismantling the militias and strengthening the National Army so that it is truly a national institution that can provide the security so desperately desired by all Iraqis in every province.

We are now three months into the surge, and our troops have made gains in reducing the still horrific levels of violence on Baghdad through their heroic efforts. Yet it is deeply concerning to me that—mirroring the slowness with which the Iraqi government has moved on political reforms—their sacrifice remains by and largely unmatched by their Iraqi counterparts.

Two weeks ago, Leon Panetta, a member of the Iraq Study Group, wrote the following in a New York Times Op-Ed, ''. . . every military commander we talked to felt that the absence of national reconciliation was the fundamental cause of violence in Iraq. As one American general told us, 'if the Iraqi government does not make political progress on reforms, all the troops in the world will not provide security.' '' He went on to enumerate the progress or, more to the point, the lack of progress toward the agreed upon benchmarks and concluded that 'unless the United States finds new ways to bring strong pressure on the Iraqis, things are not likely to pick up any time soon.'''

In fact, over the past few months, many have come to the realization that political action by the Iraqi government is a paramount precursor to

national reconciliation and stability and, without it, the Baghdad Security Plan is only a temporary, tactical fix for one specific location. And while we are hearing about incremental successes, I agree with Thomas Friedman who said recently in an interview, ''there's only one metric for the surge working, and that is whether we're seeing a negotiation among Iraqis to share power, to stabilize the political situation in Iraq, which only they can do . . . telling me that the violence is down 10 percent or 8 percent here or 12 percent there, I don't really think that's the metric at all.''

To this day, the public looks to the United States Senate to temper the passions of politics and to bridge divides. And if ever there were a moment when Americans are imploring us to live up to the moniker of ''world's greatest deliberative body,'' that moment is upon us.

If I had a son or daughter or other family member serving in Iraq, I would want at least the assurance that someone was speaking up to tell the Iraqi government—and frankly our government as well—that my family's sacrifice must be matched by action and sacrifice on the part of the Iraqi government. I would want to know that the most profound of all issues was fully debated by those who are elected to provide leadership. For those of us who seek success in Iraq, and believe that a strategy predicated on political and diplomatic solutions—not merely increased troop levels—presents the strongest opportunity to reach that goal, let us coalesce around this bill, which will allow us to speak as one voice strong . . . together . . . and united in service to a purpose we believe to be right.

By Mr. LEAHY (for himself, Mr. HATCH, Mr. SCHUMER, Mr. CORNYN, and Mr. WHITEHOUSE):

S. 1145. A bill to amend title 35, United States Code, to provide for patent reform; to the Committee on the Judiciary.

Mr. LEAHY. Mr. President, our patent system is grounded in the Constitution. Among the specifically enumerated powers of Congress in Article I, Section 8, stands the command to ''promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective discoveries.'' Those discoveries have, since the founding of our Nation, made us the envy of the world. Our inventors, our research institutions, and the many companies that commercialize those discoveries have brought a wealth of new products and processes to our society; we have all been the beneficiaries of that creativity and hard work.

Vermont has long played an important role in bringing such inventions to the public, combining 'Yankee ingenuity' with lots of sweat equity. In fact, the very first U.S. patent was granted to Samuel Hopkins, a farmer in Pittsford, VT, who discovered a process for making potash. That ethic continues to the present day; just last year, inventors in IBM's Essex Junction plant received 360 patents 10 percent of IBM's total U.S. patents.

Vermont is special, of course, but not unique in this regard. American inventors are in every community, every company and school. They are individuals tinkering on the weekends in their garages. They are teams of PhDs in our largest corporations. They are scientists training students in laboratories at our colleges and universities. Our patent laws should support and reward all American innovators—independent inventors, small businesses, venture capitalists, academic researchers, and large corporations. To do so, we must update our patent laws. Crafted for an earlier time, when smokestacks rather than microchips were the emblems of industry, those laws have served well but need some refinements.

Senator HATCH and I introduced an earlier version of this bill, S. 3818, last August. At that time, I said we had taken the first step down a road to real, constructive patent reform, which could reduce the unnecessary burdens of litigation in the patent system and enhance the quality of patents granted by the Patent and Trademark Office. Senator HATCH wisely noted that we would have to have continuing conversations about issues that remained unresolved. We have spent the time since then hearing from all manner of interested parties, and indeed we have learned as much since we introduced S. 3818 as we had in the two years prior to its introduction.

In this Congress, the partnership is not only bipartisan but bicameral. We have reached not only across the aisle but across the Hill to work out a bill that joins the Senate and the House, Democrats and Republicans, so that today we are introducing a Leahy-Hatch bill in the Senate that mirrors a Berman-Smith bill in the House. The message is both strong and clear: We have a unified and resolute approach to improving the nation's patent system. We will all have time to focus on the bill's many provisions in the weeks to come, but I would highlight three significant changes we have made since last summer, aided by the many stakeholders in this process.

First, the Patent Reform Act of 2007 now includes a pure ''first-to-file'' system, which will inject needed clarity and certainty into the system. The United States stands alone among nations that grant patents in giving priority for a patent to the first inventor, as opposed to the first to file a patent application for a claimed invention. The result is a lack of international consistency, and a complex and costly system in the United States to determine inventors' rights. At the same time, our legislation provides important protections for inventors at universities, by permitting them to discuss publicly their work without losing priority for their inventions.

Second, poor patent quality has been identified as a key element of the law that needs attention. After a patent is issued, a party seeking to challenge the validity and enforceability of the patent has two avenues under current law: by reexamination proceeding at the USPTO or by litigation in federal district court. The former is used sparingly and some see it as ineffective; the latter, district court litigation, can be unwieldy and expensive. S. 3818 had created a new, post-grant review to provide an effective and efficient system for considering challenges to the validity of patents. The Patent Reform Act of 2007 has improved that system, and in particular, we have addressed concerns about misuse of the procedure. Post-grant review will include protections to avoid the possibility of misuse of the post-grant process. The Director is instructed to prescribe rules to prevent harassment or abuse, successive petitions are prohibited, and petitioners are barred from raising the same arguments in court.

Third, we are keenly aware that a sound patent system needs fair and equitable remedies. As products have become more complex, often involving hundreds or even thousands of patented aspects, litigation has not reliably produced damages awards in infringement cases that correspond to the value of the infringed patent. Our bill last summer was our first effort to ensure that damages awards accurately reflected the harm caused by infringement. Subsequent conversations with many affected parties have led us to language that, we believe, better serves that purpose and avoids potential pitfalls.

The Patent Reform Act of 2007 is also significant for what is not included. S. 3818 would have made three considerable changes to the patent laws that, upon further consideration and after listening to the affected parties, we have decided not to make in this year's legislation. First is the requirement that patent applicants not intentionally misrepresent a material fact or fail to disclose material information to the PTO. Candor and truthfulness are the backbone of the patent application system, and are protected by the inequitable conduct doctrine. S. 3818 would have weakened that doctrine, but it is preserved this year. Second, we maintain the traditional rule on attorneys' fees, instead of shifting fees and other expenses to the non-prevailing party as was proposed in S. 3818. Finally, we do not inject Congress into the ongoing litigation over the extra-territorial provision, section 271(f). S. 3818 would have repealed the provision in its entirety; the Patent Reform Act of 2007 does not, while the interpretation of the provision is currently pending before the Supreme Court. If the Court does not resolve that issue, we will revisit it in the legislative process.

If we are to maintain our position at the forefront of the world's economy, if

we are to continue to lead the globe in innovation and production, if we are to continue to enjoy the fruits of the most creative citizens, then we must have a patent system that produces high quality patents, that limits counterproductive litigation over those patents, and that makes the entire system more streamlined and efficient. This bill is an important step towards that goal. I look forward to immediate and intense debate that will inform both the Members of Congress and the public about these improvements, that will allow us to further refine our legislation, and that will lead us to consideration on the Senate floor.

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

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

S. 1145

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 ''Patent Reform Act of 2007''.

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

SEC. 2. REFERENCE TO TITLE 35, UNITED STATES CODE.

Whenever in this Act a section or other provision is amended or repealed, that amendment or repeal shall be considered to be made to that section or other provision of title 35, United States Code.

SEC. 3. RIGHT OF THE FIRST INVENTOR TO FILE.

(a) DEFINITIONS.—Section 100 is amended by adding at the end the following:

''(f) The term 'inventor' means the individual or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention.

''(g) The terms 'joint inventor' and 'coinventor' mean any 1 of the individuals who invented or discovered the subject matter of a joint invention.

''(h) The 'effective filing date of a claimed invention' is—

''(1) the filing date of the patent or the application for patent containing the claim to the invention; or

''(2) if the patent or application for patent is entitled to a right of priority of any other application under section 119, 365(a), or 365(b) or to the benefit of an earlier filing date in the United States under section 120, 121, or 365(c), the filing date of the earliest such application in which the claimed invention is disclosed in the manner provided by the first paragraph of section 112.

''(i) The term 'claimed invention' means the subject matter defined by a claim in a patent or an application for a patent.

''(j) The term 'joint invention' means an invention resulting from the collaboration of inventive endeavors of 2 or more persons working toward the same end and producing an invention by their collective efforts.''.

(b) CONDITIONS FOR PATENTABILITY.—

(1) IN GENERAL.—Section 102 is amended to read as follows:

''§ 102. Conditions for patentability; novelty

''(a) NOVELTY; PRIOR ART.—A patent for a claimed invention may not be obtained if—

''(1) the claimed invention was patented, described in a printed publication, or in public use or on sale—

''(A) more than one year before the effective filing date of the claimed invention; or

''(B) one year or less before the effective filing date of the claimed invention, other than through disclosures made by the inventor or a joint inventor or by others who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

''(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

''(b) EXCEPTIONS.—

''(1) PRIOR INVENTOR DISCLOSURE EXCEPTION.—Subject matter that would otherwise qualify as prior art under subparagraph (B) of subsection (a)(1) shall not be prior art to a claimed invention under that subparagraph if the subject matter had, before the applicable date under such subparagraph (B), been publicly disclosed by the inventor or a joint inventor or others who obtained the subject matter disclosed directly or indirectly from the inventor, joint inventor, or applicant.

''(2) DERIVATION AND COMMON ASSIGNMENT EXCEPTIONS.—Subject matter that would otherwise qualify as prior art only under subsection (a)(2), after taking into account the exception under paragraph (1), shall not be prior art to a claimed invention if—

''(A) the subject matter was obtained directly or indirectly from the inventor or a joint inventor; or

''(B) the subject matter and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.

''(3) JOINT RESEARCH AGREEMENT EXCEPTION.—

''(A) IN GENERAL.—Subject matter and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying the provisions of paragraph (2) if—

''(i) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention;

''(ii) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

''(iii) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

''(B) For purposes of subparagraph (A), the term 'joint research agreement' means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.

''(4) PATENTS AND PUBLISHED APPLICATIONS EFFECTIVELY FILED.—A patent or application for patent is effectively filed under subsection (a)(2) with respect to any subject matter described in the patent or application—

''(A) as of the filing date of the patent or the application for patent; or

''(B) if the patent or application for patent is entitled to claim a right of priority under section 119, 365(a), or 365(b) or to claim the benefit of an earlier filing date under section 120, 121, or 365(c), based upon one or more prior filed applications for patent, as of the filing date of the earliest such application that describes the subject matter.''.

(2) CONFORMING AMENDMENT.—The item relating to section 102 in the table of sections for chapter 10 is amended to read as follows:

''102. Conditions for patentability; novelty.''.

(c) CONDITIONS FOR PATENTABILITY; NON-OBVIOUS SUBJECT MATTER.—Section 103 is amended to read as follows:

''§ 103. Conditions for patentability; non-obvious subject matter

''A patent for a claimed invention may not be obtained though the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.''.

(d) REPEAL OF REQUIREMENTS FOR INVENTIONS MADE ABROAD.—Section 104, and the item relating to that section in the table of sections for chapter 10, are repealed.

(e) REPEAL OF STATUTORY INVENTION REGISTRATION.—

(1) IN GENERAL.—Section 157, and the item relating to that section in the table of sections for chapter 14, are repealed.

(2) REMOVAL OF CROSS REFERENCES.—Section 111(b)(8) is amended by striking ''sections 115, 131, 135, and 157'' and inserting ''sections 131 and 135''.

(f) EARLIER FILING DATE FOR INVENTOR AND JOINT INVENTOR.—Section 120 is amended by striking ''which is filed by an inventor or inventors named'' and inserting ''which names an inventor or joint inventor''.

(g) CONFORMING AMENDMENTS.—

(1) RIGHT OF PRIORITY.—Section 172 is amended by striking ''and the time specified in section 102(d)''.

(2) LIMITATION ON REMEDIES.—Section 287(c)(4) is amended by striking ''the earliest effective filing date of which is prior to'' and inserting ''which has an effective filing date before''.

(3) INTERNATIONAL APPLICATION DESIGNATING THE UNITED STATES: EFFECT.—Section 363 is amended by striking ''except as otherwise provided in section 102(e) of this title''.

(4) PUBLICATION OF INTERNATIONAL APPLICATION: EFFECT.—Section 374 is amended by striking ''sections 102(e) and 154(d)'' and inserting ''section 154(d)''.

(5) PATENT ISSUED ON INTERNATIONAL APPLICATION: EFFECT.—The second sentence of section 375(a) is amended by striking ''Subject to section 102(e) of this title, such'' and inserting ''Such''.

(6) LIMIT ON RIGHT OF PRIORITY.—Section 119(a) is amended by striking ''; but no patent shall be granted'' and all that follows through ''one year prior to such filing''.

(7) INVENTIONS MADE WITH FEDERAL ASSISTANCE.—Section 202(c) is amended—

(A) in paragraph (2)—

(i) by striking ''publication, on sale, or public use,'' and all that follows through ''obtained in the United States'' and inserting ''the 1-year period referred to in section 102(a) would end before the end of that 2-year period''; and

(ii) by striking ''the statutory'' and inserting ''that 1-year''; and

(B) in paragraph (3), by striking ''any statutory bar date that may occur under this title due to publication, on sale, or public use'' and inserting ''the expiration of the 1-year period referred to in section 102(a)''.

(h) REPEAL OF INTERFERING PATENT REMEDIES.—Section 291, and the item relating to that section in the table of sections for chapter 29, are repealed.

(i) ACTION FOR CLAIM TO PATENT ON DERIVED INVENTION.—Section 135(a) is amended to read as follows:

''(a) DISPUTE OVER RIGHT TO PATENT.—

''(1) INSTITUTION OF DERIVATION PROCEEDING.—An applicant may request initiation of a derivation proceeding to determine the right of the applicant to a patent by filing a request which sets forth with particularity the basis for finding that an earlier applicant derived the claimed invention from the applicant requesting the proceeding and, without authorization, filed an application claiming such invention. Any such request may only be made within 12 months after the date of first publication of an application containing a claim that is the same or is substantially the same as the claimed invention, must be made under oath, and must be supported by substantial evidence. Whenever the Director determines that patents or applications for patent naming different individuals as the inventor interfere with one another because of a dispute over the right to patent under section 101, the Director shall institute a derivation proceeding for the purpose of determining which applicant is entitled to a patent.

''(2) REQUIREMENTS.—A proceeding under this subsection may not be commenced unless the party requesting the proceeding has filed an application that was filed not later than 18 months after the effective filing date of the application or patent deemed to interfere with the subsequent application or patent.

''(3) DETERMINATION BY PATENT TRIAL AND APPEAL BOARD.—In any proceeding under this subsection, the Patent Trial and Appeal Board—

''(A) shall determine the question of the right to patent;

''(B) in appropriate circumstances, may correct the naming of the inventor in any application or patent at issue; and

''(C) shall issue a final decision on the right to patent.

''(4) DERIVATION PROCEEDING.—The Board may defer action on a request to initiate a derivation proceeding until 3 months after the date on which the Director issues a patent to the applicant that filed the earlier application.

''(5) EFFECT OF FINAL DECISION.—The final decision of the Patent Trial and Appeal Board, if adverse to the claim of an applicant, shall constitute the final refusal by the Patent and Trademark Office on the claims involved. The Director may issue a patent to an applicant who is determined by the Patent Trial and Appeal Board to have the right to patent. The final decision of the Board, if adverse to a patentee, shall, if no appeal or other review of the decision has been or can be taken or had, constitute cancellation of the claims involved in the patent, and notice of such cancellation shall be endorsed on copies of the patent distributed after such cancellation by the Patent and Trademark Office.''.

(j) ELIMINATION OF REFERENCES TO INTERFERENCES.—(1) Sections 6, 41, 134, 141, 145, 146, 154, 305, and 314 are each amended by striking ''Board of Patent Appeals and Interferences'' each place it appears and inserting ''Patent Trial and Appeal Board''.

(2) Sections 141, 146, and 154 are each amended—

(A) by striking ''an interference'' each place it appears and inserting ''a derivation proceeding''; and

(B) by striking ''interference'' each additional place it appears and inserting ''derivation proceeding''.

(3) The section heading for section 134 is amended to read as follows:

''§ 134. Appeal to the Patent Trial and Appeal Board''.

(4) The section heading for section 135 is amended to read as follows:

''§ 135. Derivation proceedings''.

(5) The section heading for section 146 is amended to read as follows:

''§ 146. Civil action in case of derivation proceeding''.

(6) Section 154(b)(1)(C) is amended by striking ''INTERFERENCES'' and inserting ''DERIVATION PROCEEDINGS''.

(7) The item relating to section 6 in the table of sections for chapter 1 is amended to read as follows:

''6. Patent Trial and Appeal Board.''.

(8) The items relating to sections 134 and 135 in the table of sections for chapter 12 are amended to read as follows:

''134. Appeal to the Patent Trial and Appeal Board.

''135. Derivation proceedings.''.

(9) The item relating to section 146 in the table of sections for chapter 13 is amended to read as follows:

''146. Civil action in case of derivation proceeding.''.

(10) CERTAIN APPEALS.—Subsection 1295(a)(4)(A) of title 28, United States Code, is amended to read as follows:

''(A) the Patent Trial and Appeal Board of the United States Patent and Trademark Office with respect to patent applications, derivation proceedings, and post-grant review proceedings, at the instance of an applicant for a patent or any party to a patent interference (commenced before the effective date of the Patent Reform Act of 2007), derivation proceeding, or post-grant review proceeding, and any such appeal shall waive any right of such applicant or party to proceed under section 145 or 146 of title 35;''.

SEC. 4. INVENTOR'S OATH OR DECLARATION.

(a) INVENTOR'S OATH OR DECLARATION.—

(1) IN GENERAL.—Section 115 is amended to read as follows:

''§ 115. Inventor's oath or declaration

''(a) NAMING THE INVENTOR; INVENTOR'S OATH OR DECLARATION.—An application for patent that is filed under section 111(a), that commences the national stage under section 363, or that is filed by an inventor for an invention for which an application has previously been filed under this title by that inventor shall include, or be amended to include, the name of the inventor of any claimed invention in the application. Except as otherwise provided in this section, an individual who is the inventor or a joint inventor of a claimed invention in an application for patent shall execute an oath or declaration in connection with the application.

''(b) REQUIRED STATEMENTS.—An oath or declaration under subsection (a) shall contain statements that—

''(1) the application was made or was authorized to be made by the affiant or declarant; and

''(2) such individual believes himself or herself to be the original inventor or an original joint inventor of a claimed invention in the application.

''(c) ADDITIONAL REQUIREMENTS.—The Director may specify additional information relating to the inventor and the invention that is required to be included in an oath or declaration under subsection (a).

''(d) SUBSTITUTE STATEMENT.—

''(1) IN GENERAL.—In lieu of executing an oath or declaration under subsection (a), the applicant for patent may provide a substitute statement under the circumstances described in paragraph (2) and such additional circumstances that the Director may specify by regulation.

''(2) PERMITTED CIRCUMSTANCES.—A substitute statement under paragraph (1) is permitted with respect to any individual who—

''(A) is unable to file the oath or declaration under subsection (a) because the individual—

''(i) is deceased;

''(ii) is under legal incapacity; or

''(iii) cannot be found or reached after diligent effort; or

''(B) is under an obligation to assign the invention but has refused to make the oath or declaration required under subsection (a).

''(3) CONTENTS.—A substitute statement under this subsection shall—

''(A) identify the individual with respect to whom the statement applies;

''(B) set forth the circumstances representing the permitted basis for the filing of the substitute statement in lieu of the oath or declaration under subsection (a); and

''(C) contain any additional information, including any showing, required by the Director.

''(e) MAKING REQUIRED STATEMENTS IN ASSIGNMENT OF RECORD.—An individual who is under an obligation of assignment of an application for patent may include the required statements under subsections (b) and (c) in the assignment executed by the individual, in lieu of filing such statements separately.

''(f) TIME FOR FILING.—A notice of allowance under section 151 may be provided to an applicant for patent only if the applicant for patent has filed each required oath or declaration under subsection (a) or has filed a substitute statement under subsection (d) or recorded an assignment meeting the requirements of subsection (e).

''(g) EARLIER-FILED APPLICATION CONTAINING REQUIRED STATEMENTS OR SUBSTITUTE STATEMENT.—The requirements under this section shall not apply to an individual with respect to an application for patent in which the individual is named as the inventor or a joint inventor and that claims the benefit under section 120 or 365(c) of the filing of an earlier-filed application, if—

''(1) an oath or declaration meeting the requirements of subsection (a) was executed by the individual and was filed in connection with the earlier-filed application;

''(2) a substitute statement meeting the requirements of subsection (d) was filed in the earlier filed application with respect to the individual; or

''(3) an assignment meeting the requirements of subsection (e) was executed with respect to the earlier-filed application by the individual and was recorded in connection with the earlier-filed application.

''(h) SUPPLEMENTAL AND CORRECTED STATEMENTS; FILING ADDITIONAL STATEMENTS.—

''(1) IN GENERAL.—Any person making a statement required under this section may withdraw, replace, or otherwise correct the statement at any time. If a change is made in the naming of the inventor requiring the filing of 1 or more additional statements under this section, the Director shall establish regulations under which such additional statements may be filed.

''(2) SUPPLEMENTAL STATEMENTS NOT REQUIRED.—If an individual has executed an oath or declaration under subsection (a) or an assignment meeting the requirements of subsection (e) with respect to an application

for patent, the Director may not thereafter require that individual to make any additional oath, declaration, or other statement equivalent to those required by this section in connection with the application for patent or any patent issuing thereon.

''(3) SAVINGS CLAUSE.—No patent shall be invalid or unenforceable based upon the failure to comply with a requirement under this section if the failure is remedied as provided under paragraph (1).''.

(2) RELATIONSHIP TO DIVISIONAL APPLICATIONS.—Section 121 is amended by striking ''If a divisional application'' and all that follows through ''inventor.''.

(3) REQUIREMENTS FOR NONPROVISIONAL APPLICATIONS.—Section 111(a) is amended—

(A) in paragraph (2)(C), by striking ''by the applicant'' and inserting ''or declaration'';

(B) in the heading for paragraph (3), by striking ''AND OATH''; and

(C) by striking ''and oath'' each place it appears.

(4) CONFORMING AMENDMENT.—The item relating to section 115 in the table of sections for chapter 10 is amended to read as follows:

''115. Inventor's oath or declaration.''.

(b) FILING BY OTHER THAN INVENTOR.—Section 118 is amended to read as follows:

''§ 118. Filing by other than inventor

''A person to whom the inventor has assigned or is under an obligation to assign the invention may make an application for patent. A person who otherwise shows sufficient proprietary interest in the matter may make an application for patent on behalf of and as agent for the inventor on proof of the pertinent facts and a showing that such action is appropriate to preserve the rights of the parties. If the Director grants a patent on an application filed under this section by a person other than the inventor, the patent shall be granted to the real party in interest and upon such notice to the inventor as the Director considers to be sufficient.''.

(c) SPECIFICATION.—Section 112 is amended—

(1) in the first paragraph——

(A) by striking ''The specification'' and inserting ''(a) IN GENERAL.—The specification'';

(B) by striking ''of carrying out his invention'' and inserting ''or joint inventor of carrying out the invention''; and

(2) in the second paragraph—

(A) by striking ''The specifications'' and inserting ''(b) CONCLUSION.—The specifications''; and

(B) by striking ''applicant regards as his invention'' and inserting ''inventor or a joint inventor regards as the invention'';

(3) in the third paragraph, by striking ''A claim'' and inserting ''(c) FORM.—A claim'';

(4) in the fourth paragraph, by striking ''Subject to the following paragraph,'' and inserting ''(d) REFERENCE IN DEPENDENT FORMS.—Subject to subsection (e),'';

(5) in the fifth paragraph, by striking ''A claim'' and inserting ''(e) REFERENCE IN MULTIPLE DEPENDENT FORM.—A claim''; and

(6) in the last paragraph, by striking ''An element'' and inserting ''(f) ELEMENT IN CLAIM FOR A COMBINATION.—An element''.

SEC. 5. RIGHT OF THE INVENTOR TO OBTAIN DAMAGES.

(a) DAMAGES.—Section 284 is amended—

(1) in the first paragraph—

(A) by striking ''Upon'' and inserting ''(a) AWARD OF DAMAGES.—

''(1) IN GENERAL.—Upon'';

(B) by aligning the remaining text accordingly; and

(C) by adding at the end the following:

''(2) RELATIONSHIP OF DAMAGES TO CONTRIBUTIONS OVER PRIOR ART.—The court shall conduct an analysis to ensure that a reasonable royalty under paragraph (1) is applied only to that economic value properly attributable to the patent's specific contribution over the prior art. In a reasonable royalty analysis, the court shall identify all factors relevant to the determination of a reasonable royalty under this subsection, and the court or the jury, as the case may be, shall consider only those factors in making the determination. The court shall exclude from the analysis the economic value properly attributable to the prior art, and other features or improvements, whether or not themselves patented, that contribute economic value to the infringing product or process.

''(3) ENTIRE MARKET VALUE.—Unless the claimant shows that the patent's specific contribution over the prior art is the predominant basis for market demand for an infringing product or process, damages may not be based upon the entire market value of that infringing product or process.

''(4) OTHER FACTORS.—In determining damages, the court may also consider, or direct the jury to consider, the terms of any nonexclusive marketplace licensing of the invention, where appropriate, as well as any other relevant factors under applicable law.'';

(2) by amending the second undesignated paragraph to read as follows:

''(b) WILLFUL INFRINGEMENT .—

''(1) INCREASED DAMAGES.—A court that has determined that the infringer has willfully infringed a patent or patents may increase the damages up to three times the amount of damages found or assessed under subsection (a), except that increased damages under this paragraph shall not apply to provisional rights under section 154(d).

''(2) PERMITTED GROUNDS FOR WILLFULNESS.—A court may find that an infringer has willfully infringed a patent only if the patent owner presents clear and convincing evidence that—

''(A) after receiving written notice from the patentee—

''(i) alleging acts of infringement in a manner sufficient to give the infringer an objectively reasonable apprehension of suit on such patent, and

''(ii) identifying with particularity each claim of the patent, each product or process that the patent owner alleges infringes the patent, and the relationship of such product or process to such claim,

the infringer, after a reasonable opportunity to investigate, thereafter performed one or more of the alleged acts of infringement;

''(B) the infringer intentionally copied the patented invention with knowledge that it was patented; or

''(C) after having been found by a court to have infringed that patent, the infringer engaged in conduct that was not colorably different from the conduct previously found to have infringed the patent, and which resulted in a separate finding of infringement of the same patent.

''(3) LIMITATIONS ON WILLFULNESS.—(A) A court may not find that an infringer has willfully infringed a patent under paragraph (2) for any period of time during which the infringer had an informed good faith belief that the patent was invalid or unenforceable, or would not be infringed by the conduct later shown to constitute infringement of the patent.

''(B) An informed good faith belief within the meaning of subparagraph (A) may be established by—

''(i) reasonable reliance on advice of counsel;

''(ii) evidence that the infringer sought to modify its conduct to avoid infringement once it had discovered the patent; or

''(iii) other evidence a court may find sufficient to establish such good faith belief.

''(C) The decision of the infringer not to present evidence of advice of counsel is not relevant to a determination of willful infringement under paragraph (2).

''(4) LIMITATION ON PLEADING.—Before the date on which a court determines that the patent in suit is not invalid, is enforceable, and has been infringed by the infringer, a patentee may not plead and a court may not determine that an infringer has willfully infringed a patent. The court's determination of an infringer's willfulness shall be made without a jury.''; and

(3) in the third undesignated paragraph, by striking ''The court'' and inserting ''(c) EXPERT TESTIMONY.—The court''.

(b) DEFENSE TO INFRINGEMENT BASED ON EARLIER INVENTOR.—Section 273 of title 35, United States Code, is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by striking ''of a method''; and

(ii) by striking ''review period;'' and inserting ''review period; and'';

(B) in paragraph (2)(B), by striking the semicolon at the end and inserting a period; and

(C) by striking paragraphs (3) and (4);

(2) in subsection (b)—

(A) in paragraph (1)—

(i) by striking ''for a method''; and

(ii) by striking ''at least 1 year before the effective filing date of such patent, and'' and all that follows through the period and inserting ''and commercially used, or made substantial preparations for commercial use of, the subject matter before the effective filing date of the claimed invention.'';

(B) in paragraph (2)—

(i) by striking ''The sale or other disposition of a useful end result produced by a patented method'' and inserting ''The sale or other disposition of subject matter that qualifies for the defense set forth in this section''; and

(ii) by striking ''a defense under this section with respect to that useful end result'' and inserting ''such defense''; and

(C) in paragraph (3)—

(i) by striking subparagraph (A); and

(ii) by redesignating subparagraphs (B) and (C) as subparagraphs (A) and (B), respectively;

(3) in paragraph (7), by striking ''of the patent'' and inserting ''of the claimed invention''; and

(4) by amending the heading to read as follows:

''§ 273. Special defenses to and exemptions from infringement''.

(c) TABLE OF SECTIONS.—The item relating to section 273 in the table of sections for chapter 28 is amended to read as follows:

''273. Special defenses to and exemptions from infringement.''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to any civil action commenced on or after the date of enactment of this Act.

SEC. 6. POST-GRANT PROCEDURES AND OTHER QUALITY ENHANCEMENTS.

(a) REEXAMINATION.—Section 303(a) is amended to read as follows:

''(a) Within 3 months after the owner of a patent files a request for reexamination under section 302, the Director shall determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request, with or without consideration of other patents or printed publications. On the Director's own initiative, and at any time, the Director may determine whether a substantial new question of patentability is raised by patents and publications discovered by the Director, is cited under section 301, or is cited by any person other than the owner of the patent

under section 302 or section 311. The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.''.

(b) REEXAMINATION.—Section 315(c) is amended by striking ''or could have raised''.

(c) REEXAMINATION PROHIBITED AFTER DISTRICT COURT DECISION.—Section 317(b) is amended—

(1) in the subsection heading, by striking ''FINAL DECISION'' and inserting ''DISTRICT COURT DECISION''; and

(2) by striking ''Once a final decision has been entered'' and inserting ''Once the judgment of the district court has been entered''.

(d) EFFECTIVE DATES.—Notwithstanding any other provision of law, sections 311 through 318 of title 35, United States Code, as amended by this Act, shall apply to any patent that issues before, on, or after the date of enactment of this Act from an original application filed on any date.

(e) POST-GRANT OPPOSITION PROCEDURES.—

(1) IN GENERAL.—Part III is amended by adding at the end the following new chapter:

''CHAPTER 32—POST-GRANT REVIEW PROCEDURES

''§ 321. Petition for post-grant review

''Subject to sections 322, 324, 332, and 333, a person who is not the patent owner may file with the Office a petition for cancellation seeking to institute a post-grant review proceeding to cancel as unpatentable any claim of a patent on any ground that could be raised under paragraph (2) or (3) of section 282(b) (relating to invalidity of the patent or any claim). The Director shall establish, by regulation, fees to be paid by the person requesting the proceeding, in such amounts as the Director determines to be reasonable.

''§ 322. Timing and bases of petition

''A post-grant proceeding may be instituted under this chapter pursuant to a cancellation petition filed under section 321 only if—

''(1) the petition is filed not later than 12 months after the grant of the patent or issuance of a reissue patent, as the case may be;

''(2)(A) the petitioner establishes a substantial reason to believe that the continued existence of the challenged claim in the petition causes or is likely to cause the petitioner significant economic harm; or

''(B) the petitioner has received notice from the patent holder alleging infringement by the petitioner of the patent; or

''(3) the patent owner consents in writing to the proceeding.

''§ 323. Requirements of petition

''A cancellation petition filed under section 321 may be considered only if—

''(1) the petition is accompanied by payment of the fee established by the Director under section 321;

''(2) the petition identifies the cancellation petitioner; and

''(3) the petition sets forth in writing the basis for the cancellation, identifying each claim challenged and providing such information as the Director may require by regulation, and includes copies of patents and printed publications that the cancellation petitioner relies upon in support of the petition; and

''(4) the petitioner provides copies of those documents to the patent owner or, if applicable, the designated representative of the patent owner.

''§ 324. Prohibited filings

''A post-grant review proceeding may not be instituted under paragraph (1), (2), or (3) of section 322 if the petition for cancellation requesting the proceeding identifies the same cancellation petitioner and the same patent as a previous petition for cancellation filed under the same paragraph of section 322.

''§ 325. Submission of additional information; showing of sufficient grounds

''The cancellation petitioner shall file such additional information with respect to the petition as the Director may require. The Director may not authorize a post-grant review proceeding to commence unless the Director determines that the information presented provides sufficient grounds to proceed.

''§ 326. Conduct of post-grant review proceedings

''(a) IN GENERAL.—The Director shall—

''(1) prescribe regulations, in accordance with section 2(b)(2), establishing and governing post-grant review proceedings under this chapter and their relationship to other proceedings under this title;

''(2) prescribe regulations setting forth the standards for showings of substantial reason to believe and significant economic harm under section 322(2) and sufficient grounds under section 325;

''(3) prescribe regulations establishing procedures for the submission of supplemental information after the petition for cancellation is filed; and

''(4) prescribe regulations setting forth procedures for discovery of relevant evidence, including that such discovery shall be limited to evidence directly related to factual assertions advanced by either party in the proceeding, and the procedures for obtaining such evidence shall be consistent with the purpose and nature of the proceeding.

''(b) POST-GRANT REGULATIONS.—Regulations under subsection (a)(1)—

''(1) shall require that the final determination in a post-grant proceeding issue not later than one year after the date on which the post-grant review proceeding is instituted under this chapter, except that, for good cause shown, the Director may extend the 1-year period by not more than six months;

''(2) shall provide for discovery upon order of the Director;

''(3) shall prescribe sanctions for abuse of discovery, abuse of process, or any other improper use of the proceeding, such as to harass or to cause unnecessary delay or unnecessary increase in the cost of the proceeding;

''(4) may provide for protective orders governing the exchange and submission of confidential information; and

''(5) shall ensure that any information submitted by the patent owner in support of any amendment entered under section 328 is made available to the public as part of the prosecution history of the patent.

''(c) CONSIDERATIONS.—In prescribing regulations under this section, the Director shall consider the effect on the economy, the integrity of the patent system, and the efficient administration of the Office.

''(d) CONDUCT OF PROCEEDING.—The Patent Trial and Appeal Board shall, in accordance with section 6(b), conduct each post-grant review proceeding authorized by the Director.

''§ 327. Patent owner response

''After a post-grant proceeding under this chapter has been instituted with respect to a patent, the patent owner shall have the right to file, within a time period set by the Director, a response to the cancellation petition. The patent owner shall file with the response, through affidavits or declarations, any additional factual evidence and expert opinions on which the patent owner relies in support of the response.

''§ 328. Proof and evidentiary standards

''(a) IN GENERAL.—The presumption of validity set forth in section 282 shall not apply in a challenge to any patent claim under this chapter.

''(b) BURDEN OF PROOF.—The party advancing a proposition under this chapter shall have the burden of proving that proposition by a preponderance of the evidence.

''§ 329. Amendment of the patent

''(a) IN GENERAL.—In response to a challenge in a petition for cancellation, the patent owner may file 1 motion to amend the patent in 1 or more of the following ways:

''(1) Cancel any challenged patent claim.

''(2) For each challenged claim, propose a substitute claim.

''(3) Amend the patent drawings or otherwise amend the patent other than the claims.

''(b) ADDITIONAL MOTIONS.—Additional motions to amend may be permitted only for good cause shown.

''(c) SCOPE OF CLAIMS.—An amendment under this section may not enlarge the scope of the claims of the patent or introduce new matter.

''§ 330. Decision of the Board

''If the post-grant review proceeding is instituted and not dismissed under this chapter, the Patent Trial and Appeal Board shall issue a final written decision with respect to the patentability of any patent claim challenged and any new claim added under section 329.

''§ 331. Effect of decision

''(a) IN GENERAL.—If the Patent Trial and Appeal Board issues a final decision under section 330 and the time for appeal has expired or any appeal proceeding has terminated, the Director shall issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable and incorporating in the patent by operation of the certificate any new claim determined to be patentable.

''(b) NEW CLAIMS.—Any new claim held to be patentable and incorporated into a patent in a post-grant review proceeding shall have the same effect as that specified in section 252 for reissued patents on the right of any person who made, purchased, offered to sell, or used within the United States, or imported into the United States, anything patented by such new claim, or who made substantial preparations therefore, prior to issuance of a certificate under subsection (a) of this section.

''§ 332. Relationship to other pending proceedings

''Notwithstanding subsection 135(a), sections 251 and 252, and chapter 30, the Director may determine the manner in which any reexamination proceeding, reissue proceeding, interference proceeding (commenced before the effective date of the Patent Reform Act of 2007), derivation proceeding, or post-grant

review proceeding, that is pending during a post-grant review proceeding, may proceed, including providing for stay, transfer, consolidation, or termination of any such proceeding.

''§ 333. Effect of decisions rendered in civil action on future post-grant review proceedings

''If a final decision has been entered against a party in a civil action arising in whole or in part under section 1338 of title 28 establishing that the party has not sustained its burden of proving the invalidity of any patent claim—

''(1) that party to the civil action and the privies of that party may not thereafter request a post-grant review proceeding on that patent claim on the basis of any grounds, under the provisions of section 311, which that party or the privies of that party raised or had actual knowledge of; and

''(2) the Director may not thereafter maintain a post-grant review proceeding previously requested by that party or the privies of that party on the basis of such grounds.

''§ 334. Effect of final decision on future proceedings

''(a) IN GENERAL.—If a final decision under section 330 is favorable to the patentability of any original or new claim of the patent challenged by the cancellation petitioner, the cancellation petitioner may not thereafter, based on any ground which the cancellation petitioner raised during the post-grant review proceeding—

''(1) request or pursue a reexamination of such claim under chapter 31;

''(2) request or pursue a derivation proceeding with respect to such claim;

''(3) request or pursue a post-grant review proceeding under this chapter with respect to such claim; or

''(4) assert the invalidity of any such claim, in any civil action arising in whole or in part under section 1338 of title 28.

''(b) EXTENSION OF PROHIBITION.—If the final decision is the result of a petition for cancellation filed on the basis of paragraph (2) of section 322, the prohibition under this section shall extend to any ground which the cancellation petitioner raised during the post-grant review proceeding.

''§ 335. Appeal

''A party dissatisfied with the final determination of the Patent Trial and Appeal Board in a post-grant proceeding under this chapter may appeal the determination under sections 141 through 144. Any party to the post-grant proceeding shall have the right to be a party to the appeal.''.

(f) CONFORMING AMENDMENT.—The table of chapters for part III is amended by adding at the end the following:

''32. Post-Grant Review Proceedings .. 321''.

(g) REGULATIONS AND EFFECTIVE DATE.—

(1) REGULATIONS.—The Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (in this subsection referred to as the ''Director'') shall, not later than the date that is 1 year after the date of the enactment of this Act, issue regulations to carry out chapter 32 of title 35, United States Code, as added by subsection (e) of this section

(2) APPLICABILITY.—The amendments made by subsection (e) shall take effect on the date that is 1 year after the date of the enactment of this Act and shall apply to patents issued before, on, or after that date, except that, in the case of a patent issued before that date, a petition for cancellation under section 321 of title 35, United States Code, may be filed only if a circumstance described in paragraph (2), (3), or (4) of section 322 of title 35, United States Code, applies to the petition.

(3) PENDING INTERFERENCES.—The Director shall determine the procedures under which interferences commenced before the effective date under paragraph (2) are to proceed, including whether any such interference is to be dismissed without prejudice to the filing of a cancellation petition for a post-grant opposition proceeding under chapter 32 of title 35, United States Code, or is to proceed as if this Act had not been enacted. The Director shall include such procedures in regulations issued under paragraph (1).

SEC. 7. DEFINITIONS; PATENT TRIAL AND APPEAL BOARD.

(a) DEFINITIONS.—Section 100 (as amended by this Act) is further amended—

(1) in subsection (e), by striking ''or inter partes reexamination under section 311'';

(2) by adding at the end the following:

''(k) The term 'cancellation petitioner' means the real party in interest requesting cancellation of any claim of a patent under chapter 31 of this title and the privies of the real party in interest.''.

(b) PATENT TRIAL AND APPEAL BOARD.—Section 6 is amended to read as follows:

''§ 6. Patent Trial and Appeal Board

''(a) ESTABLISHMENT AND COMPOSITION.—There shall be in the Office a Patent Trial and Appeal Board. The Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks, and the administrative patent judges shall constitute the Patent Trial and Appeal Board. The administrative patent judges shall be persons of competent legal knowledge and scientific ability who are appointed by the Director. Any reference in any Federal law, Executive order, rule, regulation, or delegation of authority, or any document of or pertaining to the Board of Patent Appeals and Interferences is deemed to refer to the Patent Trial and Appeal Board.

''(b) DUTIES.—The Patent Trial and Appeal Board shall—

''(1) on written appeal of an applicant, review adverse decisions of examiners upon application for patents;

''(2) on written appeal of a patent owner, review adverse decisions of examiners upon patents in reexamination proceedings under chapter 30; and

''(3) determine priority and patentability of invention in derivation proceedings under subsection 135(a); and

''(4) conduct post-grant opposition proceedings under chapter 32.

Each appeal and derivation proceeding shall be heard by at least 3 members of the Patent Trial and Appeal Board, who shall be designated by the Director. Only the Patent Trial and Appeal Board may grant rehearings. The Director shall assign each post-grant review proceeding to a panel of 3 administrative patent judges. Once assigned, each such panel of administrative patent judges shall have the responsibilities under chapter 32 in connection with post-grant review proceedings.''.

SEC. 8. STUDY AND REPORT ON REEXAMINATION PROCEEDINGS.

The Under Secretary of Commerce for Intellectual Property and Director of the Patent and Trademark Office shall, not later than 3 years after the date of the enactment of this Act—

(1) conduct a study of the effectiveness and efficiency of the different forms of proceedings available under title 35, United States Code, for the reexamination of patents; and

(2) submit to the Committees on the Judiciary of the House of Representatives and the Senate a report on the results of the study, including any of the Director's suggestions for amending the law, and any other recommendations the Director has with respect to patent reexamination proceedings.

SEC. 9. SUBMISSIONS BY THIRD PARTIES AND OTHER QUALITY ENHANCEMENTS.

(a) PUBLICATION.—Section 122(b)(2) is amended—

(1) by striking subparagraph (B); and

(2) in subparagraph (A)—

(A) by striking ''(A) An application'' and inserting ''An application''; and

(B) by redesignating clauses (i) through (iv) as subparagraphs (A) through (D), respectively.

(b) PREISSUANCE SUBMISSIONS BY THIRD PARTIES.—Section 122 is amended by adding at the end the following:

''(e) PREISSUANCE SUBMISSIONS BY THIRD PARTIES.—

''(1) IN GENERAL.—Any person may submit for consideration and inclusion in the record of a patent application, any patent, published patent application or other publication of potential relevance to the examination of the application, if such submission is made in writing before the earlier of—

''(A) the date a notice of allowance under section 151 is mailed in the application for patent; or

''(B) either—

''(i) 6 months after the date on which the application for patent is published under section 122, or

''(ii) the date of the first rejection under section 132 of any claim by the examiner during the examination of the application for patent,

whichever occurs later.

''(2) OTHER REQUIREMENTS.—Any submission under paragraph (1) shall—

''(A) set forth a concise description of the asserted relevance of each submitted document;

''(B) be accompanied by such fee as the Director may prescribe; and

''(C) include a statement by the submitter affirming that the submission was made in compliance with this section.''.

SEC. 10. VENUE AND JURISDICTION.

(a) VENUE FOR PATENT CASES.—Section 1400 of title 28, United States Code, is amended by striking subsection (b) and inserting the following:

''(b) Any civil action arising under any Act of Congress relating to patents, other than an action for declaratory judgment or an action seeking review of a decision of the Patent Trial and Appeal Board under chapter 13 of title 35, may be brought only—

''(1) in the judicial district where either party resides; or

''(2) in the judicial district where the defendant has committed acts of infringement and has a regular and established place of business.

''(c) Notwithstanding section 1391(c) of this title, for purposes of venue under subsection (b), a corporation shall be deemed to reside in the judicial district in which the corporation has its principal place of business or in the State in which the corporation is incorporated.''.

(b) INTERLOCUTORY APPEALS.—Subsection (c)(2) of section 1292 of title 28, United States Code, is amended by adding at the end the following:

''(3) of an appeal from an interlocutory order or decree determining construction of claims in a civil action for patent infringement under section 271 of title 35.

Application for an appeal under paragraph (3) shall be made to the court within 10 days after entry of the order or decree, and proceedings in the district court under such paragraph shall be stayed during pendency of the appeal.''.

SEC. 11. REGULATORY AUTHORITY.

Section 3(a) is amended by adding at the end the following:

''(5) REGULATORY AUTHORITY.—In addition to the authority conferred by other provisions of this title, the Director may promulgate such rules, regulations, and orders that the Director determines appropriate to carry out the provisions of this title or any other law applicable to the United States Patent and Trademark Office or that the Director determines necessary to govern the operation and organization of the Office.''.

SEC. 12. TECHNICAL AMENDMENTS.

(a) JOINT INVENTIONS.—Section 116 is amended—

(1) in the first paragraph, by striking ''When'' and inserting ''(a) JOINT INVENTIONS.—When'';

(2) in the second paragraph, by striking ''If a joint inventor'' and inserting ''(b) OMITTED INVENTOR.—If a joint inventor''; and

(3) in the third paragraph, by striking ''Whenever'' and inserting ''(c) CORRECTION OF ERRORS IN APPLICATION.—Whenever''.

(b) FILING OF APPLICATION IN FOREIGN COUNTRY.—Section 184 is amended—

(1) in the first paragraph, by striking ''Except when'' and inserting ''(a) FILING IN FOREIGN COUNTRY.—Except when'';

(2) in the second paragraph, by striking ''The term'' and inserting ''(b) APPLICATION.—The term''; and

(3) in the third paragraph, by striking ''The scope'' and inserting ''(c) SUBSEQUENT MODIFICATIONS, AMENDMENTS, AND SUPPLEMENTS.—The scope''.

(c) REISSUE OF DEFECTIVE PATENTS.—Section 251 is amended—

(1) in the first paragraph, by striking ''Whenever'' and inserting ''(a) IN GENERAL.—Whenever'';

(2) in the second paragraph, by striking ''The Director'' and inserting ''(b) MULTIPLE REISSUED PATENTS.—The Director'';

(3) in the third paragraph, by striking ''The provision'' and inserting ''(c) APPLICABILITY OF THIS TITLE.—The provisions''; and

(4) in the last paragraph, by striking ''No reissued patent'' and inserting ''(d) REISSUE PATENT ENLARGING SCOPE OF CLAIMS.—No reissued patent''.

(d) EFFECT OF REISSUE.—Section 253 is amended—

(1) in the first paragraph, by striking ''Whenever'' and inserting ''(a) IN GENERAL.—Whenever''; and

(2) in the second paragraph, by striking ''in like manner'' and inserting ''(b) ADDITIONAL DISCLAIMER OR DEDICATION.—In the manner set forth in subsection (a),''.

(e) CORRECTION OF NAMED INVENTOR.—Section 256 is amended—

(1) in the first paragraph, by striking ''Whenever'' and inserting ''(a) CORRECTION.—Whenever''; and

(2) in the second paragraph, by striking ''The error'' and inserting ''(b) PATENT VALID IF ERROR CORRECTED.—The error''.

(f) PRESUMPTION OF VALIDITY.—Section 282 is amended—

(1) in the first undesignated paragraph, by striking ''A patent'' and inserting ''(a) IN GENERAL.—A patent'';

(2) in the second undesignated paragraph, by striking ''The following'' and inserting ''(b) DEFENSES.—The following''; and

(3) in the third undesignated paragraph, by striking ''In actions'' and inserting ''(c) NOTICE OF ACTIONS; ACTIONS DURING EXTENSION OF PATENT TERM.—In actions''.

SEC. 13. EFFECTIVE DATE; RULE OF CONSTRUCTION.

(a) EFFECTIVE DATE.—Except as otherwise provided in this Act, the provisions of this Act shall take effect 12 months after the date of the enactment of this Act and shall apply to any patent issued on or after that effective date.

(b) CONTINUITY OF INTENT UNDER THE CREATE ACT.—The enactment of section 102(b)(3) of title 35, United States Code, under section (3)(b) of this Act is done with the same intent to promote joint research activities that was expressed, including in the legislative history, through the enactment of the Cooperative Research and Technology Enhancement Act of 2004 (Public Law 108–453; the ''CREATE Act''), the amendments of which are stricken by section 3(c) of this Act. The United States Patent and Trademark Office shall administer section 102(b)(3) of title 35, United States Code, in a manner consistent with the legislative history of the CREATE Act that was relevant to its administration by the Patent and Trademark Office.

Mr. HATCH. Mr. President, I rise today to introduce with Senate Judiciary Committee Chairman PATRICK LEAHY the Patent Reform Act of 2007, S. 1145. S. 1145 represents years of careful negotiation and input from a wide-spectrum of stake holders. In fact, the 2006 Hatch-Leahy bill has served as a blueprint for this year's legislation and contains substantially similar language. Chairman LEAHY's desire to have a piece of legislation that is both bipartisan and bicameral is a great undertaking and represents a tremendous commitment by Congress to move forward in streamlining and strengthening our patent system.

The patent system is the bedrock of innovation, especially in today's global economy. Last year, more than 440,000 patent applications were filed at the United States Patent and Trademark Office (USPTO). The sheer volume of patent applications reflects the vibrant, innovative spirit that has made America a world-wide leader in science, engineering, and technology. Because America's ingenuity continues to fund our economy, we must protect new ideas and investments in innovation and creativity. Patents encourage technological advancement by providing incentives to invent, invest in, and disclose new technology. Now, more than ever, it is important to ensure efficiency and increased quality in the issuance of patents. This in turn creates an environment that fosters entrepreneurship and the creation of jobs: two significant pillars in our economy. In my home State of Utah alone, there are over 3,200 technology and 500 life science companies, and eight percent year-over-year growth. Utah leads the western States region in creating and sustaining these companies.

Additionally, the concentration of college graduates in Utah is contributing to the State's technological friendliness, attracting growth companies to Utah and creating new ones. There is a large, young adult population in Utah attending not only the two world-class research universities of the University of Utah and Utah State University, but also Brigham Young University, Utah Valley State College and Weber State University. These universities and colleges are strong economic drivers that encourage technology industry growth in my State.

For years, Chairman LEAHY and I have been working together to craft meaningful patent reform to address problems that have been identified through a series of hearings and discussions with stake holders. This bill addresses many of the problems with the substantive, procedural, and administrative aspects of the patent system, which governs how entities here in the United States apply for, receive, and eventually make use of patents.

The Patent Reform Act of 2007 includes provisions to improve patent quality. Many complaints about the current patent system deal with the number of suspect and over-broad patents that are issued. Because bad patents are generally of little value to productive companies, in many cases their value is maximized by using them as a basis for infringement suits against deep-pocket defendants. This bill institutes a robust post-grant review process so that third parties can challenge suspect patents in an administrative process, rather than through costly litigation. In the bill we introduced today, Section 6 has been tightened by including an anti-harassment provision to discourage companies from colluding and perpetually harassing one company. I am hopeful this will serve as a deterrent to those who seek to abuse post-grant review process.

In addition, S. 1145 is designed to harmonize U.S. law with the law of other countries by instituting a first-to-file system. The United States is the only significant country following the first-to-invent system, in which the right of the patent lies with the first inventor, rather than the first inventor to file for a patent. The Patent Reform Act of 2007 provides greater certainty because the filing date of an application can very rarely be challenged.

S. 1145 also seeks to provide fair and equitable remedies. Some claim that courts have allowed damages for infringement to be based on the market for an entire product when all that was infringed is a minor component of the product. The bill's language preserves the current rule that mandates that a damages award shall not be less than a reasonable royalty for the infringed patent, and further requires the court to conduct an analysis to ensure that when a reasonable royalty is the award, it reflects only the economic value of the patent's specific contribution over the prior art.

There are a few provisions I believe need further discussion. I was disappointed that the inequitable conduct provision from last year's bill was removed. Attorneys well know that the inequitable conduct defense has been overpleaded and has become a drag on the litigation process. I think last year's language struck the correct balance by focusing on the patentability of the claims in dispute and properly prevented parties from asserting the defense frivolously. Let me hasten to add that I do believe there should be consequences for misconduct. I believe that reforms to the inequitable conduct defense should focus on the nature

of the misconduct and not permit the unenforceability of a perfectly valid patent on a meritorious invention. And, sanctions should be commensurate with the misconduct.

Moreover, establishing inequitable conduct is supposed to require independent proof that: (1) the information at issue was material; and (2) the person who failed to disclose it or made the misrepresentation had the specific intention of misleading the USPTO. The two elements have become linked, and courts often discount the intent requirement by finding that the information is ''highly material.'' In fact, the materiality standard has become so inclusive that virtually anything now is portrayed as material. Information should only be considered material when it causes the USPTO to improperly grant patent claims. Using a standard of whether USPTO examiners would reject the claims is a good approximation of materiality because of the prima facie standard they use to determine whether the claims meet the requirements for patentability. Unfortunately, this bill preserves the status quo.

A provision that would provide attorneys' fees and costs to a prevailing party was also left out of this bill. I included this provision in last year's bill to discourage weak cases from clogging the already-burdened judicial system. This is not a new concept in the realm of intellectual property. In fact, I note, Section 505 of the Copyright Act clearly provides courts the discretion to award attorneys' fees and costs. It seems logical that we would provide the same discretion in S. 1145 and I look forward to discussing this issue with Chairman LEAHY.

We opted this year not to include a provision that would repeal Section 271(f) of Title 35, pending a Supreme Court decision that is expected soon. Section 271(f) creates a cause of action for infringement due to foreign sales when a component of a patented invention is supplied from this country, knowing that a component will be combined in an infringing manner outside the United States. In the event of an unfavorable ruling, Chairman LEAHY and I are committed to addressing this issue using the legislative process.

Patent law is vital to our Nation's ability to compete in the global economy. S. 1145 is designed to ensure that the United States remains at the forefront of developing and translating new ideas into tangible goods and services through an effective patent review and protection system

This bill represents a commitment from Congress to move forward in streamlining and strengthening our patent system. I am hopeful that further refinements will be made to this bill during the legislative process. I am committed to moving this legislation forward and hope that we can join efforts to refine and enact this important bill.

By Mr. SALAZAR (for himself, Mr. THUNE, Mr. TESTER, Mr. BURR, Mrs. MURRAY, Mr. GRASSLEY, Mr. WYDEN, Ms. COLLINS, Mr. PRYOR, Mr. ENZI, Mrs. LINCOLN, Ms. SNOWE, Mr. KERRY, Mr. BINGAMAN, Mr. SMITH, Mr. BAUCUS, and Mr. DORGAN):

S. 1146. A bill to amend title 38, United States Code, to improve health care for veterans who live in rural areas, and for other purposes; to the Committee on Veterans' Affairs.

Mr. SALAZAR. Mr. President, today I am introducing the Rural Veterans Healthcare Improvement Act of 2007, with my colleague from South Dakota, Senator THUNE, and my colleague from Montana, Senator TESTER. We are pleased to be joined by Senators BURR, MURRAY, GRASSLEY, WYDEN, COLLINS, PRYOR, ENZI, LINCOLN, SNOWE, KERRY, BINGAMAN, SMITH, BAUCUS, and DORGAN.

Over the last two years my colleagues have heard me speak repeatedly about the challenges that are facing rural America. In the America where I grew up—the America of farmers, ranchers, small business owners, and generations of close-knit families—it is getting more difficult to make a living, to access affordable healthcare, and to provide opportunities for kids to learn and grow.

The challenges facing veterans in rural communities are particularly grave. For generations, men and women from rural America have devoted themselves to the cause of freedom without hesitation and in numbers greatly beyond their proportion of the U.S. population. Yet we consistently overlook the unique challenges these men and women face after they return home to their families and friends in the heartland of America. When it comes to the VA healthcare system, we fail our Nation's rural veterans by not doing more to ensure they can access the high-quality health care they have earned. We owe them much better.

Over and over, I hear from veterans in my state about obstacles to care. In northwest Colorado, veterans must brave three and four hour drives on winding mountain roads to reach the VA hospital in Grand Junction.

In northeast Colorado I have heard from a veteran who must travel 500 miles round trip just to get a simple blood test at a VA hospital. I think most of my colleagues would agree with me that this is ludicrous.

I wish I could say these are isolated circumstances. Unfortunately, they are not. Because of gaps in the network of VA hospitals and clinics, we hear stories like this all the time.

Every day, veterans from rural communities throughout the country are forced to put off crucial treatment because they live too far from VA facilities and can't get the care they need. As a result, rural veterans die younger and suffer from more debilitating illnesses—all because our system is not equipped to address their needs and provide care accordingly. A 2004 study of over 750,000 veterans conducted by Dr. Jonathan Perlin, the Under Secretary for Health at the VA, consistently found that veterans living in rural areas are in poorer health than their urban counterparts.

Last year, we took an important first step in improving care for rural veterans. Thanks to the bipartisan efforts of my colleagues on the Veterans' Affairs Committee, we were able to create the Office of Rural Health within the VA. The Office of Rural Health is charged with working to reduce the wide disparities between care for rural and non-rural veterans by developing and refining policies and programs to improve care and services for rural veterans. Because nearly one in every four veterans is from a rural area, the creation of this Office of Rural Health is crucial if we are to live up to our promise to provide all of our Nation's veterans with high-quality services.

The bill we are introducing today, the Rural Veterans Healthcare and Improvement Act of 2007, builds on last year's work by giving direction and resources to the Office of Rural Health and by making healthcare more accessible to veterans in rural areas.

The bill tasks the Office of Rural Health with developing demonstration projects that would expand care in rural areas through partnerships between the VA, Centers for Medicare and Medicaid Services, and the Department of Health and Human Services at critical access hospitals and community health centers. The bill also instructs the Director of the Office of Rural Health to carry out demonstration projects in partnership with the Indian Health Service to improve healthcare for Native American veterans.

In addition, the Rural Veterans Healthcare Improvement Act of 2007 establishes centers of excellence to research ways to improve care for rural veterans. The centers would be based at VA medical centers with strong academic connections. The Office of Rural Health would establish between one and five centers across the country with the advice of an advisory panel.

The Rural Veterans Healthcare Improvement Act includes two key provisions that will help veterans in rural areas reach healthcare facilities.

First, the bill establishes the VetsRide grant program to provide innovative transportation options to veterans in remote rural areas. The bill tasks the Director of the Office of Rural Health to create a program that would provide grants of up to $50,000 to veterans' service organizations and State veterans' service officers to assist veterans with travel to VA medical

centers and to improve healthcare access in remote rural areas. The bill authorizes $3 million per year for the grant program through 2012.

Secondly, the bill increases the reimbursement rates for veterans for their travel expenses related to VA medical care so that they are compensated at the same rate paid to federal employees.

Finally, our bill requires the VA to report to Congress on the assessment it is conducting of its fee-based healthcare policies. We need to improve the VA's fee-based healthcare policies to be more equitable and efficient in helping veterans in rural areas get the care they deserve.

With almost one-quarter of our Nation's veterans living in rural communities, and with the obstacles they face in accessing high-quality care, it is evident that we need to do a better job of making sure they receive the care they deserve. The creation of the Office of Rural Veterans Healthcare was a first step, and this legislation will move us further down the path toward improved care.

I want to again thank my colleague from South Dakota, Senator THUNE, and my colleague from Montana, Senator TESTER, for their efforts on this bill. We have a strong group of 17 Senators from both sides of the aisle behind this bill so far.

I know that each and every one of my colleagues deals with veterans' issues and feels a deep sense of gratitude towards the brave men and women who have fought for our freedom. I hope we can join together to move this legislation through Congress and send it to the President for his signature.

Mr. President, I yield the floor.

By Mrs. MURRAY:

S. 1147. A bill to amend title 38, United States Code, To terminate the administrative freeze on the enrollment into the health care system of the Department of Veterans Affairs of veterans in the lowest priority category for enrollment (referred to as ''Priority 8''); to the Committee on Veterans' Affairs.

Mrs. MURRAY. Mr. President, I rise today to introduce the Honor Our Commitment to Veterans Act.

More than four years ago, the Bush Administration cut off enrollment of Priority 8 veterans in the VA healthcare system. Priority 8 veterans are those veterans without service-connected disabilities whose income is above a means tested level that varies across the country. Many of these so-called ''high-income veterans'' have annual incomes as low as $26,902.

When the Administration announced its intention to suspend healthcare enrollment for new Priority 8 veterans, they said that they were doing so in order to reduce the backlog and alleviate a longstanding funding crisis within the VA.

There is no doubt that the VA has problems. Nearly five years into this war, our veterans are facing lengthy waits just to get in the door to see a primary care physician. They are having trouble accessing critical mental health services, and some are waiting up to two years for benefits claims to be processed. These are real problems facing real people, and they deserve real solutions.

But instead of cutting off enrollment to veterans of modest means four years ago, the Bush Administration should have asked Congress for the resources necessary to address its shortcomings and increase access to this high quality health care system.

It is absolutely unacceptable that veterans in need of care are being prohibited from enrolling in the system that is supposed to serve them. Veterans who have fought hard to secure our freedoms shouldn't have to fight for access to health care at home. Our veterans deserve better.

That is why I am introducing the Honor Our Commitment to Veterans Act today, which would permit new Priority 8 veterans to enroll in the VA healthcare system.

According to a recent Congressional Research Service report, the VA estimates that if the enrollment freeze was lifted, approximately 273,000 Priority 8 veterans would have been eligible to receive medical care from VA in FY2006, and 242,000 Priority 8 veterans would be eligible in FY2007.

This legislation, which has been introduced in the House by Congressman STEVE ROTHMAN of New Jersey, would correct the injustice perpetrated in 2003 by allowing all new Priority 8 veterans to enroll in the VA healthcare system.

By Mr. KOHL (for himself, Mr. BAUCUS, and Mr. CONRAD):

S. 1149. A bill to amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to authorize the interstate distribution of State-inspected meat and poultry if the Secretary of Agriculture determines that the State inspection requirements are at least equal to Federal inspection requirements and to require the Secretary to reimburse State agencies for part of the costs of the inspections; to the Committee on Agriculture, Nutrition, and Forestry.

Mr. KOHL. Mr. President, I am today introducing with Senators BAUCUS and CONRAD a bill that will eliminate the prohibition on interstate commerce in State-inspected meat and poultry products. Senator HATCH is also introducing a State meat inspection measure and I congratulate him on his bill. We are working together and in collaboration with the National Association of State Departments of Agriculture and a coalition of national, State, and local agricultural organizations on this effort. I expect our coalition to grow over time. Together, we intend to push for changes that will protect public health and safety and at the same time help state-inspected meat and poultry processors compete in new markets.

Removing the current prohibition will help level the playing field for small businesses and spur additional competition in the marketplace. It will help main street businesses—who often specialize in local, organic, grass-fed or artisinal products—meet emerging markets. And it will help livestock producers who want more options for marketing their livestock.

For too long, processors with State-inspected facilities have been unfairly constrained to selling only within their home States. Meanwhile, foreign-processed meat can be shipped anywhere in the United States so long as the originating Nation's inspection program is deemed equivalent to U.S. Federal standards. We want our State-inspected processors to be treated at least as well. This is an effort to give main street businesses the same opportunity our Government confers on foreign processors.

I look forward to working with Senators HATCH, BAUCUS and CONRAD and a number of our House colleagues on this topic in the months to come.

By Ms. SNOWE (for herself and Mr. COLEMAN):

S. 1153. A bill to require assessment of the impact on small business concerns of rules relating to internal controls, and for other purposes; to the Committee on Banking, Housing, and Urban Affairs.

Ms. SNOWE. Mr. President, I rise today with my colleague Senator COLEMAN, to introduce the ''Small Business Regulatory Review Act.'' This is a targeted, non-controversial measure. It would ensure that the Securities and Exchange Commission (SEC) and the Public Company Accounting Oversight Board (PCAOB) fully consider the impacts of their final rules mandating how small public companies must comply with the internal control requirements of the Sarbanes-Oxley Act.

Our Nation's small stock companies are the cornerstone of our entrepreneurial economy, and it is essential that we carefully address the regulatory barriers that impede their growth.

The Sarbanes-Oxley Act was essential in restoring investor confidence after accounting fraud and massive company deceptions shook the public's trust in U.S. markets. The horrendous debacle of corporate greed from companies like Enron and Worldcom forced not only thousands of employees to lose their jobs, but also wiped out the life savings of many retirees. Now, as we refine Sarbanes-Oxley's regulations, we must carefully preserve investor protections and ensure company transparency and accountability.

In my home State of Maine, small publicly-traded companies are indispensable to the strength and renewal of our economy. However, the fact is that many of these small stock companies are struggling mightily with the cost and regulatory burden imposed by Sarbanes-Oxley compliance, regardless of

their industry. Whether it's a utility company, a dairy pharmaceutical company that makes large animal vaccines, or a community bank that fears being smothered by the combined weight of Sarbanes-Oxley and banking regulations, it is crucial that Maine's home grown companies focus their energies on developing new products, entering new markets, and creating jobs—not on compliance.

This is why I rise today, with Senator COLEMAN, to introduce the ''Small Business Regulatory Review Act of 2007.'' Our bill would require the SEC to conduct a small business analysis, consistent with the Regulatory Flexibility Act (RFA), before the SEC publishes its final rules on small business internal controls compliance. This noncontroversial provision simply restates existing law, ensuring that the SEC conducts a final RFA analysis. As the SEC should already be conducting this analysis as part of its final rulemaking process, this bill will impose no additional delay.

Our bill would also require the SEC to publish a small business compliance guide, consistent with the Small Business Regulatory Enforcement Fairness Act (SBREFA). This compliance guide would explain, in plain language, the small business requirements under the rule. The SEC should publish this small businesses compliance guide when it publishes its final rule, so that small business understand the new requirements. As this non-controversial provision also restates existing law, this measure would impose no additional delay on the SEC's rulemaking process.

Regulations disproportionately affect small businesses and significantly hinder their competitiveness. In 2004, Senator ENZI and I jointly requested that the Government Accountability Office (GAO) study the effects of the Sarbanes-Oxley Act on small public companies' access to capital. The study found that the costs for complying with Sarbanes-Oxley were nine times greater for smaller companies than for large stock companies. We must reduce the burden imposed by Sarbanes-Oxley so that our small stocks in Maine, Minnesota, and across the country can continue to be some of the world's fastest growing and most innovative companies.

Finally, to address this disproportionate regulatory burden on small businesses, our bill would require that the GAO re-analyze the impact of these rules on small public companies two years after final rules are published. The GAO's report would include an assessment of the costs and time commitments the SEC and PCAOB requirements impose on small businesses and whether these costs are expected to decrease or increase in the future. Additionally, the final report would include recommendations, and regulatory alternatives, on how to simplify or improve the process of complying with SEC and PCAOB small company stock requirements. This provision simply ensures that the rules do not impose unintended, undue burdens on small businesses.

The ''Small Business Regulatory Review Act of 2007'' will help to ensure that small stock companies do not suffer from additional unintended consequences which harm their ability to compete, innovate, and grow—and, most importantly, create jobs.

By Mr. DORGAN (for himself, Mr. BROWNBACK, Ms. LANDRIEU, Mr. ALLARD, Mr. HARKIN, Mrs. MURRAY, Mr. ROBERTS, Mr. NELSON of Nebraska, Mr. SALAZAR, Mr. HAGEL, Mr. THUNE, and Mr. LEVIN):

S. 1155. A bill to treat payments under the Conservation Reserve Program as rentals from real estate; to the Committee on Finance.

Mr. DORGAN. Mr. President, today I am joined by Senator BROWNBACK and ten of our colleagues in introducing the Conservation Reserve Program Tax Fairness Act of 2007. This legislation clarifies once and for all that Conservation Reserve Program (CRP) payments received by active or retired farmers, or other landowners for that matter will be treated for Federal tax purposes as rental payments that are not subject to self-employment taxes.

Let me take a moment to describe this problem. For many years now, the Internal Revenue Service (IRS) has been taking the erroneous position that CRP payments received by farmers are self-employment income derived from a trade or business and therefore are subject to Self-Employment Contributions Act (SECA) taxes. Regrettably, the IRS and the Treasury Department proposed a new ruling late last year that not only requires active farmers to pay SECA taxes on CRP payments but expands similar tax treatment to CRP payments received by retired farmers and other landowners.

This latest ruling proposed by the IRS would impose a significant financial hardship on family farmers and others who have voluntarily agreed to take environmentally-sensitive lands out of farm production and place them in the Conservation Reserve Program in return for an annual rental payment from the Commodity Credit Corporation of the U.S. Department of Agriculture.

Today, North Dakota has some 3.4 million acres with about $112 million in rental payments in the CRP program. Left intact, the IRS's ruling would mean that farmers in North Dakota may owe an additional $16 million in Federal taxes this coming year. A typical North Dakota farmer with 160 acres of CRP would owe nearly $750 in new self-employment taxes because of the agency's ill-advised position.

If the IRS decides to pursue back taxes on returns filed by farmers in past years, the amount of taxes owed by individual farmers for CRP payments could amount to thousands of dollars. That would be devastating to many farmers and others who depend on CRP rental payments to make ends meet. As a result, the proposed change in our bill applies to CRP payments made in open tax years before, on, or after the date of its enactment.

We believe the IRS's position on the tax treatment of CRP payments is dead wrong. In our judgment, forcing CRP recipients to pay self-employment taxes on CRP payments is not what Congress intended, nor is it supportable in law. The U.S. Tax Court, the Federal court with the most expertise on tax issues, shares our view that the IRS position is improper. In fact, the U.S. Tax Court ruled in the late 1990's that CRP payments are properly treated by farmers as rental payments and, thus, not subject to self-employment taxes. Unfortunately, the IRS challenged the Tax Court decision and the Tax Court was later reversed by a Federal appellate court.

In February, IRS Commissioner Mark Everson sent a letter to me and a number of our colleagues who are concerned about this issue. In his letter, Commissioner Everson made clear that the IRS would not change its position that CRP payments are subject to self-employment tax as income derived from a trade or business—absent new statutory language passed by the Congress and enacted into law.

With the legislation we are introducing today, Congress will send a clear message to the IRS that its misguided effort to subject CRP payments to self-employment taxes is inappropriate and will not be allowed to stand. Our bill also makes sure that Federal trust funds that would have received SECA revenues but for the enactment of our bill are held harmless through the use of revenue transfers from the Treasury general fund.

Senator BROWNBACK and I ask our colleagues to support this much-needed tax relief for family farmers and other CRP recipients by cosponsoring the Conservation Reserve Program Tax Fairness Act. And we hope you will work with us to get this legislation enacted into law without delay.

By Mr. DODD (for himself, Mr. KENNEDY, Mr. HARKIN, Mr. BINGAMAN, Mrs. MURRAY, Mrs. CLINTON, and Mr. BROWN):

S. 1156. A bill to amend the Federal Food, Drug, and Cosmetic Act to reauthorize the Best Pharmaceuticals for Children program; to the Committee on Health, Education, Labor, and Pensions.

Mr. DODD. Mr. President, I rise today to introduce the Best Pharmaceuticals for Children Amendments of 2007, which is a bill to reauthorize the Best Pharmaceuticals for Children Act—BPCA. If Congress doesn't act, this successful program will expire on October I, 2007. I thank my colleagues Senators KENNEDY, HARKIN, BINGAMAN, MURRAY, CLINTON and BROWN who are joining me as original cosponsors of this important legislation.

I am pleased that Senators KENNEDY and ENZI, the distinguished chairman and ranking member of the Health Education Labor, and Pensions—HELP—Committee, have included this bill in the chairman's mark for S. 1082, which is expected to be voted on today in the HELP Committee.

I would also like to recognize the contributions and leadership of former Senator Mike De Wine, a friend and colleague, who always fought to ensure children would not be treated as second-class citizens when it came to drug and device development. He was a champion of BPCA along with me even when it wasn't popular to hold that view.

The story of the Best Pharmaceuticals for Children Act is one of huge success for children and their families. Children with a wide range of diseases such as HIV/AIDS, cancer, allergies, asthma, neurological and psychiatric disorders, and obesity can now lead healthier, more productive lives as a result of new information about the safety and efficacy of drugs they use to treat and manage their diseases where previously there was none.

Children are not simply little adults and results of the drug studies conducted under the BPCA have shown us that they should not be treated as such. Pediatric drug studies conducted. under the BPCA showed that children may have been exposed to ineffective drugs, ineffective dosing, overdosing, or side effects that were previously unknown.

Since the BPCA's passage in 1997 and its reauthorization in 2002, FDA has requested nearly 800 studies involving more than 45,000 children in clinical trials. Useful new pediatric information is now part of product labeling for 119 drugs. By comparison, in the 7 years prior to the BPCA's passage, only 11 studies of marketed drugs were completed. In the past 10 years, there has been a twentyfold increase in the number of drugs studied in infants, children, and adolescents since BPCA was enacted.

Labeling changes resulting from clinical studies under the BPCA have informed physicians of the proper dosing in the examples of Viracept, a protease inhibitor used in a combination therapy for the treatment of HIV, and Neurontin, a pain relief medication used to treat children with chronic pain. For children with epilepsy, the BPCA studies informed physicians that the drugs Keppra and Trileptal could be used safely and effectively at an even earlier age than previously known. Studies of Imitrex as a result of the BPCA showed no better results than placebo for the treatment of migraine headaches in adolescents. These same studies also showed serious adverse events due to Imitrex in pediatric populations and therefore the drug is not recommended to treat migraines in anyone less than 18 years of age.

Recent studies of the BPCA by the Government Accountability Office—GAO—and by several authors from Duke University in an article which appeared in the Journal of the American Medical Association—JAMA—have demonstrated that the program is a success and have identified opportunities to strengthen the program. Authors of the recent JAMA article found that outside of the BPCA, the FDA is limited in the number and scope of studies for which it can require pediatric data for existing products on the market.

Data from this article showed that only a minority of drugs studied under the BPC, about 20 percent, had more than $1 billion in annual sales. In fact, the median drug granted exclusivity was a small-market drug with annual sales of $180 million and 30 percent of drugs studied had sales less than $200 million. This article went on to say that a universal reduction in the length of pediatric exclusivity from 6 to 3 months would mean that products with small profit margins may not be submitted for pediatric testing.

The BPCA has always tried to strike the right balance between cost to consumers and benefits to children. I believe there is an ongoing need to evaluate the cost of the incentive as it relates to reaching the goal of having medications properly studied and labeled for children. In fact, that is why I strongly support a 5–year sunset of the BPCA.

After 10 years, experience and data has shown us that for a small number of drugs, pediatric exclusivity has far exceeded the ''carrot'' it was intended to provide for manufacturers. As the authors of the recent JAMA article noted, ''our study shows that the Pediatric Exclusivity Program overcompensates blockbuster products for performing clinical trials in children, while other products have more modest returns on investment under this program.''

The bill I am introducing today contains a reasonable, workable proposal to address cost concerns without jeopardizing the extraordinary success of BPCA. I have worked closely with the chairman and ranking member of the HELP Committee to craft this proposal into the form it appears in this legislation and in the bipartisan chairman's mark which is expected to be voted on in the HELP Committee today.

On March 27, the HELP Committee held a hearing, which I chaired, entitled ''Ensuring Safe Medicines and Medical Devices for Children.'' We learned from pediatricians and a parent of five children, four of whom are HIV-positive, Mrs. Susan Belfiore, about the tremendous impact BPCA has had on the quality of life for countless numbers of children and their families. We received testimony with many suggestions for improvements to BPCA which I believe are reflected in this bill. I would also add that in the month since I circulated this bill as a draft, I received comments from several pharmaceutical companies. Some have been strongly supportive of this effort and many of their ideas and suggestions are incorporated in this bill.

The success of the BPCA has transformed the drug development process for children. It is my hope that we will achieve similar success with another piece of legislation I recently introduced called the Pediatric Medical Device Safety and Improvement Act. It is also contained within the chairman's mark to S. 1082 and I thank Chairman KENNEDY and Ranking Member ENZI for working with me to ensure that medical devices used in children are safe and are designed specifically for their use.

The BPCA has had a long history of bipartisan support and it has been my longstanding hope that this initiative will continue to be bipartisan as the chairman's mark to S. 1082 moves to the Senate floor. The safety of our Nation's children is not a partisan issue.

As the parent of two young children, I know that it is essential that products used in children's growing bodies, whether they be drugs or devices, are appropriately tested and designed specifically for their use. We must continue the tremendous success of BPCA and its complementary program, the Pediatric Research Improvement Act, of which I am an original cosponsor, by strengthening both programs through the reauthorization process this year. It is essential that we use the past experience of both programs to ensure they will continue to thrive in the future.

I urge my colleagues to support this legislation.

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

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

S. 1156

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 ''Best Pharmaceuticals for Children Amendments of 2007''.

SEC. 2. PEDIATRIC STUDIES OF DRUGS.

(a) IN GENERAL.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) in subsection (a), by inserting before the period at the end the following: '', and, at the discretion of the Secretary, may include preclinical studies'';

(2) in subsection (b)—

(A) in paragraph (1)(A)(i), by striking ''(D)'' both places it appears and inserting ''(E)'';

(B) in paragraph (1)(A)(ii), by striking ''(D)'' and inserting ''(E)'';

(C) by striking ''(1)(A)(i)'' and inserting ''(A)(i)(I)'';

(D) by striking ''(ii) the'' and inserting ''(II) the'';

(E) by striking ''(B) if the drug is designated'' and inserting ''(ii) if the drug is designated'';

(F) by striking ''(2)(A)'' and inserting ''(B)(i)'';

(G) by striking ''(i) a listed patent'' and inserting ''(I) a listed patent'';

(H) by striking ''(ii) a listed patent'' and inserting ''(II) a listed patent'';

(I) by striking ''(B) if the drug is the subject'' and inserting ''(ii) if the drug is the subject'';

(J) by striking ''If'' and all that follows through ''subsection (d)(3)'' and inserting the following:

''(1) IN GENERAL.—Except as provided in paragraph (2), if, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe and the reports thereof are submitted and accepted in accordance with subsection (d)(3), and if the Secretary determines that labeling changes are appropriate, such changes are made within the timeframe requested by the Secretary—''; and

(K) by adding at the end the following:

''(2) EXCEPTION.—The Secretary shall not extend the period referred to in paragraph (1)(A) or in paragraph (1)(B) later than 9 months prior to the expiration of such period.'';

(3) in subsection (c)—

(A) in paragraph (1)(A)(i), by striking ''(D)'' both places it appears and inserting ''(E)'';

(B) in paragraph (1)(A)(ii), by striking ''(D)'' and inserting ''(E)'';

(C) by striking ''(1)(A)(i)'' and inserting ''(A)(i)(I)'';

(D) by striking ''(ii) the'' and inserting ''(II) the'';

(E) by striking ''(B) if the drug is designated'' and inserting ''(ii) if the drug is designated'';

(F) by striking ''(2)(A)'' and inserting ''(B)(i)'';

(G) by striking ''(i) a listed patent'' and inserting ''(I) a listed patent'';

(H) by striking ''(ii) a listed patent'' and inserting ''(II) a listed patent'';

(I) by striking ''(B) if the drug is the subject'' and inserting ''(ii) if the drug is the subject'';

(J) by striking ''If'' and all that follows through ''subsection (d)(3)'' and inserting the following:

''(1) IN GENERAL.—Except as provided in paragraph (2), if the Secretary determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under section 505(b)(1) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe and the reports thereof are submitted and accepted in accordance with subsection (d)(3), and if the Secretary determines that labeling changes are appropriate, such changes are made within the timeframe requested by the Secretary—''; and

(K) by adding at the end the following:

''(2) EXCEPTION.—The Secretary shall not extend the period referred to in paragraph (1)(A) or in paragraph (1)(B) later than 9 months prior to the expiration of such period.'';

(4) by striking subsection (d) and inserting the following:

''(d) CONDUCT OF PEDIATRIC STUDIES.—

''(1) REQUEST FOR STUDIES.—

''(A) IN GENERAL.—The Secretary may, after consultation with the sponsor of an application for an investigational new drug under section 505(i), the sponsor of an application for a new drug under section 505(b)(1), or the holder of an approved application for a drug under section 505(b)(1), issue to the sponsor or holder a written request for the conduct of pediatric studies for such drug. In issuing such request, the Secretary shall take into account adequate representation of children of ethnic and racial minorities. Such request to conduct pediatric studies shall be in writing and shall include a timeframe for such studies and a request to the sponsor or holder to propose pediatric labeling resulting from such studies.

''(B) SINGLE WRITTEN REQUEST.—A single written request—

''(i) may relate to more than 1 use of a drug; and

''(ii) may include uses that are both approved and unapproved.

''(2) WRITTEN REQUEST FOR PEDIATRIC STUDIES.—

''(A) REQUEST AND RESPONSE.—

''(i) IN GENERAL.—If the Secretary makes a written request for pediatric studies (including neonates, as appropriate) under subsection (b) or (c), the applicant or holder, not later than 180 days after receiving the written request, shall respond to the Secretary as to the intention of the applicant or holder to act on the request by—

''(I) indicating when the pediatric studies will be initiated, if the applicant or holder agrees to the request; or

''(II) indicating that the applicant or holder does not agree to the request and the reasons for declining the request.

''(ii) DISAGREE WITH REQUEST.—If, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the applicant or holder does not agree to the request on the grounds that it is not possible to develop the appropriate pediatric formulation, the applicant or holder shall submit to the Secretary the reasons such pediatric formulation cannot be developed.

''(B) ADVERSE EVENT REPORTS.—An applicant or holder that, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, agrees to the request for such studies shall provide the Secretary, at the same time as submission of the reports of such studies, with all postmarket adverse event reports regarding the drug that is the subject of such studies and are available prior to submission of such reports.

''(3) MEETING THE STUDIES REQUIREMENT.—Not later than 180 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 180 days, whether the studies fairly respond to the written request, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with the requirements of the Secretary for filing.

''(4) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.'';

(5) by striking subsections (e) and (f) and inserting the following:

''(e) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—

''(1) IN GENERAL.—The Secretary shall publish a notice of any determination, made on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, that the requirements of subsection (d) have been met and that submissions and approvals under subsection (b)(2) or (j) of section 505 for a drug will be subject to the provisions of this section. Such notice shall be published not later than 30 days after the date of the Secretary's determination regarding market exclusivity and shall include a copy of the written request made under subsection (b) or (c).

''(2) IDENTIFICATION OF CERTAIN DRUGS.—The Secretary shall publish a notice identifying any drug for which, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, a pediatric formulation was developed, studied, and found to be safe and effective in the pediatric population (or specified subpopulation) if the pediatric formulation for such drug is not introduced onto the market within 1 year of the date that the Secretary publishes the notice described in paragraph (1). Such notice identifying such drug shall be published not later than 30 days after the date of the expiration of such 1 year period.

''(f) INTERNAL REVIEW OF WRITTEN REQUESTS AND PEDIATRIC STUDIES.—

''(1) INTERNAL REVIEW.—

''(A) IN GENERAL.—The Secretary shall create an internal review committee to review all written requests issued and all reports submitted on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, in accordance with paragraphs (2) and (3).

''(B) MEMBERS.—The committee under subparagraph (A) shall include individuals, each of whom is an employee of the Food and Drug Administration, with the following expertise:

''(i) Pediatrics.

''(ii) Biopharmacology.

''(iii) Statistics.

''(iv) Drugs and drug formulations.

''(v) Legal issues.

''(vi) Appropriate expertise pertaining to the pediatric product under review.

''(vii) One or more experts from the Office of Pediatric Therapeutics, including an expert in pediatric ethics.

''(viii) Other individuals as designated by the Secretary.

''(2) REVIEW OF WRITTEN REQUESTS.—All written requests under this section shall be reviewed and approved by the committee established under paragraph (1) prior to being issued.

''(3) REVIEW OF PEDIATRIC STUDIES.—The committee established under paragraph (1) shall review all studies conducted pursuant to this section to determine whether to accept or reject such reports under subsection (d)(3).

''(4) TRACKING PEDIATRIC STUDIES AND LABELING CHANGES.—The committee established under paragraph (1) shall be responsible for tracking and making available to the public, in an easily accessible manner, including through posting on the website of the Food and Drug Administration—

''(A) the number of studies conducted under this section;

''(B) the specific drugs and drug uses, including labeled and off-labeled indications, studied under this section;

''(C) the types of studies conducted under this section, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;

''(D) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons such formulations were not developed;

''(E) the labeling changes made as a result of studies conducted under this section;

''(F) an annual summary of labeling changes made as a result of studies conducted under this section for distribution pursuant to subsection (k)(2); and

''(G) information regarding reports submitted on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007.'';

(6) in subsection (g)—

(A) in paragraph (1)—

(i) by striking ''(c)(1)(A)(ii)'' and inserting ''(c)(1)(A)(i)(II)''; and

(ii) by striking ''(c)(2)'' and inserting ''(c)(1)(B)'';

(B) in paragraph (2), by striking ''(c)(1)(B)'' and inserting ''(c)(1)(A)(ii)'';

(C) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively;

(D) by striking ''LIMITATIONS.—A drug'' and inserting ''LIMITATIONS.—

''(1) IN GENERAL.—Notwithstanding subsection (c)(2), a drug''; and

(E) by adding at the end the following:

''(2) EXCLUSIVITY ADJUSTMENT.—

''(A) ADJUSTMENT.—

''(i) IN GENERAL.—With respect to any drug, if the organization designated under subparagraph (B) notifies the Secretary that the combined annual gross sales for all drugs with the same active moiety exceeded $1,000,000,000 in any calendar year prior to the time the sponsor or holder agrees to the initial written request pursuant to subsection (d)(2), then each period of market exclusivity deemed or extended under subsection (b) or (c) shall be reduced by 3 months for such drug.

''(ii) DETERMINATION.—The determination under clause (i) of the combined annual gross sales shall be determined—

''(I) taking into account only those sales within the United States; and

''(II) taking into account only the sales of all drugs with the same active moiety of the sponsor or holder and its affiliates.

''(B) DESIGNATION.—The Secretary shall designate an organization other than the Food and Drug Administration to evaluate whether the combined annual gross sales for all drugs with the same active moiety exceeded $1,000,000,000 in a calendar year as described in subparagraph (A). Prior to designating such organization, the Secretary shall determine that such organization is independent and is qualified to evaluate the sales of pharmaceutical products. The Secretary shall re-evaluate the designation of such organization once every 3 years.

''(C) NOTIFICATION.—Once a year at a time designated by the Secretary, the organization designated under subparagraph (B) shall notify the Food and Drug Administration of all drugs with the same active moiety with combined annual gross sales that exceed $1,000,000,000 during the previous calendar year.''.

(7) in subsection (i)—

(A) in the heading, by striking ''SUPPLEMENTS'' and inserting ''CHANGES'';

(B) in paragraph (1)—

(i) in the heading, by inserting ''APPLICATIONS AND'' after ''PEDIATRIC'';

(ii) by inserting ''application or'' after ''Any'';

(iii) by striking ''change pursuant to a report on a pediatric study under'' and inserting ''change as a result of any pediatric study conducted pursuant to''; and

(iv) by inserting ''application or'' after ''to be a priority''; and

(C) in paragraph (2)(A), by—

(i) striking ''If the Commissioner'' and inserting ''If, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Commissioner''; and

(ii) striking ''an application with'' and all that follows through ''on appropriate'' and inserting ''the sponsor and the Commissioner have been unable to reach agreement on appropriate'';

(8) by striking subsection (m);

(9) by redesignating subsections (j), (k), (l), and (n), as subsections (k), (m), (o), and (p), respectively;

(10) by inserting after subsection (i) the following:

''(j) OTHER LABELING CHANGES.—If, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary determines that a pediatric study conducted under this section does or does not demonstrate that the drug that is the subject of the study is safe and effective, including whether such study results are inconclusive, in pediatric populations or subpopulations, the Secretary shall order the labeling of such product to include information about the results of the study and a statement of the Secretary's determination.'';

(11) in subsection (k), as redesignated by paragraph (9)—

(A) in paragraph (1)—

(i) by striking ''a summary of the medical and'' and inserting ''the medical, statistical, and''; and

(ii) by striking ''for the supplement'' and all that follows through the period and inserting ''under subsection (b) or (c).'';

(B) by redesignating paragraph (2) as paragraph (3); and

(C) by inserting after paragraph (1) the following:

''(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—Beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary shall require that the sponsors of the studies that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(4)(F) distribute, at least annually (or more frequently if the Secretary determines that it would be beneficial to the public health), such information to physicians and other health care providers.'';

(12) by inserting after subsection (k), as redesignated by paragraph (9), the following:

''(l) ADVERSE EVENT REPORTING.—

''(1) REPORTING IN YEAR ONE.—Beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, during the 1-year period beginning on the date a labeling change is made pursuant to subsection (i), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109). In considering such reports, the Director of such Office shall provide for the review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such Committee regarding whether the Secretary should take action under this section in response to such reports.

''(2) REPORTING IN SUBSEQUENT YEARS.—Following the 1-year period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics all pediatric adverse event reports for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such Committee regarding whether the Secretary should take action in response to such reports.

''(3) EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.'';

(13) by inserting after subsection (m), as redesignated by paragraph (9), the following:

''(n) REFERRAL IF PEDIATRIC STUDIES NOT COMPLETED.—

''(1) IN GENERAL.—Beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, if pediatric studies of a drug have not been completed under subsection (d) and if the Secretary, through the committee established under subsection (f), determines that there is a continuing need for information relating to the use of the drug in the pediatric population (including neonates, as appropriate), the Secretary shall carry out the following:

''(A) For a drug for which a listed patent has not expired, make a determination regarding whether an assessment shall be required to be submitted under section 505B. Prior to making such determination, the Secretary may take not more than 60 days to certify whether the Foundation for the National Institutes of Health has sufficient funding at the time of such certification to initiate 1 or more of the pediatric studies of such drug referred to in the sentence preceding this paragraph and fund 1 or more of such studies in their entirety. Only if the Secretary makes such certification in the affirmative, the Secretary shall refer such pediatric study or studies to the Foundation for the National Institutes of Health for the conduct of such study or studies.

''(B) For a drug that has no listed patents or has 1 or more listed patents that have expired, determine whether there are funds available under section 736 to award a grant to conduct the requested studies pursuant to paragraph (2).

''(2) FUNDING OF STUDIES.—If, pursuant to paragraph (1), the Secretary determines that there are funds available under section 736 to award a grant to conduct the requested pediatric studies, then the Secretary shall issue a proposal to award a grant to conduct the requested studies. If the Secretary determines that funds are not available under section 736, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act for the conduct of studies.

''(3) PUBLIC NOTICE.—The Secretary shall give the public notice of—

''(A) a decision under paragraph (1)(A) not to require an assessment under section 505B and the basis for such decision;

''(B) the name of any drug, its manufacturer, and the indications to be studied pursuant to a grant made under paragraph (2); and

''(C) any decision under paragraph (2) to refer a drug for inclusion on the list established under section 409I of the Public Health Service Act.

''(4) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of Title 18, United States Code.'';

(14) in subsection (p), as redesignated by paragraph (9)—

(A) striking ''6-month period'' and inserting ''3-month or 6-month period'';

(B) by striking ''subsection (a)'' and inserting ''subsection (b)''; and

(C) by striking ''2007'' both places it appears and inserting ''2012''.

(b) EFFECTIVE DATE.—Except as otherwise provided in the amendments made by subsection (a), such amendments shall apply to written requests under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) made after the date of enactment of this Act.

SEC. 3. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.

Section 409I of the Public Health Service Act (42 U.S.C. 284m) is amended—

(1) by striking subsections (a) and (b) and inserting the following:

''(a) LIST OF PRIORITY ISSUES IN PEDIATRIC THERAPEUTICS.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary, acting through the Director of the National Institutes of Health

and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop and publish a priority list of needs in pediatric therapeutics, including drugs or indications that require study. The list shall be revised every 3 years.

''(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing and prioritizing the list under paragraph (1), the Secretary shall consider—

''(A) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;

''(B) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of therapeutics, including drugs and biologics, may be beneficial in pediatric populations; and

''(C) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators.

''(b) PEDIATRIC STUDIES AND RESEARCH.—The Secretary, acting through the National Institutes of Health, shall award funds to entities that have the expertise to conduct pediatric clinical trials or other research (including qualified universities, hospitals, laboratories, contract research organizations, practice groups, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct the drug studies or other research on the issues described in subsection (a). The Secretary may use contracts, grants, or other appropriate funding mechanisms to award funds under this subsection.'';

(2) in subsection (c)—

(A) in the heading, by striking ''CONTRACTS'' and inserting ''PROPOSED PEDIATRIC STUDY REQUESTS'';

(B) by striking paragraphs (4) and (12);

(C) by redesignating paragraphs (1), (2), and (3), as paragraphs (2), (3), and (4);

(D) by inserting before paragraph (2), as redesignated by subparagraph (C), the following:

''(1) SUBMISSION OF PROPOSED PEDIATRIC STUDY REQUEST.—The Director of the National Institutes of Health shall, as appropriate, submit proposed pediatric study requests for consideration by the Commissioner of Food and Drugs for pediatric studies of a specific pediatric indication identified under subsection (a). Such a proposed pediatric study request shall be made in a manner equivalent to a written request made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act, including with respect to the information provided on the pediatric studies to be conducted pursuant to the request. The Director of the National Institutes of Health may submit a proposed pediatric study request for a drug for which—

''(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act; or

''(ii) there is a submitted application that could be approved under the criteria of section 505(j) of the Federal Food, Drug, and Cosmetic Act; and

''(B) there is no patent protection or market exclusivity protection for at least 1 form of the drug under the Federal Food, Drug, and Cosmetic Act; and

''(C) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.'';

(E) in paragraph (2), as redesignated by subparagraph (C)—

(i) by inserting ''based on the proposed pediatric study request for the indication or indications submitted pursuant to paragraph (1)'' after ''issue a written request'';

(ii) by striking ''in the list described in subsection (a)(1)(A) (except clause (iv))'' and inserting ''under subsection (a)''; and

(iii) by inserting ''and using appropriate formulations for each age group for which the study is requested'' before the period at the end;

(F) in paragraph (3), as redesignated by subparagraph (C)—

(i) in the heading, by striking ''CONTRACTS'';

(ii) by striking ''paragraph (1)'' and inserting ''paragraph (2)'';

(iii) by striking ''or if a referral described in subsection (a)(1)(A)(iv) is made,'';

(iv) by striking ''for contract proposals'' and inserting ''for proposals''; and

(v) by inserting ''in accordance with subsection (b)'' before the period at the end;

(G) in paragraph (4), as redesignated by subparagraph (C)—

(i) by striking ''contract''; and

(ii) by striking ''paragraph (2)'' and inserting ''paragraph (3)'';

(H) in paragraph (5)—

(i) by striking the heading and inserting ''CONTRACTS, GRANTS, OR OTHER FUNDING MECHANISMS''; and

(ii) by striking ''A contract'' and all that follows through ''is submitted'' and inserting ''A contract, grant, or other funding may be awarded under this section only if a proposal is submitted'';

(I) in paragraph (6)(A)—

(i) by striking ''a contract awarded'' and inserting ''an award''; and

(ii) by inserting '', including a written request if issued'' after ''with the study''; and

(3) by inserting after subsection (c) the following:

''(d) DISSEMINATION OF PEDIATRIC INFORMATION.—Not later than 1 year after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary, acting through the Director of the National Institutes of Health, shall study the feasibility of establishing a compilation of information on pediatric drug use and report the findings to Congress.''

''(e) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—There are authorized to be appropriated to carry out this section—

''(A) $200,000,000 for fiscal year 2008; and

''(B) such sums as are necessary for each of the 4 succeeding fiscal years.

''(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.''.

SEC. 4. REPORTS AND STUDIES.

(a) GAO REPORT.—Not later than January 31, 2011, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to Congress a report that addresses the effectiveness of section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) in ensuring that medicines used by children are tested and properly labeled, including—

(1) the number and importance of drugs for children that are being tested as a result of the amendments made by this Act and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

(2) the number and importance of drugs for children that are not being tested for their use notwithstanding the provisions of this Act and the amendments made by this Act, and possible reasons for the lack of testing, including whether the number of written requests declined by sponsors or holders of drugs subject to section 505A(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(g)(2)), has increased or decreased as a result of the amendments made by this Act;

(3) the number of drugs for which testing is being done and labeling changes required, including the date labeling changes are made and which labeling changes required the use of the dispute resolution process established pursuant to the amendments made by this Act, together with a description of the outcomes of such process, including a description of the disputes and the recommendations of the Pediatric Advisory Committee;

(4) any recommendations for modifications to the programs established under section 505A of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355a) and section 409I of the Public Health Service Act that the Secretary determines to be appropriate, including a detailed rationale for each recommendation; and

(5)(A) the efforts made by the Secretary to increase the number of studies conducted in the neonate population; and

(B) the results of those efforts, including efforts made to encourage the conduct of appropriate studies in neonates by companies with products that have sufficient safety and other information to make the conduct of the studies ethical and safe.

(b) IOM STUDY.—Not later than 3 years after the date of enactment of this Act, the Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine to conduct a study and report to Congress regarding the written requests made and the studies conducted pursuant to section 505A of the Federal Food, Drug, and Cosmetic Act. The Institute of Medicine may devise an appropriate mechanism to review a representative sample of requests made and studies conducted pursuant to such section in order to conduct such study. Such study shall—

(1) review such representative written requests issued by the Secretary since 1997 under subsections (b) and (c) of such section 505A;

(2) review and assess such representative pediatric studies conducted under such subsections (b) and (c) since 1997 and labeling changes made as a result of such studies; and

(3) review the use of extrapolation for pediatric subpopulations, the use of alternative endpoints for pediatric populations, neonatal assessment tools, and ethical issues in pediatric clinical trials.

SEC. 5. TRAINING OF PEDIATRIC PHARMACOLOGISTS.

(a) INVESTMENT IN TOMORROW'S PEDIATRIC RESEARCHERS.—Section 452G(2) of the Public Health Service Act (42 U.S.C. 285g–10(2)) is amended by adding before the period at the end the following: '', including pediatric pharmacological research''.

(b) PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM.—Section 487F(a)(1) of the Public Health Service Act (42 U.S.C. 288–6(a)(1)) is amended by inserting ''including pediatric pharmacological research,'' after ''pediatric research,''.

SEC. 6. FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH.

Section 499(c)(1)(C) of the Public Health Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by striking ''and studies listed by the Secretary pursuant to section 409I(a)(1)(A) of the is Act and referred under section 505A(d)(4)(C) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(a)(d)(4)(C)'' and inserting ''and studies for which the Secretary issues a certification under section 505A(n)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(n)(1)(A))''.

SEC. 7. CONTINUATION OF OPERATION OF COMMITTEE.

Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended by adding at the end the following:

''(d) CONTINUATION OF OPERATION OF COMMITTEE.—Notwithstanding section 14 of the

Federal Advisory Committee Act (5 U.S.C. App.), the advisory committee shall continue to operate during the 5-year period beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007.''.

SEC. 8. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC DRUGS ADVISORY COMMITTEE.

Section 15 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (B), by striking ''and'' after the semicolon;

(ii) in subparagraph (C), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following:

''(D) provide recommendations to the internal review committee created under section 505A(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(f)) regarding the implementation of amendments to sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a and 355c) with respect to the treatment of pediatric cancers.''; and

(B) by adding at the end the following:

''(3) CONTINUATION OF OPERATION OF SUBCOMMITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act (5 U.S.C. App.), the Subcommittee shall continue to operate during the 5-year period beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007.''; and

(2) in subsection (d), by striking ''2003'' and inserting ''2009''.

SEC. 9. EFFECTIVE DATE AND LIMITATION FOR RULE RELATING TO TOLL-FREE NUMBER FOR ADVERSE EVENTS ON LABELING FOR HUMAN DRUG PRODUCTS.

(a) IN GENERAL.—Notwithstanding subchapter II of chapter 5, and chapter 7, of title 5, United States Code (commonly known as the ''Administrative Procedure Act'') and any other provision of law, the proposed rule issued by the Commissioner of Food and Drugs entitled ''Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products'', 69 Fed. Reg. 21778, (April 22, 2004) shall take effect on January 1, 2008, unless such Commissioner issues the final rule before such date.

(b) LIMITATION.—The proposed rule that takes effect under subsection (a), or the final rule described under subsection (a), shall, notwithstanding section 17(a) of the Best Pharmaceuticals for Children Act (21 U.S.C. 355b(a)), not apply to a drug—

(1) for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355);

(2) that is not described under section 503(b)(1) of such Act (21 U.S.C. 353(b)(1)); and

(3) the packaging of which includes a toll-free number through which consumers can report complaints to the manufacturer or distributor of the drug.

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 154—DEMANDING THE RETURN OF THE USS ''PUEBLO'' TO THE UNITED STATES NAVY

Mr. ALLARD submitted the following resolution; which was referred to the Committee on Foreign Relations:

S. RES. 154

Whereas the USS *Pueblo*, which was attacked and captured by the Navy of North Korea on January 23, 1968, was the first ship of the United States Navy to be hijacked on the high seas by a foreign military force in more than 150 years;

Whereas 1 member of the USS *Pueblo* crew, Duane Hodges, was killed in the assault, while the other 82 crew members were held in captivity, often under inhumane conditions, for 11 months;

Whereas the USS *Pueblo*, an intelligence collection auxiliary vessel, was operating in international waters at the time of the capture, and therefore did not violate the territorial waters of North Korea;

Whereas the capture of the USS *Pueblo* resulted in no reprisals against the Government or people of North Korea and no military action at any time; and

Whereas the USS *Pueblo*, though still the property of the United States Navy, has been retained by the Government of North Korea for more than 30 years, was subjected to exhibition in the North Korean cities of Wonsan and Hungham, and is now on display in Pyongyang, the capital city of North Korea: Now, therefore, be it

Resolved, That the Senate—

(1) demands the return of the USS *Pueblo* to the United States Navy; and

(2) directs the Secretary of the Senate to transmit copies of this resolution to the President, the Secretary of Defense, and the Secretary of State.

SENATE RESOLUTION 155—EXPRESSING THE SENSE OF THE SENATE ON EFFORTS TO CONTROL VIOLENCE AND STRENGTHEN THE RULE OF LAW IN GUATEMALA

Mr. DODD (for himself and Mr. LEAHY) submitted the following resolution; which was referred to the Committee on Foreign Relations:

S. RES. 155

Whereas warring parties in Guatemala ended a 36-year internal armed conflict with a peace agreement in 1996, but the country has since faced alarming levels of violence, organized crime, and corruption;

Whereas the alleged involvement of senior officials of the National Civilian Police in the murder of three Salvadoran parliamentarians and their driver, and the subsequent killing of four of the police officers while in custody underscored the need to purge and strengthen law enforcement and judicial institutions in Guatemala;

Whereas high-level officials of the Government of Guatemala have acknowledged the infiltration of organized criminal networks into the state apparatus and the difficulty of combating these networks when they are deeply entrenched in public institutions;

Whereas, in its 2006 Country Report on Human Rights Practices in Guatemala, the Department of State noted that police corruption was a serious problem in Guatemala and that there were credible allegations of involvement by individual police officers in criminal activity, including rapes, killings, and kidnappings;

Whereas, in its most recent report on Guatemala, the United Nations High Commissioner for Human Rights notes that impunity continues to undermine the credibility of the justice system in Guatemala and that the justice system is still too weak to confront organized crime and its powerful structures; and

Whereas, the Government of Guatemala and the United Nations signed an agreement on December 12, 2006, to establish the International Commission against Impunity in Guatemala (Comisión Internacional Contra la Impunidad en Guatemala—CICIG), to assist local authorities in investigating and dismantling the illegal security groups and clandestine organizations that continue to operate in Guatemala: Now, therefore, be it

Resolved, That—

(1) it is the sense of the Senate that the International Commission against Impunity in Guatemala is an innovative mechanism to support local efforts to confront the entrenched and dangerous problem posed by illegal armed groups and clandestine security organizations in Guatemala and their infiltration into state institutions;

(2) the Senate commends the Government of Guatemala, local civil society organizations, and the United Nations for such a creative effort;

(3) the Senate encourages the Guatemalan Congress to enact necessary legislation required to implement the International Commission against Impunity in Guatemala and other pending legislation needed to fulfill the 1996 peace agreement;

(4) the Senate calls on the Government of Guatemala and all sectors of society in Guatemala to unreservedly support the investigation and prosecution of illegal armed groups and clandestine security organizations; and

(5) the Senate reiterates its commitment to support the Government of Guatemala in its efforts to strengthen the rule of law in that country, including the dismantling of the clandestine groups, the purging of the police and judicial institutions, and the implementation of key justice and police reforms.

SENATE RESOLUTION 156—COMMENDING THE ACHIEVEMENTS OF THE RUTGERS UNIVERSITY WOMEN'S BASKETBALL TEAM AND APPLAUDING THE CHARACTER AND INTEGRITY OF THE PLAYERS AS STUDENT-ATHLETES

Mr. LAUTENBERG (for himself, Mr. MENENDEZ, Mr. LEAHY, and Mr. OBAMA) submitted the following resolution; which was considered and agreed to:

S. RES. 156

Whereas under head coach C. Vivian Stringer the Rutgers University women's basketball team (referred to in this preamble as the ''Lady Knights'') finished an extraordinary 2006–2007 season with a 27–9 record;

Whereas, after losing 4 of their first 6 games, the Lady Knights refused to give up and spent their winter break in the gym honing their skills and working to become a better team for the rest the season;

Whereas, on March 6, 2007, the Lady Knights upset the top-seeded University of Connecticut team for their first-ever Big East Championship title;

Whereas the young women of the Lady Knights displayed great talent in their run to the Final Four of the women's National Collegiate Athletic Association (NCAA) tournament;

Whereas 5 freshmen played an integral role in the team's march to the championship game;

Whereas the Lady Knights showed enormous composure with tournament wins against teams playing in their home States;

Whereas, through hard work and determination, the young team fought through improbable odds to reach the NCAA title game;

Whereas the team was just the third number 4 seed in history to reach the championship;