(Mr. BURNS) was added as a cosponsor of S. 2085, a bill to provide a supplemental payment to assist agricultural producers in mitigating increasing input costs, including energy and fertilizer costs.

S. 2088

At the request of Mr. ALLARD, the name of the Senator from New Hampshire (Mr. SUNUNU) was added as a cosponsor of S. 2088, a bill to assist low-income families, displaced from their residences in the States of Alabama, Louisiana, and Mississippi as a result of Hurricane Katrina, by establishing within the Department of Housing and Urban Development a homesteading initiative that offers displaced low-income families the opportunity to purchase a home owned by the Federal Government, and for other purposes.

S. RES. 33

At the request of Mr. LEVIN, the name of the Senator from Connecticut (Mr. LIEBERMAN) was added as a cosponsor of S. Res. 33, a resolution urging the Government of Canada to end the commercial seal hunt.

S. RES. 283

At the request of Mr. ALLEN, the name of the Senator from Hawaii (Mr. INOUYE) was added as a cosponsor of S. Res. 283, a resolution recognizing the contributions of Korean Americans to the United States and encouraging the celebration of ''Korean American Day''.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Ms. MIKULSKI:

S. 2097. A bill to assist members of the Armed Forces in obtaining United States citizenship, and for other purposes; to the Committee on the Judiciary.

Ms. MIKULSKI. Mr. President, I am here today to talk about a bill I will be introducing that rights a wrong and corrects a terrible injustice. I am introducing legislation called the Kendell Frederick Citizenship Assistance Act of 2005. This is legislation was inspired by a young man from the State of Maryland, who was in the Army, had a green card, was serving this country, though not a citizen, and was killed while serving in Iraq. He was killed by a roadside bomb on his way to be fingerprinted, on his way to become a U.S. citizen. He died on his way to become a U.S. citizen because of the failed and flawed information he was given by our immigration system.

He was a terrific young man, who came to this country when he was fifteen from Trinidad. He joined his mother here in the U.S. and wanted so much to be part of this country. He wanted to serve this country and so he joined the ROTC when he was in high school. In fact, Randallstown High School has one of the best high school ROTCs programs that Maryland has. After graduation, he then joined the Army and off he went to train to serve this country.

He was killed by the botched bureaucracy of the U.S. Government, by their incompetence, by their indifference, by their ineptitude; and this is absolutely inexcusable. Every military death in Iraq is a tragedy, but this one did not need to happen. I am going to tell you a little bit about him and then tell you what happened.

As I said, he graduated from high school and he decided to join the Army with hopes that he would go back to school. In the Army he was a generator mechanic assigned to a heavy combat battalion. His job was to keep that battalion running. All he wanted was to do a good job, help his buddies stay alive, stay alive himself, defend what we were doing in Iraq and, along the way, become an American citizen and come back home and resume his life. He had been trying to become an American citizen for a while. He started working on it when he joined the Army.

Mr. President, because I know of your keen interest in national security, I understand that you know when you join the Army you are fingerprinted and a background check is run. We just don't let anybody join the United States Army. You can't get in if you are a drug dealer, if you have an extensive criminal record or if you would be a threat to the security of the United States. You can't get in if there is even a hint that you might be connected to a terrorist organization. So Kendell Frederick was accepted into the Army after all these security checks were run and his background was vetted. Then he sent in his citizenship application but, guess what, he checked the wrong box. What did that mean? Here he was, training for war, packing up to go to Iraq, saying goodbye to his mom, his brother and two sisters and in the middle of this he checked the wrong box saying that he was not in the military. So his application was derailed, not once but three different times.

The first time was after his mother checked the correct box saying that Kendell was in the military. Immigration sent the application to the wrong office, not the one that handles military applications that is on a fast track but the general one where all the applications are all stacked up. Second, Immigration rejected the fingerprints that were sent from the military. There was no explanation. His mother did not know why the fingerprints had been rejected. He had sent in the paperwork from Iraq. As I said, Kendell had already been fingerprinted, had already had his background vetted when he joined the military. So here was a guy who had been fingerprinted and cleared to join the military. The Army had said, you are OK, Kendell. He had an FBI background check run. The FBI said you are OK, Kendell. The Army wants somebody like you. But when he tried to get through Immigration, they said no, the fingerprints he had taken when he joined the military and even the fingerprints he sent into immigration were not enough.

Finally, when his mother called this 1–800 Immigration number—you try to call that number—she got no help. It is like trying to make a call from the Superdome in the middle of Katrina. You are not going to get help going to get the right answer. His mother called that number. They told his mother that he had to return from Baghdad and go to Baltimore to get his fingerprints. His mother got on the phone again, because he can't call from Baghdad—he is being shot at, he is trying to defend himself and the troops of the United States of America—so he was a little busy, couldn't afford to get a busy signal from Immigration.

When his mother called and said, ''My boy is in Baghdad,'' Immigration at the 800 number told her, there was nothing they could do. They didn't even know their own rules. They didn't know their own system. They didn't know their own laws. Immigration was wrong. They gave his mother the wrong information.

So here is Kendell, still keeping in touch, still trying to do his job, trying to get his fingerprints taken to become a U.S. citizen. Finally, there was an arrangement made. His staff sergeant came to his rescue and made arrangements for him to be fingerprinted at a nearby air base so he could complete this application. On October 19, with the help of his staff sergeant, he was traveling in a convoy to get his fingerprints. He didn't usually go in convoys, but that day he was on that convoy to get his fingerprints to become an American citizen—to compensate for the botched mistakes of Immigration—and on his way a roadside bomb killed him.

They told his mother that immigration would give Kendell U.S. citizenship. They granted his citizenship a week after he died. He was buried at Arlington, as he should have been. He was trying to do the right thing, yet he was given the wrong information.

As I said, his staff sergeant tried to help him, his mother tried to help him, but the system, the immigration system, failed him time and time again.

When I called his mother—and I try to call all the families of our military from Maryland who die; some I reach, some I do not—I spoke to his mother. She said to me that she did not want another mother to go through what she went through, to go through what her son went through. Service members and their moms and dads should not be worrying about what box to check, where the fingerprints are, et cetera. She said Immigration should know their own rules. When we explained to her the rules of Immigration, that he should have been fast tracked, that these fingerprints should have been OK, that he did not have to pay a $400 fee, she said, ''Nobody told me that.'' Every time I called, I got different information.

I am introducing legislation today to prevent this from happening again. His mother asked me to introduce legislation, and she asked me to call it the

Kendell Frederick law. I am doing that today, and over in the House Congressman ELIJAH CUMMINGS is doing the same thing. We made this promise when we stood in the church, a small, humble church in an African-American community in Baltimore. We made this pledge to his mother that we would do this for her and we are here today to do just that.

The legislation I am introducing today makes it easier for military servicemembers to become citizens. The provisions cut through the redtape. It requires Immigration to use the fingerprints the military takes when the person enlists in the military.

It requires the creation of a military citizen advocate to inform the servicemembers about the citizenship process and help with the application.

It also means they won't leave boot camp unless they are absolutely apprised of all of the rules and all of the regulations about how to apply to become a U.S. citizen.

The very process they have to go through to join the military, fingerprinting and FBI background check, should be good enough. Because you see, deep down inside, we believe that if you are good enough to fight for this country, you are good enough to become a citizen of this country.

There is a pileup of 3,000 people with green cards fighting in our military today who have applied to become American citizens. You should not have to be standing in that kind of line. We are not saying let anyone become a U.S. citizen, but these are men and women who joined the military and fighting for this country. They have a green card, they have been fingerprinted, and they have passed an FBI check. Why do they have to go through it all over again?

We are passing a law that would stop this needless bureaucracy, and we are establishing a special 800 number for our military and their families.

We talk a lot about standing up for our troops, and we certainly should stand up for our troops. This means we should stand up for them and enable them to follow their dreams. They are certainly standing up for us.

Today, we introduced the Kendell Frederick bill to make sure that anyone in the military who wants to be a U.S. citizen, who has a green card, and who passed the fingerprint checks will be able to do so quickly and easily. If they are willing to fight for America and die for America, they should be able to become an American citizen.

I will be circulating a ''Dear Colleague'' to my colleagues to join it. I hope we can pass this legislation on a bipartisan basis so that as men and women such as Kendell Frederick fight for freedom, we ensure that their memory is not in vain.

I thank the Chair.

By Ms. MURKOWSKI (for herself, Mr. AKAKA, and Mr. BINGAMAN):

S. 2098. A bill to amend the Energy Employees Occupational Illness Compensation Program Act of 2000 to clarify the eligibility of certain employees of the Department of Energy under that Act; to the Committee on Health, Education, Labor, and Pensions.

Ms. MURKOWSKI. Mr. President, I send to the desk for appropriate reference legislation that will clarify that citizens of the former Trust Territory of the Pacific Islands are eligible for coverage and potential compensation under the Energy Employees Occupational Illness Compensation Program Act, EEOICPA, for workers who developed radiogenic cancers and other ailments after working at the Pacific Test Site in the Marshall Islands.

An estimated up to 500 Republic of Marshall Islanders and other Micronesian workers may have been employed by the Department of Energy, or its predecessor agency, or Department subcontractors prior to 1986 when the Trusteeship was terminated for all areas except Palau. Both Bikini and Enewetak Atolls were the sites for numerous nuclear and thermonuclear tests. Other atolls, such as Rongelap and Utrik, were affected by fallout from the Bravo hydrogen bomb test in March 1954.

Congress, in 2000, approved a compensation program to provide aid and pay medical bills for those who suffered radiation-caused illnesses because of working on the nuclear weapons program. Congress specifically set up a ''Special Exposure Cohort'' to provide compensation to certain workers with radiogenic cancer and other illnesses because it was presumed that their illnesses resulted from workplace exposure to radiation caused by their Government work. Congress, in 2004, amended the act, first approved in the 2001 Military Construction Authorization Act, to speed payments of compensation, including funds for lost wages to workers or their heirs, to those who worked for the Department of Energy and its predecessor agency on nuclear weapons programs.

Earlier this year the Committee on Energy and Natural Resources held an oversight hearing to review a number of issues raised by the government of the Republic of the Marshall Islands related to the effects of the nuclear testing program. One of the issues was coverage for residents of the then-trust territory who were employed during the testing and subsequent cleanup. During that period, the United States was the administering authority over the area under a United Nations Trusteeship Agreement and exercised all the powers of a sovereign. It seems somewhat incongruous for the Congress to have established a program that applied to U.S. citizens but not to those who lived and worked under U.S. administration.

That also seems reasonable, since there is little other reason for the specific inclusion of the Pacific Test Site if the workers were not to be covered. During Senate debate, Senator BINGAMAN, a conferee on the amendment, submitted a list of DOE facilities intended to be covered by the act—a list which included the Marshall Islands, 146 Cong. Rec. S. 4754–7.

While most of the issues raised by the Minister of Foreign Affairs for the Marshall Islands during our oversight hearing are now being discussed with various Federal agencies under the auspices of Secretary of the Interior Norton, this is an issue that will require congressional action, given the interpretations from Federal agencies that questioned whether Congress intended the Act to apply extraterritorially. The act, of course, applies to individuals not jurisdictions and the specific mention of the Pacific Test Site and Enewetak would seem to indicate that Congress intended to include workers at the site.

Subsequent to the hearing, I had the privilege to meet privately with the President of the Marshall Islands when he visited Washington in early September. We had a good meeting and at the time I offered my assistance in ensuring that the proper agencies or groups would review the issues they had raised. As I indicated, most of these issues are properly now being discussed with representatives of the Marshalls through a multi-agency dialogue headed by Secretary Norton. This issue, however, may be one that is best handled directly through the congressional process. Therefore, when I was asked by the Marshall's Embassy here in Washington if I would introduce a bill to clarify worker eligibility so that the proper congressional committees could review it, I agreed.

Given the paperwork, record and radiation dosage requirements for receipt of compensation, it is far from clear how many Marshallese and Micronesian workers will actually qualify for the up to $150,000 in compensation, plus medical benefits and lost wage compensation for ailments caused by radiation stemming from the weapons tests. That is an issue that I hope the congressional committees will consider sympathetically. But it is only just that the program be opened equally to all Department of Energy workers or subcontract workers who labored to produce nuclear weapons to help this Nation's national defense at a critical period of the Cold War. As an Alaskan from a State whose workers have been compensated for injuries they gained resulting from underground weapons testing at Amchitka Island in the Aleutian Chain almost immediately after the ending of weapons testing in the atmosphere over the Marshall Islands, it is impossible not to support aid for the Marshallese.

While Congress and the administration continue to weigh additional aid to the Republic of the Marshall Islands, passage of this measure would be a sign of this Nation's continued commitment to aid the islanders who in February 1946 followed the advice of Bikinian leader, King Juda, and agreed to leave the Bikini Atoll so America could use

it for weapons testing saying, ''We will go believing that everything is in the hands of God.''

I appreciate the understanding and the patience shown by the Marshall's Government and their citizens as we proceed to review the issues raised concerning the effects of the nuclear testing program, and I hope the introduction of this legislation will be seen as an example of our commitment to see that those issues receive a full and fair review and discussion.

By Mr. REID (for himself, Mr. ENSIGN, Mr. BENNETT, and Mr. HATCH):

S. 2099. A bill to amend the Nuclear Waste Policy Act of 1982 to require commercial nuclear utilities to transfer spent nuclear fuel from spent nuclear fuel pools into spent nuclear fuel dry casks and convey to the Secretary of Energy title to all spent nuclear fuel thus safely stored; to the Committee on Environment and Public Works.

Mr. REID. Mr. President, I rise today for Senator ENSIGN, Senator BENNETT and myself to introduce a bill to increase the safety and security of our Nation's nuclear power infrastructure, The Spent Nuclear Fuel On-Site Storage Security Act of 2005.

I am convinced that the proposed Yucca Mountain nuclear waste dump will never be built because of the myriad of scientific, safety and technical problems in which it is mired. It simply is neither safe nor secure, as illustrated by several significant scientific, legal, and budgetary setbacks this past year.

Here are some of the highlights: On July 9, 2004, the DC Circuit Court of Appeals sided with the people of Nevada in a lawsuit to stop the proposed Yucca Mountain project. The court decided that U.S. Environmental Protection Agency's radiation standard for the site was not stringent enough to protect the public from the significant risks associated with nuclear waste and failed to follow the recommendation by the National Academy of Sciences.

On August 31, 2004, the Nuclear Regulatory Commission's Atomic Safety and Licensing Board rejected Department of Energy's Yucca Mountain document database, saying it had failed to make public many of the documents that it had in its possession. The Board said, ''Given the 15 years that DOE had to gather, review, and produce its documents and the fact that the date of production, and the incompleteness of its privilege review, it is clear to us that DOE did not meet its obligation, in good faith, to make all reasonable efforts to make all documentary materials available.''

On October 4, 2004, the DOE Inspector General found that DOE has given away more than $500,000 worth of Yucca Mountain construction equipment in 2003. Half a million dollars is a tremendous amount of the people's money to waste.

On November 22, 2004, the Nuclear Waste Technical Review Board said DOE does not have a plan for safely transporting nuclear waste to the proposed repository.

On February 7, 2005, Dr. Margaret Chu, most recently the Director of the Office of Civilian Radioactive Waste Management, said the project would be delayed until 2012 and that DOE's license application to the Nuclear Regulatory Commission would not be filed until December 2005, delayed a year. To date, the license application still has not been filed.

On February 8, 2005, the Nuclear Waste Technical Review Board have called for hearings to review concerns over the corrosion of the titanium drip shields that are intended to keep water from leaking into casks inside Yucca Mountain.

On February 28, 2005, a DOE official said the proposed Yucca Mountain repository may not open until 2015.

On March 16, 2005, DOE revealed that documents and models about water infiltration at Yucca Mountain, a key issue, had been falsified.

On July 18, 2005, DOE announced that it will use dedicated train service for its rail transport of spent nuclear fuel and high-level waste to Yucca Mountain, a shift from two decades of administration policy that ignores the fact that about one-third of reactor sites are not capable of shipping fuel by rail.

On August 22, 2005, EPA published its revised radiation standards for the proposed Yucca Mountain high-level waste dump. These standards are wholly inadequate, do not meet the law's requirements and do not protect public health and safety.

On October 13, 2005, DOE began a series of actions to overhaul the Yucca Mountain project. We are going back to the drawing board, frequently revisiting proposals discarded decades ago as unsafe or unworkable.

On October 25, 2005, DOE announced that it would be redesigning the spent fuel storage process, both the containers and facilities.

On November 16, 2005, the DOE Inspector General announced that DOE has ignored numerous admitted instances of falsification of technical and scientific date on the project, showing that years of quality assurance problems continue.

On November 17, 2005, DOE sent a detailed letter to its contractor specifying some of the desired changes in the site proposal.

At the December 7, 2005, at the NRC–DOE quarterly meeting on Yucca Mountain, DOE announced that it expects to re-baseline the project mid-2006, requiring many of the technical and scientific analyses to be redone.

On November 19, 2005, the Energy and Water Appropriations bill became law, cutting the Yucca Mountain budget to $577 million, half of what DOE said it would need to keep the project on track.

In numerous media reports, DOE has confirmed that it is preparing a legislative package that addresses Yucca Mountain. Clearly, DOE cannot meet the current public health, safety and technical requirements.

It should be clear to anyone that the proposed Yucca Mountain project is scientifically unsound and that it cannot meet the requirements of law. It is not going anywhere. Delay after delay costs the taxpayers billions and billions of dollars for a project that the courts have ruled does not meet sufficient safety or public health standards. I do not believe that Yucca Mountain will ever open, and Nevada and the country will be safer for our successful efforts to stop the project.

Yet, we must safely store spent nuclear fuel.

A 1979 study by the Sandia National Laboratory determined that, if all the water were to drain from a spent fuel pool, dense-packed spent fuel would likely heat up to the point where it would burst and then catch fire, releasing massive quantities of volatile radioactive fission products into the air. Both the short-term and the long-term contamination impacts of such an event could be significantly worse than those from Chernobyl. The consequences would be so severe and would affect such a large area that all precautions must be taken to preclude them. This is the type of serious, avoidable risk against which all the Nation's nuclear sites can and should be protected to counter terrorist threats.

It is time to look at other nuclear waste alternatives. Fortunately, the technology to realize a viable, safe and secure alternative is readily available and can be fully implemented within 6 years if we act now. That technology is dry cask storage.

The technology for long-term storage of spent nuclear fuel in dry storage casks has improved dramatically in the past 20 years. Seventeen cask designs have. been licensed by the Nuclear Regulatory Commission, which says that spent nuclear fuel can be safely stored using dry cask storage on-site at the nuclear power plants for at least 100 years. Already, dry casks safely store spent nuclear fuel at 34 sites throughout the country, many of them near communities, water ways and transportation routes. The Nuclear Energy Institute has projected 83 of the 103 active reactors will have dry storage by 2050.

Compared to water-filled pools, dry storage casks are significantly less vulnerable to natural and human-induced disasters, including floods, tornadoes, temperature extremes, sabotage, and missile attacks. In addition, dry storage casks are not subject to drainage risks, whether intentional or accidental.

On March 28, 2005, the Washington Post revealed that a classified National Academy of Sciences report concluded that the government does not fully understand the risks a terrorist attack

could pose to spent nuclear fuel pools and that it ought to expedite the removal of the fuel to dry storage casks that are more resilient to attack.

Our bill requires commercial nuclear utilities to safely transfer spent nuclear fuel from temporary storage in water-filled pools to secure storage in licensed, on-site dry cask storage facilities. After transferal, the Secretary of Energy will take title and full responsibility for the possession, stewardship, maintenance, and monitoring of all spent fuel thus safely stored. Finally, our bill establishes a grant program to compensate utilities for expenses associated with transferring the waste. The costs of transferring the waste and providing the grants will be offset by withdrawals from the utility-funded Nuclear Waste Fund.

Nuclear facilities currently provide 20 percent of our Nation's electricity, but in light of the events of September 11, they also present a security risk that we simply must address. There cannot be any weak links in the chain of security of our Nation's nuclear power infrastructure. There is absolutely no justification for endangering the public by densely packing nuclear waste in vulnerable spent fuel pools when it can be stored safely and securely in dry casks. This bill guarantees all Americans that our Nation's nuclear waste will be stored in the safest way possible.

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

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

S. 2099

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 ''Spent Nuclear Fuel On-Site Storage Security Act of 2005''.

SEC. 2. DRY CASK STORAGE OF SPENT NUCLEAR FUEL.

(a) IN GENERAL.—Title I of the Nuclear Waste Policy Act of 1982 (42 U.S.C. 10121 et seq.) is amended by adding at the end the following:

''Subtitle I—Dry Cask Storage of Spent Nuclear Fuel

''SEC. 185. DRY CASK STORAGE OF SPENT NUCLEAR FUEL.

''(a) DEFINITIONS.—In this section:

''(1) CONTRACTOR.—The term 'contractor' means a person that holds a contract under section 302(a).

''(2) SPENT NUCLEAR FUEL POOL.—The term 'spent nuclear fuel pool' means a water-filled container in which spent nuclear fuel rods are stored.

''(3) SPENT NUCLEAR FUEL DRY CASK.—The term 'spent nuclear fuel dry cask' means the container, and all the components and systems associated with the container, in which spent nuclear fuel is stored at a Commission-licensed independent spent fuel storage facility located at the power reactor site. The design of any such spent nuclear fuel dry cask shall be approved by the Commission.

''(b) TRANSFER OF SPENT NUCLEAR FUEL.—

''(1) IN GENERAL.—A contractor shall transfer spent nuclear fuel from spent nuclear fuel pools to spent nuclear fuel dry casks at a Commission-licensed independent spent fuel storage facility located at the power reactor site.

''(2) SPENT NUCLEAR FUEL STORED AS OF DATE OF ENACTMENT.—A contractor shall complete the transfer of all spent nuclear fuel that is stored in spent nuclear fuel pools as of the date of enactment of this subsection not later than 6 years after the date of enactment of this subsection.

''(3) SPENT NUCLEAR FUEL STORED AFTER DATE OF ENACTMENT.—A contractor shall complete the transfer of any spent nuclear fuel that is stored in a spent nuclear fuel pool after the date of enactment of this subsection not later than 6 years after the date on which the spent nuclear fuel is discharged from the reactor.

''(4) INADEQUATE FUNDS.—If funds are not available to complete a transfer under paragraph (2) or (3), the contractor may apply to the Commission to extend the deadline for the transfer to be completed.

''(c) FUNDING.—The Secretary shall make grants to compensate a contractor for expenses incurred in carrying out subsection (b), including costs associated with—

''(1) licensing and construction of an independent spent fuel storage facility located at the power reactor site;

''(2) construction and delivery of spent nuclear fuel dry casks;

''(3) transfers of spent nuclear fuel;

''(4) documentation relating to the transfers;

''(5) security; and

''(6) hardening.

''(d) CONVEYANCE OF TITLE.—

''(1) DETERMINATION.—Not later than 30 days after the transfer of spent nuclear fuel from a spent nuclear fuel pool to a spent nuclear fuel dry cask, the Commission shall determine whether the contractor carried out the transfer in full compliance with regulations promulgated by the Commission.

''(2) NONCOMPLIANCE.—If the Commission determines that any technical standard or compliance provision under the regulations was not complied with, the Commission shall—

''(A) notify the contractor; and

''(B) take such actions as are necessary to obtain full compliance.

''(3) CERTIFICATION AND CONVEYANCE OF TITLE.—When the Commission determines that the contractor has fully complied with the regulations—

''(A) the Commission shall certify that safe transfer has been accomplished; and

''(B) the Secretary shall accept the conveyance of title to the spent nuclear fuel dry cask (including the contents of the cask) from the contractor.

''(4) RESPONSIBILITY.—A conveyance of title under paragraph (3)(B) shall confer on the Secretary full responsibility (including financial responsibility) for the possession, stewardship, maintenance, and monitoring of all spent nuclear fuel transferred to the Secretary.''.

(b) FUNDING.—Section 302(d) of the Nuclear Waste Policy Act of 1982 (42 U.S.C. 10222(d)) is amended—

(1) in paragraph (5), by striking ''and'' at the end;

(2) in paragraph (6), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(7) the provision of grants under section 185(d).''.

SEC. 3. IMMEDIATE CONVEYANCE OF TITLE TO SPENT NUCLEAR FUEL PREVIOUSLY CERTIFIED TO BE IN COMPLIANCE.

Not later than 30 days after the date of enactment of this Act, the Secretary of Energy shall accept the conveyance of title to all spent nuclear fuel with respect to which, before the date of enactment of this Act, the Nuclear Regulatory Commission has certified that a contractor under section 302 of the Nuclear Waste Policy Act of 1982 (42 U.S.C. 10222) has completed transfer to spent nuclear fuel dry casks in compliance with applicable regulations in effect as of the date of transfer.

By Mr. SMITH (for himself and Mr. KERRY):

S. 2100. A bill to amend the Internal Revenue Code of 1986 to improve the deduction for depreciation; to the Committee on Finance.

Mr. SMITH. Mr. President, our economy has changed dramatically in recent years as a result of the development of new technologies and industries. However, we have not updated our tax depreciation system to reflect these advancements. In fact, the recovery periods used to calculate depreciation allowances have not been adjusted since 1986—and in some cases not since 1962. For example, a personal computer has a depreciable life of 5 years even though its economic life is only 2 to 3 years.

Today, I am introducing legislation that will respond to these changes by modernizing and simplifying the tax depreciation rules. Senator KERRY has joined me in introducing the Tax Depreciation, Modernization and Simplification Act of 2005, which will encourage capital investment and make it easier for companies to comply with the tax law.

This legislation will allow the Treasury Department, in consultation with Congress, to modify and create new class lives for capital assets. Any new classification created by the Treasury Department must reflect the anticipated useful life and decline in value over time of the asset. In addition, it should take into account when the asset is technologically or functionally obsolete for its original purpose. With this new regulatory authority, Treasury will be able to develop class lives that are more in line with assets' economic lives.

Another provision in this legislation deals with the mid-quarter convention. The mid-quarter convention is one of the placed-in-service conventions that directs when depreciation for an asset begins or ends. The mid-quarter convention, however, creates significant complexity. Taxpayers must wait until after the tax year ends to determine whether to use the half-year or mid-quarter convention. Therefore, consistent with a Joint Committee on Taxation recommendation, the bill eliminates the mid-quarter convention for simplification purposes.

Small businesses are the heart of our economy. We, in Congress, should do everything we can to ease the administrative burdens for small businesses. That is why we should make small business expensing permanent. These rules permit small businesses to expense immediately up to $100,000 of the cost of property each year. This proposal will maintain this important simplification which is set to expire at the end of 2007.

Finally, this legislation will allow for mass asset accounting. Currently, companies must generally calculate depreciation on an item-by-item basis. For example, if a company has 200 desks or 200 computers, they must account for and depreciate each item separately. This can be a challenge and an administrative burden for companies—especially with small items, like chairs and telephones. Therefore, the bill will permit all companies to elect to use mass asset accounting for property that costs less than $10,000.

The bipartisan Tax Depreciation, Modernization and Simplification Act of 2005 will make much needed changes to the tax depreciation system. I look forward to working with my colleagues to enact these important reforms and 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. 2100

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 ''Tax Depreciation, Modernization, and Simplification Act of 2005''.

SEC. 2. AUTHORITY TO MODIFY CLASS LIVES.

(a) IN GENERAL.—Paragraph (1) of section 168(i) of the Internal Revenue Code of 1986 is amended to read as follows:

''(1) CLASS LIFE.—

''(A) IN GENERAL.—Except as provided in this section, the term 'class life' means the class life (if any) which would be applicable with respect to any property as of January 1, 1986, under subsection (m) of section 167, as in effect on the day before the date of the enactment of the Revenue Reconciliation Act of 1990 (determined without regard to paragraph (4) thereof and as if the taxpayer had made an election under such subsection).

''(B) SECRETARIAL AUTHORITY.—

''(i) IN GENERAL.—Except as provided in clause (ii), the Secretary, after consultation with Congress, may prescribe by regulation—

''(I) a new class life for any property, or

''(II) a class life for any property which does not have a class life within the meaning of subparagraph (A).

''(ii) EXCEPTIONS.—Clause (i) shall not apply to—

''(I) residential rental property or nonresidential real property, or

''(II) property for which a class life, classification, or recovery period is assigned under subsection (e)(3) (other than subparagraph (C)(v) thereof) or subparagraph (B), (C), or (D) of subsection (g)(3).

''(iii) STANDARDS.—Any class life prescribed or modified under clause (i) shall reasonably reflect the anticipated useful life and the anticipated decline in value over time of the property to the industry or other group, and shall take into account when the property is technologically or functionally obsolete for the original purpose under which it was acquired.

''(iv) CONSULTATION.—Not later than 60 days before the date on which the Secretary publishes any proposed regulation under clause (i), the Secretary shall submit to Congress the proposed regulation together with a report containing the information considered by the Secretary in modifying or prescribing any class life under the regulation.

''(v) MONITORING.—The Secretary, through an office established in the Treasury, shall monitor and analyze actual experience with respect to depreciable assets to which this subparagraph applies.

''(C) EFFECT OF MODIFICATION.—Any class life with respect to any property prescribed or modified under subparagraph (B) shall be used in classifying such property under subsection (e) and in applying subsection (g).''.

(b) APPLICATION OF CONGRESSIONAL REVIEW ACT.—For purposes of applying chapter 8 of title 5, United States Code, to any regulation prescribed under section 168(i)(1)(B) of the Internal Revenue Code of 1986, each class life prescribed under such section shall be considered to be a separate rule.

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

SEC. 3. ELIMINATION OF MID-QUARTER CONVENTION.

(a) IN GENERAL.—Subsection (d) of section 168 of the Internal Revenue Code of 1986 is amended—

(1) by striking paragraph (3) and redesignating paragraph (4) as paragraph (3), and

(2) in paragraph (3), as redesignated by paragraph (1), by striking subparagraph (C).

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to property placed in service after the date of the enactment of this Act.

SEC. 4. MASS ASSET ACCOUNTING.

(a) IN GENERAL.—Section 168 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subsection:

''(l) MASS ASSET ACCOUNTING.—

''(1) ELECTION.—

''(A) IN GENERAL.—In lieu of the deduction otherwise allowed under this section with respect to an item of qualified property, the taxpayer may elect to add the adjusted basis of such property to the mass asset account of the taxpayer to which such qualified property is assigned and to determine the deduction under this section using the applicable depreciation method with respect to such mass asset account.

''(B) ELECTION TO APPLY TO ALL ASSETS OF THE TAXPAYER WITH SAME RECOVERY PERIOD.—An election made under subparagraph (A) shall be made in such manner as the Secretary may by regulations prescribe and shall apply to all qualified property of the taxpayer which has the same applicable recovery period for such taxable year and all subsequent taxable years.

''(C) ELECTION IRREVOCABLE.—Any election made under this paragraph shall be irrevocable except with the consent of the Secretary. The Secretary shall prescribe rules for the proper accounting of assets in a mass asset account in the case of any such revocation.

''(2) SPECIAL RULES.—

''(A) MODIFICATION OF DEPRECIATION METHOD.—In applying the applicable depreciation method to any mass asset account, subsection (b) shall be applied without regard to paragraph (1)(B) thereof.

''(B) ADJUSTMENT TO REFLECT HALF-YEAR CONVENTION.—In applying the deduction allowable under subsection (a) to any mass asset account, the amount of the deduction under subsection (a) shall be—

''(i) 100 percent of the deduction otherwise allowed under this section in the case of qualified property placed in service before the beginning of the taxable year, and

''(ii) 50 percent of the deduction otherwise allowed under this section with respect to qualified property placed in service during the taxable year.

''(C) SALE OF QUALIFIED PROPERTY.—

''(i) IN GENERAL.—In the case of the sale of any property the adjusted basis of which has been added to a mass asset account, the balance of the mass asset account to which such property was assigned shall be reduced (but not below zero) by the amount of the proceeds from such sale.

''(ii) RECOGNITION OF GAIN.—If the proceeds from the sale of any property the adjusted basis of which has been added to a mass asset account exceed the balance of such mass asset account, then the excess shall be treated as ordinary income.

''(3) QUALIFIED PROPERTY.—

''(A) IN GENERAL.—For purposes of this subsection, the term 'qualified property' means any tangible property—

''(i) to which an applicable depreciation method under paragraph (1) or (2) of subsection (b) applies, and

''(ii) the cost of which is not more than $10,000.

''(B) INFLATION ADJUSTMENT.—

''(i) IN GENERAL.—In the case of any taxable year beginning after 2006, the $10,000 amount under subparagraph (A)(ii) shall be increased by an amount equal to—

''(I) such dollar amount, multiplied by

''(II) the cost-of-living adjustment determined under section 1(f)(3) for the calendar year in which the taxable year begins, determined by substituting 'calendar year 2005' for 'calendar year 1992' in subparagraph (B) thereof.

''(ii) ROUNDING.—If any amount as adjusted under the clause (i) is not a multiple of $1,000, such amount shall be rounded to the next lowest multiple of $1,000.

''(4) MASS ASSET ACCOUNT.—The term 'mass asset account' means an account of the taxpayer which reflects the adjusted basis of all qualified property to which the same applicable depreciation method and applicable recovery period applies.''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to property placed in service after the date of the enactment of this Act.

SEC. 5. PERMANENT EXTENSION OF EXPENSING FOR SMALL BUSINESSES.

(a) DOLLAR LIMITATION.—Paragraph (1) of section 179(b) of the Internal Revenue Code of 1986 is amended by striking ''$25,000 ($100,000 in the case of taxable years beginning after 2002 and before 2008)'' and inserting ''$100,000''.

(b) REDUCTION IN LIMITATION.—Paragraph (2) of section 179(b) of such Code is amended by striking ''$200,000 ($400,000 in the case of taxable years beginning after 2002 and before 2008)'' and inserting ''$400,000''.

(c) INFLATION ADJUSTMENTS.—Subparagraph (A) of section 179(b)(5) of such Code is amended by striking ''and before 2008''.

(d) ELECTION.—Paragraph (2) of section 179(c) of such Code is amended by striking ''and before 2008''.

(e) COMPUTER SOFTWARE.—Clause (ii) of section 179(d)(1)(A) is amended by striking ''and before 2008''.

Mr. KERRY. Mr. President, today Senator SMITH and I are introducing the Tax Depreciation, Modernization, and Simplification Act of 2005. Last July, the Senate Finance Subcommittee on Long-Term Growth and Debt Reduction, on which Senator SMITH is chairman and I am ranking member, held a hearing on updating our depreciation system. During the hearing, we heard that the current depreciation system is out of date and that changes should be made.

Our tax system allows, as a current expense, a depreciation deduction that represents a reasonable allowance for the exhaustion, wear and tear of property used, or of property held for the production of income. Since 1981, the

depreciation deduction for most tangible property has been under rules specified in section 168 of the Internal Revenue Code. The Modified Accelerated Cost Recovery System, or MACRS, specified under section 168 applies to most new investment in tangible property. MACRS depreciation allowances are computed by determining a recovery period called a class life and an applicable recovery method for each asset.

The current depreciation system has not kept pace with technological advances. Several industries were not even contemplated when class lives were assigned in 1981, and some class lives even date back to 1962.

In the 1980s it would have been difficult to imagine what our reliance on computer and wireless technology would be today. At that time, for example, the wireless industry was in its infancy, and there was no specifically assigned life for wireless equipment. As a result, today's depreciation system is like playing ''audit roulette.'' There is no certainty in how these assets should be depreciated.

All this matters because it impacts investment, innovation, competitiveness, and ultimately the quality and quantity of jobs in America. My home State of Massachusetts is a leader in the high tech industry. Massachusetts employs hundreds of thousands of skilled workers in key technology sectors, including computer hardware, life sciences, software, medical products, semiconductor, defense technology and telecommunications. We have learned in Massachusetts that a strategic tax policy can have a positive effect on economic competitiveness.

For these reasons, we are introducing the Tax Depreciation, Modernization, and Simplification Act of 2005. This legislation makes four important changes to the current depreciation system.

First, the legislation creates a process that provides the Department of Treasury with the authority to modernize class lives. The Secretary of the Treasury will prescribe regulations to provide a new class life for certain eligible property. Eligible property does not include residential rental property, nonresidential real property, or property for which Congress has specifically legislated the recovery period.

The purpose of this provision is to provide Treasury with a mechanism to modify class lives that reasonably reflect the anticipated useful life and the anticipated decline in value over time of the property to the industry and take into account when the property becomes technologically or functionally obsolete to perform its original purpose. Treasury will also have the authority to modify class lives in order to more accurately reflect economic depreciation. For example, a personal computer has a depreciable life of 5 years, but it has an economic life of only 2 to 3 years. Even though a computer can be used for 5 years, it becomes economically obsolete after a couple of years because of the newer, faster, and more advanced computers on the market.

Our depreciation system has not been adequately updated since Congress revoked Treasury's rule making authority in 1988. When the MACRS system was enacted in 1986, Congress directed Treasury to establish an office to monitor and analyze the actual experience with class lives and to modify class lives if the new class life reasonably reflected the anticipated useful life and the anticipated decline in value over time of the property to the industry. The authority was then revoked because Congress did not agree with all of the decisions made by Treasury.

The authority provided in this legislation addresses this previous problem by requiring Treasury to consult with Congress 60 days prior to publishing any proposed regulations. In addition, the Congressional Review Act would apply to any regulation proposed by Treasury and each class life prescribed by Treasury would be considered a separate rule.

Providing Treasury with the authority to modify class lives would allow the process to move more efficiently than allowing Congress to make piecemeal changes to the current depreciation system. Congress would provide guidelines, and Treasury would have the role of administering the guidelines. Under the legislation, Treasury would monitor and analyze the actual experience of depreciable assets and report their findings to Congress. We expect Treasury to establish guidelines that will take into consideration the fact that some assets lose a significant percentage of their original value in the early part of their lives. This legislation specifically provides consultation with Congress in order for Congress to continue to have a role in this important tax policy issue.

We do not expect Treasury within the first year or two to review all classes of assets. Rather, we expect Treasury to begin with new assets that do not fit into the system, assets that have underdone technological advances, and existing assets that do not really fit into the current system. For example, the current system creates an irrational result for fiber optic lines. The class life of a fiber optic line depends upon whether if it is used for one-way or two-way communications.

Second, the legislation would eliminate the mid quarter convention. The placed-in-service conventions determine the point in time during the year that the property is considered ''placed in service'' and this determines when depreciation for an asset begins or ends. Under current law, there are the half-year, mid month, and mid quarter conventions. The mid quarter convention is a source of complexity because it requires an analysis of the depreciable basis of property placed in service during the last 3 months of any taxable year. The Joint Committee on Taxation recommended the elimination of the mid-quarter convention in its 2001 recommendations on simplifying the Federal tax system. The calculation of the mid-quarter convention is burdensome, and it requires taxpayers to wait until after the end of the taxable year to determine whether the proper placed-in-service convention was used to calculate depreciation for assets during the taxable year.

Third, the legislation would allow taxpayers to elect to use mass asset accounting for assets with a cost of less than $10,000. Generally, taxpayers calculate depreciation on an item-by-item basis. The bill would allow taxpayers to elect to use mass asset accounting for all assets with the same recovery period. This provision will help simplify the recordkeeping associated with depreciation.

Fourth, the legislation would permanently extend increased expensing for small businesses. In lieu of depreciation, a taxpayer with a small amount of annual investment may elect to deduct such costs. The Jobs and Growth Tax Relief Reconciliation Act of 2003 increased the amount a taxpayer may deduct from $25,000 to $100,000 and increased the total amount of investment a business can make in a year and still qualify for expensing from $200,000 to $400,000. In addition, the Act allows off-the-shelf computer software to be eligible for the provision. These changes originally were effective for 3 years. The American Jobs Creation Act of 2004 provided an additional 2 year extension of this provision through 2007.

The Tax Depreciation, Modernization, and Simplification Act of 2005 would make the $100,000 and $400,000 amounts permanent and index them for inflation. Off-the-shelf computer software would be eligible for the provision. Increased expensing for small businesses helps lower the cost of capital for small businesses and eliminates complicated recordkeeping. In addition, it should reduce administrative costs for small businesses.

The provisions in this legislation will not be the only recommendations made on how to improve our current depreciation system, but the four components of this legislation will result in updating and simplifying the current depreciation system. The Tax Depreciation, Modernization, and Simplification Act of 2005 will provide certainty for taxpayers and put an end to ''audit roulette.''

By Mr. REID (for Mr. LIEBERMAN (for himself, Mr. COCHRAN, Mr. CARPER, and Mrs. HUTCHISON)):

S. 2104. A bill to amend the Public Health Service Act to establish the American Center for Cures to accelerate the development of public and private research efforts towards tools and therapies for human diseases with the goal of early disease detection, prevention, and cure, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

(At the request of Mr. REID, the following statement was ordered to be printed in the RECORD.)

Mr. LIEBERMAN. Mr. President, today, Senator COCHRAN, Senator CARPER, Senator HUTCHISON, and I are introducing the American Center for CURES Act of 2005, which would establish the American Center for Cures, within the National Institutes of Health (NIH). The purpose of the Center would be to bring promising and novel diagnostics, therapies, drugs, and tools to treat disease faster to the public.

We continue to face significant health challenges. In the US today, chronic diseases account for 7 out of 10 deaths, with the major killers being heart attack, cancer and stroke. Seventy percent of the $1.7 trillion dollars we spend on healthcare each year goes to chronic disease care. Around the world, HIV, tuberculosis, and malaria kill 4, 3, and 2 million people a year. On the horizon are emerging manmade and natural threats such as SARS, flu and bioterrorism. There are other diseases that we need better treatments and cures for, but that we do not devote enough attention to. Diseases of social stigma, such as depression, which is the most frequent reason people visit their physician, and seizure disorder, which is the primary neurological disorder in children, are often neglected. We have bacteria growing and spreading in our hospitals that do not respond to our antibiotic supply. These are the health challenges facing us in the 21st century.

Fortunately, the United States has no equal in the biomedical sciences. This is due in large part to our nation's premier biomedical research investment the—NIH, which receives $28 billion per year after a doubling of their budget of $14 billion from 1998 to 2003. The NIH is comprised of 27 major institutes and centers, leading the way for the world in cancer, cardiovascular, infectious disease and allergy advancements for health promotion and relief from the burdens of disease. US biomedical advances are also due to our dynamic biotechnology and pharmaceutical sectors.

In our search for answers to our pressing health problems, the NIH has grown in the number of Institutes and Centers and in funding. At the same time, Congress and others have wanted to ensure that we are building on NIH's strengths to respond to complex health problems requiring interdisciplinary and collaborative work. Therefore, Congress commissioned the 2003 National Academy of Sciences report, ''Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges'', that examined whether and how we could optimize the NIH's organizational structure to meet our next set of health challenges.

The report stated that ''no organization as important as NIH should remain frozen in organization space''. At the same time, the report cautioned that any changes in organizational structure to achieve greater progress in chronic and emerging diseases were not without some difficulty and risk. The NAS report made a number of recommendations and our CURES legislation addresses the six major points.

First, CURES seeks to strengthen the clinical research process by streamlining the clinical trials process by creating Centralized Internal Review Boards (CIRB). CIRB's would focus on simplifying the human subjects review processes for multi-institutional clinical trials. CURES also significantly augments current NIH investments to train the clinical research workforce of the future, and provides additional funding for multidisciplinary teams of researchers examining issues of quality and design of clinical trials. We need to continue to bring safe and effective diagnostics and therapeutics, but more efficiently.

Secondly, our proposal enhances and increases trans-NIH strategic planning and funding. Currently, the NIH's 27 Centers and Institutes each have their own directors and budgets and thus, operate independently. The resulting structural and organizational stovepipes are limited in their ability to capitalize on the NIH's collective research capacity to address complex problems using the expertise of multiple fields. For example, the problem of diabetic retinopathy could be tackled by researchers in the Institutes of the Eye, Diabetes, Digestive and Kidney disease, Biomedical Imaging and Bioengineering, and Allergy Immunology and Infectious disease. However, there are few mechanisms for such trans-Institute initiatives that could lead to a cure or treatment. To address this problem, CURES has created multiple funding mechanisms for trans-Institute research and cross-fertilization of ideas. Strategic planning and prioritizing disease research is also integral to achieving progress more quickly. Therefore, the American Center for CURES Act would establish a CURES council, comprised of key health stakeholders to produce a translational research agenda for the Center based on research breakthroughs and areas of health need.

Thirdly, the American Center for CURES Act of 2005 strengthens the Office of the NIH Director. Our legislation emphasizes the need for greater budgetary support and flexibility in the area of translational research. This follows much of the NIH Director's current efforts with the NIH Roadmap. Our legislation further supports the spirit of the NIH Roadmap with organizational and funding commitments that bring translational research investment to a necessary and appropriate scale, which has not been the case to date. The NIH Director, with the CURES Advisory Council, would play a key role in these efforts by recommending appointees for the Director of the American Center for CURES to the President. The NIH Director will also be a co-chair of the Center's Council and have a leading role in setting the research and funding priorities for translational research projects at the NIH. The NIH Director will also head other initiatives outlined in the legislation, such as launching a publicly accessible electronic database for all published NIH funded research.

Fourth, our legislation creates a Director's Special Projects Program, called the Health Advanced Research Projects Agency (HARPA). The NAS committee recommended the creation of a program to support high-risk, high-potential payoff research. The Department of Defense has had significant success with its Defense Advanced Research Program Agency (DARPA), where a group of expert portfolio managers invest in and oversee innovative, multidisciplinary, collaborative projects to advance specific fields or to develop needed technologies. DARPA has lead to the creation of stealth technology, satellite surveillance, lasers, internet, and e-mail. Based on this model, HARPA would be housed within the Center and would help lead breakthrough advances using a translational ''challenge model'' in biomedical research. Breakthroughs could include a vaccine or other treatment against HIV or genetic probes pivotal to the elucidation of disease producing genes. HARPA would also be the key funding mechanism for trans-Institute research to prioritize and foster collaborative and trans-Institute research initiatives.

Fifth, the NAS report recommended that the NIH intramural research program be more unique, innovative, and risk-taking. In response, CURES creates an Office of Intramural Risk Mapping, within the Office of Technology Transfer, which will oversee NIH's intramural research programs to help assure they are complementary to extramural and private sector research. The Office will also ensure that intramural research is also innovative and risk-taking to produce more novel and promising biomedical breakthroughs. The office will also make funds available to trans-Institute and center initiatives that focus on health risk analysis and corresponding scientific risk opportunity.

Sixth, our legislation addresses the NAS report recommendation to standardize data and information management systems. The report was clear that the NIH must increase its capacity for data gathering and reporting to meet its obligations ''. . . for effective management, accountability, and transparency.'' Cures seek to improve the sharing of information by providing funding to the National Library of Medicine to create and maintain a publicly accessible database of all publications resulting from NIH-funded research and by establishing a national electronic registry and results database to increase enrollment in public and private clinical trials and to share

efficacy and safety outcomes emanating from NIH-funded clinical research endeavors. Cures focuses on the need to expand the NLM facilities according to the demands of new scientific discoveries and fields, especially within the areas of genomics and proteinomics.

In addition to the NAS report recommendations, other changes in the biomedical research landscape demand more targeted investments in promising and novel treatments. Our current response to research on important health problems is arguably dichotomous. We invest public money into the NIH or we hope the private market will produce essential drugs and tools. However, there needs to be greater collaboration between the private and public sectors. Private sector investment in biomedical research has grown to approximately $46 billion per year—far more than our public sector investment in NIH. For new and effective therapies to become available, we need to build better public and private partnerships. Cures includes key provisions to accomplish this. Cures promotes the innovative efforts of small to medium sized biotechnology and bioengineering firms who require additional support in key traditionally under-funded stages of product development—the so called R&D ''Valley of Death.'' It expands the NIH's current small business support and rapid access to interventional development programs to move basic science through the product development pipeline faster. These programs would facilitate NIH partnerships with private industry in the preclinical stage of the R&D process so as to formulate a plan for health research translation and commercialization from the outset. Additionally, our legislation would move the NIH's Office of Technology Transfer into the American Center for Cures, where it would survey research being conducted in the private and public sectors to avoid duplication, target promising research investments, and broker more flexible and productive agreements for licensing and patents between the public and private sectors. The HARPA entity within the center is also designed to promote public-private joint R&D efforts.

Today, we are proposing the establishment of the American Center for Cures, whose mission would be to promote more rapid translation of public and private research into therapies, diagnostics and tools, which can effectively treat and possibly cure diseases of critical importance to domestic and global health. With more targeted investment in translating our basic science research into diagnostics and therapeutics, we hope to bring more tangible health benefits to Americans and people all over the world.

I ask unanimous consent that explanatory materials on the legislation including, ''Short Summary of the American Center for CURES Act of 2005,'' ''Explanation of How the American Center for CURES Act of 2005 Addresses the Findings of the 2003 National Academy of Sciences Report: 'Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges','' ''Section by Section Summary of the American Center for CURES Act of 2005,'' the full text of the legislation, and ''Quotes in Support of the American Center for CURES Act of 2005'' be printed in the RECORD.

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

A SHORT SUMMARY OF THE AMERICAN CENTER FOR CURES ACT OF 2005

A bill to facilitate more rapid development of novel diagnostics, therapies, and cures

From 1998–2003, Congress doubled funding to the world's leader in biomedical research, the National Institutes of Health (NIH), to $28 billion per year. In order to meet 21st century health challenges and optimize the use of this public investment, Senators Lieberman and Cochran have introduced legislation to increase the capacity of the NIH to produce effective treatments, diagnostics and cures for our nation's most burdensome diseases using a novel approach to publicly funded research.

Cures will do the following:

Create an American Center for Cures (ACC) in the NIH to orchestrate focused research and development of solutions to pressing ailments. The ACC, led by a Center Director, will identify and promote translational research, which involves developing basic science research for application purposes, in the public and private sectors. The ACC will fund innovative and collaborative research, breakdown bottlenecks in clinical research, and facilitate information exchange.

Establish an advisory council comprised of key health experts and stakeholders to advise the ACC on national medical needs and novel developments in all sectors. To use public funds effectively, a centralized mechanism to track research on health threats is necessary. A Council will inform the ACC on biomedical needs, technical feasibility issues, and current research breakthroughs.

Create a Health Advanced Projects Agency for research promotion. A research projects agency will promote strategic risk-taking and follow a ''challenge model'' to support innovative multidisciplinary research between NIH Institutes, other federal agencies, grantees and business partners, for projects with the potential for significant health impact. Funding for projects will be flexible and outcomes based.

Promote the innovative efforts of small to medium sized biotechnology and bioengineering firms. The ACC will support firms requiring assistance in key traditionally underfunded stages of research and development, the R&D ''Valley of Death''. Funding will be available to assist companies with promising and novel therapeutics and diagnostics in both preclinical and clinical stages.

Strengthen the clinical research process. Clinical trials are essential to ensuring the safety and efficacy of new products. The ACC will streamline clinical trial protocols to supply the public with new treatments in a timelier, more efficient, and more economical way. It will augment NIH training funds to create a clinical research workforce of the future. It will establish a clinical trial registry and results database to promote information sharing and to avoid duplicative efforts.

Facilitate complete and efficient transfer of intellectual property from development at the molecular level to clinical trials and into production. Active participation of the commercial sector in development is critical. An Office of Technology Transfer in the ACC will catalog and disseminate the NIH translational research portfolio and oversee NIH intellectual property licensing.

EXPLANATION OF HOW THE AMERICAN CENTER FOR CURES ACT OF 2005 ADDRESSES THE FINDINGS OF THE 2003 NATIONAL ACADEMY OF SCIENCES REPORT: ''ENHANCING THE VITALITY OF THE NATIONAL INSTITUTES OF HEALTH: ORGANIZATIONAL CHANGE TO MEET NEW CHALLENGES''

BACKGROUND

The health challenges facing the U.S. and the world today are a mix of infectious diseases, such as HIV, tuberculosis and malaria, long-standing chronic such as diabetes and cancer, and new emerging threats, such as SARS and avian influenza. In the context of these growing concerns, Congress commissioned the National Academy of Sciences (NAS) in 2001 to report on ''whether the current structure and organization of NIH are optimally configured for the scientific needs of the 21st century.'' Indeed, NIH is America's premier public research investment and between 1998 and 2003, the NIH budget of $14 billion dollars doubled to $28 billion. By commissioning the NAS report, Congress asked how it might optimize its burgeoning research investment. Congress solidified its support for the NIH but simultaneously posed questions of NIH can best address domestic and global health needs:

Are the 27 NIH Institutes and Centers able to coordinate their research goals and priorities to reflect the multidisciplinary nature of today's health problems?

How is the NIH producing and sharing biomedical knowledge from multiple disciplines to spur the development of clinical tools, drugs, and other therapies to battle long-standing and emerging diseases?

Can the NIH respond effectively to acute health threats, such as to burgeoning HIV infection rates and the threat of a bioterrorism attack?

Is the NIH cultivating the next generation of researchers to build upon the great works of NIH past?

The end result was the 2003 NAS and Institute of Medicine (IOM) report, ''Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges''. The report reinforced NIH successes over the last 50 years as the national and global leader in biomedical research. NIH accomplished this by developing a cutting edge internal research infrastructure and a democratic extramural grant program that almost single-handedly supports University-based research in the biological sciences. However, the report also cautioned that ''no organization as important as NIH should remain frozen in organizational space'' and any changes in organizational structure to achieve greater progress in chronic and emerging diseases, however essential, would face difficulty and risk.

NAS REPORT FINDINGS

The NAS report made a total of 14 recommendations. In the final analysis, the NAS report recommended maintaining the general structure of NIH to ensure NIH's strengths would be protected: conducting essential basic science, and disease, behavioral, organ, and system based research in its intramural program and funding peer-reviewed grants to University researches in its extramural program. However, the report also recognized the need for organizational changes which could help institutes work across their respective stovepipes, foster a culture of risk-taking and innovation, and

give the NIH director, other leadership, and the public the power to prioritize NIH research to solve the Nation's most burdensome health problems. Collectively, these changes would enhance the capacity of the NIH to not only pursue fundamental knowledge about the nature and behavior of living systems, but to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. This is NIH's mission.

CURES ADDRESSES THE SIX KEY RECOMMENDATIONS OF THE NAS REPORT

1. Strengthen Clinical Research: The NAS report recommended that the NIH ''pursue a new organizational strategy to better integrate leadership, funding, and management of its clinical research enterprise''. Senators Lieberman, Cochran, Carper, and Hutchison are introducing a proposal that creates the American Center for Cures (ACC), headed by a Cures Director. One of the new Director's key charges will be to promote and simplify the clinical research endeavor. The Director will establish a national electronic registry and results database for clinical trials in order to increase enrollment of research subjects and improve sharing efficacy and safety outcomes emanating from the clinical research endeavor. The Director will fund multidisciplinary clinical research teams in the academic and private sector, create Centralized Internal Review Boards (CIRB) to simplify the human subjects review processes for multi-institutional clinical trials, and augment NIH investments in training the clinical research workforce of the future.

2. Enhance and Increase Trans-NIH Strategic Planning and Funding: The 27 NIH Centers and Institutes with their own directors and budgets generally operate independently. The resulting structural and organizational stovepipes are limited in their ability to capitalize on the NIH's collective research capacity to address complex problems from different fields. For example, the problem of diabetic retinopathy could be tackled by researchers in the Institutes of the Eye, Diabetes, Digestive and Kidney disease, Biomedical Imaging and Bioengineering, and Allergy Immunology and Infectious disease. To address this problem, Cures funds innovative multidisciplinary collaborative research across NIH institutes and centers. NIH Institute and Center Directors on the Cures Council will be entrusted to coordinate the intramural research agenda with that of the ACC.

3. Strengthen the Office of the NIH Director: The NAS report emphasizes the need for the NIH Director to have more budgetary support and flexibility. Dr. Zerhouni's office has taken these steps with the NIH Roadmap. The Cures legislation further supports the spirit of the NIH Roadmap with organizational and funding commitments that bring the translational research investment to necessary and appropriate scale. The NIH Director and the Cures Advisory Council will recommend appointees for the Cures Director to the President. The NIH Director will be a co-chair of the ACC Council that will set the research and funding priorities for translational research projects at the NIH. The NIH Director will head efforts to establish a publicly accessible electronic database for all published NIH funded research, among other initiatives.

4. Create a Director's Special Projects Program: The NAS committee recommended the creation of a program to support high-risk, high-potential payoff research. The Department of Defense has had significant success with its Defense Advanced Research Program Agency (DARPA), where a group of expert portfolio managers invest in and oversee innovative, multidisciplinary, collaborative projects to advance specific fields or to develop needed technologies. DARPA has lead to the creation of the stealth technology, satellite surveillance, lasers, internet, and email. A Health Advanced Research Program Agency (HARPA) will be established within the ACC to help lead breakthrough advances, using a translational ''challenge'' model in biomedical research, such as a vaccine against HIV or genetic probes pivotal to the elucidation of disease producing genes.

5. Promote Innovation and Risk-Taking in Intramural Research: The NAS report recommended that the NIH intramural research portfolio be distinct from that of the extramural program and private sector. Cures creates an Office of Intramural Risk Mapping which will oversee the intramural research programs of the NIH to be certain they are complementary to extramural and private programs. The office will make funds available to groups of institutes and centers to promote engagement in multi-institute projects that focus on health risk analysis and corresponding scientific risk opportunity.

6. Standardize Data and Information Management Systems: The NAS committee recommended that the NIH must increase its capacity for data gathering and reporting to meet its obligations ''. . . for effective management, accountability, and transparency''. Cures seeks to improve the sharing of information by providing funding to the National Library of Medicine to create and maintain a publicly accessible database of all publications resulting from NIH-funded research and by establishing a national electronic registry and results database to increase enrollment in public and private clinical trials and to share efficacy and safety outcomes emanating from the clinical research endeavor. Cures focuses on the need to grow the NLM facilities according to the demands of new scientific discoveries and fields, especially within the areas of genomics and proteinomics.

CURES BUILD ON THE NIH ROADMAP

In response to the NAS report, NIH Director Dr. Elias Zerhouni launched the NIH Roadmap in FY 2004 with $128 million in funding from existing NIH budget allocations. Funding increases every year until FY 2009 and tops out at $507 million. The NIH Roadmap consists of:

New Pathways to Discovery to obtain a deeper understanding of biological systems based on new models.

Research Teams of the Future to facilitate collaboration across institutes by awarding grants to support institutional partnerships and cutting-edge research.

Re-engineering the Clinical Research Enterprise reforms the clinical trial process to allow for broader participation from community-level patients and providers.

While the NIH roadmap addresses some of the concerns of the NAS report, it does not address key provisions including increasing the power of the NIH Director, establishing an advanced research projects agency, and establishing a new leadership that can facilitate the research essential to moving products faster from bench to bedside. Unlike CURES, the roadmap relies on traditional academic-government relationships. CURES builds on the Roadmap to cultivate new relationships between NIH researchers and innovative industrial partners. Unlike the roadmap, which asks the NIH to focus on new priorities with old tools and funds, Cures provides much higher levels of funding for a Center uniquely devoted to translating research to produce new therapies and even cures to the most important diseases.

SECTION BY SECTION SUMMARY OF THE AMERICAN CENTER FOR CURES ACT OF 2005

A bill to facilitate more rapid development of novel diagnostics, therapies and cures critical to national and global health

Background

When it comes to investments and advancements in biomedical research, the United States has no equal. Its National Institutes of Health (NIH) is the world's largest public source of biomedical research funding with an annual budget of over $28 billion. The NIH is comprised of 27 major institutes and centers, leading the way in cancer, cardiovascular, infectious disease and allergy advancements for health promotion and relief from the burdens of disease.

The private sector is also investing substantial resources in increasing both longevity and quality of life. These companies now invest more than the federal government in biomedical research and development (R&D). Potent pharmaceuticals and cutting edge medical devices provide health care professionals with a therapeutic arsenal that has increased lifespan seven years since 1960 and dropped neonatal mortality four fold. Partnerships between NIH and private industry are not often recognized for their key roles in bringing new treatments to the public, but are of great importance as they have led to life-changing therapies from to Taxol to Claritin to HIV anti-retrovirals.

But how can biomedical R&D proceed even faster? How can partnerships between NIH's Institutes and Centers, disease-based NGO's, biotech companies and small and large pharmaceuticals occur even more frequently? Towards which diseases should our resources be prioritized in the first place? How can NIH and the private sector be more responsive to emerging public health threats such as bioterrorism, an avian flu pandemic, antibiotic resistance, and a waning vaccine supply?

Center for Cures

In response to these pressing questions and the capacity of the NIH to address our health needs, Senators Lieberman, Cochran, Carper and Hutchison are proposing a $5 billion dollar annual investment to create the American Center for Cures (ACC). The mission of this new NIH Center will be to promote more rapid translation of public and private research into therapies, diagnostics and tools, which can effectively treat and possibly cure diseases of critical importance to domestic and global health. The ACC will enhance NIH's ability to not only pursue fundamental knowledge about the nature and behavior of living systems, but to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. This is NIH's mission.

Specifically, the American Center for Cures will:

(1) Direct new resources towards the world's most burdensome diseases and towards biomedical, bioengineering, and biotechnological research with the greatest therapeutic impact and promise.

(2) Create an ACC national advisory board consisting of key health experts and stakeholders, who will help identify the critical diseases and health threats requiring greater public and private investment.

(3) Create a special Health Advanced Research Projects Agency (HARPA) to support innovative multidisciplinary collaborate research between NIH Institutes, between NIH and other federal agencies and between NIH grantees and business partners, for projects with the potential for significant health impact.

(4) Create health-centered Federally Funded Research and Development Centers (FFRDC) which will bring together interdisciplinary teams of experts including scientists, clinicians, epidemiologists, and

pharmacists for a time limited period to focus on developing therapeutic breakthroughs for important disease entities.

(5) Invest further in the development of an expert workforce which will augment the nation's translational research capacity. Such an effort will include training new clinical researchers and bioinformatics professionals.

(6) Promote risk-taking and collaboration between NIH Institutes and Centers.

(7) Streamline the clinical research process essential to determining if new treatments are effective and safe.

(8) Promote the innovative efforts of small to medium sized biotechnology and bioengineering firms who require additional support in key traditionally under-funded stages of product development—the so called R&D ''Valley of Death''.

(9) Facilitate NIH partnerships with private industry in the preclinical stage of the R&D process so as to formulate a plan for health research translation and commercialization from the outset.

(10) Standardize NIH information management systems and reporting requirements of publicly funded research to improve information sharing between the applied science, translational research and business communities.

A section by section summary of the legislation is included below.

Section 1: Short title.

Section 2: Table of contents.

Section 3: Findings.

Section 4: Amends Title IV of the Public Health Services Act to establish a new Center at the National Institutes of Health (NIH) called the American Center for Cures (ACC).

PART J—AMERICAN CENTER FOR CURES

Section 499A: Definitions.

Section 499B(a): States the mission of the proposed American Center for Cures (ACC), which is to increase the capacity of the NIH to promote translational research between its Institutes and Centers, between the NIH and other Federal agencies and between NIH grantees and business partners so as to speed the development of effective diagnostics, therapies and cures essential to human health and well being.

The ACC shall formulate and implement a strategy for the nation's translational research investment based on (1) a prioritization of biomedical research based on disease burden and research promise, and (2) funding for innovative, multi-disciplinary, and collaborative research.

The ACC will be guided in part by a series of ''Grand Challenges'' or strategic challenges that direct the health research community towards multi-staged projects with the potential to transform the healthcare landscape. Examples include: the creation of laboratory diagnostics that enable the country to detect quickly and accurately to acute health threats, such as an avian flu pandemic or a bioterrorism attack; a commitment by researchers and manufacturers from public and private sectors to develop vaccines for the world's most deadly infectious diseases including HIV, tuberculosis, and malaria. Other examples are provided in this section.

Section 499B(b): Establishes a Director of Cures (to be called in this document the ''Director'') who will administer the ACC. The President of the United States will appoint the Director. The NIH Director in consultation with the Cures Advisory Council (Section 499B(c)) will recommend candidates for the Director to the President. The NIH Director will work with the Director to promote the nation's translational research efforts.

The Director will have at his disposal an annual acceleration fund of $5 billion dollars to provide support for research and development of breakthrough biomedical discoveries and to carry out the purposes of the ACC. No less than one half of the acceleration fund will be allocated to a Health Advanced Research Projects Agency described in Subpart II.

Section 499B(c): Establishes a Cures Council to advise and direct the translational research efforts of the ACC. The Council will be co-chaired by the Director of Cures and the Director of NIH. Membership will include NIH Institute and Center Directors; leaders from at least 9 federal agencies including the Director of the Agency for Healthcare Research and Quality (AHRQ), the Director of the Defense Advanced Research Projects Agency (DARPA), and the President of the Institute of Medicine (IOM); no fewer than three leaders from the small business community; three leaders from large pharmaceutical or biotechnology companies; and three leaders from academia. All Council members will be appointed by the President.

The Council shall establish subcommittees including one of NIH Institute and Center Directors to coordinate research priorities in, and ensure sharing of research agendas among, the Institutes and Centers. The subcommittee shall also coordinate the ACC research agenda with that of the NIH Institutes and Centers.

The Council will make recommendations that help the Director set research priorities for the ACC. The Council shall consider risk and burden of disease as well as lines of research uniquely poised to deliver effective diagnostics and therapies.

The Council shall be aided by the Office of Intramural Risk Opportunity and Mapping of the Office of Technology Transfer established in subpart V.

The Council shall conduct an annual assessment of ACC priorities and progress and make this available to the public in written and electronic forms.

Section 499B(d): The Director of Cures shall prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate for the Center.

The Director will receive directly all funds appropriated by Congress for obligation and expenditure by the Center.

SUBPART 1—FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTERS

Section 499C: Federally Funded Research and Development Centers (FFRDC's) will serve as sites for multidisciplinary and cross-scientific research within particular areas of health. The Director may establish one or more FFRDC's to carry out activities related to the mission of the ACC. These Centers will establish, as appropriate, technology test beds and incubators, utilize cooperative agreements with the private sector, and conduct large-scale multi-disciplinary translational research projects in health or disease areas which are essential to medical advancement, but lack adequate private sector funding.

The FFRDC's shall consult widely with representatives from private industry, institutions of higher education, nonprofit institutions, other federal governmental agencies, and other federally funded research and development centers.

The Director shall ensure that competitive mechanisms are used to select and to promote the ongoing quality and performance of the FFRDC's.

Contracts between the ACC and FFRDC's shall be for no longer than 7 years, after which time refunding shall be contingent upon approval by the Director and the Cures Council.

Each FFRDC shall biannually submit a report on the activities carried out by the Centers under this section to the Director and the appropriate committees of Congress.

For any fiscal year, the Director may use not more than 25 percent of the funds available in the Director's Acceleration Fund for FFRDC's.

SUBPART 2—HEALTH ADVANCED RESEARCH PROJECTS AGENCY

Section 499d. Technological and scientific innovations often require strategic risk taking and significant funding streams that are rapid and are outcomes based. Funds must also encourage expert multidisciplinary collaboration. This section establishes at the ACC a Health Advanced Research Projects Agency (HARPA) for these purposes.

HARPA will be headed by a Director of the Research Projects Agency who will be appointed by the Director of Cures.

HARPA shall be composed of not more than 100 expert portfolio managers in key health areas, as determined by the Director of HARPA in conjunction with the Director and Cures Council.

HARPA shall undertake the grand challenges formulated by the Center and encourage innovative, multidisciplinary, and collaborative research between NIH Institutes and Centers, between the NIH and other Federal agencies, and between NIH grantees and business partners.

Management and organizing principles include an agency which is small, flexible, entrepreneurial, and non-hierarchical; which empowers portfolio managers to foster research opportunities free from bureaucratic impediments; which seeks to employ the strongest scientific and technical talent in the Nation; which rotates a significant portion of the staff every 3–5 years, which leverages comparable matching investment from other NIH institutes and centers, federal agencies, and from the private and non profit sectors; which creates a translational research model that supports fundamental research breakthroughs, early and late stage applied development, prototyping, knowledge diffusion, and technology deployment; which establishes metrics to evaluate research success; which ensures that revolutionary research dominates HARPA's agenda and portfolio. Other management and organizing principles are provided.

HARPA activities will include supporting basic and applied research to promote revolutionary technology changes which address health needs. It will advance the development, testing, evaluation, prototyping and deployment of critical health products. Multiple other activities are provided.

HARPA will have flexible hiring practices as described in the Strom Thurmond National Defense Authorization Act, 1999.

HARPA will have the authority to flexibly fund projects, including the prompt awarding, releasing, enhancing and withdrawal of monies.

HARPA will be funded through the Director's acceleration fund at a minimum of $2.5 billion dollars annually.

SUBPART 3—CLINICAL TRIALS

Clinical trials are an essential part of the research and development process. This is where the effectiveness and safety of products are scientifically and systematically investigated. However, clinical trials are complex, expensive, and time-consuming, making it difficult for individuals to perform all the functions necessary to successfully organize and implement clinical trials. This subpart improves how clinical trials are conducted and how their results are disseminated. It also promotes the development of a future clinical research workforce.

Section 499E. Increasing Research Study Participation: The Director of NIH shall create a national electronic clinical trial registry with the National Library of Medicine

(NLM) as specified in Subpart 6, Section 499H (b). The ACC shall publicize the registry with special attention given to minority groups, who are frequently underrepresented in clinical trials.

Section 499E–1. Grants for Quality Clinical Trial and Execution: The Director shall provide grants for clinical trial design and execution to academic centers or to private firms with highly promising therapeutic entities to fund multidisciplinary clinical research teams, whose members may include project managers, clinicians, epidemiologists, and nursing staff.

Section 499E–2. Streamlining the Regulatory Process Governing Clinical Research: This section streamlines the regulatory process governing clinical research, which has become increasingly unwieldy due to necessary but complex patient privacy and safety rules. The ACC shall establish a series of Centralized Institutional Review Boards (CIRB) to ensure human subject safety and well-being for multi-institutional clinical trials. CIRB's shall be established in accordance with professional best practices and Good Clinical Practice (GCP) guidelines.

A CIRB shall be housed at the Institute or Center with expertise on the subject of the clinical trial or outside of the NIH in a public or private institution with comparable expertise and organizational capacity.

CIRB's will be available at the request of public or private institutions and funded through user fees or Center funds.

The CIRB shall act on behalf, in whole or in part, of the bodies ordinarily responsible for the safety of research subjects in a locality, on a contractual basis.

The CIRB will review and package research applications for facilitated electronic review by local IRB's participating in multi-center clinical trials. Local IRB review can be performed by a subcommittee that is empowered to make decisions in a timely manner. Local IRB's can either accept or reject the CIRB review.

Local IRB's which are part of the CIRB network shall be responsible for taking into consideration local characteristics such as educational level of research subjects to assure sound selection of research subjects and to minimize risks to vulnerable populations.

Each CIRB shall regularly communicate important information electronically to the local institutional review boards.

Section 499E–3. Training Clinical Researchers of the Future: The ACC will augment NIH's investment into programs developing the nation's clinical research workforce. These programs include: the NIH's Mentored Patient-oriented Research Career Development Award, NIH grants to help institutions develop curricula for clinical researchers, and NIH grants to fund participants in clinical science programs, which shall include but not be limited to clinical science certificates or clinical science Masters' Degrees.

Section 499E–4. Clinical Research Study and Clinical Trial: The Director shall commission the Institute of Medicine (IOM) to study the regulations protecting patient safety and anonymity so that in a contemporary clinical research context, a more realistic balance can be achieved between clinical research promotion and regulatory requirements governing research subject safety and privacy. The IOM will issue a written report within eighteen months of the passage of the Cures act which shall consider changes to the current Health Insurance Portability and Accountability Act (HIPAA) to further promote the clinical research endeavor.

Section 499E–5. Authorization of Appropriations from the Directors Acceleration Fund. $100 million dollars for Sections 499E–1(1), $50 million dollars for Section 499E–2, $200 million dollars for Section 499E–3, $2.5 million dollars for Section 499E–4.

SUBPART 4—VALLEY OF DEATH

Small businesses are major drivers of innovation. Facile, motivated, numerous, and creative, these small businesses can extend the limits of R&D in a way large companies with secure product lines are unable to do. However, small businesses often encounter difficulty securing capital in the so called, ''Valley of Death''—the period between a research idea with possible application to the time the safety and efficacy of a product is demonstrated in human clinical trials. Common end-pathways within the Valley of Death include development of pharmacological assays, scale-up of production from lab-scale to clinical-trials scale, development of suitable formulations, evaluation of chemical stability, evaluation of materials testing for durability or reactivity, undertaking initial toxicology studies, and planning and implementation of clinical trials.

Section 499F. Small Business Partnerships: The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are effective major investments in promoting the R&D portfolios of small businesses. SBIR and STTR receive 2.5% and 0.3% of the budgets, respectively, of federal agencies with R&D budgets greater than $100 million dollars. SBIR/STTR grants and contracts consist of three phases. Phase I plans for product development and procurement. Phase II addresses implementation of the plan. Phase III involves commercialization yet by law is ineligible for SBIR/STTR funding. Management and orientation of SBIR/STTR programs at the NIH can be improved.

This section moves the NIH's SBIR and STTR programs from the Extramural Research Office to the new Office of Bioscientific Enterprise Development (OBED) in the ACC Office of Technology Transfer (OTT).

The NIH currently awards its SBIR and STTR grants and contracts through a peer review process. Now, not less than 35% of SBIR and STTR grants and contracts shall be rewarded on a competitive basis by an OBED program manager with significant managerial, technical, and translational research experience to expertly assess the quality of a SBIR or STTR proposal.

Program managers will place special emphasis on partnering grantees with potential purchasers or investors of technology from the start of the research and development process with potential purchasers or investors including federal agencies such as the NIH.

ACC shall reduce the time between Phase I and Phase II funding to 6 months or less. Currently, grantees can wait up to 5 years to learn whether or not they are a recipient of a phase II grant.

An SBIR/STTR project manager may petition the OTT for Phase III funding from the Director's acceleration fund for projects requiring a supplementary funds to finalize product commercialization. The maximum funding for Phase III funding of a project shall be $2,000,000 for a maximum of 2 years.

All recipients of SBIR/STTR funding are required to report to the OTT whether there was eventual commercial success of the product. OTT shall keep a publicly accessible electronic record of all SBIR/STTR investments in research and development. The record shall include at minimum the following information: the grantee, a description of the funded research, the amount of money awarded in each phase of SBIR/STTR research, and if applicable, the nature of the products developed.

For each fiscal year, the two grants program managers who have had the greatest success in helping to commercialize products may be awarded a bonus up to $10,000.

Section 499F–1. Rapid Access to Intervention Development: The National Cancer Institute of the NIH has a successful translational research program called RAID (Rapid Access to Interventional Development). RAID lends essential expertise and resources including access to laboratories and facilities to researchers outside of the NIH. OTT shall expand upon this program and establish other RAID programs, designed to accelerate the process of bringing promising and novel discoveries from the laboratory to the pre-clinical trial stage.

RAID awardees have traditionally been selected to receive access to laboratories, facilities and other NIH supports for the preclinical development of drugs, biologics, diagnostics and devices, using the peer review process. Now, not less than 35% of RAID awards shall be awarded on a competitive basis by a program manager with significant managerial, technical, and translational research experience to adequately assess the quality of a project proposal.

Eligible awardees include university researchers, non-profit research organizations, and firms of less than 100 employees in collaboration with one or more university or non-profit organizations.

The Office may discontinue support at any point when the entity fails to meet commercialization success criteria established by the Office.

Examples of RAID support are given. These include advice regarding the investigational new drug or investigational new device filing with the Food and Drug Administration.

The Office shall not support products past proof-of-principle clinical trials.

Section 499F–2. Toxicity Studies: Toxicity studies are essential to the development of any drug therapy, but are difficult to stage. The Center for Cures shall support ongoing research into the most efficient methods of screening for human toxicity, including using cell-based and animal model technologies.

OTT may offer support for toxicity studies to private companies licensing NIH intellectual property.

Section 499F–3. Additional funding sources and models: The Director of the Center for Cures may provide acceleration funds for flexible contracts for translational research development to entities that license intellectual property from NIH where such contracts support innovation and commercialization.

Section 499F–4. Authorization of Appropriations from the Directors Acceleration Fund. $400 million dollars for Sections 499F for $100 million dollars for 499F–1.

SUBPART 5—OFFICE OF TECHNOLOGY TRANSFER

The Office of Technology Transfer (OTT) should be one of the NIH's most active entities. It is within the process of technology transfer where basic science research informs applications to health and where ideas are brought from bench to bedside and back to the bench. The OTT should be a library of innovation administered by experts who have experience in linking the translational research community with industry. This subpart improves upon the current research translation authorities of NIH's OTT.

Section 499G. Restructuring: The NIH Office of Technology Transfer in the NIH Director's Office shall be transferred to a new OTT Office in the American Center for Cures.

Section 499G–1. Marketing Function: The OTT office shall create a program for transfer management & support that cultivates industry interest in NIH funded research, reaches out to potential industry partners, coordinates patents from different NIH Institutes and Centers, and manages Cooperative Research and Development Agreements (CRADA's), biological licensing agreements,

material transfer agreements, and intellectual property licensing.

To promote government-industry partnerships, the OTT shall create an electronic database within the National Library of Medicine that tabulates translational research efforts occurring at the NIH. The OTT shall hold an annual translational research conference the bring together public and private stakeholders.

The OTT shall develop a program for transfer management & support which will be familiar with the NIH's intramural and extramural research portfolio as well as with the interests of small and large biotech and pharmaceutical industries. For those Institutes or Centers with their own OTT offices, the new OTT program for transfer management & support will work closely with those offices to coordinate industry outreach efforts.

As appropriate, OTT shall register CRADA's within a publicly accessible electronic database maintained by NLM.

Section 499G–2. Office of Intramural Risk Opportunity and Mapping: An Office of Intramural Risk Mapping within OTT shall oversee the intramural research programs of the NIH to be certain they are complementary, non-duplicative, and distinct from extramural and private programs.

The Office shall identify and map health risks and scientific opportunities and update the data on these topics as necessary to ensure they are current. This information is to be provided to the Cures Council on a biannual basis to help them prioritize the nation's translational research investment.

The Office shall make funds available to groups of NIH Institutes and Centers to promote multidisciplinary projects that focus on health risk analysis and corresponding scientific risk opportunity. Preference will go to projects that demonstrate a high degree of collaboration and which address diseases with the great burden or research promise, and that are most likely to result in the development of a diagnostic or therapeutic prototype.

$150 million dollars is authorized to be appropriated from the Director's Acceleration Fund to fund the Office.

Section 499G–3. Patenting and Licensing Incentives: The OTT shall make every effort to increase licensing to stimulate the availability of products for clinical use. The OTT shall recommend to the Director incentives that create private sector, financial, commercial, and academic interest in the NIH's IP portfolio. These incentives may include extensions of NIH health patents, restoration of NIH health patents, and partnering options to pursue exclusive and nonexclusive licensing to one or multiple partners in the government, industrial, and/or academic sectors.

The Director shall encourage OTT to develop flexible models for contracts that fulfill the needs of industry and the public.

Section 499G–4. Translational Researcher Development: The Director shall oversee development of a curriculum for internships in translational research encompassing rotations through multiple NIH Institutes and Centers, the clinical trial design process, the NLM, and other related disciplines with an emphasis on practical experience.

Tuition grants for extramural translational research programs shall be administered under the supervision of the Director.

The ACC shall train interdisciplinary scientists in the science of risk analysis & mapping through a program of internships and fellowships.

Section 499G–6. Translational Research Training Program: The NIH Director shall ensure that each NIH Institute or Center establishes a translational research training program.

SUBPART 6—DEVELOPING INFORMATION SYSTEMS

The NIH's National Center for Biotechnology Information (NCBI) at the NLM provides essential information resources to scientists worldwide and is the underpinning of much of NIH conducted biomedical research. The NCBI's databases and computational and linkage tools nurture information sharing and are critical to identifying interconnections, developing insights, and accelerating biomedical breakthroughs.

Section 499H. Advancing National Health Information Infrastructure.

The NLM shall develop new computational methods to assist in the processing of genomic data. There is authorized to be appropriated $2.5 million dollars to support the computational infrastructure and $5.5 million dollars to hire expert biologists and computer scientists trained in bioinformatics.

Secretary of Health and Human Services acting through the Director of NIH will work with the NLM to construct a clinical trial registry and clinical results database tracking all phase III clinical trials taking place in the United States. This registry and database will expand upon the NLM's current information system and database.

The registry of clinical trials shall include at least the following: clinical trial title, description of the product under study, the hypothesis to be tested, brief description of the intervention, the study design, methodology, duration and location, participation criteria, contact information and sponsoring organization.

The databank of clinical trial results shall consist of at least the following: trial start date and completion date, summary of the results of the trial, summary data tables with respect to the primary and secondary outcome measures, information on the statistical significance of the results, links to publications in peer reviewed journals relating to the trial, a description of the process used to review the results of the trial, and safety data concerning the trial.

Public or private entities shall register a phase III clinical trial not later than 3 months after submitting the Food and Drug Administration (FDA) approves the clinical trial protocol and report phase III clinical trial results not later than 3 months after completing the trial. Information provided to the NLM must be accurate and updated.

Penalties for not registering clinical trials or reporting clinical trial results can be loss of future public funding or in cases where an entity does not receive public funding, a fine of up to $2,000,000 dollars.

The Secretary may waive clinical trial submission requirements upon a written request from the responsible person if the Secretary determines that providing the waiver is in the public's interest or consistent with protection of the public's health.

Section 499H–1. Publication Requirement for Research: The Director of the NIH shall require that for any research funded by the NIH, Centers for Disease Control and Prevention (CDC), and the Agency for Healthcare Research and Quality (AHRQ), there will be a standardized report of this research for public viewing. Department of Health and Human Services (DHHS) grantees shall provide the NLM an electronic copy of the final version of all peer-reviewed manuscripts accepted for publication for display on their digital library archive, PubMed Central, within 6 months from the date of its publication.

Failure to submit required information to the NLM within 6 months from the date of publication may result in loss of public funding for investigators.

Section 499H–2. Informatics Training and Workforce Development. 21st Century technologies for analyzing DNA, RNA, proteins, and other biologically important molecules are generating a ''tsunami of data'' which are far beyond the understanding of unaided human cognition, but hold the key to improved understanding of human health and disease. Training of individuals in ''clinical bioinformatics''—translational research that applies computerized analytic methods of molecules, cells, tissues, and body systems to the prevention, diagnosis and treatment of human disease—will be pivotal to fostering this emerging and important data-intensive field.

The NIH shall develop a multi-faceted approach to increasing the number of persons trained in clinical bioinformatics. This shall include but not be limited to augmenting secondary school science programs, undergraduate degree programs in Bioinformatics, NIH bioinformatics graduate training programs, and Centers of Excellence in Clinical Bioinformatics.

Authorization of Appropriations from the Cures Acceleration Fund is $50 million dollars for this section.

Section 499H–3. NLM Expansion of Facilities. In 2002, Congress authorized an expansion of the NLM. These facilities may be essential to the NLM's capacity to fill its numerous informatics functions. The Director will commission the IOM to report to Congress on the impact of not funding the expansion of facilities.

SUBPART 7—RESEARCH TOOLS

Innovation requires proper tools for discovery. These include animal models that can be surrogates for human systems and markers that illuminate otherwise invisible cells, DNA, proteins and viruses. Arguably, the development of research tools is subject to the same market forces as more common end products—drugs, medical devices, and vaccines.

Section 499I. NIH Research Tool Inventory: The Director of NIH shall direct the head of each NIH Institute and Center to perform an annual review of its research tool inventory for the specific purpose of enabling each Institute and Center to understand processes for research tool distribution, frequency of use, IP status, and utility. Each NIH Institute and Center shall also describe in its review the type and quantity of research tools it desires to obtain in order to better fulfill its R&D goals.

The ACC shall enter this inventory into an electronic research tool database and use this database to oversee the prioritization and funding of new projects to fulfill pressing needs and to encourage promising technologies.

Section 499I–1. Exceptions to Tool Guidelines: The Director of NIH may advise the OTT to provide exceptions to prohibition against patenting and licensing research tools under some appropriate circumstances when exclusive or non-exclusive licensing provides the swiftest, and most efficacious final development of an important health care technology.

S. 2104

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 ''American Center for Cures Act of 2005''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

SEC. 3. FINDINGS.

Congress finds the following:

(1) The National Institutes of Health (referred to in this section as the ''NIH'') is the United States premier biomedical research investment with annual appropriations exceeding $28,000,000,000.

(2) The mission of the NIH is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability.

(3) The pace of knowledge application to promote health and reduce disease can be influenced through strategic funding and reorganization of some aspects of the traditional research endeavor. This process is known as translational research investment.

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

(A) to acute man-made or natural health threats;

(B) to the complexity and multi-disciplinary nature of chronic diseases, which are responsible for 7 out of every 10 deaths in the United States and for more than 70 percent of the $1,700,000,000,000 spent in the United States on health care each year; and

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

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

SEC. 4. AMERICAN CENTER FOR CURES.

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

''PART J—AMERICAN CENTER FOR CURES

''SEC. 499A. DEFINITIONS.

''In this part:

''(1) CENTER.—The term 'Center' means the American Center for Cures established under section 499B.

''(2) COUNCIL.—The term 'Council' means the Cures Council established under section 499B.

''(3) DIRECTOR.—The term 'Director' means the Director of the American Center for Cures.

''(4) INCUBATOR.—The term 'incubator' means an economic development organization designed to accelerate the growth and success of entrepreneurial individuals, concepts, and companies.

''(5) RESEARCH TOOL.—The term 'research tool' means a resource that scientists use in their laboratories that has no immediate therapeutic or diagnostic value, including cell lines, monoclonal antibodies, reagents, laboratory equipment and machines, databases, and computer software.

''(6) TEST BED.—The term 'test bed' means the pilot environment to prototype innovation.

''(7) TRANSLATIONAL RESEARCH.—The term 'translational research' means investigation in which knowledge obtained from fundamental research such as with genes, cells, or animals, is transformed through early and late stage development prototyping and testing into diagnostic or therapeutic interventions that can be applied to the treatment or prevention of disease or frailty.

''SEC. 499B. ESTABLISHMENT OF AMERICAN CENTER FOR CURES.

''(a) IN GENERAL.—There is established within the National Institutes of Health an American Center for Cures—

''(1) whose mission shall be to increase the capacity of the National Institutes of Health to promote translational research, including between the institutes and centers of the National Institutes of Health, between the National Institutes of Health and other Federal agencies, and between grantees and business partners of the National Institutes of Health, so as to speed the development of effective therapies, diagnostics, and cures essential to human health and well being;

''(2) that shall formulate and implement a strategy for the Nation's translational research investment, which strategy shall include—

''(A) a prioritization of biomedical research on diseases based on disease burden and research promise; and

''(B) funding for innovative, multidisciplinary, and collaborative research across the institutes and centers of the National Institutes of Health, across Federal agencies, and between public and private partners of the National Institutes of Health;

''(3) that shall be guided, in part, by a series of 'Grand Challenges' formulated through collaboration between the Director of Cures and the Council, that shall be strategic challenges that direct the public and private health research community towards collaborative multi-staged projects that have the potential to transform the healthcare environment, such as—

''(A) the creation of laboratory diagnostics that enable the Nation to detect quickly and accurately acute health threats such as an avian flu pandemic or a bioterrorism attack;

''(B) a focus on therapeutic delivery systems targeting individual viruses or hard to reach cells in the body, such as the brain, using advances in nanotechnology;

''(C) accelerated research into the potential of stem cells to replace the form and function of tissues lost to patients suffering from diseases such as spinal cord injury, Parkinson's disease, and insulin-dependent diabetes;

''(D) creation of a biomedical informatics infrastructure that can organize the human genome and the proteins for which the genome codes in ways that scientists can better understand the genetic contribution to phenotypic disease;

''(E) the elaboration of adjuvant technology that can bolster the effectiveness of vaccines;

''(F) development of antigen sparing vaccines such as those based on triggering the innate immune response;

''(G) development of rapid vaccine manufacturing capacity from new production methods such as viral cell culture or bioengineering technology;

''(H) creation of a fast track clinical trial infrastructure that incorporates a national doctor and patient registry, centralized investigational review boards, electronic medical records, and other health information technologies;

''(I) a focus on addressing less profitable conditions for which research and development efforts are insufficient, such as—

''(i) orphan, small population, and third world diseases;

''(ii) antibiotic resistance;

''(iii) a threat of a flu epidemic or pandemic;

''(iv) diseases associated with social stigma such as depression and seizure disorders; or

''(v) other comparable problems;

''(J) a commitment by researchers and manufacturers from all sectors to develop vaccines for the world's most deadly infectious diseases, including HIV, tuberculosis, and malaria; and

''(K) other appropriate challenges; and

''(4) that shall have other appropriate purposes.

''(b) DIRECTOR OF THE CENTER AND THE DIRECTOR OF NIH.—

''(1) IN GENERAL.—The Center shall be administered by a Director of Cures who shall be appointed by the President with the advice and consent of the Senate. The Director of the NIH, in consultation with the Council, shall recommend candidates for the Director of Cures to the President.

''(2) ACTIVITIES.—

''(A) DIRECTOR OF NIH.—The Director of NIH shall—

''(i) work with the Director of Cures to promote translational research efforts; and

''(ii) serve as a co-chair of the Council.

''(B) DIRECTOR OF CURES.—

''(i) ACCELERATION FUND.—

''(I) IN GENERAL.—The Director of Cures shall have at the Director's disposal an annual acceleration fund to provide support for research and development of breakthrough biomedical discoveries and to carry out the purpose of the Center. Amounts in the fund may be available through grants, contracts, and cooperative agreements to public sector entities, private sector entities, and non-governmental organizations. The Director of Cures shall allocate not less than ½ of the acceleration funds to the Health Advanced Research Projects Agency described in subpart 2. The remainder of such funds shall be available to the Federally Funded Research and Development Centers described in subpart 1 and other activities of the Center.

''(II) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to fund the acceleration fund under subclause (I) $5,000,000,000 for fiscal year 2007 and each succeeding fiscal year.

''(ii) DIRECT OTHER OFFICES.—The Director of Cures shall direct other offices within the Center that are established under this part.

''(c) COUNCIL.—

''(1) ESTABLISHMENT.—There is established within the Center a Cures Council that shall convene not less frequently than twice a year to help advise and direct the translational research efforts of the Center.

''(2) MEMBERSHIP.—

''(A) IN GENERAL.—The Council shall be composed of the following members:

''(i) The Director of NIH and the Director of Cures who shall be Council co-chairs.

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

''(iii) Heads from not less than 9 Federal agencies, including—

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

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

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

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

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

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

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

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

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

''(B) OTHER MEMBERS.—Membership of the Council shall also include not fewer than 3 leaders from the small business community, 3 leaders from large pharmaceutical or biotechnology companies, and 3 leaders from academia, all of whom shall be appointed by the President.

''(3) SUBCOMMITTEES.—The Council or the Council co-chairs may form subcommittees of the Council as needed.

''(4) RECOMMENDATIONS; COORDINATION.—The Council shall make recommendations that help the Director of Cures set research priorities for the Center. In making recommendations, the Council shall consider risk and burden of disease as well as lines of research uniquely poised to deliver effective diagnostics and therapies. The Council shall also coordinate research priorities in, and ensure sharing of research agendas among, the institutes and centers of the National Institutes of Health.

''(5) OFFICE OF INTRAMURAL RISK OPPORTUNITY AND MAPPING.—The Council shall be aided by the Office of Intramural Risk Opportunity and Mapping of the Office of Technology Transfer of the Center established in subpart 5.

''(6) ANNUAL ASSESSMENT.—The Council shall make an annual assessment of the priorities and progress of the Center and shall make the assessment available to the public in written and electronic form.

''(d) BUDGET AND FUNDS.—The Director of Cures shall—

''(1) prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate for the Center, after reasonable opportunity for comment (but without change) by the Secretary, the Director of NIH, and the Council; and

''(2) receive from the President and the Office of Management and Budget directly all funds appropriated by Congress for obligation and expenditure by the Center.

''Subpart 1—Federally Funded Research and Development Centers

''SEC. 499C. FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTERS.

''(a) IN GENERAL.—The Director of Cures is authorized to establish 1 or more Federally Funded Research and Development Centers that shall carry out activities related to the mission of the Center, as described in section 499B(a)(1).

''(b) DUTIES.—

''(1) IN GENERAL.—The Federally Funded Research and Development Centers shall serve as sites for the performance of multidisciplinary and cross-disciplinary research and shall—

''(A) establish, as appropriate, technology test beds and incubators;

''(B) utilize cooperative agreements with the private sector; and

''(C) conduct large-scale multidisciplinary translational research projects in health or disease areas that are essential to medical advancement but lack adequate private sector funding.

''(2) CONSULTATION.—In carrying out the duties described in paragraph (1), the Federally Funded Research and Development Centers shall consult widely with representatives from private industry, institutions of higher education, nonprofit institutions, other Federal governmental agencies, and other federally funded research and development centers.

''(c) COMPETITION.—The Director of Cures shall ensure that competitive mechanisms are used to select and to promote the ongoing quality and performance of the Federally Funded Research and Development Centers.

''(d) TERM OF FUNDING.—Federally Funded Research and Development Centers shall be funded for not more than 7 years, after which time the Federally Funded Research and Development Centers' re-funding shall be contingent upon approval by the Director of Cures and the Council.

''(e) REPORTS.—Each Federally Funded Research and Development Center receiving funding under this section shall submit a biannual report to the Director and the appropriate committees of Congress on the activities carried out by the Federally Funded Research and Development Center under this section.

''(f) FUNDING FOR SUPPORT.—For any fiscal year, the Director of Cures may use not more than 25 percent of the funds available to the Director under the acceleration fund under section 499B(b)(2)(B)(i)(II) to establish Federally Funded Research and Development Centers under this section.

''Subpart 2—Health Advanced Research Projects

''SEC. 499D. HEALTH ADVANCED RESEARCH PROJECTS AGENCY.

''(a) ESTABLISHMENT.—There is established within the Center a Health Advanced Research Projects Agency (referred to in this section as the 'Research Projects Agency') that shall—

''(1) carry out activities related to the mission of the Center, as described in section 499B(a)(1); and

''(2) be headed by a Director of the Research Projects Agency who is appointed by the Director of Cures.

''(b) COMPOSITION.—The Research Projects Agency shall be composed of not more than 100 portfolio managers in key health areas, which areas are determined by the Director of the Research Projects Agency in conjunction with the Director of Cures and the Council.

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

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

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

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

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

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

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

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

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

''(8) Tolerate risk-taking in research pursuits.

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

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

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

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

''(3) The Research Projects Agency, consistent with recommendations of the Council, with the priorities of the Director of Cures, and with the need to discuss challenges described in section 499B(a)(3), shall emphasize—

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

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

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

''(iii) remedies for orphan and small population diseases;

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

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

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

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

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

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

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

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

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

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

''(f) EMPLOYEES.—

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

''(2) TERM.—

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

''(B) EXTENSION.—The Director of the Research Projects Agency may, in the case of a particular employee of the Research Projects Agency, extend the term to which employment is limited under subparagraph (A) by up to 2 years if the Director of the Research Projects Agency determines that such action is necessary to promote the efficiency of the Research Projects Agency.

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

''(h) FUNDING.—The Research Projects Agency shall utilize funds received from the acceleration fund, described in section 499B(b)(2)(B)(i), for the Agency's research and development activities. There is authorized to be appropriated from such fund $2,500,000,000 to carry out the activities of the Research Projects Agency.

''Subpart 3—Clinical Trials

''SEC. 499E. INCREASING RESEARCH STUDY PARTICIPATION.

''The Director of NIH shall establish a national clinical study registry within the National Library of Medicine of the National Institutes of Health in accordance with section 499H. The Center shall publicize the registry, with attention given to minority groups that are frequently underrepresented in clinical trials.

''SEC. 499E–1. GRANTS FOR QUALITY CLINICAL TRIAL DESIGN AND EXECUTION.

''The Director of Cures—

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

''(2) may award grants for clinical trial design and execution to researchers from small firms with highly promising novel therapeutic entities.

''SEC. 499E–2. STREAMLINING THE REGULATORY PROCESS GOVERNING CLINICAL RESEARCH.

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

''(1) IN GENERAL.—The Director of Cures shall establish a series of Centralized institutional Review Boards (referred to in this section as 'CIRBs') to serve as human subject safety and well being custodians for multi-institutional clinical trials that are funded partially or in full by public research dollars.

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

''(A) use joint review;

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

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

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

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

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

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

''(d) REVIEW PROCESS.—

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

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

''(e) RESEARCH APPLICATIONS.—

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

''(2) LOCAL REVIEW.—Local institutional review board review may be performed by a subcommittee of the local institutional review board that is empowered to make decisions in a timely manner.

''(3) CIRB REVIEW.—A local institutional review board may accept or reject a CIRB review. In the case in which a local institutional review board accepts a CIRB review, the CIRB shall assume responsibility for annual, amendment, and adverse event reviews.

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

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

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

''SEC. 499E–3. TRAINING CLINICAL RESEARCHERS OF THE FUTURE.

''The Center shall augment the National Institutes of Health's investment into programs dedicated to developing the clinical research workforce for tomorrow. The programs shall include:

''(1) The National Institutes of Health's Mentored Patient-Oriented Research Career Development Award to support the career development of investigators who have made a commitment to focus their research endeavors on patient-oriented research.

''(2) The National Institutes of Health's award to encourage mentorship among particularly talented early- and mid-career investigators doing clinical research who want to train new investigators.

''(3) The National Institutes of Health grants to help institutions develop curricula for clinical researchers leading to a clinical science certificate or master's degree.

''(4) The National Institutes of Health grants to fund participants in clinical science programs, including clinical science certificates or clinical science masters' degrees.

"SEC. 499E–4. CLINICAL RESEARCH STUDY AND CLINICAL TRIAL.

''The Director of NIH shall—

''(1) commission the Institute of Medicine of the National Academies to study the rules that protect patient safety and anonymity so that in a contemporary clinical research context, a better balance can be achieved between clinical research promotion and regulatory requirement governing research subject safety and privacy; and

''(2) request that the Institute of Medicine issue a written report not later than 18 months after the date of enactment of this part that shall—

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

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

"SEC. 499E–5. AUTHORIZATION OF APPROPRIATIONS.

''There are authorized to be appropriated from the acceleration fund of the Director of Cures described in section 499B(b)(2)(B)(i)—

''(1) $100,000,000 to carry out section 499E–1(1) for fiscal year 2007 and each succeeding fiscal year;

''(2) $50,000,000 to carry out section 499E–2 for fiscal year 2007 and each succeeding fiscal year;

''(3) $200,000,000 to carry out section 499E–3 for fiscal year 2007 and each succeeding fiscal year; and

''(4) $2,500,000 to carry out section 499E–4.

"Subpart 4—Valley of Death

"SEC. 499F. SMALL BUSINESS PARTNERSHIPS.

''(a) ESTABLISHMENT OF THE OFFICE OF BIOSCIENTIFIC ENTERPRISE DEVELOPMENT.—

''(1) ESTABLISHMENT.—There is established within the Office of Technology Transfer of the Center (as established in subpart 5) an Office of Bioscientific Enterprise Development (referred to in the subpart as the 'OBED').

''(2) TRANSFERS.—

''(A) IN GENERAL.—The OBED shall include the functions (including related personnel and resources) of the following programs of the Office of Extramural Research in the Office of the Director of the National Institutes of Health:

''(i) The Small Business Innovation Research program (referred to in this subpart as the 'SBIR').

''(ii) The Small Business Technology Transfer program (referred to in this subpart as the 'STTR').

''(B) TIME FOR TRANSFERS.—The Secretary shall ensure that the programs described in subparagraph (A) are transferred to the OBED not later than 6 months after the date of enactment of this part.

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

''(1) IN GENERAL.—Not less than 35 percent of the grants and contracts awarded by the SBIR and STTR shall be awarded on a competitive basis by an OBED program manager with sufficient managerial, technical, and translational research expertise to expertly assess the quality of a SBIR or STTR proposal. The OBED, through such project manager, shall place special emphasis on SBIR and STTR grant and contract applications that identify from the onset products with commercial potential that influence human health.

''(2) POTENTIAL PURCHASERS OR INVESTORS.—The OBED shall administer non-peer reviewed grants and contracts under this subsection through program managers who shall place special emphasis on partnering grantees and entities awarded contracts from the very beginning of the research and development process with potential purchasers or investors of the products, including large pharmaceutical or biotechnology companies, venture capital firms, and Federal agencies (including the National Institutes of Health).

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

''(A) 6 months; or

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

''(4) PHASE III.—

''(A) FUNDING.—A program manager under this subsection may petition the Director of Cures for Phase III funding of the grant or contract for a project that requires a boost to finalize procurement of a product. The maximum funding for Phase III funding of a project shall be $2,000,000 for a maximum of 2 years. Such Phase III funding shall come from the acceleration fund, as described in section 499B(b)(2)(B)(i), of the Director of Cures.

''(B) REPORT SUCCESS.—Each recipient of a SBIR or STTR grant or contract, as a condition of receiving such grant or contract, shall report to the OBED whether there was eventual commercial success of the product developed with the assistance of the grant or contract.

''(5) RECORD.—

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

''(B) CONTENTS.—The record described in subparagraph (A) shall include, at minimum, the following information:

''(i) The grantee or entity awarded a contract.

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

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

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

''(6) BONUS.—For each fiscal year, for the non-peer reviewed SBIR and STTR grants or contracts, the 2 program managers who are most successful in terms of the number of grantees or entities awarded a contract who complete Phase III shall each be awarded a $10,000 bonus.

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

''(a) ESTABLISHMENT OF OFFICE.—The Office of Technology Transfer of the Center shall establish an Office of Rapid Access to Intervention Development (referred to in this subpart as the 'RAID') that—

''(1) is designed to assist translating promising, novel, and scientifically meritorious therapeutic interventions to clinical use by providing support to help investigators navigate the product development pipeline;

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

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

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

''(b) PROJECTS.—

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

''(2) SELECTION.—Not less than 35 percent of the projects selected under paragraph (1) shall be selected on a competitive basis by a program manager with sufficient managerial, technical, and translational research expertise to adequately assess the quality of a project proposal. Projects under paragraph (1) may also be selected from a peer review process.

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

''(A) a university researcher;

''(B) a nonprofit research organization; or

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

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

''(c) DISCOVERIES FROM LAB TO CLINIC.—The program under subsection (b) shall accelerate the process of bringing discoveries from the laboratory to the clinic through—

''(1) the development of pharmacological assays;

''(2) the scale-up of production from lab scale to clinical-trials scale;

''(3) the development of suitable formulations;

''(4) the evaluation of chemical stability;

''(5) the evaluation of materials testing for durability or reactivity;

''(6) undertaking initial toxicology studies;

''(7) planning clinical trials; and

''(8) advice regarding the investigational new drug or investigational new device filing with the Food and Drug Administration.

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

"SEC. 499F–2. TOXICITY STUDIES.

''(a) ONGOING RESEARCH.—The Center shall support ongoing research into the most efficient methods of screening for in vivo toxicity, including using cell-based and animal model technologies.

''(b) OFFER OF STUDIES.—The Director of Cures shall direct the Office of Technology Transfer of the Center to offer toxicity studies as an available feature to precede completion of licensing agreement contracts because toxicity studies are expensive and rate-limiting barriers to the licensing of intellectual property from the National Institutes of Health.

"SEC. 499F–3. ADDITIONAL FUNDING SOURCES AND MODELS.

''The Director of Cures may provide acceleration funds, described in section 499B(b)(2)(B)(i), for innovative custom contracts for translational research development to entities that license intellectual property from the National Institutes of Health where such contracts support innovation and new models of cooperation and commercialization.

"SEC. 499F–4. AUTHORIZATION OF APPROPRIATIONS.

''There are authorized to be appropriated from the acceleration fund of the Director of Cures described in section 499B(b)(2)(B)(i)—

''(1) $400,000,000 to carry out section 499F for fiscal year 2007 and each succeeding fiscal year; and

''(2) $100,000,000 to carry out section 499F–1 for fiscal year 2007 and each succeeding fiscal year.

''Subpart 5—Office of Technology Transfer

''SEC. 499G. RESTRUCTURING.

''(a) ESTABLISHMENT.—There is established within the Center an Office of Technology Transfer (referred to in this subpart as the 'OTT').

''(b) TRANSFERS.—The OTT shall include the functions (and related personnel and resources) of the Office of Technology Transfer in the Office of the Director of the National Institutes of Health.

''SEC. 499G–1. MARKETING FUNCTION.

''(a) IN GENERAL.—The OTT shall establish a program that—

''(1) cultivates industry interest in funded research of the National Institutes of Health;

''(2) reaches out to potential industry partners;

''(3) coordinates patents from the other institutes and centers of the National Institutes of Health; and

''(4) manages Cooperative Research and Development Agreements, biological licensing agreements, material transfer agreements, and intellectual property licensing.

''(b) PROMOTION.—The program under subsection (a) shall assist in promoting the success of government and industry partnerships for the development of new technologies by soliciting involvement of the private sector from the beginning of the translational research process, including by creating an electronic database within the National Library of Medicine, which shall be updated regularly, that tabulates translational research efforts occurring at the National Institutes of Health. The OTT shall hold an annual national translational research conference that brings together researchers and industry representatives from across fields from both the private and public sectors.

''(c) TRANSFER MANAGEMENT AND SUPPORT.—The OTT shall develop a program for transfer management and support that is familiar with the National Institutes of Health's intramural and extramural research portfolio, which program's mission is to reach out to potential industry partners to cultivate interest in collaboration with public researchers with the goal of product development and procurement. For those Institutes or Centers with their own Office of Technology Transfer Offices, the OTT shall work closely with those offices to coordinate industry outreach efforts. Those offices, on a biannual basis, shall meet with the OTT and shall submit a report to the OTT describing the translational research efforts of the Center or Institute and corresponding efforts to attract commercial interest in their research portfolio.

''(d) MANAGEMENT.—

''(1) IN GENERAL.—The OTT shall manage the Cooperative Research and Development Agreements between industry and public research partners.

''(2) REGISTRATION.—The OTT shall—

''(A) as appropriate, register the agreements within a publicly accessible electronic database maintained by the National Library of Medicine of the National Institutes of Health; and

''(B) oversee the collaborative process in terms of pre-determined outputs, negotiating problems that may occur between collaborating entities, and assuring intellectual property protections necessary for successful product development.

''SEC. 499G–2. OFFICE OF INTRAMURAL RISK OPPORTUNITY AND MAPPING.

''(a) ESTABLISHMENT.—There is established in the Office of Technology Transfer of the Center, an Office of Intramural Risk Opportunity and Mapping that shall oversee the intramural research programs of the National Institutes of Health to be certain they are complementary and distinct from extramural and private programs.

''(b) REVIEWS AND REPORTS.—The Office of Intramural Risk Opportunity and Mapping shall—

''(1) conduct regular reviews of the intramural research programs of the National Institutes of Health; and

''(2) report every 2 years on such reviews.

''(c) HEALTH RISKS AND OPPORTUNITIES.—The Office of Intramural Risk Opportunity and Mapping shall—

''(1) identify and map public health risks and scientific opportunities and keep data on such topics current and updated; and

''(2) provide the information described in paragraph (1) to the Council on a biannual basis to help the Council prioritize the Nation's translation research investment.

''(d) TRANS-NIH COLLABORATIVE RESEARCH.—

''(1) IN GENERAL.—The Office of Intramural Risk Opportunity and Mapping shall make, in coordination with the Director of Cures and the Director of NIH, funds available to groups of institutes and centers of the National Institutes of Health to promote engagement in multi-institute projects that focus on translational research endeavors.

''(2) FUNDING.—Funding levels and periods of funding under paragraph (1) shall be flexible as necessary to achieve trans-institute project objectives. Preference for funding shall be given to projects that promote high levels of cross-disciplinary collaboration, that address diseases with the greatest burden or research promise, and that are most likely to result in the development of a diagnostic or therapeutic prototype.

''(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, from the acceleration fund of the Director of Cures described in section 499B(b)(2)(B)(i), to carry out this subsection $150,000,000.

''SEC. 499G–3. PATENTING AND LICENSING INCENTIVES.

''(a) IN GENERAL.—The OTT shall make every effort to increase licensing throughput in order to stimulate the availability of useful products for patients.

''(b) INCENTIVES.—The OTT shall develop incentives that create private sector, financial, commercial, and academic interest in the National Institutes of Health's intellectual property portfolio, which incentives may include the following:

''(1) The patent extension of National Institutes of Health's health patents, in which there is an extension of the time during which the licensee has exclusive right to the intellectual property.

''(2) The patent restoration of National Institutes of Health's health patents, in which there is restoration of the full patent life, or another agreed upon term, of a technology to the licensee from the time of Food and Drug Administration passage or other agreed upon milestone.

''(3) Partnering options, which are options to pursue exclusive and nonexclusive licensing to 1 or more partners in the government, industrial, or academic sectors.

''(c) CUSTOMIZED MODELS.—The Director of Cures shall encourage the OTT to cultivate customized models for contracts that fulfill the needs of industry and the public.

''SEC. 499G–4. TRANSLATIONAL RESEARCHER DEVELOPMENT.

''(a) IN GENERAL.—The Director of Cures shall oversee the development of a curriculum for internships in interdisciplinary research that will encompass rotations through multiple institutes and centers of the National Institutes of Health (including the National Library of Medicine), the clinical trial design process, and other related disciplines with an emphasis on practical experience.

''(b) TUITION GRANTS.—The Director of Cures shall award tuition grants for extramural interdisciplinary research programs.

''(c) TRAINING.—The Center shall train interdisciplinary scientists in the science and art of risk analysis and mapping through a program of internships and fellowships.

''SEC. 499G–5. TRANSLATIONAL RESEARCH TRAINING PROGRAM.

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

''Subpart 6—Developing Information Systems

''SEC. 499H. ADVANCING NATIONAL HEALTH INFORMATION INFRASTRUCTURE.

''(a) GENOMIC DATA.—

''(1) IN GENERAL.—The National Center for Biotechnology Information of the National Library of Medicine of the National Institutes of Health shall develop new computational methods to aid in the processing of genomic data by novice and experienced researchers.

''(2) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, from the acceleration fund of the Director of Cures described in section 499B(b)(2)(B)(i), to carry out paragraph (1) $8,000,000, of which—

''(A) $2,500,000 is authorized to be appropriated to support the program's computational infrastructure; and

''(B) $5,500,000 is authorized to be appropriated for hiring biologists and computer scientists who are trained in bioinformatics.

''(b) DATABASE.—The Secretary, acting through the Director of NIH, shall undertake, in collaboration with the National Library of Medicine of the National Institutes of Health, construction of a clinical study registry and results database that may expand upon the National Library of Medicine's information system and database.

''(c) CLINICAL TRIAL INFORMATION.—

''(1) IN GENERAL.—

''(A) IN GENERAL.—The clinical study registry and results database, described in subsection (b), shall consist of a registry of phase III clinical trials taking place in the United States and a database of their results.

''(B) CLINICAL STUDY REGISTRY.—Participation in the clinical study registry shall be mandatory for both public and private entities.

''(C) RESULTS DATABASE.—Participation in the clinical trial results database shall be mandatory for both public and private entities. The clinical trial results database shall include even negative studies, which demonstrate no therapeutic effect.

''(2) REGISTRY OF CLINICAL TRIALS.—The registry of clinical trials shall include not less than the following:

''(A) The clinical trial title.

''(B) A description of the product under study.

''(C) The hypothesis to be tested.

''(D) The intervention.

''(E) The study design, methodology, duration, and location.

''(F) Participation criteria.

''(G) Contact information.

''(H) Sponsoring organization.

''(3) CLINICAL TRIAL RESULTS.—The database of clinical trial results shall consist of not less than the following:

''(A) The trial start date and completion date.

''(B) A summary of the results of the trial in a standard, non-promotional summary format.

''(C) Summary data tables with respect to the primary and secondary outcome measures.

''(D) Information on the statistical significance of the results and publications in peer reviewed journals relating to the trial, with, when available, an electronic link to the journal article.

''(E) A description of the process used to review the results of the trial, including a statement about whether the results have been peer reviewed by reviewers independent of the trial sponsor.

''(F) Safety data concerning the trial, including a summary of all adverse events specifying the number and type of events.

''(G) Reference information to the clinical trial in the clinical registry.

''(d) REGISTRATION OF TRIALS AND REPORTING OF RESULTS.—

''(1) WEBSITE PUBLICATION.—Each principal investigator of a public clinical trial or responsible person for a private clinical trial shall register phase III clinical trials in accordance with paragraph (2) and report phase III clinical trial results in accordance with paragraph (2) with the National Library of Medicine of the National Institutes of Health. The National Library of Medicine shall make the information available for viewing on the Library's Website, www.clinicaltrials.gov. The National Library of Medicine shall electronically link each registered clinical trial with its database of results and link each database of results with its registered clinical trial.

''(2) TIMELINE OF REGISTRATION.—

''(A) IN GENERAL.—An entity described in paragraph (1) shall register a clinical trial not later than 3 months after the Food and Drug Administration has approved the entity's clinical trial protocol and report clinical trial results not later than 3 months after completing the clinical trial, which shall be defined as the point where the specified trial duration has been surpassed and the analysis of the data is complete or the trial is stopped because of vital positive or negative findings, or as the point determined by the judgment of the Secretary. All information submitted to the National Library of Medicine shall be accurate and updated

''(B) LOSS OF FUNDING.—In the case in which an entity described in paragraph (1) does not register a clinical trial or report on clinical trial results in accordance with subparagraph (A), the Secretary may—

''(i) not award a grant, contract, cooperative agreements, or any other award to the principal investigators of such entity until the principal investigators comply with the requirements under subparagraph (A); and

''(ii) in the case of an entity that does not receive Federal funding for the clinical trial, fine the entity $10,000 a day for a sum not to exceed $2,000,000 until the responsible person for the clinical trial complies with the requirements under subparagraph (A).

''(C) WAIVER.—The Secretary may waive the requirements of subparagraph (A) upon a written request from the responsible person if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is in the public's interest or consistent with the protection of public health.

''SEC. 499H–1. PUBLIC ACCESS REQUIREMENT FOR RESEARCH.

''(a) IN GENERAL.—The Secretary shall require all funded investigators, whether direct employees of the Department of Health and Human Services or recipients of grants, contracts, or other support of the National Institutes of Health, the Centers for Disease Control and Prevention, or the Agency for Healthcare Research and Quality, to submit to the National Library of Medicine of the National Institutes of Health (referred to in this section as the 'National Library of Medicine'), upon acceptance for publication in a journal or other publication included in the PubMed directory, final manuscripts resulting from research in which direct costs are supported in whole or in part by the National Institutes of Health, the Centers for Disease Control and Prevention, or the Agency for Healthcare Research and Quality.

''(b) PUBLIC AVAILABILITY.—

''(1) IN GENERAL.—The National Library of Medicine shall include all such manuscripts described in subsection (a), after peer review, for display in the National Library of Medicine's digital library archive, PubMed Central. The copyright holder of a manuscript described in subsection (a) may request the author's manuscript be replaced with final published text.

''(2) TIMELINE.—A manuscript described in subsection (a) shall become publicly available on the Internet through PubMed Central not later than 6 months after the date of publication of the manuscript.

''(3) LOSS OF FUNDING FOR FAILURE TO SUBMIT ON TIME.—Failure to submit required information under this section to the National Library of Medicine within 6 months of the date of publication of the manuscript involved shall be considered by the Secretary in the context of grant compliance review and may result in the loss of public funding for the investigators involved as determined appropriate by the agency involved.

''SEC. 499H–2. INFORMATICS TRAINING AND WORKFORCE DEVELOPMENT.

''(a) IN GENERAL.—The Director of NIH shall develop a multi-faceted approach to increasing the number of persons trained in clinical bioinformatics by implementing appropriate programs, including the programs described in subsection (b).

''(b) PROGRAMS.—The programs under this subsection are the following:

''(1) K–12 SCIENCE PROGRAM.—The National Library of Medicine of the National Institutes of Health shall develop with the National Science Foundation a kindergarten through grade 12 clinical informatics education curriculum that shall include an assessment component. The National Library of Medicine shall award not more than 500 schools each $30,000 to implement the curriculum.

''(2) UNDERGRADUATE DEGREE PROGRAMS IN BIOINFORMATICS.—The National Library of Medicine of the National Institutes of Health shall—

''(A) award grants to academic health centers and graduate training programs to collaborate with an undergraduate institution of higher education's department of biology, chemistry, or computer science to develop curricula leading to a bachelor's degree in bioinformatics; and

''(B) encourage grantees to form an inter-institutional consortium.

''(3) INCREASING THE NUMBER OF NIH BIOINFORMATICS GRADUATE TRAINING PROGRAMS.—The National Library of Medicine of the National Institutes of Health shall increase the number of bioinformatics graduate training programs through funding existing graduate training programs of the National Institutes of Health to meet the expanding needs for training and outreach to the biomedical community. The programs shall focus on the skills needed to apply bioinformatics methods specifically to problems of human health and disease. The Director of NIH shall hire 12 individuals with a doctorate in molecular biology and expertise in training and developing educational programs to assist in carrying out the programs under this paragraph.

''(4) CENTERS OF EXCELLENCE IN CLINICAL BIOINFORMATICS.—The National Library of Medicine of the National Institutes of Health, through the Center, shall establish Centers of Excellence in Clinical Bioinformatics that shall have state-of-the-art computational methods and tools applicable to human disease prevention, diagnosis, and treatment. The Centers of Excellence in Clinical Bioinformatics shall provide graduate student and postdoctoral support, through distinguished faculty, in order to contribute to the highest level of training in the bioinformatics workforce pipeline.

''(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, from the acceleration fund of the Director of Cures described in section 499B(b)(2)(B)(i), to carry out this section $50,000,000 for fiscal year 2007 and each succeeding fiscal year of which—

''(1) $15,000,000 is authorized to be appropriated for fiscal year 2007 and each succeeding fiscal year to carry out subsection (b)(1); and

''(2) $2,000,000 is authorized to be appropriated to carry out subsection (b)(3).

''SEC. 499H–3. NATIONAL LIBRARY OF MEDICINE EXPANSION OF FACILITIES.

''(a) SENSE OF CONGRESS.—It is the sense of Congress that Congress should make special effort to fund the expansion of facilities of the National Library of Medicine of the National Institutes of Health. These facilities are essential to the National Library of Medicine being able to fulfill its many informatics functions, which include providing essential informational resources to scientists worldwide and advancing the underpinning of much of the National Institutes of Health conducted biomedical research.

''(b) REPORT.—The Director shall request that the Institute of Medicine of the National Academies report to Congress on the impact of not providing funding for the expansion of facilities described in subsection (a).

''Subpart 7—Research Tools

''SEC. 499I. NIH RESEARCH TOOL INVENTORY.

''(a) ANNUAL REVIEW.—The Director of NIH shall direct the head of each institute and center of the National Institutes of Health to perform an annual review of the institute or center's research tool inventory for the specific purpose of enabling each institute or center to understand the research tool distribution, frequency of use, intellectual property status, and utility. Each institute and center of the National Institutes of Health shall describe in the institute or center's annual review the type and quantity of research tools the institute or center desires to obtain to better fulfill the institute or center's research and development goals.

''(b) DATABASE.—The Director of Cures shall—

''(1) enter the information obtained from the annual review under subsection (a) into an electronic research tool database; and

''(2) use such database to oversee the prioritization and funding of new projects to fulfill pressing needs and promising technologies.

''SEC. 499I–1. EXCEPTIONS TO TOOL GUIDELINES.

''The Director of Cures may advise the Office of Technology Transfer of the Center to provide exceptions to prohibitions against patenting and licensing research tools under some circumstances of customized contracts when exclusive or non-exclusive licensing provides the swiftest and most efficacious final development of an important health care technology.''.

(b) CONFORMING AMENDMENT.—Section 401(b)(1) of the Public Health Service Act (42 U.S.C. 281(b)(1)) is amended by adding at the end the following:

''(S) The American Center for Cures.''.

QUOTES IN SUPPORT OF THE AMERICAN CENTER FOR CURES ACT OF 2005

''The American Center for Cures will be a tremendous addition to our nation's valuable tradition of biomedical research. By emphasizing translational and applications research as well as discovery of diagnostic markers, the ACC will bring the hope of basic science discovery to the reality of patient care. The mandate and goal will be to prevent, early diagnose, or cure the diseases that cause such suffering to humanity. This effort will promote health diplomacy that will bring the genius and resources of our nation to better the health of all Americans.''—Secretary Tommy Thompson, Former Secretary, Department of Health and Human Services, Former Governor, State of Wisconsin.

''The need for a federal focus on finding cures has long been a top priority for all of us who seek the rapid translation of scientific advances into personal health benefits. With their landmark legislative proposal, Senators Cochran and Lieberman have taken a critical step along our path to cures.''—S. Robert Levine MD, Chairman of the Health Priorities Project of the Progressive Policy Institute.

''As Governors around the country look to transform our complex health care system, we must seek new cost-effective solutions that continue to improve our overall health and productivity,'' said Michigan Governor Jennifer M. Granholm. ''The American Center for Cures represents a bi-partisan effort to devote significant and lasting resources toward an innovative approach to disease treatment and management, offering Americans grappling with chronic and debilitating diseases the lasting gift of hope.''—Governor Jennifer Granholm, Michigan.

''Finding cures will improve the health of mankind. As an example, by simply delaying the onset of Alzheimer's disease by five years, the health and productivity of older Americans will be enhanced. Developing cures will provide American families with a better quality of health care that can be sustained over a longer period of time. That is why I urge the establishment of the American Center for Cures.''—Governor Tom Vilsack, Iowa.

The American Center for Cures is a timely and creative proposal for tackling an urgent national challenge: the skyrocketing costs of treating and preventing chronic diseases. The confluence of such diseases and a graying population not only threatens to make health care unaffordable, but also jeopardizes prospects for healthy and successful aging. The Center would focus the prodigious talents of our scientific community on specific strategies to cure disease, saving lives and money over the long run.—Will Marshall, President, Progressive Policy Institute.

''The American Center for Cures is a simple, bold, breakthrough idea: A can-do country ought to have the capacity to solve chronic problems, not just treat them.''—Bruce Reed, President, Democratic Leadership Council.

''I think this goes a long way toward improving NIH's ability to do large projects across institutes and to facilitate translational research. I am happy to support this concept . . . there are already a lot of good ideas here.''—Leland Hartwell, Ph.D., Nobel Laureate, Medicine and Physiology, President, Fred Hutchinson Cancer Research Center.

''I believe the American Center for Cures (ACC) is a wonderful effort that focuses physicians and scientists on bringing the discoveries of the laboratory to the patient. The lives of many Americans will be improved by having the ACC bring to bear new resources in the fight against chronic neurological diseases such as Alzheimer's, Parkinson's, multiple sclerosis, and other neurodegenerative disorders. I enthusiastically support the American Center for Cures and hope that my colleagues in biomedical research will join me.''—Stanley Prusiner, M.D., Nobel Laureate, Medicine and Physiology, University of California, San Francisco.

''The proposed ACC offers a blend of existing federal activities in health research with several new initiatives, all aimed at speeding the move from discovery to products that help human health. The proposal has multiple components including strengthening existing NIH authorities in support of small business. When enacted and in operation the results of this new focused activity should be very visible with improvements to the public health that would not be possible without this new money with mandates on how it is spent.''—Robert Day, M.D., Ph.D., M.P.H., Emeritus Professor and Dean, University of Washington School of Public Health and Community Medicine, Emeritus Professor and Director, Fred Hutchinson Cancer Research Center, Member, Public Health Sciences, Member, National Cancer Advisory Board, National Cancer Policy Board.

''The establishment of an American Center for Cures with its emphasis, prominence and integration into the rest of the United States organization of health care related ventures would represent an enormous step forward. The focus of the Center on translation of basic science initiatives to the clinical arena will benefit those whose support has taken us to the present date. I applaud the initiative.''—Fritz H Bach, M.D., Lewis Thomas Distinguished Professor, Harvard Medical School.

''Medical discoveries over the past century have greatly increased the quality and quantity of human life. New insights into biology will make even more advances possible. The American Center for Cures will make the translation of biological discoveries to the patient occur not only faster but much more likely to happen. It is hard to imagine another investment that would extend the quality and quantity of life than fully funding the American Center for Cures.''—James O. Armitage, M.D., Joe Shapiro Professor of Medicine, University of Nebraska College of Medicine, Member, National Cancer Advisory Board.

''I am pleased to support the American Center for Cures (ACC) proposed legislation that you introduced to the United Sates Senate on Wednesday, December 7. This legislation is critical and in the translation of advances in fundamental biomedical science to improvements in the care of people. Please let me know if I can help make this dream a reality.''—Lee Goldman, M.D., MPH, Julius R. Krevans Distinguished Professor and Chair, Associate Dean for Clinical Affairs, University of California San Francisco School of Medicine, President, Association of Professors of Medicine.

''I enthusiastically support The American Center for Cures (ACC) Senate legislation. The ACC will focus our nation's scientists and doctors on applying basic scientific discoveries to help the patient. This critical approach to research will not only help our friends and loved ones with their health, it will be the 21st Century American approach to solving the health care financial crisis. By eliminating or reducing certain diseases for all Americans, the looming federal and state Medicare and Medicaid financial tsunami will be markedly reduced. There is no time to lose. I urge the immediate passage of the ACC legislation.'' —Stephen Gleason, D.O., Ph.D., Former CEO Mercy Clinics, Former VP Medical Operations for Catholic Health Initiatives, Former White House advisor, Former chief of staff, Governor Tom Vilsack, Former Presidential Representative to the World Health Organization, Assistant Professor, Mayo Graduate School of Medicine.

''The American Center for Cures will be the engine that brings basic science discoveries and apply them to the patient. It has been said that women and minorities are not dying from the lack of research, they are dying from the lack of research being applied to them. The ACC will focus the talent of the greatest scientists and clinicians for one singular purpose: to cure, prevent, or diagnose earlier diseases that afflict so many in the world. As a mother, nurse, researcher, and educator, I believe that the ACC will bring better health to all of us. The time is now . . . let us not waste another moment.''—Sandra Underwood, RN, PhD, University of Wisconsin School of Nursing.

''The American Center for Cures is a remarkable idea that will be the bridge between the promise of scientific opportunities and the reality of our nation's health needs—to deliver cures. Americans deserve a center that is totally dedicated to finding cures for our most devastating and debilitating chronic diseases. The ACC is the natural extension of the doubling of the NIH budget. Now we must have as a top national priority an accountable, mission-driven Center for Cures to rapidly identify ''cure opportunities'' already created by federal, academic and private research laboratories and proactively accelerate and rapidly translate these opportunities into real cures.

In an era of expanding needs, exploding knowledge of the biomedical sciences, and demands of the public to have the knowledge applied to their loved ones' ailments, the American Center for Cures offers new hope and dynamic reality to Americans. The American Center for Cures is the opportunity to commit the American genius, resources, and ethic to a greater cause in a ''moonshot'' approach to diseases.''—Richard J. Boxer, M.D., Clinical Professor, Health Policy, Medical College of Wisconsin, Clinical Professor, Family and Community Medicine, Medical College of Wisconsin, Clinical Professor, Surgery/Urology, University of Wisconsin-Madison.

''Having reviewed the material you so kindly sent me, I want to applaud this pioneering, entrepreneurial approach which will undoubtedly accelerate the process by which we discover and implement cures for diseases and improve and enrich the quality of life of tens of millions of Americans. I hope that this bold solutions-oriented approach will have overwhelmingly bi-partisan support in Congress and that it will be signed into law by the President at the earliest possible moment.''—Steve Grossman, Former Chair, Democratic National Committee, C.E.O. Massachusetts Envelope Company.

''The American Center for Cures is the best new idea in Washington DC in a generation. It is timely, creative and compelling.''—Joe Andrew, Former Chair, Democratic National Committee, Sonnenschein, Nath and Rosenthal, LLP.

''The combination of NIH and industry-supported research, combined with venture capital, has been very successful in bringing new drugs based on fundamental biological discoveries into commercial reality. In areas that combine fundamental biology and physical science and engineering—biomedical devices, analytical, genomic, and diagnostic tools, bioinformation systems, tissue engineering—the current system works substantially less well.''—George Whitesides, Ph.D., Professor of Chemistry, Harvard Medical School, (given in 2004).

''The concept of the new institute is exciting.''—Arthur W. Nienhuis, M.D., Director,

St. Jude Children's Research Hospital, (given in 2004).

''The concept and its underlying philosophy are right on target. We need to open cancer research in prevention, early diagnosis, and cure to scientists in diverse fields that include physicists, chemists, computer scientists and mathematicians.''—Frederick P. Li, M.D., Director, Division of Cancer Epidemiology and Control, Dana-Farber Cancer Institute, (given in 2004).

''The 20th Century saw a 100-percent increase in worldwide life expectancy—one of the greatest achievements in history. Today's children face different challenges, including a higher risk of dying from cancer and other diseases of aging than their grandparents did. In the 21st Century, our challenge is to use incredible advancements in information technology and biology to defeat such diseases as cancer, Alzheimer's, diabetes, Parkinson's and many other afflictions that take years of quality life from our loved ones. The most-important benefit will be reduced human suffering. And the value to our economy will be measured in trillions of dollars. The American Center for Cures (ACC) legislation recognizes and responds to the imperative of defeating these deadly diseases in our lifetimes. I believe we can do that if we summon the will to change the way we pursue new medical solutions. FasterCures supports passage of the ACC legislation and urges its rapid implementation. There is not a moment to lose.''—M. Millken, Chairman, FasterCures/The Center for Accelerating Medical Solutions.

''The American Center for Cures will be extraordinarily important for all Americans, and indeed all humanity. The new Center will combine scientific disciplines that have previously not been brought to bear upon biomedical problems. This is a unique and desperately needed approach will break through the impasse and finally bring the formidable power of all science to focus and solve the diseases that plague the world. The American Center for Cures has been designed to bring accountability and responsibility for ultimate cures. Its success will be measured by cures and cures alone. As a father, husband, entrepreneur, and one who has seen too much suffering, I believe it is incumbent upon us to take a bold approach to biomedical research that will make our children and future generations free of the diseases that have afflicted us and our ancestors. Let our descendents look back at our generation and say, 'They reached for the stars, and found they were capable of conquering old paradigms, fears, and diseases.' ''—Lou Weisbach, C.E.O. Stadium Capital Associates, Founder, HA-LO Industries, Inc.

''Oscar Wilde once wrote, ''Morality, like art, begins with a line being drawn someplace.'' With tremendous suffering and disease so prevalent in our country, the American Center for Cures' (ACC) proposed legislation being introduced by Senators Lieberman and Cochran draws a line in the sand for health and extending the lifetime of every individual. From a religious point of view, this certainly responds to the notion that we are identified with life affirmation. I heartily endorse this legislation.''—Rabbi Steven B. Jacobs, Temple Kol Tikvah, Woodland Hills, CA—Rabbi Michael Lerner, Editor, Tikkun Magazine, Rabbi, Beyt Tikkun Synagogue, San Francisco, California.

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 331—EXPRESSING THE SENSE OF THE SENATE REGARDING FERTILITY ISSUES FACING CANCER SURVIVORS

Ms. LANDRIEU (for herself, Mr. BURR, Mr. BINGAMAN, Mrs. FEINSTEIN, and Mr. ISAKSON) submitted the following resolution; which was referred to the Committee on Health, Education, Labor, and Pensions:

S. RES. 331

Whereas there are more than 10,000,000 cancer survivors in the United States, and approximately 1,000,000 of those survivors were diagnosed during their reproductive years;

Whereas approximately 130,000 people under the age of 45 are diagnosed with cancer each year;

Whereas up to 90 percent of patients diagnosed with cancer under the age of 45 will undergo potentially sterilizing treatments, such as surgery, chemotherapy, or radiation;

Whereas survivorship rates have dramatically increased so that 71 percent of patients who are diagnosed with cancer under the age of 45 can expect to live at least five years beyond the diagnosis of their disease;

Whereas long-term consequences of cancer treatment are of increasing concern to patients since they are increasingly likely to survive their cancer;

Whereas the diagnosis of infertility can be as devastating for many patients as the cancer diagnosis itself;

Whereas successful fertility preservation options for men and women exist and include: sperm banking, oocyte (egg) freezing, and ovarian and testicular tissue freezing;

Whereas many cancer patients have the option of taking steps to preserve their fertility before their potentially sterilizing cancer treatment begins;

Whereas many patients do not take steps to preserve their fertility before treatment because they are not informed by their health care professionals that their fertility is at risk, or, if they are informed of the risk, they are generally not counseled on their fertility preservation options;

Whereas unrelated factors such as marital status or poor prognosis should not preclude certain patients from being informed about their fertility risks and options; and

Whereas the 2003–2004 President's Cancer Panel Report recognized that comprehensive written and verbal information regarding fertility side effects and fertility preservation options for all reproductive-age patients should be provided before treatment: Now, therefore, be it

Resolved, That it is the sense of the Senate that—

(1) cancer-related infertility is a serious quality of life issue for reproductive-age cancer patients;

(2) national and community organizations should be recognized and applauded for their work in promoting awareness of the risks of infertility and fertility preservation options for cancer survivors;

(3) the medical community should increase its efforts to ensure that discussions about the risk of infertility and fertility preservation options are an integral part of pretreatment planning and consent for treatment for all reproductive-age patients; and

(4) the Federal Government, acting through the National Institutes of Health, should endeavor to—

(A) encourage research that will strengthen fertility preservation technologies for cancer patients;

(B) continue to consider ways to improve access to fertility preservation options for cancer patients; and

(C) endeavor to raise awareness about the fertility side effects and fertility preservation options for cancer patients.

SENATE RESOLUTION 332—HONORING THE LIFE OF FORMER GOVERNOR CARROLL A. CAMPBELL, AND EXPRESSING THE DEEPEST CONDOLENCES OF THE SENATE TO HIS FAMILY

Mr. DEMINT (for himself and Mr. GRAHAM) submitted the following resolution; which was considered and agreed to:

S. RES. 332

Whereas the Senate has learned with sadness of the death of Governor Carroll Campbell;

Whereas Carroll Campbell dedicated a lifetime of service to the State of South Carolina and the United States;

Whereas Carroll Campbell served most honorably as the Governor of South Carolina from 1987 to 1995;

Whereas from 1979, and until he was elected Governor of South Carolina, Carroll Campbell served with high moral character and integrity in the United States House of Representatives;

Whereas Carroll Campbell was the first Republican elected to the House of Representatives for the 4th Congressional District since the Reconstruction period;

Whereas during his service as Governor, Carroll Campbell provided extraordinary leadership and comfort to the citizens of South Carolina throughout the devastating aftermath of Hurricane Hugo and the rebuilding of the coast;

Whereas Carroll Campbell improved the economy of South Carolina and the livelihood of its citizens by attracting world class businesses;

Whereas Carroll Campbell worked diligently to restructure the Government of South Carolina, making it more accessible and responsive to its citizens;

Whereas Carroll Campbell focused on improving the quality of public education provided by the State of South Carolina to all of its citizens;

Whereas Carroll Campbell was as devoted to his principles as he was to his loving family, which included his wife Iris, his sons Carroll and Mike, and his grandchildren ''Blakeney'' Herlong Campbell, Carroll ''Berrett'' Campbell, Michael ''Rhodes'' Campbell, and Marie ''Riley'' Campbell; and

Whereas Carroll Campbell was a visionary who worked to improve the lives of all South Carolinians: Now, therefore, be it

Resolved, That the Senate—

(1) extends its prayers and deepest condolences to the entire Campbell family;

(2) honors the life of Carroll Campbell and expresses profound gratitude for his years of public service; and

(3) acknowledges with appreciation the unfaltering commitment and loyalty of Carroll Campbell to his family and the State of South Carolina.